

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SOTERA WIRELESS, INC.,
Petitioner,

v.

MASIMO CORPORATION,
Patent Owner.

IPR2020-00967
Patent RE47,244 E

Before JOSIAH C. COCKS, JENNIFER MEYER CHAGNON, and
AMANDA F. WIEKER, *Administrative Patent Judges*.

CHAGNON, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)
Dismissing Petitioner's Motion to Exclude
37 C.F.R. § 42.64

I. INTRODUCTION

A. Background

Sotera Wireless, Inc. (“Petitioner”)¹ filed a Petition requesting *inter partes* review of claims 1–26 (“the challenged claims”) of U.S. Patent No. RE47,244 E (Ex. 1001, “the RE244 patent”). Paper 1 (“Pet.”). Masimo Corporation (“Patent Owner”) filed a Preliminary Response. Paper 7. We instituted an *inter partes* review of all challenged claims 1–26 on all grounds of unpatentability, pursuant to 35 U.S.C. § 314. Paper 13 (“Inst. Dec.”).²

After institution, Patent Owner filed a Response (Paper 24, “PO Resp.”) to the Petition, Petitioner filed a Reply (Paper 28, “Pet. Reply”), and Patent Owner filed a Sur-reply (Paper 32, “PO Sur-reply”). Additionally, Petitioner filed a Motion to Exclude certain deposition testimony (Paper 37, “MTE”), Patent Owner filed an Opposition (Paper 38), and Petitioner filed a Reply (Paper 39). An oral hearing was held on September 8, 2021, and a transcript of the hearing is included in the record. Paper 42 (“Tr.”).

We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons set forth below, Petitioner has met its burden of showing, by a preponderance of the evidence, that challenged claims 1–26 of the RE244 patent are unpatentable.

¹ Petitioner identifies Sotera Wireless, Inc. and Hon Hai Precision Industry Co., Ltd. (“Hon Hai”) as real parties-in-interest to this proceeding. Pet. 1. Petitioner states that Hon Hai is named as a real party-in-interest due to its involvement in a related proceeding. *Id.*

² To address institution considerations under 35 U.S.C. § 314(a), and with our authorization, Petitioner filed a Preliminary Reply (Paper 11) and Patent Owner filed a Preliminary Sur-reply (Paper 12). We do not refer to either paper in this Final Written Decision.

B. Related Proceedings

The parties identify *Masimo Corp. v. Sotera Wireless, Inc.*, Case No. 3:19-cv-01100-BAS-NLS (S.D. Cal.) as a related matter involving the RE244 patent. Pet. 2; Paper 5, 1.

Patent Owner identifies the following *inter partes* review proceedings, involving patents related to the RE244 patent and which are asserted in the related district court matter:

IPR2020-00912, challenging U.S. Patent No. 10,213,108 B2;
IPR2020-00954, challenging U.S. Patent No. 9,788,735 B2;
IPR2020-01015, challenging U.S. Patent No. 9,795,300 B2;
IPR2020-01019, challenging U.S. Patent No. RE47,353 E;
IPR2020-01033, challenging U.S. Patent No. RE47,249 E;
IPR2020-01054, challenging U.S. Patent No. 9,872,623 B2;
IPR2020-01078, challenging U.S. Patent No. RE47,218 E; and
IPR2020-01082, challenging U.S. Patent No. 10,255,994 (institution denied).
Paper 6, 2.

Patent Owner further identifies various applications that claim priority to, or share a priority claim with, the RE244 patent. *Id.* at 1.

C. The RE244 Patent

The RE244 patent, titled “Alarm Suspend System,” was filed May 1, 2017, and issued on February 19, 2019. Ex. 1001, codes (22), (45), (54).

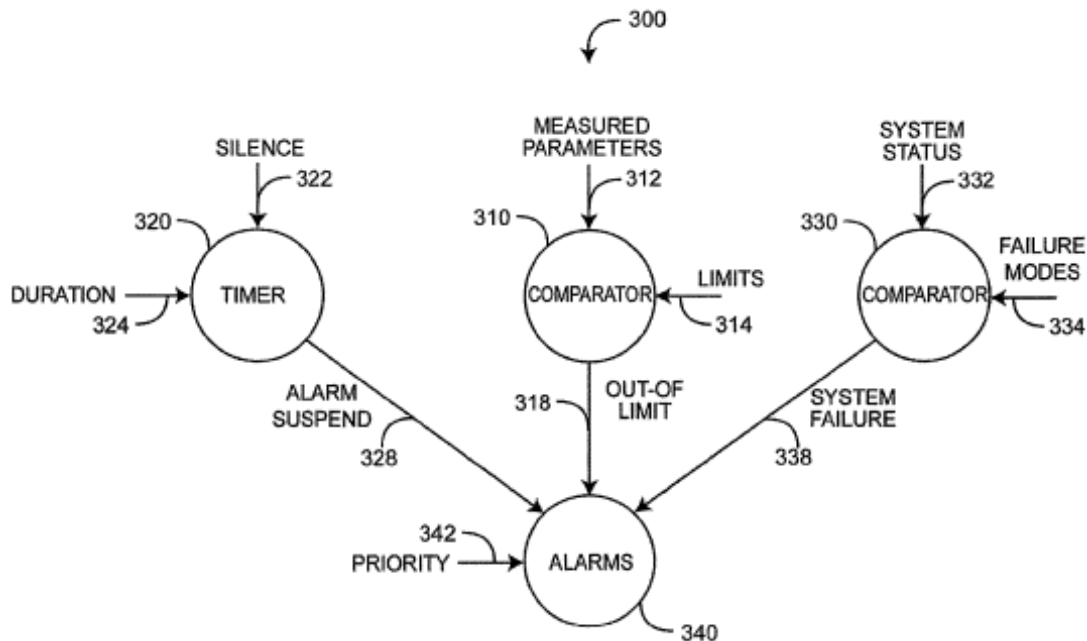
The RE244 patent was filed as a reissue application of U.S. Patent No. 9,153,121. *Id.* at code (64).³

The RE244 patent describes a physiological measurement system that utilizes an alarm suspend system. *Id.* at 4:25–26. The disclosed system includes physiological monitor 101 and noninvasive sensor 105, which measures, e.g., pulse oximetry parameters, carboxyhemoglobin, methemoglobin, and/or total hemoglobin. *Id.* at 4:25–36, Fig. 1. The monitor may include a display, touch keys, and controls including “an alarm silence button [] that is pressed to temporarily suspend out-of-limit parameter alarms and system alarms, such as low battery.” *Id.* at 4:37–48.

The alarm suspend system both prevents unnecessary disturbances to patients and distractions to caregivers. *Id.* at 2:33–36. “Advantageously, an alarm suspend system provides a parameter-dependent variation in the alarm suspend duration, as described below, utilizing a common silence button or other suspend initiator.” *Id.* at 4:60–63. “The alarm suspend period is typically long enough to give a caregiver sufficient time to intervene with appropriate patient treatment yet short enough to ensure that patient health is not endangered if intervention is ineffective.” *Id.* at 2:38–42.

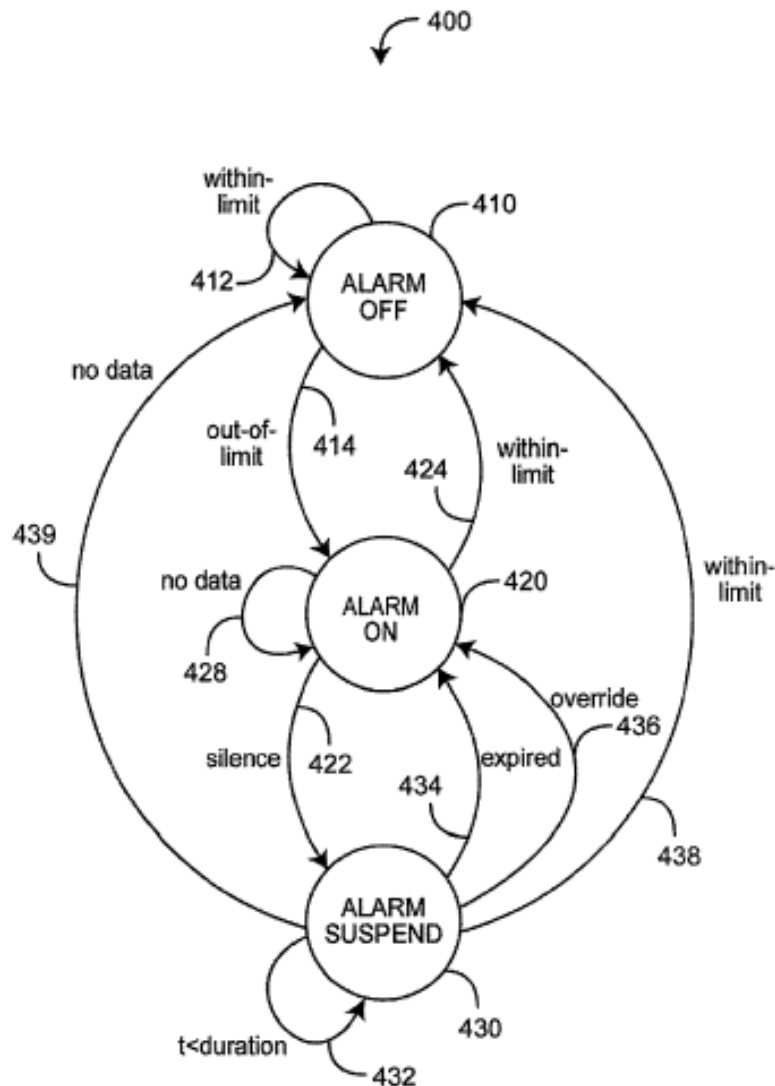
³ The RE244 patent claims earliest priority through a series of continuation applications to Provisional application No. 61/084,615, filed on July 29, 2008. Ex. 1001, codes (60), (63). The specific priority date of the challenged claims is not at issue in this proceeding, and we need not make any determination in this regard for purposes of this Decision.

Figure 3 of the RE244 patent, reproduced below, illustrates a flow diagram of an alarm suspend system. *Id.* at 4:16–17.



As shown in Figure 3, above, “[a]larm triggers include system failures 338 and out-of-limit parameters 318.” *Id.* at 5:43–44. Out-of-limit parameters are identified by comparing measured parameters 312 to default or user-specified limits 314. *Id.* at 5:51–52. Out-of-limit condition 318 triggers alarm 340 that can be suspended 328 by user-initiated silence request 322. *Id.* at 5:52–56. Suspend durations may vary depending on the parameter. *Id.* at 6:23–28. For example, “relatively slow treatment parameters, such as [methemoglobin (‘HbMet’)], [carboxyhemo- globin (‘HbCO’)], [total haemoglobin (‘Hbt’) and [Pleth Variability Index (‘PVi’)], are assigned relatively long suspend durations. Similarly, relatively fast treatment parameters, such as [oxygen saturation (‘SpO₂’)] and [pulse rate (‘PR’)], are assigned relatively short suspend durations.” *Id.* at 6:28–33.

Figure 4, reproduced below, illustrates an alarm suspend “that operates independently for each measured parameter that can trigger an alarm.” *Id.* at 5:66–6:1.



As shown in Figure 4, above, the alarm is initially off 410, and remains off so long as the measured parameter is within its set limits 412. *Id.* at 6:1–3. When a measured parameter becomes outside its set limit 414 (i.e., it is “out-of-limit”), the system triggers alarm 420. *Id.* at 6:1–4. A user may activate silence request 422 that suspends alarm 430, for example, by pressing the alarm silence button, which then suspends 430 the alarm for predetermined

duration 432. *Id.* at 6:5–10. The predetermined duration “may be a function of the out-of-limit parameter.” *Id.* at 5:60–61. When the predetermined duration expires, the alarm is activated until the triggering parameter is within limit 424 or the user again silences 422 the alarm. *Id.* at 6:10–14. “[A]larm suspend 430 deactivates if the measured parameter becomes within limits 438, such as when the patient condition improves, or if no physiological data is detected 439.” *Id.* at 6:14–17. Alternatively, alarm suspend override 436 reactivates alarm 420 when a measured parameter changes by a sufficient out-of-limit amount. *Id.* at 6:19–22.

D. Illustrative Claim

Of the challenged claims, claims 1, 13, and 18 are independent. Claims 2–12 and 23–26 depend from claim 1; claims 14–17 depend from claim 13; and claims 19–22 depend from claim 18. Independent claim 1 of the RE244 patent is reproduced below, and is illustrative of the challenged claims.⁴

1. A physiological measurement system comprising:

a noninvasive physiological sensor configured to be positioned on a patient and output a signal responsive to a physiological condition of the patient; and

one or more processors in communication with the noninvasive physiological sensor, the one or more processors configured to electronically:

process the signal;

⁴ The RE244 patent is a reissue patent. As is standard when printing the claims of a reissue patent, matter enclosed in heavy brackets [] was deleted from the original claims and matter printed in italics was added in the reissued claims. For convenience, we produce a clean version of reissued claim 1.

responsive to processing the signal, determine a measurement of a physiological parameter based at least in part upon the signal;

determine that the measurement of the physiological parameter satisfies an alarm activation threshold;

initiate a parameter-specific alarm delay or suspension period of time corresponding to the physiological parameter, the parameter-specific alarm delay or suspension period of time being one of a plurality of parameter-specific alarm delay or suspension periods of time, the parameter-specific alarm delay or suspension period of time being different from at least one other parameter-specific alarm delay or suspension period of time corresponding to at least one other physiological parameter for which the one or more processors are configured to determine at least one measurement; and

activate an alarm for the physiological parameter in response to expiration of an amount of delay or suspension associated with the parameter-specific alarm delay or suspension period of time.

Ex. 1001, 7:39–8:12.

E. Applied References and Evidence

Petitioner relies on the following references in the asserted grounds.

Pet. 5–8.

Reference	Issue Date/ Publication Date	Exhibit
U.S. Patent No. 5,865,736 (“Baker-1”)	Feb. 2, 1999	Ex. 1005
U.S. Publication No. 2009/0247851 A1 (“Batchelder”)	Oct. 1, 2009	Ex. 1006
U.S. Patent No. 8,792,949 B2 (“Baker-2”)	Jul. 29, 2014	Ex. 1007

Reference	Issue Date/ Publication Date	Exhibit
U.S. Publication No. 2005/0038332 A1 ("Saidara")	Feb. 17, 2005	Ex. 1008
U.S. Publication No. 2003/0135087 A1 ("Hickle")	Jul. 17, 2003	Ex. 1009
S. Malangi, <i>Simulation and mathematical notation of alarms unit for computer assisted resuscitation algorithm</i> , New Jersey Institute of Technology, Theses 526, (2003) ("Malangi")	Jul. 12, 2004	Ex. 1010

Petitioner also submits the Declaration of George E. Yanulis, EngD (Ex. 1003) and the Declaration of Bryan Bergeron, MD (Ex. 1040). Patent Owner submits the Declaration of Jack Goldberg (Ex. 2011).

The parties also rely upon deposition testimony of Dr. Yanulis (Ex. 2017 (Feb. 4, 2021, deposition); Ex. 2018 (Feb. 5, 2021, deposition); *see also* Exs. 2025–2026 (errata)), Dr. Bergeron (Ex. 2022 (June 24, 2021, deposition)), and Mr. Goldberg (Ex. 1042 (April 13, 2021, deposition); Ex. 1043 (April 14, 2021, deposition)).

F. Asserted Grounds of Unpatentability

We instituted an *inter partes* review based on the following grounds.
Inst. Dec. 10–11, 51.

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1, 6–8, 13, 14, 18, 19, 23–26	103 ⁵	Baker-1
1, 2, 6–9, 13–16, 18–26	103	Baker-1, Batchelder
1, 2, 6–9, 13–15, 18–26	103	Baker-1, Batchelder, Baker-2
3–5, 10–12, 16, 17	103	Baker-1, Batchelder, Baker-2, Hickie
1, 2, 6–9, 13–15, 18–26	103	Saidara, Malangi
3–5, 10–12, 16, 17, 26	103	Saidara, Malangi, Hickie

II. ANALYSIS

A. Legal Standards

To prevail in its challenges to the patentability of the claims, Petitioner must demonstrate by a preponderance of the evidence that the challenged claims are unpatentable. 35 U.S.C. § 316(e). “In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify “with particularity . . . the evidence that supports the grounds for the challenge to

⁵ Because the application leading to the RE244 patent has an effective filing date before March 16, 2013, patentability is governed by the version of 35 U.S.C. §§ 102 and 103 preceding the Leahy-Smith America Invents Act (“AIA”), Pub L. No. 112-29, 125 Stat. 284 (2011).

each claim”)). This burden of persuasion never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review).

A claim is unpatentable under 35 U.S.C. § 103(a) if “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness.⁶ *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). Consideration of the *Graham* factors “helps inform the ultimate obviousness determination.” *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1048 (Fed. Cir. 2016) (en banc).

An obviousness analysis “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR*, 550 U.S. at 418; *accord In re Translogic Tech., Inc.*, 504 F.3d 1249, 1259 (Fed. Cir. 2007). However, Petitioner cannot satisfy its burden of proving obviousness by employing “mere conclusory statements,” but “must instead articulate specific reasoning, based on evidence of record” to support an obviousness determination. *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1380–81 (Fed. Cir. 2016).

⁶ Patent Owner has not presented objective evidence of non-obviousness.

Petitioner also must articulate a reason why a person of ordinary skill in the art would have combined the prior art references. *In re NuVasive*, 842 F.3d 1376, 1382 (Fed. Cir. 2016).

At this final stage, we determine whether a preponderance of the evidence of record shows that the challenged claims would have been rendered obvious in view of the asserted prior art. We analyze the asserted grounds of unpatentability in accordance with these principles.

B. Level of Ordinary Skill in the Art

We review the grounds of unpatentability in view of the understanding of a person of ordinary skill in the art at the time of the invention. *Graham*, 383 U.S. at 17. Petitioner contends that a person having ordinary skill in the art “would have been a person with at least a B.S. degree in electrical or biomedical engineering or a related field with at least two years’ experience designing patient monitoring systems,” wherein “[l]ess work experience may be compensated by a higher level of education, and vice versa.” Pet. 13 (citing Ex. 1003 ¶¶ 33–41); *see* Ex. 1040 ¶ 28.

Patent Owner applies the level of ordinary skill in the art identified by Petitioner. PO Resp. 8 n.5 (citing Ex. 2011 ¶¶ 18–19).

We adopt Petitioner’s assessment, which appears consistent with the level of skill reflected in the Specification and prior art.

C. Claim Construction

For this *inter partes* review proceeding, claim terms

shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b), including construing the claim in accordance with the ordinary and customary meaning of such

claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.

37 C.F.R. § 42.100(b) (2019).⁷

Under the standard set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–19 (Fed. Cir. 2005) (en banc), claim terms are given their ordinary and customary meaning, as would have been understood by a person of ordinary skill in the art at the time of the invention, in light of the language of the claims, the specification, and the prosecution history of record. *See Thorner v. Sony Comput. Entm’t Am. LLC*, 669 F.3d 1362, 1365–66 (Fed. Cir. 2012). We construe terms only to the extent necessary to resolve the controversy. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).⁸

1. Overview of the Claim Construction Dispute

Independent claim 1 recites, *inter alia*, “determin[ing] that the measurement of the physiological parameter satisfies an *alarm activation threshold*” and “initiat[ing] a *parameter-specific alarm delay or suspension period of time*.” Ex. 1001, 7:39–8:12 (emphases added). Independent

⁷ Although our rules state that “[a]ny prior claim construction determination concerning a term of the claim in a civil action, or a proceeding before the International Trade Commission, that is timely made of record in the inter partes review proceeding will be considered” (37 C.F.R. § 42.100(b)), no such construction is of record in this proceeding.

⁸ In our Institution Decision, we preliminary determined that the claims do not require a “predetermined, fixed, or pre-set” period of time. *See* Inst. Dec. 25–26. Resolution of this issue, however, is not necessary to resolve the controversy before us. *See, e.g.*, PO Resp. 66–67; *see Nidec*, 868 F.3d at 1017.

claim 13 includes similar limitations. *Id.* at 9:33–10:14. Independent claim 18 recites “initiat[ing] a first *parameter-specific alarm delay or suspension period of time*” and “delay[ing] or suspend[ing] activation of an alarm . . . for the first parameter-specific alarm delay or suspension period of time while the *first alarm activation threshold* is satisfied.” *Id.* at 10:38–11:15 (emphases added).

The arguments and evidence before us raise the question of whether the claims, when considered as a whole, require suspending activated alarms only (i.e., post-alarm suspension), or whether the claims also encompass delaying initial alarm activation (i.e., pre-alarm delays). *See* Pet. Reply 2. The Petition presents different grounds to account for these alternate constructions. Pet. 14. Specifically, the Baker-1 grounds “are directed to a construction encompassing delays *before* an alarm is activated (i.e., pre-alarm delays),” and the Saidara grounds “are directed to temporary suspension of active alarms (i.e., post-alarm suspensions).” *Id.* Thus, resolution of this question is dispositive as to certain asserted grounds of unpatentability.

a) “alarm activation threshold”

Claim 1 recites “determin[ing] that the measurement of the physiological parameter satisfies an alarm activation threshold.” Ex. 1001, 7:55–56; *see also id.* at 9:56–59 (similar in claim 13); *id.* at 10:66–11:4 (claim 18 recites “delay[ing] or suspend[ing] activation of an alarm . . . while the first alarm activation threshold is satisfied by the measurement of the first measured physiological parameter”).

In the Institution Decision, in addressing Patent Owner’s arguments distinguishing the asserted art, we preliminarily were “not persuaded that

satisfying an alarm activation threshold requires actual activation (or indication) of an alarm,” i.e., triggering an audible or visual alarm indicator. Inst. Dec. 27; *see id.* at 26–28.

After institution, Petitioner argues that “[t]he plain meaning of ‘alarm activation threshold’ necessarily requires the determination that a parameter exceeds a threshold automatically *results in alarm activation*.” Pet. Reply 3 (citing Ex. 1040 ¶ 70) (emphasis added).

In the Sur-reply, Patent Owner agrees with our initial determination, asserting that “meeting the alarm activation threshold is a separate requirement from activating the alarm.” PO Sur-reply 4–5.

b) “parameter-specific alarm delay or suspension period of time”

Claim 1 recites “initiat[ing] a parameter-specific alarm delay or suspension period of time corresponding to the physiological parameter.” Ex. 1001, 7:57–59; *see also id.* at 10:52–55 (similar in claim 18); *id.* at 9:47–50, 60–63 (claim 13 recites storing and initiating a first parameter-specific alarm delay or suspension period of time corresponding to a first physiological parameter).

Petitioner contends that the claimed “parameter-specific alarm delay or suspension period of time,” “must be interpreted in light of the Specification, which only teaches suspension of active alarms,” i.e., alarms that have already indicated an alarm condition in which a parameter exceeds an alarm activation threshold by, e.g., emitting audible or visual indicators. Pet. 14 (citing Ex. 1003 ¶ 45). Petitioner also contends that during prosecution of the application that issued as the RE244 patent, the Examiner “rejected the claims in view of prior art that teaches suspending active alarms.” *Id.* (citing Ex. 1003 ¶¶ 30, 45; Pet. 10–12).

However, Petitioner notes that, in the related district court proceeding (*see supra* § I.B), Patent Owner asserted that this claim language is satisfied by systems in which activation of an alarm, e.g., the emission of audible or visual indicators, is delayed until a measured parameter exceeds a threshold for a predetermined period of time. Pet. 13–14. In light of these arguments, Petitioner presumes that Patent Owner’s construction of “alarm delay or suspension period of time” encompasses a “delay [that] is *part of* the alarm threshold,” or in other words, “if the parameter returns to a normal range within the ‘annunciation delay’ period, the alarm never activates.” *Id.* at 14 (citing Ex. 1003 ¶ 44).

In our Institution Decision, we did not expressly construe “alarm delay or suspension period of time,” and we applied the plain and ordinary meaning of the claim language for purposes of institution. *See* Inst. Dec. 23–25. In applying the prior art to the claims, we determined on the preliminary record that Baker-1’s pre-alarm delay provided a sufficient showing of this claim limitation for purposes of institution. *See id.* at 39–42. We specifically provided instruction to the parties, however, that “[d]uring trial, the parties are encouraged to develop the record regarding the proper construction of this phrase in light of the Specification.” *Id.* at 24–25.

After institution, Petitioner maintains its position that “alarm delay or suspension period[s] of time” “are time periods in which an activated alarm is temporarily silenced or deactivated, [which is] the specification’s only disclosure.” Pet. Reply 3–4 (citing Ex. 1001, 2:33–36, 3:1–2, 3:31–32, 3:58–60, 4:46–48, 4:58–60, 5:51–58, 6:3–9; Ex. 1003 ¶ 45; Ex. 1040 ¶ 71). Or, in other words, Petitioner maintains the position that the claims are limited to post-alarm suspensions, and do not encompass pre-alarm delays.

Despite our instruction to do so, Patent Owner does not address the construction of “alarm delay or suspension period of time” in the Patent Owner Response.⁹ *See generally* PO Resp. Patent Owner instead asserts that “[n]one of [its] arguments depend on a different pre-alarm/post-alarm construction,” and “the parties raise no patentability controversy regarding the pre-alarm or post-alarm claim scope.” PO Sur-reply 1. Patent Owner contends that “[t]here’s no need to consider a narrow construction on which none of [Patent Owner’s] arguments depend.” Tr. 35:11–13; *see id.* at 34:19–35:19; *see also* PO Sur-reply 1 (“The Board should not reach this construction issue.”).

Nonetheless, for the first time, in the Sur-reply, Patent Owner argues that the Specification of the RE244 does not, in fact, support Petitioner’s proposed construction that limits the claims to only post-alarm suspensions, but rather supports its apparent contention that the claims also encompass pre-alarm delays. *See* PO Sur-reply 2–5 (citing Ex. 1001, 3:58–4:9, 4:60–63, 5:60–65, 6:15–20, 6:38–41; Ex. 1042, 118:2–120:20; Ex. 2022, 22:13–23:2, 23:8–20, 65:20–66:6, 174:2–10).

c) Explicit Construction is Appropriate

Despite Patent Owner’s contention that we need not address this question of claim construction, the law is clear that obviousness under 35 U.S.C. § 103 is a “two-step inquir[y].” *Medichem, S.A. v. Rolabo, S.L.*, 353 F.3d 928, 933 (Fed. Cir. 2003); *see also* Tr. 65:5–16. The first step “is a

⁹ *See* Tr. 40:5–16 (Patent Owner’s counsel agreeing Patent Owner was on notice of the Board’s instruction to develop the record on this issue but, instead, concluded that “It’s not something that needs to be developed”); *see also id.* at 39:7–40:16 (larger discussion).

proper construction of the claims. . . . The second step in the analysis requires a comparison of the properly construed claim to the prior art.” *Id.* While it is also true that only those claim terms that are in controversy need to be construed, and only to the extent necessary to resolve the controversy, *see Nidec*, 868 F.3d at 1017, a party’s allegation that terms are not disputed, or that construction is unnecessary because resolution of a *different* issue may be dispositive, does not preclude construction. This is especially so where resolution of a particular claim construction issue also is dispositive to allegations of unpatentability. *See* Tr. 8:20–9:1 (Petitioner’s counsel indicating that if the Board agrees with Petitioner’s contention that “these patents are properly construed as not covering [pre-alarm] delays . . . then the grounds 1 through 4 [(i.e., the Baker-1 grounds)] are out. You would not have to decide grounds 1 through 4 if you decide our way” on the claim construction question.); *id.* at 35:3–6 (Patent Owner’s counsel noting that “[Patent Owner] has never disputed that the claims will cover both [pre-alarm delays and post-alarm suspensions] and in fact none of [Patent Owner’s] arguments depend on a narrower construction. Not a single page of [Patent Owner’s] briefs makes an argument based on the narrow construction.”); *id.* at 39:10–40:16 (Patent Owner’s counsel discussing the strategic decision not to address the issue related to Petitioner’s proposed narrow construction).

For purposes of this Decision, to resolve the issues raised by Petitioner’s asserted grounds, we construe “alarm activation threshold” and “alarm delay or suspension period of time” only to the extent that we find that the claims, when considered as a whole, do not encompass pre-alarm delays. Our reasoning follows.

2. *The Parties' Reliance on the RE244 Specification*

Both Petitioner and Patent Owner contend that the Specification of the RE244 patent supports its respective position.

a) Petitioner's Position

As Petitioner notes, “[n]either ‘alarm activation threshold’ nor ‘alarm delay or suspension period of time’ appear in the specification” of the RE244 patent. Pet. Reply 2.

Petitioner contends that the Specification “only teaches suspension of active alarms.” Pet. 14 (citing Ex. 1003 ¶ 45); *see also* Ex. 1040 ¶ 63.

According to Petitioner,

The specification only describes a system that (1) compares a measured parameter to set limits; (2) automatically activates an alarm when the parameter is out-of-limits; (3) thereafter, suspends the activated alarm for a “parameter-specific” duration in response to a user request; and (4) “resumes,” “retriggers,” or “reactivates” the alarm after the suspension duration.

Pet. Reply 2–3 (citing, *inter alia*, Ex. 1003 ¶¶ 21–25, 45, 46; Ex. 1040 ¶ 64).

Petitioner cites the Abstract in support of its claim construction position (*see id.* at 2–3), which teaches, “An alarm suspend system utilizes an alarm trigger responsive to physiological parameters and corresponding limits on those parameters. . . . *Audible and visual alarms respond to the alarm trigger. An alarm silence button is pressed to silence the audible alarm for a predetermined suspend time.*” Ex. 1001, code (57) (emphasis added).

Petitioner also cites numerous portions of the RE244 Specification in support of its position that the claims are limited to suspensions of active alarms (*see* Pet. Reply 2–4). For example, Petitioner relies upon the

Specification's disclosure that "alarms are triggered by out-of-limit parameters and system failures." Ex. 1001, 2:18–19.

Petitioner also relies upon the Specification's teachings that, when an active alarm is suspended by a user, it will remain suspended for a predetermined period of time but will be reactivated if the triggering condition persists. *Id.* at 2:33–38. Specifically, the Specification teaches that "[a]n *audible alarm* may be *temporarily suspended* by pressing an alarm silence button so as to prevent unnecessary disturbance to the patient and distraction of the caregiver. During alarm suspension, visual alarms remain active. If an alarm condition persists after a predetermined alarm suspend period, the audible alarm resumes." *Id.* (emphasis added).

The Specification further explains that the suspension period "is typically long enough to give a caregiver sufficient time to intervene with appropriate patient treatment yet short enough to ensure that patient health is not endangered if intervention is ineffective." *Id.* at 2:38–42; *see also id.* at 2:55–57 ("When patient treatment time exceeds the maximum alarm suspend period, an audible alarm will constantly reactivate."); *id.* at 2:57–60 ("[A] single alarm suspend duration for all parameters is inadequate to cope with the many different types of parameters measured by the advanced monitors.").

Petitioner additionally relies upon the following portions of the Specification, which are consistent with the disclosures discussed above; the cited portions of the Specification repeatedly describe that an alarm is automatically triggered when an alarm activation threshold is satisfied, the activated alarm may be suspended by a user, and the alarm will reactivate if the alarm activation threshold is still satisfied:

One aspect of an alarm suspend system for silencing the alarms is an alarm trigger responsive to any of various parameters and predetermined limits corresponding to the parameters *An audible alarm is responsive to the alarm trigger. An alarm silence button is actuated so as to suspend the audible alarm.* A timer tracks the duration of the suspended alarm and is initiated by actuation of an alarm silence button. The timer *retriggers the audible alarm* after the timed duration has lapsed/expired.

Ex. 1001, 2:61–3:6 (emphases added).

Another aspect of an alarm suspend system is a partition of measured parameters into at least a first group and a second group. *An audible alarm is triggered if at least one parameter is outside of predetermined limits. The audible alarm is suspended in response to a silence request.* A first duration is associated with the first group and a second duration is associated with the second group. *The audible alarm is reactivated* after at least one of the first duration and the second duration.

Id. at 3:28–36 (emphases added).

A further aspect of an alarm suspend system *deactivates an audible alarm* for one of a short duration and a long duration according to the alarm-triggering parameter. A first group of parameters is associated with the short duration and a second group of parameters is associated with the long duration. The first group and the second group are partitioned according to a fast treatment time and a short treatment time associated with the parameters.

Id. at 3:58–65 (emphasis added).

The speaker 150 provides an *audible alarm in response to physiological measurements that violate preset conditions, such as an out-of-limit parameter*, as well as system failures, such as a low battery condition. The controls 140 include *an alarm silence button 144 that is pressed to temporarily suspend out-of-limit parameter alarms* and system alarms, such as low battery.

Id. at 4:42–48 (emphases added).

The *alarm silence button 144 is pressed to temporarily suspend audible alarms*. Advantageously, an alarm suspend system provides a parameter-dependent variation in the alarm suspend duration, as described below, utilizing a common silence button or other suspend initiator.

Id. at 4:58–63 (emphasis added).

As shown in FIG. 3, measured parameters 312 are compared 310 to default or user-specified limits 314. *An out-of-limit condition 318 triggers an alarm 340. An alarm suspend 328 is user-initiated by a silence request 322*. This may be a press of a silence button 144 (FIG. 1) on a monitor front panel 110 (FIG. 1). In an embodiment, the *alarm suspend 328 silences audible alarms* and modifies the display of visual alarms. The alarm suspend 328 is based on a timer 320, which ends the alarm suspend 328 after a predetermined duration 324. The duration 324 may be a function of the out-of-limit parameter 312. In an advantageous embodiment, the duration 324 relates to, or is a function of, the treatment time for the alarm-triggering parameter so as to avoid nuisance alarms while maintaining alarm integrity.

Id. at 5:51–65 (emphases added).

FIG. 4 illustrates an alarm suspend embodiment 400 that operates independently for each measured parameter that can trigger an alarm. An alarm is initially off 410. *The alarm remains off as long as the parameter is within its set limits 412. If a parameter is measured outside of its set limits 414, an alarm is triggered 420*. The alarm may audible, visual or both audible and visual. *A user can request to silence the alarm by pressing an alarm silence button 144 (FIG. 1), for example*. The silence request 422 *suspends the alarm 430 which turns off audible alarms but, in an embodiment, does not deactivate visual alarms*. The audible alarm remains suspended 430 for a predetermined duration 432. *When the suspend duration has passed, the alarm suspend expires 434 and audible alarms are once again activated 420*. The alarm remains on 428 until the triggering parameter is within limits 424 or a user *once again requests silence 422*.

Id. at 5:66–6:14 (emphases added).

b) Patent Owner's Position

Patent Owner, in turn, argues that the Specification “explains how a processor would immediately delay or suspend an alarm rather than activate an alarm.” PO Sur-reply 2. In support, Patent Owner cites the following portions of the Specification (*see id.*):

A further aspect of an alarm suspend system deactivates an audible alarm for one of a short duration and a long duration according to the alarm-triggering parameter. A first group of parameters is associated with the short duration and a second group of parameters is associated with the long duration. The first group and the second group are partitioned according to a fast treatment time and a short treatment time associated with the parameters. An override reactivates the audible alarm if the trigger parameter changes more than a predetermine amount during the corresponding duration. In various embodiments, the first group comprises parameters related to the measurement of normal hemoglobin and the second group comprises parameters related to the measurement of abnormal hemoglobin. The long duration is greater than about 120 seconds and the short duration is less than or equal to about 120 seconds. A pop-up window for the display allows selection of the long duration and the short duration in response to the silence button.

Ex. 1001, 3:58–4:9.

Other alarm features apply to both slow treatment and fast treatment parameters. For example, an alarm delay of 0, 5, 10 or 15 seconds applies to all enabled parameters.

Id. at 6:38–41.

Patent Owner also notes that the Specification “expressly contemplates ‘*other* suspend initiator[s]’ besides a user request, and does not require reactivation after a temporary delay.” PO Sur-reply 3 (citing Ex. 1001, 4:60–63, 6:15–20) (alteration in original). The cited portions of the Specification teach:

Advantageously, an alarm suspend system provides a parameter-dependent variation in the alarm suspend duration, as described below, utilizing a common silence button or other suspend initiator.

Ex. 1001, 4:60–63.

The alarm suspend 430 deactivates if the measured parameter becomes within limits 438, such as when the patient condition improves, or if no physiological data is detected 439, such as no sensor, sensor off, no cable or malfunctioning sensor situations, to name a few.

Id. at 6:15–20.

Patent Owner also argues that “the specification relates to situations where a condition that would otherwise cause an alarm resolves after some time without a clinician intervening.” PO Sur-reply 3. Patent Owner cites the following disclosure: “The duration 324 may be a function of the out-of-limit parameter. In an advantageous embodiment, the duration 324 relates to, or is a function of, the treatment time for the alarm-triggering parameter so as to avoid nuisance alarms while maintaining alarm integrity.” Ex. 1001, 5:60–65.

Patent Owner relies on the testimony of its expert, Mr. Goldberg, in support of its position that the Specification provides support for pre-alarm delays. PO Sur-reply 4 (citing Ex. 1042, 118:3–120:20).

3. Discussion

Contrary to Patent Owner’s assertions, we find that every disclosed embodiment of the claimed invention includes suspension of an activated alarm and no disclosed embodiment includes parameter-specific pre-alarm delays. Based on the overwhelming and clear disclosure in the Specification of the RE244 patent, we agree with Petitioner that “the correct

construction—the construction that most accurately delineates the scope of the claimed invention” requires delay or suspension of an activated alarm, and precludes delays or suspensions that occur before activation of an alarm, i.e., pre-alarm delays. *See PPC Broadband, Inc. v. Corning Optical Comm’ns RF, LLC*, 815 F.3d 734, 740–42 (Fed. Cir. 2016).

We recognize that we do not import limitations from the Specification into the claims. *Thorner*, 669 F.3d at 1366–67 (“We do not read limitations from the specification into claims.”). It is indisputable, however, that claims must be interpreted in light of the Specification of which they are a part. *Phillips*, 415 F.3d at 1315–1316. This is because the claims “do not stand alone. Rather, they are part of ‘a fully integrated written instrument,’ consisting principally of a specification that concludes with the claims. For that reason, claims ‘must be read in view of the specification, of which they are a part.’” *Id.* As the Court of Appeals for the Federal Circuit has stated, “the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.” *Vitrionics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) (“[I]ntrinsic evidence is the most significant source of the legally operative meaning of disputed claim language.”).

The Specification in this case is overwhelmingly clear that to construe the claims to encompass pre-alarm delays, as Patent Owner suggests, would be inconsistent therewith.¹⁰ *See Power Integrations, Inc. v. Fairchild*

¹⁰ The claims of the RE244 patent recite “parameter-specific alarm *delay or* suspension period of time.” We recognize that our construction does not give separate meaning to the “delay or” portion of the claim. However, “[t]he preference for giving meaning to all terms, however, is not an inflexible rule that supersedes all other principles of claim construction.”

Semiconductor Int'l, Inc., 711 F.3d 1348, 1360–63 (Fed. Cir. 2013) (affirming a narrower claim construction, where the specification reflects that the patentee did not consider broader claim scope as part of the invention); *see also Netword, LLC v. Centraal Corp.*, 242 F.3d 1347, 1352 (Fed. Cir. 2001) (“The claims are directed to the invention that is described in the specification; they do not have meaning removed from the context from which they arose. . . . Although the specification need not present every embodiment or permutation of the invention and the claims are not limited to the preferred embodiment of the invention, neither do the claims enlarge what is patented beyond what the inventor has described as the invention.” (internal citations omitted)).

Based on the arguments and evidence of record, we are persuaded by Petitioner’s evidence demonstrating that the claims do not encompass pre-alarm delays. As Petitioner demonstrates, the Specification consistently and exclusively discloses suspending only *active* alarms, in which an audible or visual indicator has been activated as a result of a monitored parameter exceeding a designated threshold. *See, e.g.*, Ex. 1001, 2:33–38 (“An audible alarm may be temporarily suspended by pressing an alarm silence button If an alarm condition persists after a predetermined alarm suspend period, the audible alarm resumes.”), 2:61–3:6 (“An audible alarm is responsive to the alarm trigger. An alarm silence button is actuated so as to suspend the audible alarm.”), 3:28–36 (“An audible alarm is triggered if at

SimpleAir, Inc. v. Sony Ericsson Mobile Communications AB, 820 F.3d 419, 429 (Fed. Cir. 2016); *see also ERBE Elektromedizin GmbH v. Canady Tech. LLC*, 629 F.3d 1278, 1286 (Fed. Cir. 2010) (“surplusage may exist in some claims”). *See* Tr. 7:3–6 (Petitioner’s counsel confirming that Petitioner is proposing the same construction also for the claims of the RE244 patent).

least one parameter is outside of predetermined limits. The audible alarm is suspended in response to a silence request.”), 3:58–65 (“A further aspect of an alarm suspend system deactivates an audible alarm.”), 4:42–48 (“The speaker 150 provides an audible alarm in response to physiological measurements that violate preset conditions, such as an out-of-limit parameter, as well as system failures, such as a low battery condition. The controls 140 include an alarm silence button 144 that is pressed to temporarily suspend out-of-limit parameter alarms and system alarms, such as low battery.”), 4:58–63 (“The alarm silence button 144 is pressed to temporarily suspend audible alarms.”), 5:51–65 (“An out-of-limit condition 318 triggers an alarm 340. An alarm suspend 328 is user-initiated by a silence request 322. This may be a press of a silence button 144 (FIG. 1) on a monitor front panel 110 (FIG. 1).”), 5:66–6:14 (“If a parameter is measured outside of its set limits 414, an alarm is triggered 420. The alarm may [be] audible, visual or both audible and visual. A user can request to silence the alarm by pressing an alarm silence button 144 (FIG. 1), for example. The silence request 422 suspends the alarm 430 which turns off audible alarms but, in an embodiment, does not deactivate visual alarms.”).

We have reviewed the entirety of the Specification, including the portions cited by Patent Owner, and we discern *no* disclosure in which a parameter-specific alarm is delayed or prevented from activating in the first place. Patent Owner’s arguments to the contrary are not persuasive.

As noted above, Patent Owner points to the Specification’s disclosure that “[o]ther alarm features apply to both slow treatment and fast treatment parameters. For example, an alarm delay of 0, 5, 10 or 15 seconds applies to all enabled parameters” (Ex. 1001, 6:38–41). *See* PO Sur-reply 2. This

disclosure, however, does not relate to the claimed “*parameter-specific* alarm delay or suspension period of time.” Rather, the Specification expressly states that the delay discussed at column 6, lines 38–41 “applies to *all* enabled parameters.” Ex. 1001, 6:38–41 (emphases added); *see* Pet. 14 (quoting Ex. 1001, 6:38–49; citing Ex. 1003 ¶¶ 24, 45); Pet. Reply 4 n.2. As such, this is plainly not the *parameter-specific* alarm delay or suspension period of time recited in the claims. Patent Owner’s counsel admits as much. Tr. 77:3–11 (acknowledging that “[i]n that specific example [at Ex. 1001, 6:39–40] it’s talking about an alarm delay that apparently is not being applied specifically”); *see also id.* at 76:4–78:9 (larger discussion); *ERBE Elektromedizin GmbH v. Int’l Trade Com’n*, 566 F.3d 1028, 1034–36 (Fed. Cir. 2009) (disclosure of an unrelated feature in the specification does not support a broader claim construction where the specification does not tie that feature to the disputed claim language, particularly where inconsistent with the rest of the specification).

Patent Owner also relies on Mr. Goldberg’s deposition testimony. PO Sur-reply 4–5. We recognize Mr. Goldberg’s testimony that, “in reading the patent as a whole, I believe that pre-alarm delays are, in fact, disclosed.” Ex. 1042, 118:2–13. When pressed to show support in the Specification, however, Mr. Goldberg pointed, first, to the disclosed “other suspend initiator” and, second, to the disclosed alarm suspend firmware that, he contends, “implies . . . a[n] ability to suspend the alarm other than by the alarm silence [button].” *See id.* at 118:20–123:4 (pointing to Ex. 1001, 4:60–63, 5:37, Figs. 2, 4). We do not find this testimony or Patent Owner’s argument persuasive. First, that the claimed system could suspend the alarm in a manner other than the described silence button (i.e., with the “other

suspend initiator”), does not alter the fact that the Specification only discloses suspending an alarm *after* it has been activated. Second, the firmware upon which Mr. Goldberg relies is disclosed as “respond[ing] to an alarm silence button press 288.” Ex. 1001, 5:38–41. Accordingly, we give little weight to Mr. Goldberg’s conclusory testimony that pre-alarm delays are disclosed, because this testimony is unsupported by any persuasive cited evidence. *See* 37 C.F.R. § 42.65(a).

The other portions of the Specification cited by Patent Owner (PO Sur-reply 2–4) also are not persuasive. One cited portion of the Specification indicates that the “alarm suspend system *deactivates* an audible alarm for one of a short duration and a long duration according to the alarm-triggering parameter. . . . An override *reactivates* the audible alarm if the trigger parameter changes more than a predetermine[d] amount during the corresponding duration.” Ex. 1001, 3:58–4:1 (emphases added) (cited at PO Sur-reply 2). Contrary to Patent Owner’s position, we discern that, in order to be *deactivated*, the alarm must first be *activated*. This understanding is consistent with the remainder of the Specification, which consistently describes that “[a]n audible alarm *is triggered* if at least one parameter is outside of predetermined limits” (Ex. 1001, 3:30–31), i.e., when “the measurement of the physiological parameter satisfies an alarm activation threshold” (*see, e.g., id.* at 7:55–56 (claim 1)). Similarly, in order for an alarm to be *reactivated* as described in the portion of the Specification cited by Patent Owner, it must have been *previously activated* prior to the action by the alarm suspend system which deactivated it.

A second cited portion indicates that the “duration 324 relates to, or is a function of, the treatment time for the alarm-triggering parameter so as to

avoid nuisance alarms while maintaining alarm integrity.” Ex. 1001, 5:62–65 (cited at PO Sur-reply 3). Patent Owner is correct that this portion of the Specification reflects a desire to minimize nuisance alarms, but we do not agree that this disclosure indicates that a condition may resolve without triggering an alarm, as Patent Owner’s argument suggests. PO Sur-reply 3. Rather, the portion of the Specification leading up to that cited by Patent Owner explains that

[a]n out-of- limit condition 318 triggers an alarm 340. An alarm suspend 328 is user-initiated by a silence request 322. . . . In an embodiment, the alarm suspend 328 silences audible alarms and modifies the display of visual alarms. The alarm suspend 328 is based on a timer 320, which ends the alarm suspend 328 after a predetermined duration 324.

Ex. 1001, 5:51–60. Accordingly, the cited disclosure is consistent with the remainder of the Specification, which indicates that an alarm is automatically triggered by an out-of-condition parameter, which may be suspended or held by a user’s silence request.

Accordingly, and for the reasons discussed, we determine that the claims do not encompass pre-alarm delays.

D. Obviousness over the Combined Teachings of Saidara and Malangi

Petitioner asserts that claims 1, 2, 6–9, 13–15, and 18–26 would have been obvious over the combination of Saidara and Malangi. Pet. 62–84. As noted above, *see supra* § II.C, this asserted ground of unpatentability is “directed to temporary suspension of active alarms (i.e., post-alarm suspensions).” Pet. 14.

Patent Owner disputes Petitioner’s contentions, arguing that Saidara and Malangi involve “very different devices” with different users and

environments, that Petitioner fails to provide a sufficient or supported motivation to combine them, and that the combination fails to disclose a multiple parameter device. PO Resp. 46–64.

1. Overview of Saidara (Ex. 1008)

Saidara is a U.S. Patent titled “System for Monitoring Physiological Characteristics.” Ex. 1008, code (54).

Saidara describes “apparatuses and methods for monitoring physiological characteristics such as blood glucose levels” or other characteristics, such as oxygen saturation. *Id.* ¶¶ 13, 60. Saidara’s monitoring system may include electrode sensors placed on the external surface of the skin or below the skin layer of the user to monitor physiological characteristics. *Id.* ¶ 70 (disclosing “other types of sensors,” e.g., “electrically based sensors, chemically based sensors, optically based sensors, or the like”).

Saidara also discloses that the system may “provide[] additional functions that will aid in the treatment regime,” for example, “the monitor may track meals, exercise and other activities which affect the treatment of diabetes.” *Id.* ¶ 66. Moreover, the monitor may “be coupled to an infusion pump that can further provide a medication to a user. Optionally the monitor is designed to be inconspicuous, for example a monitor design that resembles a wristwatch.” *Id.* Saidara explains that the system may display and/or log monitored information, which can then be downloaded for data analysis. *Id.* ¶ 75. “In further embodiments, the characteristic monitoring system 100, 200 can be used in a hospital environment, or the like.” *Id.*

Saidara discloses that alarms may be triggered based on various monitored conditions, e.g., high or low blood glucose markers

(hyperglycemia and hypoglycemia, respectively). *Id.* ¶ 28. Saidara’s Figure 4D is reproduced below.

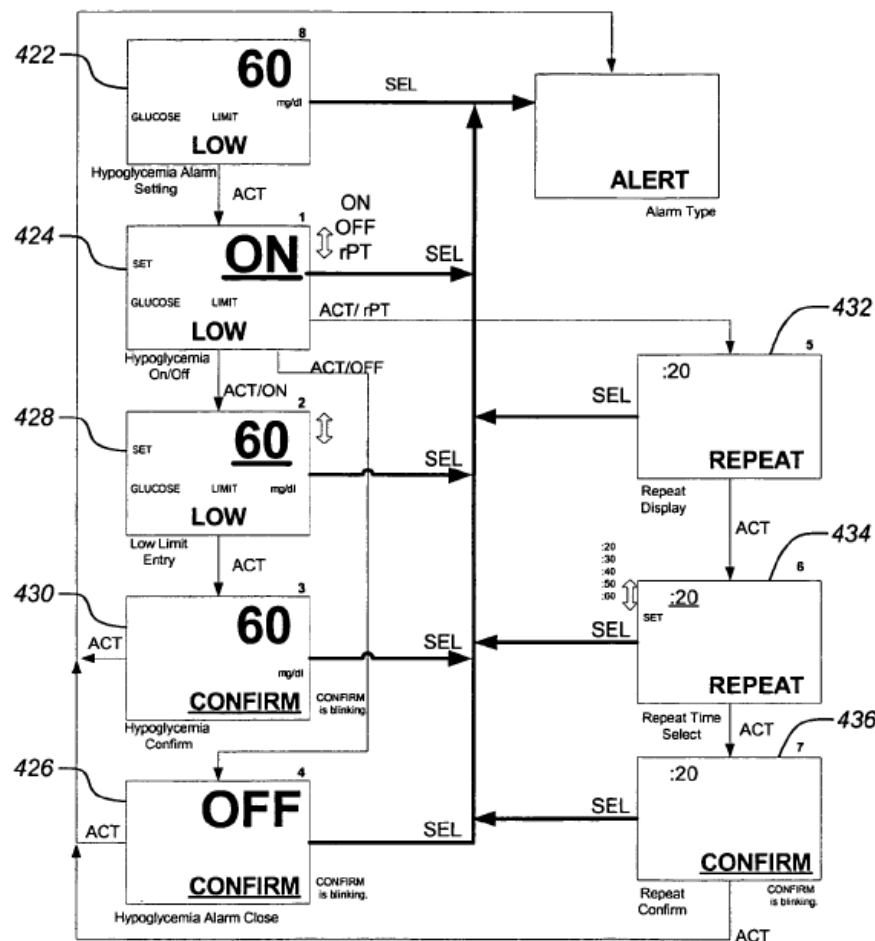


Figure 4D illustrates a flowchart of display screens that may be utilized to establish a hypoglycemia alarm. *Id.* ¶ 44. For example, through low limit entry screen 428, a user can “specify that the hypoglycemia alarm will trigger if the user’s blood glucose level is less than or equal to” a desired level, e.g., 60, 65, or 70 mg/dL. *Id.* ¶ 129.

Additional screens include, e.g., alarm repeat display screen 432, which “allows the user to set a period for delaying a repeated check of the hypoglycemia alarm condition.” *Id.* ¶ 130; *see also id.* ¶ 32 (“prevent[s] redundant alarms for a specified period”). “For the low limit alarm level, the

alarm repeat delay period can be selected from a group of values differing in 10 minute increments. For example, the alarm repeat delay period can be selected from 20, 30, 40, 50 and 60 minutes for the low limit alarm level.”

Id. ¶ 130. Saidara describes similar approaches for setting a hyperglycemia alarm, with alarm repeat delay periods selected among 1, 1½, 2, 2½, and 3 hours. *Id.* ¶¶ 44, 131–132, Fig. 4E.

Additionally, the alarm repeat delay function can be set differently for hypoglycemic and hyperglycemic alarms of different severity. *Id.* ¶ 133. Saidara explains, “[i]f a lower threshold hyperglycemic alarm is triggered, a relatively long repeat delay may be invoked. However, if a higher threshold hyperglycemic alarm is triggered, a shorter repeat delay may be used so that the user is warned more frequently because of the severity of his condition.” *Id.*

Saidara also describes an alarm snooze function for temporarily disabling an alarm. *Id.* ¶ 138. “[A]lthough both the alarm repeat delay function and the alarm snooze function prevent alarms for specified periods, they are not the same.” *Id.* ¶ 139. “The alarm repeat delay is initiated . . . in response to a first alarm. In contrast, the alarm snooze function is activated by the user directly, either by directing the monitor to snooze immediately or scheduling a snooze at a specified time.” *Id.*

2. *Overview of Malangi (Ex. 1010)*

Malangi is a thesis published by the New Jersey Institute of Technology titled “Simulation and Mathematical Notation of Alarms Unit for Computer Assisted Resuscitation Algorithm.” Ex. 1010, Title.

Malangi describes “a software system used to drive [a saline infusion] pump responsible for fluid resuscitation of patients suffering from conditions

that lead to hypotension,” under operation of a caregiver or paramedic. *Id.* at 1–2.¹¹ The system includes a number of alarms that communicate when various undesirable conditions occur, e.g., falling blood pressure (“BP”). *Id.* at 6. “Alarms may be silenced for a given period of time by pressing a soft ‘silence alarm’ button on the screen. All active alarms are reset if there is a ‘pump unplugged’ alarm.” *Id.* at 7.

Malangi’s Table 2.1 is reproduced below, and lists various alarm causes with associated priorities and silence times.

Table 2.1 Alarms Table

Alarm	Priority	Silence Time
Pump unplugged (during manual or auto control mode)	1	2
Continuity Fault (in. no Back EMF)	2	5
Impedance	3	2
Occlusion	4	2
Falling Patient BP	5	2
Failure to reach 60 mmHg in % minutes or failure to reach set point in 20 minutes	6	5
Loss of control BP Source	7	-
No BP (polling failure / no data stream)	8	-
Cuff pressures not available	9	-
Cuff pressure is invalid (out of range)	10	-
Can not measure BP after 3 minutes	11	-
BP source can not be corroborated	12	-
Loss of non-control BP source	13	-

Table 2.1 identifies situations associated with various alarms, wherein each alarm is associated with a priority level and a silence time. *Id.* at 7.

The alarms are controlled by various procedures and functions, including “*Function silencealarms*,” which “silences the alarm when caregiver chooses to silence it. It calls the *Reminder* in which a timer is set for the silence time of that particular alarm.” *Id.* at 12–13, 18–19. For example, “Falling Patient BP” is associated with a silence time of “2,”

¹¹ Citations in this Decision reference the native page numbers in Malangi, not the page numbers added in Petitioner’s exhibit.

whereas the condition of “Failure to reach 60 mmHg . . .” is associated with a silence time of “5.” *Id.* at 6–7.

3. *Discussion of Independent Claim 1*

a) *“A physiological measurement system comprising”*

Petitioner asserts that, to the extent it is limiting, Saidara discloses the subject matter of the preamble of claim 1. Pet. 62–63. Petitioner contends that Saidara discloses “methods and systems for ‘monitoring physiological characteristics.’” *Id.* at 63 (citing, e.g., Ex. 1008 ¶ 60).

The evidence of record supports Petitioner’s undisputed contention. Saidara discloses “methods and systems for the convenient operation of monitoring physiological characteristics.” Ex. 1008 ¶ 60.

b) *“a noninvasive physiological sensor configured to be positioned on a patient and output a signal responsive to a physiological condition of the patient”*

Petitioner contends that Saidara discloses sensor set 102, which may use a variety of sensor types including optically-based sensors and dermal sensors, and which outputs and communicates signals responsive to conditions of a patient to a monitor. Pet. 63 (citing Ex. 1008 ¶¶ 66, 70). Petitioner contends that Saidara teaches that its system can measure SpO₂ and that a person of ordinary skill in the art would have been motivated to use a typical non-invasive pulse oximeter sensor to perform this SpO₂ measurement, because it would provide more comfort and flexibility than an invasive or implantable sensor. *Id.* (citing Ex. 1008 ¶¶ 12, 30, 76; Ex. 1003 ¶¶ 167–168).

Patent Owner argues that Saidara teaches a user-focused single-parameter glucose monitor.¹² PO Resp. 46, 53. Patent Owner also argues that it is unclear how Saidara’s typically invasive implanted or subcutaneous glucose monitor would have been modified to employ a non-invasive sensor, especially given Dr. Yanulis’s testimony that non-invasive glucose sensors were neither taught by Saidara nor commercially available in 2008. *Id.* at 49, 61, 62 n.7 (citing Ex. 2018, 412:10–413:9, 421:6–19); *see also* PO Sur-reply 21, 23, 25.

We determine that the evidence of record supports Petitioner’s contentions. Saidara discloses “sensor set 102,” which “produces a signal that corresponds to a measured characteristic of the user, *such as* a blood glucose level. The sensor set 102 communicates these signals to a characteristic monitor 104 that is designed to interpret these signals.” Ex. 1008 ¶ 66 (emphasis added). Although Saidara’s primary embodiment monitors glucose, Saidara expressly discloses that its embodiments are applicable to “a wide variety” of additional physiological characteristics, specifically including SpO₂. *Id.* ¶ 60. Indeed, Saidara explains that sensor set 102 also monitors oxygen saturation, for use in calibrating the sensor. *Id.* ¶ 76. That glucose is a primary embodiment does not discount Saidara’s clear teaching of additional monitoring embodiments. *See In re Lamberti*, 545 F.2d 747, 750 (CCPA 1976).

Moreover, Saidara discloses various types of sensors, including “optically based sensors,” “dermal” sensors, and sensors “used on the

¹² Many of Patent Owner’s arguments are directed to the combination of Saidara and Malangi. We address the arguments applicable to each limitation, as best we can discern them.

external surface of the skin.” Ex. 1008 ¶¶ 60, 70. Even accepting Patent Owner’s contention that, as of 2008, glucose was monitored invasively (PO Resp. 62 n.7), that does not diminish Saidara’s express disclosure that “other types of sensors” can be used in sensor set 102. Ex. 1008 ¶¶ 60, 70. We credit Dr. Yanulis’s undisputed testimony that, when Saidara’s sensor set 102 monitors SpO₂, as Saidara expressly contemplates, a person of ordinary skill in the art would have utilized a non-invasive pulse oximeter sensor because this was “the most common type” of sensor for performing SpO₂ measurements and would have improved patient comfort, flexibility, and quality of life as compared to an invasive sensor. Ex. 1003 ¶ 170; *see also* Ex. 1042, 23:2–11 (Mr. Goldberg’s testimony that pulse oximeters are used “to evaluate oxygen saturation” and “are noninvasive”).

We do not agree with Patent Owner’s characterization of the Petition as “propos[ing] to modify Saidara’s invasive blood glucose monitor into a non-invasive monitor.” PO Resp. 62 n.7. Saidara clearly explains that the system “include[s] the capability for simultaneous monitoring of multiple sensors and/or include a sensor for multiple measurements.” Ex. 1008 ¶ 73. Petitioner does not contend that the non-invasive SpO₂ pulse oximeter would also monitor glucose. Petitioner only proposes modifying Saidara’s sensor set 102 to use a noninvasive pulse oximeter sensor to monitor SpO₂. Pet. 63. Petitioner does not propose any alteration to how glucose is monitored by Saidara’s sensor set 102. *Contra* PO Resp. 46–47, 48–49, 53.

For the foregoing reasons, we determine that the evidence of record supports Petitioner’s contentions that a person of ordinary skill in the art would have used “a noninvasive physiological sensor configured to be

positioned on a patient and output a signal responsive to a physiological condition of the patient,” when measuring SpO₂ in Saidara.

- c) *“one or more processors in communication with the noninvasive physiological sensor, the one or more processors configured to electronically. . .”*

Petitioner contends that Saidara discloses communicating sensor signals to processor 108, and that such disclosure accounts for the above-noted limitation. Pet. 64 (citing, e.g., Ex. 1008 ¶ 66).

The evidence of record supports Petitioner’s undisputed contention. Saidara discloses that “sensor set 102 communicates these signals to a characteristic monitor 104,” which includes processor 108. Ex. 1008 ¶ 66, Fig. 1A.

- d) *“the one or more processors configured to electronically . . . process the signal”*

Petitioner contends that Saidara discloses that processor 108 processes the signal received from the sensor set. Pet. 64 (citing, e.g., Ex. 1008 ¶ 66, Fig. 1A).

The evidence of record supports Petitioner’s undisputed contention. Saidara discloses that “sensor signals enter the monitor 104 through a sensor input 106 and through the sensor input 106 the signals are conveyed to a processor 108,” which “determines and manipulates the sensor readings within the monitor 104” to obtain “characteristic reading[s].” Ex. 1008 ¶ 66.

- e) *“the one or more processors configured to electronically . . . responsive to processing the signal, determine a measurement of a physiological parameter based at least in part upon the signal”*

Petitioner contends that Saidara discloses that processor 108 determines measurements of physiological parameters based upon the signal received from the sensor set. Pet. 64 (citing, e.g., Ex. 1008 ¶¶ 66, 76, 125–127); *see also* Ex. 1008, Fig. 1A.

The evidence of record supports Petitioner’s undisputed contention. As noted, Saidara discloses that “sensor signals enter the monitor 104 through a sensor input 106 and through the sensor input 106 the signals are conveyed to a processor 108,” which “determines and manipulates the sensor readings within the monitor 104” to obtain “characteristic readings.” Ex. 1008 ¶ 66; *see also id.* ¶ 76 (also disclosing that “oxygen saturation level can be determined by measuring signals from the various electrodes of the sensor set 103” for use “in calibration of the sensor set 102”).

- f) *“the one or more processors configured to electronically . . . determine that the measurement of the physiological parameter satisfies an alarm activation threshold”*

Petitioner contends that Saidara discloses determining whether the measured parameter satisfies an alarm activation threshold. Pet. 64 (citing, e.g., Ex. 1008 ¶¶ 125–127).

The evidence of record supports Petitioner’s undisputed contention. Saidara discloses that

the monitor includes a sensor input capable of receiving a signal from a sensor, the signal being based on a sensed physiological characteristic value of a user, and a processor for operating an alarm based on user input from an input device. The alarm

indicates an alarm condition where the sensed physiological characteristic value exceeds a set range.

Ex. 1008 ¶ 125; *see also id.* ¶ 127 (determining whether hypoglycemia exists by comparing the measured blood glucose level to a 60 mg/dL activation threshold, and activating a visual, audible, tactile, and/or vibratory alarm when the threshold is satisfied).

g) *“the one or more processors configured to electronically . . . initiate a parameter-specific alarm delay or suspension period of time corresponding to the physiological parameter, the parameter-specific alarm delay or suspension period of time being one of a plurality of parameter-specific alarm delay or suspension periods of time, the parameter-specific alarm delay or suspension period of time being different from at least one other parameter-specific alarm delay or suspension period of time corresponding to at least one other physiological parameter for which the one or more processors are configured to determine at least one measurement”*

Petitioner’s Contentions

Petitioner contends that Saidara discloses an “alarm repeat delay period” during which subsequent alarms are prevented after a first alarm is activated. Pet. 64–65 (citing Ex. 1008 ¶¶ 128, 139); *see supra* § II.D.3.f (alarm activated after threshold satisfied).

Petitioner explains that Saidara discloses the alarm repeat delay period in the context of glucose alarms, where the delay period can be “set differently for hypoglycemic alarms and hyperglycemic alarms of different severities.” Pet. 65 (citing Ex. 1008 ¶ 133). Again, Petitioner explains that Saidara’s teachings apply to other parameters, including SpO₂. *Id.* (citing Ex. 1008 ¶¶ 60, 76). Thus, Petitioner contends that a person of ordinary skill in the art would have been motivated to modify Saidara’s glucose

monitoring device to also “monitor additional physiological parameters and apply different alarm repeat delay periods to these parameters.” *Id.* (citing Ex. 1003 ¶ 174). Petitioner relies upon Dr. Yanulis’s testimony that monitoring and providing different alarm repeat delay periods to additional physiological parameters, like SpO₂, would have provided “more comprehensive data about a patient and [achieved] the same predictable result,” namely, “prevent[ing] distraction to the caregiver from ongoing audible alarms or new alarms triggered by medical intervention, while also providing a caregiver with intermittent and repeated warnings corresponding to the severity of a continuing or worsening alarm condition that may require escalated or additional medical intervention.” Ex. 1003 ¶ 174 (cited at Pet. 65–66) (also opining that “clinicians would know the proper alarm repeat delay periods to apply to different physiological parameters” based on their training and experience treating various conditions); *see supra* § II.D.3.b (modifying Saidara’s sensor set 102 to noninvasively monitor SpO₂).

“To the extent Saidara does not disclose specific examples of alarm repeat delay periods for the identified additional monitored physiological characteristics,” Petitioner also relies upon Malangi’s teaching of silencing blood pressure alarms for various periods of time corresponding to the severity of the blood pressure measurement. Pet. 66–67 (citing, e.g., Ex. 1010, Table 2.1). Petitioner contends this teaching is similar to Saidara’s disclosure of applying different alarm delay periods based on the severity of the monitored parameter. *Id.* at 67 (citing Ex. 1003 ¶ 178).

Based on these teachings, Petitioner further contends that a person of ordinary skill in the art would have been motivated to modify Saidara’s

glucose monitoring device to also “measure additional physiological parameters, including SpO₂ and BP . . . and apply different alarm suspension periods corresponding to different parameters and the severity of a parameter measurement.” *Id.* at 68 (citing Ex. 1003 ¶ 178). Petitioner relies upon Dr. Yanulis’s testimony that this would have allowed for comprehensive monitoring of a patient’s health and would have ensured “a caregiver acknowledges the currency of alarms and can provide medical treatment without triggering additional alarms caused by the medical intervention.” Ex. 1003 ¶ 178 (cited at Pet. 68).

Patent Owner’s Arguments

Patent Owner argues that Saidara and Malangi teach “very different devices (glucose monitor versus saline infusion system), with different users (patient-user versus paramedic) in dramatically different environments (home use versus combat zone).” PO Resp. 46, 53–54.

Patent Owner argues that Saidara is a single-parameter glucose monitor for a patient-user at home, with features to help track aspects of a user’s lifestyle that might impact treatment of diabetes, such as meals, sleep, and exercise, so that the patient-user may adequately care for themselves. *Id.* at 46–48, 53–54. Patent Owner argues that Petitioner does not cite anything to suggest Saidara’s monitor is operated by a medical caregiver. *Id.* at 47. Patent Owner also argues that although Saidara provides a “generic statement” regarding other physiological parameters, Saidara provides no details about how to measure other parameters and fails to indicate why its alarms would be relevant for other parameters. *Id.* at 48; *see also* PO Sur-reply 24. Finally, Patent Owner argues there is no suggestion to combine Saidara’s glucose-related alarms with alarms related

to SpO₂, which is measured only for calibration purposes and is not reported to the patient-user or used to generate an alarm. PO Resp. 48–49, 63.

Patent Owner argues that Malangi also concerns single-parameter monitoring of only blood pressure. *Id.* at 50. Patent Owner argues that Malangi discloses a software simulation for a high output saline infusion pump to be used by a caregiver during war or other critical situations, when the patient is in a life-threatening state. *Id.* at 49–50, 54.

Given these differences, Patent Owner argues that the Board’s Institution Decision correctly determined (preliminarily) that there was an insufficient motivation to combine Saidara and Malangi. *Id.* at 51–53. According to Patent Owner, Petitioner’s purported motivations underlying the proposed combination—comprehensive patient monitoring, minimized distractions, warnings for severe conditions—do not apply to Saidara because the device is worn by a patient-user at home, without a caregiver present. *Id.* at 55, 60.¹³

Patent Owner also argues that the modification presumes that more monitoring is better, which is inconsistent with both references’ focus on single parameter monitoring. *Id.* at 56. According to Patent Owner, multi-parameter monitoring “would (1) increase device complexity by requiring additional sensors, wires, and programmable features, potentially confusing a patient-user; (2) complicate specific devices features (*e.g.*, alarm settings

¹³ Patent Owner also argues that Petitioner’s caregiver-focused reasoning is inconsistent with the contention that use of a non-invasive sensor would improve patient comfort. PO Resp. 55–56. For the reasons discussed in § II.D.3.b and below, we find Petitioner’s reasoning as to both modifications to be sound. Indeed, improving patient comfort through noninvasive SpO₂ monitoring *and* comprehensively monitoring multiple conditions are simultaneously desirable in the context of medical devices.

and review); (3) increase the size of the device, making it more noticeable; and (4) increase cost.” *Id.* (citing Ex. 2011 ¶¶ 167–168), 60–61 (citing Ex. 2005¹⁴ ¶ 29; Ex. 2011 ¶¶ 168, 172). Patent Owner also argues that Petitioner’s proposed combination rests solely on Dr. Yanulis’s testimony providing “a generic motivation,” which is unsupported by any evidence and modularly combines disparate references to supply a missing claim limitation, i.e., multi-parameter monitoring. *Id.* at 57–60.

Finally, Patent Owner argues that Petitioner fails to explain how to modify either reference in light of the other, and leaves it to the Board to piece together the combination. *Id.* at 54–55, 62. According to Patent Owner, even if Saidara and Malangi were combined, “the result would have still been a single-purpose device monitoring a single physiological parameter.” *Id.* at 61. For example, Patent Owner argues that it is unclear how to incorporate Saidara’s invasive glucose monitor with Malangi’s blood pressure cuff. *Id.* at 61–62. Patent Owner argues that “[o]ther modifications (e.g., incorporating a pulse oximeter) would likewise disrupt Saidara’s goal of inconspicuous monitoring.” *Id.* at 62 (citing Ex. 2011 ¶ 176).

Discussion – Blood Pressure

As an initial matter, we agree with Patent Owner’s arguments about the proposed modification of Saidara to include blood pressure monitoring and alarming. Primarily, we agree that Petitioner fails to meet its burden of explaining how a person of ordinary skill in the art would have incorporated Malangi’s teaching of blood pressure monitoring and alarming with Saidara’s device. PO Resp. 54–55, 61–62.

¹⁴ Ex. 2005 is the Declaration of Dr. Yanulis submitted in IPR2020-00912.

The Petition provides limited guidance in this regard. Petitioner contends that it would have been obvious to also monitor blood pressure with Saidara’s device, as taught by Malangi, and provides reasons why such a modification would have been desirable. Pet. 68. Even accepting these reasons, for the sake of argument, the Petition is silent as to how a skilled artisan would have implemented Malangi’s teachings in Saidara. *Id.* at 66–68.

In its Reply, Petitioner cites testimony that is insufficient to support its contentions. For example, Petitioner relies upon the testimony of its expert, Dr. Bergeron, that a person of ordinary skill in the art “understood how [to] measure blood pressure.” Ex. 1040 ¶ 111; Pet. Reply 23. Petitioner also relies on the testimony of Patent Owner’s expert, Mr. Goldberg, that blood pressure cuffs were prevalent. Ex. 1042, 45:18–46:7; Pet. Reply 23. Both points may well be true. However, neither Petitioner, nor the cited expert testimony, explains persuasively how a skilled artisan would have known how to integrate Malangi’s teaching of monitoring and alarming for blood pressure (whether using a prevalent and well-known blood pressure cuff or any other device) with Saidara’s particular system, nor do they discuss the detriments or benefits of such a modification, e.g., the increased size and complexity of incorporating a blood pressure cuff into Saidara’s device. It is Petitioner’s burden to do so. It is insufficient to merely establish that it was known to use blood pressure cuffs to monitor that parameter.¹⁵

¹⁵ Petitioner also cites to U.S. Patent No. 10,213,108 (Pet. Reply 25), but the cited portion only describes that a communications adapter can be applied to, e.g., a non-invasive blood pressure sensor, among various other sensors, but fails to explain whether or how the blood pressure sensor is integrated with other sensors. Ex. 1047, 5:15–24.

For the foregoing reasons, we agree with Patent Owner that Petitioner fails to explain sufficiently how a person of ordinary skill in the art would have modified Saidara to also monitor, alarm, and delay alarms for blood pressure, and leaves it to the Board to piece together the proposed modification. PO Resp. 61–62; *but see* Pet. Reply 25, *and* Ex. 1040 ¶¶ 111–113 (explaining how, apart from blood pressure monitoring, SpO₂ monitoring and alarming would have been achieved in the combination).

Discussion – Oxygen Saturation

We are persuaded, however, by Petitioner’s contention that Saidara teaches that its processor accesses an alarm repeat setting function that establishes (“one or more processors . . . initiate[s]”) an alarm repeat delay period (“alarm delay or suspension period of time”) for a monitored parameter. Pet. 64–65. Saidara explains that, through this functionality, “[s]ubsequent alarms are prevented for the alarm repeat delay period after the measurement of the concentration of blood glucose first indicates a glycemic condition.” Ex. 1008 ¶ 128; *see also id.* ¶ 130 (selecting alarm repeat setting function to set delay period).

Patent Owner is correct that Saidara teaches this delay period in the context of glucose monitoring, where different delay periods may be established for hypoglycemia, for hyperglycemia, or for different severities of either condition. *See, e.g.*, PO Resp. 46–47, 53–54; Ex. 1008 ¶¶ 130 (hypoglycemia examples), 131 (hyperglycemia examples), 133 (based on severity). However, we are persuaded by Petitioner’s contention that a person of ordinary skill in the art would have found it obvious to also monitor additional parameters, i.e., SpO₂, and to implement a suspension

period for this additional parameter. Pet. 65–66; *see supra* § II.D.3.b (modifying Saidara’s sensor set 102 to noninvasively monitor SpO₂).

Indeed, Saidara expressly teaches that its embodiments apply to SpO₂ (Ex. 1008 ¶ 60), that its system is capable of simultaneously monitoring multiple sensors and including a sensor for multiple measurements (*id.* ¶ 73), and that various alarms and monitoring aspects may be combined with other alarms and monitoring aspects (*id.* ¶ 173). *See, e.g.*, Pet. Reply 22–23. Thus, contrary to Patent Owner’s argument (PO Resp. 57–60), Saidara strongly suggests its use for multi-parameter monitoring and supports Petitioner’s reasoning. Dr. Yanulis’s testimony that monitoring, alarming, and applying alarm repeat delay periods for additional parameters would have “provide[d] more comprehensive data about a patient” and would have “prevent[ed] distraction” from ongoing alarms is also supported by these portions of Saidara. Ex. 1003 ¶ 174; Pet. Reply 24. Dr. Bergeron’s testimony is also consistent with Saidara’s teachings. Ex. 1040 ¶¶ 102–104, 112–114.

We disagree with Patent Owner’s argument that Saidara provides only a “generic statement” regarding other parameters, and does not suggest “combining glucose-related alarms with alarms relating to oxygen saturation measurements.” PO Resp. 48, 63; *see also* Ex. 2011 ¶¶ 177–178. Saidara discloses monitoring glucose. And, even though glucose may be the preferred embodiment, “all disclosures of the prior art, including unpreferred embodiments, must be considered” in determining obviousness. *Lamberti*, 545 F.2d at 750; *see also Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371, 1380 (Fed. Cir. 2005) (“[T]hat a particular combination is not a preferred embodiment does not teach away absent clear discouragement of

that combination.”). Accordingly, it would be inappropriate to discount Saidara’s express disclosures that its embodiments apply to SpO₂ and that multiple parameters may be monitored simultaneously. Ex. 1008 ¶¶ 60, 73, 173; *see also* Ex. 1043, 324:3–17 (Patent Owner’s expert, Mr. Goldberg, agreeing, “Saidara [at Ex. 1008 ¶ 73] says, an embodiment can include more than one sensor, yes. . . . A person of skill reading that would, would conclude that if you have multiple sensors, that they likely serve different purposes, and could monitor more than one physiological characteristic.”).

We also disagree with Patent Owner’s argument that SpO₂ is measured only for calibration purposes and is not reported or used to generate an alarm. PO Resp. 63; PO Sur-reply 23 (also arguing SpO₂ uses an invasive probe, *but see supra* § II.D.3.b). This argument ignores the proposed modification. Although Saidara itself does not disclose using the SpO₂ calibration measurement for reporting or alarming, we are persuaded that Saidara would have suggested as much to a skilled artisan, given Saidara’s express teaching that its embodiments apply to SpO₂ (Ex. 1008 ¶ 60), that the system is capable of simultaneous monitoring of multiple parameters (*id.* ¶ 73), and that various alarms and monitoring aspects may be combined (*id.* ¶ 173).

We also are persuaded that Malangi’s teaching of correlating the severity of a parameter measurement with the duration of an alarm suspension period would have motivated a person of ordinary skill in the art to modify Saidara to “apply different alarm suspension periods corresponding to . . . the severity of a parameter measurement in order to ensure a caregiver acknowledges the currency of alarms and can provide treatment without triggering additional alarms.” Pet. 68; Ex. 1003 ¶ 178.

This reasoning, and Dr. Yanulis’s testimony, is supported by Saidara’s disclosure of the importance of alarming based on severity, such that an intervention can be taken in the appropriate time frame before repeated alarms occur. For example, Saidara discloses:

the alarm repeat delay function can be set differently for hypoglycemic alarms and hyperglycemic alarms of different severities. If a lower threshold hyperglycemic alarm is triggered, a relatively long repeat delay may be invoked. However, if a higher threshold hyperglycemic alarm is triggered, a shorter repeat delay may be used so that the user is warned more frequently because of the severity of his condition.

Ex. 1008 ¶ 133. Dr. Bergeron’s testimony also supports this reasoning.

Ex. 1040 ¶ 110 (“Malangi simply shows that if you were to add additional physiological characteristics to the device of Saidara (as it expressly states can be done according to its embodiments), that a [person of ordinary skill in the art] would know to apply different suspension times to different parameters based on the urgency of the parameter measurement and typical treatment time for the alarming parameter.”); *see also* Pet. Reply 23–24.

We have considered Patent Owner’s argument that Saidara and Malangi contemplate different users, different goals, and different environments, such that the benefits proposed by Petitioner do not apply to Saidara. PO Resp. 46–48, 49–51, 53–55, 60–61; *see also* Inst. Dec. 49–50. Having considered the full record developed during trial, we do not agree. In response to Patent Owner’s arguments, Petitioner explains that Saidara discloses that its system can be used “in a hospital environment.” Pet. Reply 20–22, 24; Ex. 1008 ¶ 75. We are persuaded that, in such an environment, a caregiver would be involved in most patient monitoring, as Saidara suggests. *See* Ex. 1008 ¶ 74 (“Embodiments of the invention are

also useful as an evaluation tool under a physician’s supervision.”); Ex. 1043, 309:2–310:14 (“[A] person of skill would assume that most of the patients in a hospital do not have self-monitoring devices that they come in with.”).

Moreover, even if Saidara’s system is only utilized by a patient-user, the record shows persuasively that patient-users themselves also would benefit from comprehensive monitoring, minimized distractions, and warnings for severe conditions, as suggested by Saidara and Malangi. As Dr. Bergeron testified,

[i]n a situation where a user is providing their own medical treatment . . . the user would also not want to be bothered by continuous alarms while the condition is being treated, but would need to know if the treatment is not working by receiving intermittent warnings that the parameter measurement has not yet returned to normal levels.

Ex. 1040 ¶ 115; *see also* Ex. 1008 ¶¶ 60 (disclosing that its embodiments are “applicable to a wide variety of patient treatment programs . . . to use in estimating the responsive treatment”), 73 (“simultaneous monitoring”), 128 (disclosing that “[s]ubsequent alarms are prevented for the alarm repeat delay period after the measurement of the concentration of blood glucose first indicates a glycemic condition”), 133 (disclosing that “if a higher threshold hyperglycemic alarm is triggered, a shorter repeat delay may be used so that the user is warned more frequently because of the severity of his condition”); Ex. 1010, Table 2.1; *see also* Pet. Reply 24.

We have also considered Patent Owner’s argument, and the evidence cited in support, that multi-parameter monitoring would create a host of problems, inconsistent with Saidara’s and Malangi’s focus on single parameter monitoring. PO Resp. 56 (citing Ex. 2011 ¶¶ 167–168), 60–61

(citing Ex. 2005 ¶ 29; Ex. 2011 ¶¶ 168, 172). We recognize the cited testimony of both parties' experts, which reflects a general desire to minimize the size of wearable devices to improve patient comfort. However, Patent Owner fails to reconcile its argument with Saidara's *express suggestion* to monitor multiple parameters simultaneously and to combine various alarms. Ex. 1008 ¶¶ 73 ("further embodiments can include the capability for simultaneous monitoring of multiple sensors and/or include a sensor for multiple measurements"), 173 ("[v]arious alarms and/or monitoring aspects discussed above may be combined or utilized with other alarms and/or monitoring aspects"). So, while it may be true that smaller devices may impart certain benefits in certain circumstances, Saidara also reflects a desire to perform multi-parameter monitoring. As discussed above, we are persuaded by Petitioner's contentions that a person of ordinary skill in the art would have been motivated to do so, e.g., to provide more comprehensive monitoring. Pet. 65–68; Ex. 1003 ¶¶ 174, 178.

Unlike for the proposed modification regarding blood pressure, we are persuaded that Petitioner explains sufficiently how a person of ordinary skill in the art would have incorporated SpO₂ monitoring and alarming with Saidara's device. For example, the Petition explains that Saidara already discloses monitoring SpO₂ with sensor set 102, albeit for calibration purposes. Pet. 65; Ex. 1008 ¶¶ 60, 76; *see also supra* § II.D.3.b (modifying Saidara's sensor set 102 to noninvasively monitor SpO₂). In light of these teachings, Petitioner's expert, Dr. Bergeron, opines that a person of ordinary skill in the art would have found it to be "a simple act of programming to have the Saidara system take the SpO₂ measurement from the sensor set and display and monitor it according to Saidara's embodiments." Ex. 1040

¶¶ 111–113. Patent Owner does not dispute this testimony or argue that monitoring and alarming based on both glucose and SpO₂ would have been beyond the level of skill in the art.

Finally, we are persuaded that, in this modification, the alarm delay or suspension period of time is “one of a plurality of parameter-specific alarm delay or suspension periods of time” and is “different from at least one other parameter-specific alarm delay or suspension period of time” for another parameter. Specifically, Saidara’s parameter-specific delay or suspension periods for hypoglycemia and hyperglycemia both differ from the SpO₂-specific delay or suspension period. Pet. 65; Ex. 1008 ¶¶ 128, 130–133.

h) “the one or more processors configured to electronically . . . activate an alarm for the physiological parameter in response to expiration of an amount of delay or suspension associated with the parameter-specific alarm delay or suspension period of time”

Petitioner contends that Saidara discloses activating an alarm after expiration of the alarm repeat delay period. Pet. 68–70 (citing Ex. 1008 ¶¶ 128, 133, Figs. 4D–4F; Ex. 1003 ¶¶ 180–183).

The evidence of record supports Petitioner’s undisputed contentions. Specifically, as discussed above, Saidara discloses that an “alarm indicates an alarm condition where the sensed physiological characteristic value exceeds a set range.” Ex. 1008 ¶ 125; *see supra* § II.D.3.f. If an alarm repeat delay period duration has been set through the alarm repeat setting function, *see supra* § II.D.3.g, the processor determines to delay or suspend subsequent indications of the alarm, such that “[s]ubsequent alarms are prevented for the alarm repeat delay period after[, e.g.,] the measurement of the concentration of blood glucose first indicates a glycemic condition.”

Ex. 1008 ¶ 128. As discussed above, we are persuaded by Petitioner’s contentions that a person of ordinary skill in the art would have found it obvious to modify Saidara such that alarm repeat delay periods would have been set for glucose and for SpO₂. *See supra* § II.D.3.g.

Additionally, we credit Dr. Yanulis’s undisputed testimony that, if an alarm condition still persists after the alarm repeat delay period, the alarm is activated. Ex. 1003 ¶¶ 181–183; Ex. 1008 ¶ 125 (alarm if measured value exceeds range).

i) Conclusion as to Claim 1

For the reasons discussed above, we determine that Petitioner has met its burden of demonstrating by a preponderance of the evidence that claim 1 is unpatentable as obvious over Saidara and Malangi.

4. Discussion of Independent Claim 13

As to independent claim 13, Petitioner primarily relies upon its contentions made with respect to claim 1, and also identifies where Saidara teaches other limitations of the claim. *See* Pet. 75–77; *see also id.* at 75 (identifying memory 110; citing Ex. 1008 ¶ 67). Patent Owner primarily relies upon the same arguments discussed above with respect to claim 1. *See* PO Resp. 46–63. Patent Owner does, however, present additional arguments as to a single limitation of claim 13. *See id.* at 63–64. We discuss the parties’ contention as to this limitation here.

Claim 13 recites, *inter alia*, that “responsive to processing *the signal*, electronically determining a first measurement of a first physiological parameter and a second measurement of a second physiological parameter.” Ex. 1001, 9:41–44 (emphasis added).

Petitioner contends that “Saidara discloses its embodiments are applicable to a wide variety of physiological parameters, including, for example, SpO₂,” and that a person of ordinary skill in the art “would have been motivated to modify Saidara to measure additional physiological parameters, including those identified in Saidara and/or BP as disclosed in Malangi,” to provide comprehensive data about a patient. Pet. 72, 75 (citing, e.g., Ex. 1003 ¶ 174; Pet. 65–66 (which cites Ex. 1008 ¶¶ 60, 76), 72 (which cites Ex. 1003 ¶ 187)).

Patent Owner contends that claim 13 “require[s] using the same signal to determine two different physiological parameters.” PO Resp. 64. According to Patent Owner, “Petitioner does not identify two parameters determined using the same signal,” nor does Petitioner cite any evidence that the parameters of Saidara are determined from the same signal. *Id.*

In its Reply, Petitioner responds that, in Saidara, the same signal from “the same ‘sensor set 102’ is used to determine blood glucose and SpO₂ measurements.” Pet. Reply 26 (citing Ex 1040 ¶¶ 112–113). Although sensor set 102 monitors SpO₂ for sensor calibration purposes, Petitioner contends a person of ordinary skill in the art “would have had a reasonable expectation of success in displaying and monitoring the same SpO₂ measurements obtained from the signal received from ‘sensor set 102.’” *Id.*

In its Sur-reply, Patent Owner argues that the claims “require the *same* signal, not just the same sensor set, to determine two different measurements,” and Saidara’s “‘sensor set’ signal, used for sensor

calibration, is from an *invasive* monitor, whereas claims 1 and 13 are *noninvasive* sensors.”¹⁶ PO Sur-reply 25.

We determine that Patent Owner’s arguments do not adequately account for what a person of ordinary skill in the art would have understood from Saidara’s teachings. Instead, we are persuaded by Petitioner’s contentions. Saidara teaches that “sensor set 102 . . . employs a sensor that produces a signal that corresponds to a measured characteristic of the user, such as a blood glucose level.” Ex. 1008 ¶ 66; *see also id.* ¶ 76 (also disclosing that sensor set 102 can monitor SpO₂ and temperature). Saidara also explains that “sensor set 102 communicates these signals to a characteristic monitor 104 that is designed to interpret these signals to produce a characteristic reading or value for the user, i.e. a measurement of the characteristic.” *Id.* ¶ 66. And, Saidara’s Figure 1A depicts sensor signals from sensor set 102 being communicated to processor 108. *Id.* (“The sensor signals enter the monitor 104 through a sensor input 106 and through the sensor input 106 the signals are conveyed to a processor 108.”). As discussed above, Saidara also explains that multiple sensors can be monitored simultaneously, and that a sensor may include multiple measurements. *Id.* ¶ 73.

Based on these teachings, we agree with Petitioner that a skilled artisan would have reasonably appreciated that the same signal from

¹⁶ PO also argues that “Sotera fails to substantively address” claims 13–15 and 19–22, which do not depend from claim 8. PO Sur-reply 25. Petitioner’s Reply, however, lists each of claims 8, 9, 13–15, and 19–22 with respect to this discussion. Pet. Reply 26. Also, the portion of the Petition to which Petitioner cites in the Reply (i.e., regarding limitation 8(a), at Pet. 72), is cross-referenced in the Petition with respect to the relevant limitation of claim 13 (*see* Pet. 75) and claim 19 (*see id.* at 80).

Saidara's sensor set 102 may be used to determine first and second parameter measurements, e.g., blood glucose (*id.* ¶ 66) and SpO₂ (*id.* ¶ 76). *See also id.* Fig. 1A (depicting a sensor signal provided to input 106 and to processor 108). Although Saidara refers at times to multiple "signals," *see, e.g., id.* ¶ 66, it does not follow that Saidara mandates separate signals for each one of the parameter measurements that Saidara describes as being communicated from sensor set 102. We credit Dr. Bergeron's testimony to that effect as it is consistent with Saidara's disclosure. *See* Ex. 1040 ¶¶ 111–113 ("[A] PHOSITA would have a reasonable expectation of success in displaying and monitoring the same SpO₂ measurements obtained from the signal from 'sensor set 102', which is also used to measure blood glucose, since the processor has already calculated these values for calibration.").

We recognize Patent Owner's argument that claim 1 recites a noninvasive sensor. PO Sur-reply 25. However, as discussed above in § II.D.3.b, we are persuaded by Petitioner's contention that a person of ordinary skill in the art would have used a noninvasive sensor when monitoring SpO₂. Use of a noninvasive sensor within sensor set 102 to monitor SpO₂ does not preclude use of an invasive sensor within that same sensor set to measure blood glucose, as Patent Owner argues is required. *See, e.g.,* PO Resp. 62 n.7. Thus, we are persuaded that one of ordinary skill in the art would have recognized from Saidara's teachings that the same signal from sensor set 102 is communicated to sensor input 106 and to processor 108, and may be used to determine measurements of two monitored parameters, e.g., blood glucose and SpO₂. Ex. 1008 ¶ 66, Fig. 1A; *see also* Ex. 1003 ¶ 187 ("It is common in the medical field that a particular patient will require more than one vital sign parameter be

monitored while under the care of medical professionals. In such circumstances, it is highly desirable, and therefore obvious, to use one machine to monitor multiple vital sign parameters as opposed to using one machine to monitor only one parameter.”).

As noted above, Patent Owner does not offer any additional separate arguments as to the patentability of claim 13 beyond those addressed above for claim 1. *See* PO Resp. 46–64. Accordingly, Patent Owner has waived any such challenge. *See* Paper 14, 8 (“Patent Owner is cautioned that any arguments not raised in the response may be deemed waived.”); *NuVasive, Inc.*, 842 F.3d at 1380–81; Consolidated Trial Practice Guide 52 (Nov. 2019).

As discussed above, we are not persuaded by Patent Owner’s arguments as to claim 1, or the additional arguments presented as to claim 13. Having considered the record before us, and for the same reasons, we are persuaded that Petitioner has met its burden of demonstrating by a preponderance of the evidence that claim 13 is unpatentable as obvious over Saidara and Malangi.

5. Discussion of Independent Claim 18

Petitioner relies upon its contentions made with respect to claim 1, and also identifies where Saidara teaches other limitations of independent claim 18. *See* Pet. 77–79 (identifying memory 110); Ex. 1008 ¶ 67 (memory 110). Patent Owner does not offer separate arguments as to the patentability of claim 18 beyond those addressed above for claim 1.¹⁷ *See* PO Resp. 46–

¹⁷ Patent Owner also argues that Petitioner’s analysis of the “means limitation” in claim 18 is “facially deficient.” PO Resp. 65–66. According to Patent Owner, claim 18 recites “a physiological sensor means” and the

64. Accordingly, Patent Owner has waived any such patentability challenge. *See* Paper 14, 8.

As discussed above, we are not persuaded by Patent Owner's arguments as to claim 1. Having considered the record before us, and for the same reasons, we are persuaded that Petitioner has met its burden of demonstrating by a preponderance of the evidence that claim 18 is unpatentable as obvious over Saidara and Malangi.

6. Discussion of Dependent Claims 2, 6–9, 14, 15, 19–26

a) Claims 2, 6, 7, and 23–26

Petitioner contends that dependent claims 2, 6, 7, and 23–26 would have been obvious over the combined teachings of Saidara and Malangi. Pet. 70–72, 81–84; *see also, e.g.*, Ex. 1008 ¶¶ 60, 76, 117–121, 130, 132, 133, Figs. 4A, 4D–4E; Ex. 1003 ¶¶ 184–186, 226–231.

Petition does not provide a means-plus-function construction as required by 37 C.F.R. § 42.104(b)(3). *Id.* Petitioner replies that “the limitation recites sufficient structure” to perform the specified function (i.e., “outputting a signal responsive to a physiological condition of a patient” (Ex. 1001, 10:39–42)). Pet. Reply 27 (citing Ex. 1040 ¶ 117). In the Sur-reply, Patent Owner contends that Petitioner has the burden on this issue. PO Sur-reply 26–27. We credit Dr. Bergeron's testimony that a person of ordinary skill in the art “would understand that a ‘physiological sensor means’ is just a physiological sensor that provides signals to a processor for measuring physiological parameters.” Ex. 1040 ¶ 117 (cited at Pet. Reply 27). We find that the limitation includes sufficient structure to perform the claimed function, and thus, is not a means-plus-function limitation. *See TriMed, Inc. v. Stryker Corp.*, 514 F.3d 1256, 1259–1260 (Fed. Cir. 2008) (the presumption that § 112 ¶ 6 applies is overcome if “the claim recites sufficient structure for performing the described functions in their entirety”)).

Patent Owner does not offer any separate arguments as to the patentability of these dependent claims beyond those presented for claim 1. *See* PO Resp. 46–64. Accordingly, Patent Owner has waived any such challenge. *See, e.g.*, Paper 14, 8.

As discussed above, we are not persuaded by Patent Owner’s arguments as to claim 1. Having considered the record before us, we are persuaded that Petitioner has met its burden of demonstrating by a preponderance of the evidence that claims 2, 6, 7, and 23–26 are unpatentable as obvious over Saidara and Malangi. Pet. 70–72, 81–84.

b) Claims 8, 9, 14, 15, and 19–22

Claim 8 depends from independent claim 1 and recites, *inter alia*, that the processor is configured to “determine a measurement of a second physiological parameter based at least in part upon the signal.” Ex. 1001, 8:51–53. Claim 19 depends from independent claim 18 and likewise recites that “the second measurement,” of a second physiological parameter, is determined “based at least in part upon the signal.” *Id.* at 11:19–21. These limitations are similar to the specific limitation of claim 13 discussed above. Claim 9 depends from claim 8; claims 14 and 15 depend from claim 13; and claims 20–22 depend from claim 19.

Petitioner contends that dependent claims 8, 9, 14, 15, and 19–22 would have been obvious over the combined teachings of Saidara and Malangi. Pet. 72–75, 77, 80–81; *see also, e.g.*, Ex. 1008 ¶¶ 60, 76, 117–121, 134–136, Fig. 4A; Ex. 1010, 7, 12, 19–20, 35; Ex. 1003 ¶¶ 174–179, 187–192, 205–207, 218–225.

Patent Owner does not offer any separate arguments as to the patentability of these dependent claims beyond those presented for claims 1

and 13. *See* PO Resp. 46–64. Accordingly, Patent Owner has waived any such challenge. *See, e.g.*, Paper 14, 8.

As discussed above, we are not persuaded by Patent Owner’s arguments as to claims 1 or 13. Having considered the record before us, we are persuaded that Petitioner has met its burden of demonstrating by a preponderance of the evidence that claims 8, 9, 14, 15, and 19–22 are unpatentable as obvious over Saidara and Malangi. Pet. 72–75, 77, 80–81.

7. Conclusion

For the foregoing reasons, we conclude that Petitioner has shown where all the features of claims 1–2, 6–9, 13–15, and 18–26 of the RE244 patent are found in the combined teachings of Saidara and Malangi. We also conclude that Petitioner has shown that a person of ordinary skill in the art would have had adequate reason to combine teachings of Saidara and Malangi. As such, we determine that Petitioner has met its burden of demonstrating by a preponderance of the evidence that claims 1–2, 6–9, 13–15, and 18–26 are unpatentable as obvious over Saidara and Malangi.

E. Obviousness over the Combined Teachings of Saidara, Malangi, and Hickie

Petitioner contends that dependent claims 3–5, 10–12, 14, 16–17, and 26 would have been obvious over the combined teachings of Saidara, Malangi, and Hickie, relying upon Hickie for the features of these dependent claims. Pet. 84–87; *see, e.g.*, Ex. 1009 ¶¶ 3, 80, 152; Ex. 1003 ¶¶ 233–246.

Patent Owner does not offer any separate arguments as to the patentability of these dependent claims beyond those presented for

independent claims 1 and 13. *See* PO Resp. 65. Accordingly, Patent Owner has waived any such challenge. *See, e.g.*, Paper 14, 8.

As discussed above, we are not persuaded by Patent Owner's arguments as to claims 1 or 13. Having considered the record before us, we are persuaded that Petitioner has met its burden of demonstrating by a preponderance of the evidence that claims 3–5, 10–12, 14, 16–17, and 26 would have been obvious over the combined teachings of Saidara, Malangi, and Hickle. Pet. 84–87.

F. Obviousness over Baker-1, Batchelder, Baker-2, and Hickle

Petitioner contends that:

claims 1, 6–8, 13, 14, 18, 19, and 23–26 of the RE244 patent are unpatentable as obvious over Baker-1 (Pet. 29–50);

claims 1, 2, 6–9, 13–15, and 18–26 are unpatentable as obvious over Baker-1 and Batchelder (*id.* at 50–56);

claims 1, 2, 6–9, 13–15, and 18–26 are unpatentable as obvious over Baker-1, Batchelder, and Baker-2 (*id.* at 56–59); and

claims 3–5, 10–12, 16, and 17 are unpatentable as obvious over Baker-1, Batchelder, Baker-2, and Hickle (*id.* at 59–62).

As noted in the Claim Construction analysis, the asserted grounds of unpatentability based on Baker-1 are “directed to a construction encompassing delays *before* an alarm is activated (i.e., pre-alarm delays).” Pet. 14. As discussed, however, we determine that the claims do not encompass pre-alarm delays. *See supra* § II.C (Claim Construction). We, therefore, do not reach these alternative grounds of unpatentability. *See also* Tr. 8:20–9:1 (Petitioner's counsel indicating that if the Board agrees with Petitioner's contention that “these patents are properly construed as not covering [pre-alarm] delays . . . then the grounds 1 through 4 [(i.e., the

Baker-1 grounds)] are out. You would not have to decide grounds 1 through 4 if you decide our way” on the claim construction question.).

G. Motion to Exclude

Petitioner moves to exclude portions of Exhibits 2017 and 2022. MTE 1, 3, 5. We do not rely upon the identified portions of the exhibits and, as such, *dismiss* the Motion to Exclude as moot.

III. CONCLUSION

In summary:¹⁸

Claims	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1, 6–8, 13, 14, 18, 19, 23–26	103	Baker-1 ¹⁹		
1, 2, 6–9, 13–16, 18– 26	103	Baker-1, Batchelder ¹⁹		
1, 2, 6–9, 13–15, 18– 26	103	Baker-1, Batchelder, Baker-2 ¹⁹		

¹⁸ 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. 16654 (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 matters in updated mandatory notices. See 37 C.F.R. § 42.8(a)(3), (b)(2).

¹⁹ As explained above, we do not reach this ground of unpatentability. See *supra* § II.F.

3–5, 10–12, 16, 17	103	Baker-1, Batchelder, Baker-2, Hickle ¹⁹		
1, 2, 6–9, 13–15, 18– 26	103	Saidara, Malangi	1, 2, 6–9, 13– 15, 18–26	
3–5, 10–12, 16, 17, 26	103	Saidara, Malangi, Hickle	3–5, 10–12, 16, 17, 26	
Overall Outcome			1–26	

IV. ORDER

Upon consideration of the record before us, it is:

ORDERED that claims 1–26 of the RE244 patent have been shown to be unpatentable;

FURTHER ORDERED that Petitioner’s Motion to Exclude (Paper 37) is *dismissed* as moot; and

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

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Patent RE47,244 E

FOR PETITIONER:

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

FOR PATENT OWNER:

Stephen W. Larson
Jacob L. Peterson
Irfan A. Lateef
Brian C. Claassen
Jeremiah S. Helm, Ph.D.
Jarom D. Kesler
KNOBBE, MARTENS, OLSON, & BEAR, LLP
2swl@knobbe.com
2jup@knobbe.com
2ial@knobbe.com
2bcc@knobbe.com
2jgh@knobbe.com
2jzk@knobbe.com