Paper 12 Date: December 1, 2020

BEFORE THE PATENT TRIAL AND APPEAL BOARD SOTERA WIRELESS, INC., Petitioner, v. MASIMO CORPORATION, Patent Owner. IPR2020-01019 Patent RE47,353 E

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

CHAGNON, Administrative Patent Judge.

DECISION
Granting Institution of *Inter Partes* Review 35 U.S.C. § 314, 37 C.F.R. § 42.4

I. INTRODUCTION

Sotera Wireless, Inc. ("Petitioner")¹ filed a Petition requesting *inter partes* review of claims 1–25 ("the challenged claims") of U.S. Patent No. RE47,353 E (Ex. 1001, "the RE353 patent"). Paper 1 ("Pet."). Masimo Corporation ("Patent Owner") filed a Preliminary Response. Paper 6 ("Prelim. Resp."). We authorized additional briefing for the parties to address the factors laid out in our precedential Order in *Apple, Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (precedential) ("*Fintiv* Order") regarding the exercise of our discretion under 35 U.S.C. § 314(a). Paper 7. Petitioner filed a Reply (Paper 10) and Patent Owner, in turn, filed a Sur-reply (Paper 11).

We have authority to determine whether to institute an *inter partes* review under 35 U.S.C. § 314, which provides that an *inter partes* review may be instituted only upon a showing that "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a) (2018). After considering the Petition, the Preliminary Response, and the evidence of record, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing with respect to at least one claim challenged in the Petition. Accordingly, we institute an *inter partes* review of all challenged claims of the RE353 patent, based on all grounds identified in the Petition.

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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*.

The following findings of fact and conclusions of law are not final, but are made for the sole purpose of determining whether Petitioner meets the threshold for initiating review. Any final decision shall be based on the full trial record, including any response timely filed by Patent Owner. Any arguments not raised by Patent Owner in a timely-filed response may be deemed waived, even if they were presented in the Preliminary Response.

A. Related Proceedings

The parties identify *Masimo Corp. v. Sotera Wireless, Inc.*, Case No. 3:19-cv-01100-BAS-NLS (S.D. Cal.) (the "parallel proceeding") as a related matter involving the RE353 patent. Pet. 2; Paper 4, 1.

Patent Owner identifies the following *inter partes* proceedings involving patents related to the RE353 patent and asserted in the parallel proceeding:

IPR2020-00912, challenging U.S. Patent No. 10,213,108 B2; IPR2020-00954, challenging U.S. Patent No. 9,788,735 B2; IPR2020-00967, challenging U.S. Patent No. RE47,244 E; IPR2020-01015, challenging U.S. Patent No. 9,795,300 B2; 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 B2.

Paper 4, 2. Patent Owner further identifies various applications that share a priority claim with the RE353 patent.

B. The RE353 Patent

The RE353 patent, titled "Alarm Suspend System," was filed May 1, 2017, and issued on April 16, 2019. Ex. 1001 codes (22), (45), (54). The RE353 patent was filed as a reissue application of U.S. Patent No. 9,153,121 ("the '121 patent). *Id.* at code (64).² The RE353 patent describes a physiological measurement system that utilizes an alarm suspend system. *Id.* at 4:25–26. The alarm suspend system prevents unnecessary disturbances to patients and distractions to caregivers. *Id.* at 2:33–36. "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.

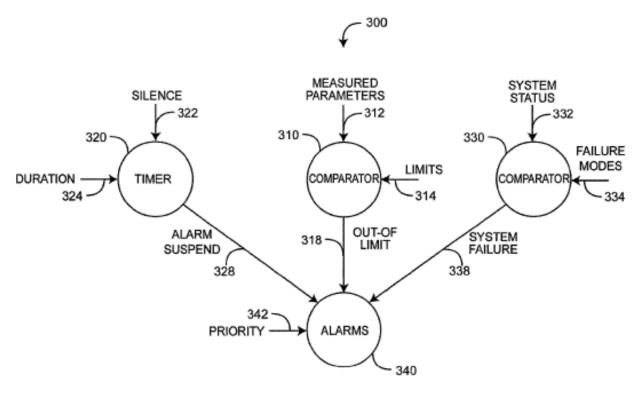
The physiological measurement system includes a noninvasive sensor connected to a physiological monitor. *Id.* at 4:25–30. The physiological measurement system incorporates "pulse oximetry in addition to advanced features, such as a multiple wavelength sensor and advanced processes for determining physiological parameters other than or in addition to those of pulse oximetry, such as carboxyhemoglobin, methemoglobin and total hemoglobin, as a few examples." *Id.* at 4:30–36. The monitor includes controls, such as "an alarm silence button [] that is pressed to temporarily suspend out-of-limit parameter alarms and system alarms, such as low battery." *Id.* at 4:46–48. "Advantageously, an alarm suspend system

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² The RE353 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.

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.

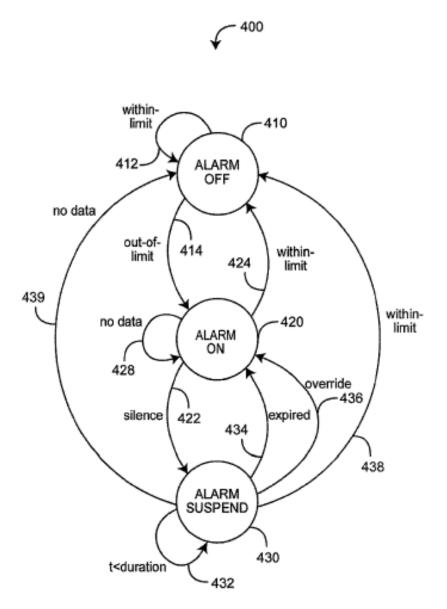
Figure 3 of the RE353 patent, reproduced below, illustrates a flow diagram of an alarm suspend system. *Id.* at 4:16–17.



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')], [carboxyhemoglobin ('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 system triggers alarm 420 when a parameter is measured outside its set limit 414 (i.e., it is "out-of-limit"). *Id.* at 6:1–4. A user may activate silence request 422 that suspends alarm 430 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 requests silence 422. *Id.* at 6:13–15. 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." *Id.* at 6:15–18. Alternatively, alarm suspend override 436 reactivates alarm 420 when a measured parameter changes by a sufficient out-of-limit amount. *Id.* at 6:20–23.

C. Illustrative Claim

Of the challenged claims, claims 1, 13, and 18 are independent. Claims 2–12 and 23–25 depend from claim 1; claims 14–17 depend from claim 13, and claims 19–22 depend from claim 18. Independent claim 1 of the RE353 patent is reproduced below, and is illustrative of the challenged claims.³

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³ The RE353 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. We acknowledge Patent Owner's argument that Petitioner's Listing of Claims "includes emphasis, double emphasis, and bracketed language without explanation." Prelim. Resp. 3. Petitioner's Listing of Claims, however, reproduces the claims as printed in the RE353 patent. We understand Petitioner's use of bold merely to enhance readability of the claim.

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

determine that an alarm should be activated in response to the measurement of the physiological parameter satisfying an alarm activation threshold;

determine that an alarm suspension should be initiated for a parameter-specific alarm suspension period of time corresponding to the physiological parameter, the parameter-specific alarm suspension period of time being one of at least a plurality of parameter-specific alarm suspension periods of time, the parameter-specific alarm suspension period of time being different from at least one other parameter-specific alarm 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;

suspend the alarm for the parameter-specific alarm suspension period of time; and

activate the alarm when the measurement of the physiological parameter satisfies the alarm activation threshold after the parameter-specific alarm suspension period of time has passed.

Ex. 1001, 7:39–8:14.

D. 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 ⁴	Ex. 1005
U.S. Publication No. 2009/0247851 ("Batchelder")	Oct. 1, 2009 ⁵	Ex. 1006
U.S. Patent No. 8,792,949 ("Baker-2")	Jul. 29, 2014 ⁶	Ex. 1007
U.S. Publication No. 2005/0038332 ("Saidara")	Feb. 17, 2005 ⁷	Ex. 1008

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⁴ Baker-1 was filed on September 30, 1997, and is prior art to the challenged claims at least under 35 U.S.C. §§ 102(a), (b), (e). *See* Ex. 1005, code (22); Pet. 6–7.

⁵ Batchelder claims priority to provisional application No. 61/070838, filed on March 26, 2008. *See* Ex. 1006, code (60). Petitioner contends that Batchelder is prior art to the challenged claims at least under 35 U.S.C. § 102(e) as of the provisional filing date. Pet. 7. Patent Owner does not challenge the status of the reference as prior art. *See generally* Prelim. Resp.

⁶ Baker-2 claims priority to provisional application No. 61/041042, filed on March 31, 2008. *See* Ex. 1007, code (60). Petitioner contends that Baker-2 is prior art to the challenged claims at least under 35 U.S.C. § 102(e) as of the provisional filing date. Pet. 7. Patent Owner does not challenge the status of the reference as prior art. *See generally* Prelim. Resp.

⁷ Saidara was filed on June 3, 2004, and is prior art to the challenged claims at least under 35 U.S.C. §§ 102(a), (b), (e). *See* Ex. 1008, code (22); Pet. 6–7.

Reference	Issue Date/ Publication Date	Exhibit
U.S. Publication No. 2003/0135087 ("Hickle")	Jul. 17, 20038	Ex. 1009
S. Malangi, Simulation and mathematical notation of alarms unit for computer assisted resuscitation algorithm, New Jersey Institute of Technology, Theses 526, (2003) ("Malangi")	Jul. 12, 2004 ⁹	Ex. 1010

Petitioner also relies on the Declaration of George E. Yanulis, EngD (Ex. 1003) to support its positions.

E. Asserted Grounds of Unpatentability

Petitioner asserts that claims 1–25 would have been unpatentable on the following grounds:

Claims Challenged	35 U.S.C. §	References
1, 6–8, 13, 14, 18, 19, 23–25	10310	Baker-1
1, 2, 6–9, 13–15, 18–25	103	Baker-1, Batchelder

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⁸ Hickle was filed on November 1, 2002, and is prior art to the challenged claims at least under 35 U.S.C. §§ 102(a), (b), (e). *See* Ex. 1009, code (22); Pet. 6–7.

⁹ Petitioner submits the Declaration of Matthew J. Brown attesting that Malangi was indexed and publicly available as of July 12, 2004. Ex. 1011, 1. Petitioner contends Malangi is prior art to the challenged claims at least under 35 U.S.C. § 102(b). Pet. 7. Patent Owner does not challenge the status of the reference as prior art. *See generally* Prelim. Resp.

¹⁰ Because the application leading to the RE353 patent was filed 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).

Claims Challenged	35 U.S.C. §	References
1, 2, 6–9, 13–15, 18–25	103	Baker-1, Batchelder, Baker-2
3–5, 10–12, 16, 17	103	Baker-1, Batchelder, Baker-2, Hickle
1, 2, 6–9, 13–15, 18–25	103	Saidara, Malangi
3–5, 10–12, 14, 16, 17, 25	103	Saidara, Malangi, Hickle ¹¹

II. ANALYSIS

A. Discretion Under 35 U.S.C. § 314(a)

Patent Owner, relying on our precedential decisions in *NHK*¹² and the *Fintiv* Order, contends that we should exercise our discretion under 35 U.S.C. § 314(a) to deny institution based on the status of the parallel district court litigation. *See* Prelim. Resp. 12–20.

1. Legal Standards

Under 35 U.S.C. § 314(a), the Director has discretion to deny institution of an *inter partes* review. *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (2016) ("[T]he agency's decision to deny a petition is a matter committed to the Patent Office's discretion."); *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1356 (2018) ("*SAS*") ("[Section] 314(a) invests the Director with discretion on the question whether to institute review."

(PTAB Sept. 12, 2018) (precedential).

¹¹ Petitioner's summary of the grounds at pages 7–8 of the Petition omits claim 14 from this asserted ground. Petitioner's detailed discussion of this ground, however, includes a discussion of claim 14, and we consider claim 14 to be included in this asserted ground. *See* Pet. 83, 86.

¹² NHK Spring Co., Ltd. v. Intri-Plex Techs., Inc., IPR2018-00752, Paper 8

(emphasis omitted)); *Harmonic v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) ("[T]he PTO is permitted, but never compelled, to institute an IPR proceeding.").

In determining whether to exercise discretion to deny institution under 35 U.S.C. § 314(a), the Board considers an early trial date in related litigation as part of an assessment of all relevant circumstances of the case, including the merits, in an effort to balance considerations such as system efficiency, fairness, and patent quality. *Fintiv* Order 5–6; *see also NHK*, Paper 8 at 19–20 (denying institution relying, in part, on § 314(a) because the parallel district court proceeding was scheduled to finish before the Board reached a final decision).

When considering an early trial date in related litigation, the Board evaluates the following factors ("*Fintiv* factors"):

- 1. whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted;
- 2. proximity of the court's trial date to the Board's projected statutory deadline for a final written decision;
- 3. investment in the parallel proceeding by the court and the parties;
- 4. overlap between issues raised in the petition and in the parallel proceeding;
- 5. whether the petitioner and the defendant in the parallel proceeding are the same party; and
- 6. other circumstances that impact the Board's exercise of discretion, including the merits.

Fintiv Order 5–6. In evaluating these factors, "the Board takes a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review." *Id.* at 6.

2. Factual Background

The progress of the related district court litigation is pertinent to discretion under 35 U.S.C. § 314(a). We summarize the progress as follows.

On June 12, 2019, Patent Owner filed a Complaint (Ex. 1033) against Petitioner in the U.S. District Court for the Southern District of California. Petitioner has filed a Motion to Stay the District Court proceedings (Ex. 1036) and Patent Owner opposed (Ex. 2001). According to the parties, the District Court has not yet ruled on the Motion. *See* Prelim. Resp. 13; Reply 2–3. The District Court has vacated all *Markman* deadlines, including the previously scheduled November 3, 2020, *Markman* hearing, pending its decision on Petitioner's Motion to Stay. *See* Ex. 1037.

Patent Owner served its infringement contentions on January 24, 2020. Ex. 1035; *see* Prelim. Resp. 15–16. Petitioner served its invalidity contentions on March 20, 2020. Ex. 2004; *see* Prelim. Resp. 15–16.

On May 29, 2020, Petitioner filed the Petition in this proceeding. *See* Paper 3 (according the Petition a filing date of May 29, 2020).

Per the court's Scheduling Order, which was modified on October 6, 2020, fact discovery closes on February 12, 2021, and expert discovery closes on May 7, 2021. Ex. 2009, 3. The Scheduling Order lists a trial date as November 30, 2021. *Id.* at 4.

Petitioner filed a stipulation in the District Court. Ex. 1038. The stipulation states that if the PTAB institutes *inter partes* review, Petitioner "will not pursue in [the District Court] the specific grounds [asserted in the *inter partes* review], or on any other ground . . . that was raised or could have been reasonably raised in an IPR (i.e., any ground that could be raised

under §§ 102 or 103 on the basis of prior art patent or printed publications)." *Id.* at 6–7.

3. Analysis of the Fintiv Factors

With this background, we consider each of the factors set forth in the *Fintiv* Order. We then weigh the factors and take a holistic view of whether efficiency and integrity of the patent system are best served by denying or instituting review.

Factor 1: whether a stay exists or is likely to be granted if a proceeding is instituted

Petitioner has filed a Motion to Stay, but the District Court has not yet ruled on the motion. Prelim. Resp. 13; Reply 2–3. Patent Owner contends that a "stay is unlikely." Prelim. Resp. 13. In particular, Patent Owner contends that "[t]he Southern District of California finds that . . . direct competition [between the parties in the relevant market] evidences significant prejudice that weighs against a stay." *Id.* at 14. Petitioner notes, however, that in the order vacating all *Markman* deadlines, the "[District] Court noted that any rescheduled *Markman* date may not be necessary, depending on how the [District] Court rules on the motion to stay." Reply 3 (citing Ex. 1037).

Because the District Court has not ruled on the pending motion to stay, we determine that this factor does not weigh for or against denying institution in this case. *See Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 15 at 12 (PTAB May 13, 2020) (informative) ("*Fintiv* DI"); *Sand Revolution II, LLC v. Cont'l Intermodal Group – Trucking LLC*, IPR2019-01393, Paper 24 at 7 (PTAB June 16, 2020) (informative) ("*Sand Revolution*").

Factor 2: proximity of the court's trial date to the Board's projected statutory deadline

As noted above, trial in the parallel proceeding currently is set to begin on November 30, 2021. Ex. 2009, 4. Patent Owner contends that this trial date "means there is little opportunity for efficiency or simplification with IPR proceedings because . . . the final written decision date will still come on or after trial." Sur-reply 3. Petitioner contends, on the other hand, that because the final written decision will issue close to the scheduled trial date, and all *Markman* deadlines have been indefinitely vacated, this factor strongly weighs in favor of instituting *inter partes* review. Reply 3–4. Petitioner also notes that the District Court "has already amended its case management order twice—including extending the trial date two months." *Id.* at 3.

"If the court's trial date is earlier than the projected statutory deadline, the Board generally has weighed this fact in favor of exercising authority to deny institution under *NHK*." *Fintiv* Order 9. On the other hand, "[i]f the court's trial date is at or around the same time as the projected statutory deadline or even significantly after the projected statutory deadline, the decision whether to institute will likely implicate other factors discussed herein, such as the resources that have been invested in the parallel proceeding." *Id*.

Here, the trial is scheduled to begin around the same time as our deadline to reach a final decision. Thus, we find that this factor does not weigh for or against denying institution in this case.

Factor 3: investment in the parallel proceeding by the court and parties

Patent Owner contends that "the parties and [District] Court have invested substantial resources litigating the validity of the patents." Prelim. Resp. 16. As noted above, the parties have already served their respective infringement contentions and initial invalidity contentions. However, as Petitioner points out, all *Markman* deadlines have been vacated, including the *Markman* hearing. Reply 4. Moreover, much other work remains in the parallel proceeding as it relates to invalidity: fact discovery is ongoing, expert reports are not yet due, and substantive motion practice is yet to come. Id. Thus, although the parties and the District Court have invested some effort in the parallel proceeding to date, further effort remains to be expended in this case before trial. The facts here are similar to those in both recent Board informative decisions. See Sand Revolution 11; Fintiv DI 14; see also Fintiv Order 10 ("If, at the time of the institution decision, the district court has not issued orders related to the patent at issue in the petition, this fact weighs against exercising discretion to deny institution under NHK.").

The *Fintiv* Order also recognizes that "notwithstanding that a defendant has one year to file a petition, it may impose unfair costs to a patent owner if the petitioner, faced with the prospect of a looming trial date, waits until the district court trial has progressed significantly before filing a petition at the Office." *Fintiv* Order 11 (footnote omitted). The Order instructs the parties to explain facts relevant to the Petition's timing. *Id.*; *see also id.* at 11–12 (considering timing of the Petition as part of the third *Fintiv* factor). Patent Owner notes that "Petitioner waited until just before the statutory deadline to file its Petition," arguing that the Petition includes

"substantially the same arguments presented in its March 20, 2020 invalidity contentions." Prelim. Resp. 16. Petitioner, on the other hand, contends that it "was not dilatory in filing this petition." Reply 5. Petitioner explains that the parties spent six months after the complaint was filed "engaged in settlement discussions." *Id.* Further, Petitioner notes that its initial invalidity contentions were filed on March 20, 2020, which was "concurrent with the nationwide shift to 'work from home' and the closing of counsels' public offices." *Id.* Petitioner contends that, thereafter, it "diligently worked to draft IPR petitions challenging nine patents and 183 claims," including the present Petition. *Id.* Patent Owner responds that "[n]ormal settlement discussions . . . cannot excuse" the delay and reiterates its contention that Petitioner "waited until just before the statutory deadline to file its Petition." Sur-reply 3.

Petitioner filed its Petition approximately two months after serving its initial invalidity contentions, and approximately two weeks before the statutory deadline. Based on the facts present here, we find that Petitioner's explanation for the timing of the Petition is reasonable, notwithstanding the closeness to the statutory deadline, particularly in view of the large number of patents and claims challenged in this and Petitioner's other related petitions for *inter partes* review, as well as the increased difficulty in preparing the Petitions due to concurrent office closures. *See* Reply 5; *supra* Section I.A (identifying related *inter partes* review proceedings).

Due to the relatively limited investment in the parallel proceeding to date and the fact that the timing of the Petition was reasonable, we find that this factor weighs in favor of not exercising discretion to deny institution under 35 U.S.C. § 314(a).

Factor 4: overlap between issues raised in the petition and in the parallel proceeding

Patent Owner contends that "Petitioner relies upon the same primary references and substantially the same invalidity arguments, under the same claim construction standard, as in the District Court." Prelim. Resp. 17; Ex. 2004 (Invalidity Contentions).

Petitioner notes that the Petition "seeks review of all claims of the RE353 Patent, not merely those at issue in the [parallel proceeding]." Reply 6; see also Ex. 2004, 1 (claims 1, 6, 7, 8, 13, 14, 18, 19, 23, and 25 of the RE353 patent are asserted in the parallel proceeding). Further, as noted above, Petitioner has filed in the District Court "a stipulation that, if IPR is instituted, they will not pursue in the District Court Litigation any ground raised or that could have been reasonably raised in an IPR." Reply 6; Ex. 1038. Petitioner contends that, because of this stipulation, "there will be no overlap of invalidity issues between the [parallel district court proceeding] and [this *inter partes* review]." Reply 6.

Patent Owner contends that the stipulation is "unclear" as to whether Petitioner reserves the right to proceed based on other references cited in the invalidity contentions. Sur-reply 3–4. We disagree with Patent Owner's contention here. The portion of the stipulation quoted by Patent Owner, states that the "stipulation is not intended . . . to limit [Petitioner's] ability to assert invalidity of the asserted claims . . . on any other ground (*i.e.*, invalidity under §§ 101, 112)." Ex. 1038, 7 (emphasis added). Petitioner's stipulation also unequivocally states, however, that it "will not pursue in this case the specific grounds . . . [in] the instituted inter parties [sic] review petition, or on any other ground . . . that was raised or could have been reasonably raised in an IPR (i.e., any ground that could be raised under

§§ 102 or 103 on the basis of prior art patents or printed publications)." Id. at 6–7 (emphasis added).

Petitioner's stipulation here mitigates any concerns of duplicative efforts between the district court and the Board, as well as concerns of potentially conflicting decisions. *See Sand Revolution* 12. Importantly, Petitioner broadly stipulates to not pursue "any ground raised or that could have been reasonably raised." Reply 6. As noted in *Sand Revolution*, such a broad stipulation better addresses concerns of duplicative efforts and potentially conflicting decisions in a much more substantial way. *Sand Revolution* 12 n.5. Accordingly, Petitioner's broad stipulation ensures that an *inter partes* review is a "true alternative" to the district court proceeding. *Id*.

Thus, we find that this factor weighs strongly in favor of not exercising discretion to deny institution under 35 U.S.C. § 314(a).

Factor 5: whether the petitioner and the defendant in the parallel proceeding are the same party

Petitioner and Patent Owner acknowledge the parties are the same in the *inter partes* proceeding and in the parallel proceeding. Prelim. Resp. 18; Reply 6–7. Thus, this factor supports denying institution. *See Fintiv* DI 15; *Sand Revolution* 12–13; *cf. Fintiv* Order 13–14 ("If a petitioner is unrelated to a defendant in an earlier court proceeding, the Board has weighed this fact against exercising discretion.").

Factor 6: other circumstances and considerations that impact the Board's exercise of discretion, including the merits

As discussed below, on this preliminary record, Petitioner has met its burden of demonstrating a reasonable likelihood that it would prevail in showing that claims of the RE353 patent are unpatentable. Although we recognize the record may change during trial, as discussed in detail below, Petitioner has made a sufficiently persuasive showing, on the record presently before us, that the prior art references cited in the Petition teach or suggest all limitations of at least one challenged claim. *See Fintiv* Order 14–15 (discussing the merits of the Petition as a consideration).

We determine that this factor does not weigh for or against denying institution in this case.

Conclusion

We take "a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review" when considering the six *Fintiv* factors. *Fintiv* Order 6. Our holistic review of the *Fintiv* factors, namely that the timing of the Petition was reasonable, the relatively limited investment in the parallel proceeding to date, and that there is minimal potential overlap of the two proceedings, indicates that the *Fintiv* factors weigh in favor of instituting *inter partes* review. As such, we are not persuaded that the interests of the efficiency and integrity of the system

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¹³ The parties include arguments directed to the merits of the asserted grounds in their discussions of Factor 6. *See* Reply 7; Sur-reply 4–7. We do not rely on these arguments in our determination below that Petitioner has presented a reasonable likelihood of success on the merits (*see infra* Sections II.F–II.I).

would be best served by invoking our authority under 35 U.S.C. § 314(a) to deny institution of a meritorious Petition. For the reasons discussed above, we decline to deny institution under § 314(a).

B. Legal Standards

"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*, 815 F.3d at 1363 (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 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. ¹⁴ *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). An obviousness analysis "need not seek out precise teachings directed to the

¹⁴ At this stage of the proceeding, the parties have not asserted or otherwise directed our attention to any objective evidence of non-obviousness.

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." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016). Instead, Petitioner 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).

We analyze the asserted grounds of unpatentability in accordance with these principles to determine whether Petitioner has met its burden to establish a reasonable likelihood of success at trial.

C. Level of Ordinary Skill in the Art

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 "[1]ess work experience may be compensated by a higher level of education, and vice versa." Pet. 13 (citing Ex. 1003 ¶¶ 33–41).

At this stage of the proceeding, Patent Owner does not contest Petitioner's definition of a person of ordinary skill in the art. *See generally* Prelim. Resp.

Based on the current record and for the purposes of this Decision, we adopt Petitioner's proposed description of the person of ordinary skill in the art.

D. 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). Further, "[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." *Id.*

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

1. "alarm suspension period of time"

Petitioner contends the term "alarm suspension period of time' must be interpreted in light of the specification, which only teaches suspension of active alarms." Pet. 14 (citing Ex. $1003 \, \P \, 45$). Petitioner also contends that during prosecution of the application that issued as the RE353 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 parallel District Court proceeding, Patent Owner asserted that this claim language is satisfied by systems in which activation of an alarm is delayed until a measured parameter exceeds a threshold for a predetermined period of time. *Id.* at 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 '... delay' period, the alarm never activates." *Id.* at 14 (citing Ex. 1003 ¶ 44).

The Petition presents different grounds depending on the interpretation of the claims. *Id.* at 14–15. Specifically, Grounds 1–4 "are directed to a construction encompassing delays *before* an alarm is activated (i.e., pre-alarm delays)," and Grounds 5 and 6 "are directed to temporary suspension of active alarms (i.e., post-alarm suspensions)." *Id.*

In its Preliminary Response, Patent Owner contends that Petitioner fails to offer an actual construction of this phrase and, instead, "improperly presents litigation-associated non-infringement arguments." Prelim. Resp. 8. Patent Owner argues that "alarm suspension period of time' has a plain meaning that needs no further construction." *Id*.

Despite raising the issue, Petitioner does not offer an express construction of this phrase. Pet. 14. At this stage of the proceeding, we agree with Patent Owner that this phrase need not be construed expressly. Accordingly, we apply the plain and ordinary meaning of "alarm suspension period of time," for purposes of this Decision. During trial, the parties are

encouraged to develop the record regarding the proper construction of this phrase in light of the Specification.

2. "predetermined," "fixed," or "pre-set" alarm suspension periods

Patent Owner further asserts that "[e]ach independent claim also requires *multiple predetermined* alarm suspension periods of time where one alarm suspension period *differs* from another." Prelim. Resp. 11. Patent Owner argues that both the plain meaning of the claim and the specification require that the suspensions periods are "predetermined." *Id.* at 12 (citing Ex. 1001, 2:37–38, 5:58–60, 6:5–11, Figs. 3, 4, code (57)). Elsewhere, Patent Owner refers to this limitation as requiring delay or suspension periods that are "fixed." *See, e.g., id.* at 3, 28, 32.

Petitioner does not discuss whether the "alarm suspension period of time" requires a "predetermined" or "fixed" period. *See generally* Pet. However, Petitioner asserted Grounds 3 and 4, as an alternative to Grounds 1 and 2, "[t]o the extent the RE353 [patent] claims require *pre-set* 'parameter-specific alarm suspension periods of time." *Id.* at 57.

At this stage of the proceeding, we do not agree that the recited "alarm suspension period of time" must be predetermined, fixed, or pre-set. In support of its position, Patent Owner identifies portions of the Specification that it contends "repeatedly confirms that the duration of suspension after the alarm condition triggers is 'predetermined.'" Prelim. Resp. 12 (citing Ex. 1001, 2:37–38, 5:58–60, 6:5–11, Figs. 3–4, code (57)).

The claims themselves, however, do not recite a predetermined, fixed, or pre-set time period. It is well-settled that "[i]t is improper for a court to add 'extraneous' limitations to a claim, that is, limitations added 'wholly apart from any need to interpret what the patentee meant by particular words

or phrases in the claim." Hoganas AB v. Dresser Indus., Inc., 9 F.3d 948, 950 (Fed. Cir. 1993) (quoting E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1433 (Fed. Cir. 1988)). Indeed, "[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction'." Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 906 (Fed. Cir. 2004) (citation omitted). Patent Owner does not demonstrate such intent. In fact, the Specification indicates that suspend "duration 324 may be a function of the out-of-limit parameter 312" (Ex. 1001, 5:60–61), at least suggesting that it need not be a specific predetermined, fixed, or pre-set value.

Accordingly, at this stage of the proceeding, we decline to import into the claims a requirement that the delay or suspension period be predetermined, fixed, or pre-set. *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004) ("Though understanding the claim language may be aided by the explanations contained in the written description, it is important not to import into a claim limitations that are not a part of the claim.").

3. Order of Claim Language

Patent Owner further asserts that each of the independent claims "(a) determines that an alarm should be activated in response to the measurement of the physiological parameter satisfying an alarm activation threshold, (b) determines that an alarm suspension should be initiated for a parameter-specific period of time, and *then* (c) suspends the alarm for the parameter-specific period of time." Prelim. Resp. 8–9. Patent Owner

proposes the Board construe the claims so "that (a) generation of the alarm condition differs from (b) the determination to suspend, which likewise differs from, and must precede, (c) the parameter-specific alarm suspension period of time." *Id.* at 10. According to Patent Owner, "[t]his is dispositive for Grounds 1–4." *Id.*

Patent Owner's arguments in this regard imply that "determin[ing] that an alarm should be activated in response to the measurement of the physiological parameter satisfying an alarm activation threshold," as claimed—to which Patent Owner also refers as "triggering" or "generation of the alarm condition"—requires actual activation (or indication) of an alarm prior to delay or suspension of the alarm. *See*, *e.g.*, *id*. (distinguishing Petitioner's prior art that discloses a delay "*before* an alarm is activated" on that basis); *see also id*. at 31–32 (distinguishing Petitioner's alleged "alarm activation threshold" on the basis that "*no* alarm is triggered after passing the . . . threshold").

Based on the record now before us, we are not persuaded that determining that an alarm *should be activated* in response to satisfying an alarm activation threshold requires actual activation (or indication) of an alarm. The phrase "alarm activation threshold" is not used in or defined by the Specification of the RE353 patent. The only place this language appears in the RE353 patent is in the claims. The phrase was first introduced in a Preliminary Amendment filed with the application that led to the '121 patent (i.e., the original patent of which the RE353 patent is a reissue). *See* Ex. 1016, 142–148. For example, independent claim 2 presented in the Preliminary Amendment recited, *inter alia*, "activate an alarm in response to determining an alarm activation threshold has been satisfied by the

physiological parameter measurement." *Id.* at 143 (emphases added). Here, the claim expressly recited activation of the alarm in addition to the recitation of satisfying the alarm activation threshold. *See Innova/Pure Water v. Safari Water Filtration*, 381 F.3d 1111, 1119 (Fed. Cir. 2004) ("While not an absolute rule, all claim terms are presumed to have meaning in a claim."). Relatedly, claim 1 of the RE353 patent expressly recites "activat[ing] the alarm when the measurement of the physiological parameter satisfies the alarm activation threshold after the parameter-specific alarm suspension period of time has passed" (Ex. 1001, 8:10–13 (emphasis added)), suggesting that, if the inventors had wanted to require actual activation (or indication) of an alarm prior to suspension of the alarm, they knew how to do so.

This evidence tends to lead to a conclusion that Patent Owner did not intend that use of the phrase "alarm activation threshold" implicitly requires an alarm to actually activate prior to delay or suspension of the alarm. Instead, we determine that the claimed "determin[ing] that an alarm should be activated in response to the measurement of the physiological parameter satisfying an alarm activation threshold" is met simply by determining that the physiological parameter is outside of its set limit, and that it does not require actual activation (or indication) of an alarm.

We need not address further Patent Owner's argument regarding the order of claim limitations at this stage of the proceeding, as it is not necessary to resolve the controversies before us. *Nidec*, 868 F.3d at 1017.

E. Overview of the Asserted References

1. Baker-1 (Ex. 1005)

Baker-1 is titled "Method and Apparatus for Nuisance Alarm Reductions." Ex. 1005, code (54). Baker-1 describes "controlling alarms in [a] medical diagnostic apparatus where an alarm is generated when a measured value for a physiological parameter passes a threshold." *Id.* at 1:54–57. "Alarms are inhibited based upon a combination of the amount of time and the amount by which the threshold is past." *Id.* at 1:60–62. In a pulse oximeter example, alarms may be set for oxygen saturation or pulse rate. *Id.* at 1:64–2:6. The combination of time and amount may calculated as an integral or some function of an integral. *Id.* at 1:62–63.

Baker-1 describes a typical pulse oximeter, including a digital display circuit, circuitry select buttons, alarm status lights, optically coupled adjustment knob, synchronization status light, LED digital view meter, and power switch. *Id.* at 2:58–64. The pulse oximeter includes a sensor attached to a patient's finger. *Id.*

Figure 2 of Baker-1 is reproduced below:

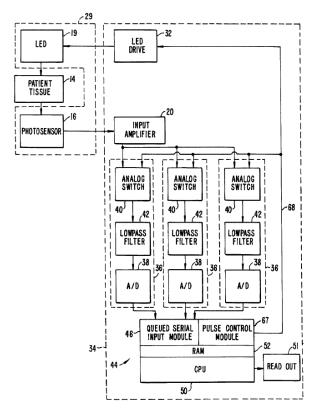


Figure 2, above, illustrates a block diagram of pulse oximetry circuitry. *Id.* at 2:35–36. Figure 2 describes sensor 29 and photosensor 16. *Id.* at 3:3–17. "The signal from photosensor 16 is provided through input amplifier 20 to . . . queued serial input module 46, which provides data to [] RAM 52 for reading and analysis by [] CPU 50," of microcontroller/processor unit (MPU) 44. *Id.*

Figure 3 of Baker-1 is reproduced below.

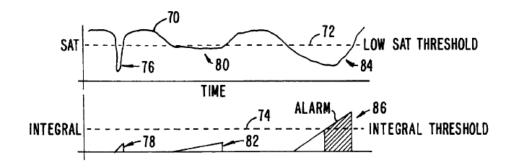


Figure 3, above, illustrates an alarm response applying an integral algorithm. *Id.* at 2:37–38, 3:32. The figure illustrates three separate incursions below low sat threshold 72. *Id.* at 3:32–33. In the first example, "deep but short incursion 76 produces [] integral value 78 which does not exceed [] integral threshold 74, and thus does not produce an alarm." *Id.* at 3:36–41. In the second example, incursion 80 barely drops below the low sat threshold, but stays there for length of time that would generate an alarm in prior systems; again, however, integral threshold 74 is not crossed, so an alarm does not signal. *Id.* at 3:42–52. In the third example, "final incursion 84 is both long enough and deep enough to cause [] integral value 86 to exceed the integral threshold and generate an alarm." *Id.* at 3:53–55. Baker-1 describes a similar integral method to screen pulse rate alarms. *Id.* at 5:29–38.

Baker-1 discloses that "rather than an integral, some other function of the time and amount of an incursion could be used to control when an alarm is generated." *Id.* at 5:46–48. Furthermore, "[a]n alarm can be considered inhibited according to an integral, or the alarm could simply have its generation controlled by the integral without anything being inhibited." *Id.* at 5:48–51.

2. Batchelder (Ex. 1006)

Batchelder is titled "Graphical User Interface for Monitor Alarm Management." Ex. 1006, code (54). Batchelder describes an alarm integration method that reduces nuisance alarms on patient monitors. *Id.* ¶ 15. "An exemplary alarm management system may be the SatSecondsTM alarm management technology." *Id.*

Batchelder's Figure 1 is reproduced below.

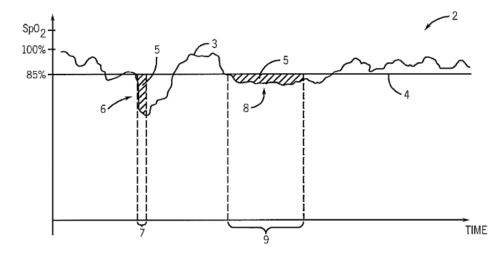


Figure 1, above, "is a graph illustrating a patient's measured SpO₂ versus time." *Id.* ¶ 9. Line 4 represents a threshold SpO₂ value. *Id.* ¶ 15. "Rather than sounding an alarm as soon as the patient's measured SpO₂ (plot 3) drops below the threshold value (line 4), the SatSeconds system measures []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

Batchelder describes a monitor device including a display, a speaker, and user inputs. See id. ¶ 24. The user inputs enable the caregiver to change the SpO₂ and SatSeconds threshold value. Id. ¶¶ 25, 26. "For example, [] SpO₂ threshold 112 may be adjusted in increments of 1% while [] SatSeconds threshold 114 may be adjusted in increments of 25. A number

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of discreet values may be available for [] thresholds 112 and 114, or the value adjustment may be continuous." *Id.* ¶ 28. Figures 5–8 of Batchelder (not reproduced herein) illustrate how changes in SpO_2 and SatSeconds thresholds effect the alarm settings. *See id.* ¶¶ 30–32.

3. Baker-2 (Ex. 1007)

Baker-2 is titled "Reducing Nuisance Alarms." Ex. 1007, code (54). Baker-2 describe an alarm condition adjustment operation that adjusts a predetermined alarm condition based on statistical parameters. *Id.* at 11:53–56. For example, the adjustment may include changing the value of a predetermined threshold, changing the type of threshold, and changing a temporal condition (such as a delay period). *Id.* at 11:58–65. A generate alarm operation "compares the adjusted threshold to the appropriate parameter to determine if the parameter exceeds the adjusted threshold (i.e., is outside of the acceptable range). If so, the alarm is generated." *Id.* at 12:35–38. Baker-2 describes that "the delay period may be selected from one or more predetermined delay periods based on the calculated accuracy." *Id.* at 15:37–41.

4. Hickle (Ex. 1009)

Hickle is titled "User Interface for Sedation and Analgesia Delivery Systems and Methods." Ex. 1009, code (54). Hickle describes a user interface for a sedation and analgesia system. *Id.* ¶ 10. The user interface displays critical parameters of the patient, and includes an alarm setting display that allows a user to enter new values for each alarm limit (e.g., high warning, high caution, low caution, low warning) with keypad 36. *Id.* ¶¶ 82, 152.

5. Saidara (Ex. 1008)

Saidara is titled "System for Monitoring Physiological Characteristics." Ex. 1008, code (54). Saidara describes "apparatuses and methods for monitoring physiological characteristics such as blood glucose levels." Id. ¶ 13. Saidara describes monitoring other physiological characteristics in addition to blood glucose, such as oxygen saturation. Id. ¶ 60. The monitoring system may include electrode sensors placed on the external surface of the skin. Id. ¶ 70. The electrode sensors can determine oxygen saturation level. Id. ¶ 76.

One or more alarms may trigger by various conditions, e.g., meal markers, exercise markers, high blood glucose markers, and low blood glucose markers. *Id.* ¶ 28. Advanced alarm functions include "an alarm repeat delay to prevent redundant alarms for a specified period and an alarm snooze function to prevent alarms generally for a specified period." *Id.* ¶ 32. Saidara further describes that "the alarm repeat delay function can be set differently for hypoglycemic alarms and hyperglycemic alarms of different severities." *Id.* ¶ 133. For example, "[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 further describes an alarm snooze function for temporarily disabling the 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

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by the user directly, either by directing the monitor to snooze immediately or scheduling a snooze at a specified time." *Id*.

6. Malangi (Ex. 1010)

Malangi is titled "Simulation and mathematical notation of alarms unit for computer assisted resuscitation algorithm." Ex. 1010, Title.

Malangi describes computer assisted resuscitation algorithm ("CARA") as a "software system used to drive the pump responsible for fluid resuscitation of patients suffering from conditions that lead to hypotension." *Id.* at 2. The system includes a number of alarm units for indicating various conditions. *Id.* at 6. "Alarms may be silenced for a given period of time by pressing a soft 'silence alarm' button on the screen." *Id.* at 7. The alarms have certain priorities and silence times, depending on the particular alarm. *Id.* at Table 2.1. "All active alarms are reset if there is a 'pump unplugged' alarm." *Id.* at 7.

The alarms are controlled by various procedures and functions, including "procedure *Add Alarms*," "procedure *Silence Alarms*," and "*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.

F. Asserted Obviousness over Baker-1

Petitioner contends that claims 1, 6–8, 13, 14, 18, 19, and 23–25 would have been obvious over Baker-1. Pet. 29–49. As noted above, this asserted ground of unpatentability is "directed to a construction encompassing delays *before* an alarm is activated (i.e., pre-alarm delays)." *Id.* at 14.

Patent Owner argues that Baker-1 does not teach or suggest all features of the claimed system and that Petitioner fails to demonstrate a reasonable expectation of success. Prelim. Resp. 25–35.

1. Independent Claim 1

a) "A physiological measurement system comprising"

Petitioner asserts that Baker-1 teaches the subject matter of the preamble of claim 1. Pet. 30. In particular, Petitioner argues that Baker-1 teaches a "medical diagnostic equipment measuring a physiological parameter." *Id.* at 30–31 (citing Ex. 1005, 2:49–51; Ex. 1003 ¶ 70).

Patent Owner does not present arguments regarding this limitation. *See generally* Prelim. Resp.

We determine that, on the record now before us, Petitioner's cited evidence sufficiently supports its contentions regarding the subject matter of the preamble.¹⁵

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 asserts that Baker-1 teaches this limitation. Pet. 31–32. In particular, Petitioner argues that Baker-1's non-invasive pulse oximeter is configured to attach to a patient's finger and output signals responsive to SpO₂ (oxygen saturation) and PR (pulse rate) measurements of a patient. *Id.*

¹⁵ Because we are persuaded that Petitioner has shown that Baker-1 teaches the preamble, we need not decide whether the preamble is limiting for purposes of this Decision.

(citing Ex. 1005, 2:48–56, 2:58—64, 3:3–15, Figs. 1, 2, claims 3, 4, 11, 12; Ex. 1003 ¶¶ 71, 72).

Patent Owner does not present arguments regarding this limitation. *See generally* Prelim. Resp.

We determine that, on the record now before us, Petitioner's cited evidence sufficiently supports its contentions regarding this limitation.

c) "one or more processors in communication with the noninvasive physiological sensor, the one or more processors configured to electronically . . ."

Petitioner asserts that Baker-1 teaches this limitation. Pet. 32. In particular, Petitioner argues that Baker-1's microcontroller/processor unit receives a signal from the noninvasive sensor for reading and analysis. *Id.* (citing Ex. 1005, 3:3-15, Fig. 2; Ex. $1003 \, \P \, 73$).

Patent Owner does not present arguments regarding this limitation. *See generally* Prelim. Resp.

We determine that, on the record now before us, Petitioner's cited evidence sufficiently supports its contentions regarding this limitation.

d) "the one or more processors configured to electronically . . . process the signal to determine a measurement of a physiological parameter based at least in part upon the signal"

Petitioner asserts that Baker-1 teaches this limitation. Pet. 33. In particular, Petitioner argues that a person of ordinary skill in the art "would understand that 'reading and analysis' of the signal received from 'sensor 29' necessarily means 'CPU 50' processes the signal and determines a measurement of a physiological parameter based on the signal, required for

calculation of the SpO₂ integral value." *Id.* (citing Ex. 1005, 3:5–15, Fig. 2, claim 17; Ex. 1003 \P 74).

Patent Owner does not present arguments regarding this limitation. *See generally* Prelim. Resp.

We determine that, on the record now before us, Petitioner's cited evidence sufficiently supports its contentions regarding this limitation.

e) "the one or more processors configured to electronically . . . determine that an alarm should be activated in response to the measurement of the physiological parameter satisfying an alarm activation threshold"

Petitioner asserts that Baker-1 teaches this limitation. Pet. 33. In particular, Petitioner argues that Baker-1 discloses a system that determines both the amount of time the measured value is past the threshold, and the amount by which the threshold is past. *Id.* (citing Ex. 1005, 1:54–2:6, 2:51–56, 3:18–31, 5:29–37, Fig. 3; Ex. 1003 ¶¶ 75, 76). Dr. Yanulis testifies that a person of ordinary skill in the art "would understand that the SpO₂ and PR thresholds of Baker-1 are alarm activation thresholds, but that the time-integral algorithms of Baker-1 simply delay[] alarm activation once those thresholds are satisfied." Ex. 1003 ¶ 75; *see also* Ex. 1005, code (57) (teaching that "an alarm is generated when *a measured value for a physiological parameter passes a threshold*; . . . [and t]he alarm is inhibited" based on how long and by how much the measured value is past the threshold (emphasis added)).

Patent Owner argues that "Baker 1 does not 'determine that an alarm should be activated' and does not 'determine that an alarm suspension should be initiated,' . . . before suspending the alarm for a period of time." Prelim. Resp. 31. According to Patent Owner,

Baker 1 distinguishes its integral algorithm from an approach (like RE353) that triggers an alarm condition after crossing a parameter threshold, followed by a parameter-specific suspension period of time before articulating an alarm. Instead, Baker 1 explains that passing the saturation threshold alone "does *not* produce an alarm," and contrasts its approach from devices where, after a "low sat[uration] threshold was passed, an alarm would have been generated." [Ex. 1005,] 3:36–41. . . . As illustrated in Figure 3 [of Baker-1], the integral value—which determines whether the alarm triggers and how long it takes to trigger—is dynamic and constantly changing.

Prelim. Resp. 31. According to Patent Owner, "Petitioner suggests the low saturation threshold in Baker 1 is the claimed 'alarm activation threshold,' . . . but Baker 1 emphasizes that *no* alarm is triggered after passing the low saturation threshold." *Id.* at 31–32 (citing Pet. 33–34; Ex. 1005, 3:38–41).

Although Patent Owner's arguments are consistent with certain embodiments disclosed in the RE353 specification, as we have discussed above, the plain language of the claims does not require that an alarm is actually activated (or that an indication of the alarm occurs) when the physiological parameter satisfies the alarm activation threshold. *See supra* Section II.D.3. The cited disclosure in Baker-1 (e.g., that the measured value is past the low saturation threshold) is sufficient to teach that the parameter is outside of its set limit, or in other words, that it "satisf[ies] the alarm activation threshold." *See id.*; *see also* Ex. 1005, Fig. 3.

We determine that, on the record now before us, Petitioner's cited evidence sufficiently supports its contentions regarding this limitation.

f) "the one or more processors configured to electronically . . . determine that an alarm suspension should be initiated for a parameter-specific alarm suspension period of time corresponding to the physiological parameter, the parameter-specific alarm suspension period of time being one of at least a

plurality of parameter-specific alarm suspension periods of time, the parameter-specific alarm suspension period of time being different from at least one other parameter-specific alarm 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 asserts that Baker-1 teaches this limitation. Pet. 34–38. In particular, Petitioner states "Baker-1 teaches parameter-specific (SpO₂ and PR) algorithms resulting in different parameter-specific alarm suspensions." *Id.* at 34 (citing Ex.1005, 1:57–63, 3:18–55; Ex. 1003 ¶ 76, 84). Baker-1 teaches "calculat[ing] the integral of the difference between the current saturation and a saturation threshold whenever the current saturation is below the saturation threshold." Ex. 1005, 3:19–21; *see also id.* at 5:29–32 (discussing a different "integral method to screen pulse rate bradycardia and tachycardia alarms"). Petitioner explains that the SpO₂ or PR alarm does not activate immediately when falling below the saturation threshold, but instead is delayed until the calculated integral value exceeds the integral threshold. Pet. 35 (citing Ex. 1005, 3:30–55, Fig. 3; Ex. 1003 ¶ 79), 38 (citing Ex. 1005, 3:30–31, 5:29–37, Fig. 3; Ex. 1003 ¶ 84).

Petitioner argues that a person of ordinary skill in the art would understand that SpO₂-related "integral threshold 74" is a predetermined value that "can be changed by a user because no values for the integral threshold are provided in Baker-1, as they are set by a user." *Id.* at 34–35 (citing Ex. 1005, 1:64–2:6; Ex. 1003 ¶ 77). Petitioner also argues that a person of ordinary skill in the art would understand that SpO₂-related "saturation threshold 72' must also be a predetermined value that can be

changed by a user because it is represented as a variable in the integral algorithm." *Id.* at 35 (citing Ex. 1005, 3:18–55, Fig. 3; Ex. 1003 ¶ 78).

Petitioner argues that "[l]ike the SpO₂ integral threshold, the [pulse rate] integral threshold is also described as a predetermined value, and a [person of ordinary skill in the art] would understand it can be changed by a user to provide customized care for a patient, and because no values for the integral threshold are provided in Baker-1." *Id.* at 37 (citing Ex. 1005, 1:64–2:6; Ex. $1003 \, \P \, 82$).

Patent Owner argues that each independent claim "requires a parameter-specific alarm suspension period of time that differs from at least one other parameter-specific alarm suspension period of time. Thus, the alarm suspension period of time must be known and fixed in the system." Prelim. Resp. 28. According to Patent Owner, Baker-1 describes fixed delays as "problematic" and, instead "uses a dynamic calculation to determine whether to trigger an alarm. As a result, in Baker 1, the time between initial measurement and alarm activation is unknown" and, moreover, the "dynamic calculation may *never* reach the threshold to trigger an alarm in the first place." *Id.* at 29; see also id. at 35 ("T]he integral value cannot be a *predetermined* suspension associated with a particular parameter because a [person of ordinary skill in the art] could not know the measured values *before* the values are measured."). For example, Patent Owner points to Figure 3 of Baker-1, in which there are multiple events that pass the saturation threshold, but do not trigger the alarm. *Id.* at 33. Patent Owner argues that a user, thus, can only determine alarm activation after the fact. Id.

We do not agree with this argument. As discussed in Section II.D.2 above, the claims do not recite a predetermined, fixed, or pre-set delay or suspension period, and we decline to import such a requirement into the claims.

Patent Owner also argues that the Petition fails to establish that an ordinarily skilled artisan would have had a reasonable expectation of success in modifying the teachings of Baker-1. Prelim. Resp. 25–28. In particular, Patent Owner argues that the Petition fails to "even *mention* a reasonable expectation of success . . . let alone identify evidence to support its position." *Id.* at 26–27.

We do not agree with this argument. Petitioner contends that a person of ordinary skill in the art would have been motivated to combine Baker-1's SpO₂ and PR alarm integral algorithms, to the extent they are not disclosed in a single embodiment, into a single monitor. Pet. 29–30. We conclude, based on the record now before us, that a person of ordinary skill in the art would have had a reasonable expectation of success making such a combination. Dr. Yanulis testifies that SpO₂ and PR are both conventional indicators of physiological problems and are conventionally measured by the same pulse oximeter device. Ex. 1003 ¶¶ 65–66. Moreover, Dr. Yanulis testifies that Baker-1's SpO₂ and PR algorithms both seek to avoid false alarms and combining them into a single device would predictably achieve this goal. *Id.* ¶ 67. The failure of Dr. Yanulis and Petitioner to employ the precise phrase "reasonable expectation of success" does not detract from this showing.

We determine that, on the record now before us, Petitioner's cited evidence and reasoning sufficiently supports its contentions regarding this limitation.

g) "the one or more processors configured to electronically . . . suspend the alarm for the parameter-specific alarm suspension period of time"

Petitioner asserts that Baker-1 teaches this limitation. Pet. 38. Specifically, Petitioner argues that Baker-1 teaches "[w]hen the SpO₂ measurement exceeds the SpO₂ threshold, the SpO₂ integral algorithm begins calculating the SpO₂ integral value and the alarm is suspended for a period of time (time n) specific to the SpO₂ measurement." *Id.* (citing Ex. 1005, 3:18–21; Ex. 1003 ¶ 86).

Patent Owner does not present arguments regarding this limitation, beyond those discussed with respect to the previous limitation. *See generally* Prelim. Resp.

We determine that, on the record now before us, Petitioner's cited evidence and reasoning sufficiently supports its contentions regarding this limitation.

h) "the one or more processors configured to electronically . . . activate the alarm when the measurement of the physiological parameter satisfies the alarm activation threshold after the parameter-specific alarm suspension period of time has passed"

Petitioner asserts that Baker-1 teaches this limitation. Pet. 33. In particular, Petitioner argues that Baker-1's CPU 50 "activates an SpO₂ alarm after the parameter-specific alarm suspension period of time has passed in response to determining the SpO₂ integral threshold is satisfied by the SpO₂

integral value and the SpO₂ measurement *still* exceeds the PR threshold." *Id.* (citing Ex. 1005, 3:32–55, Fig. 3; Ex. 1003 ¶¶ 87, 88).

Patent Owner argues that Petitioner conflates "multiple distinct limitations"—namely, determining that an alarm should be activated, then suspending the alarm, and then generating the alarm after the parameter-specific suspension period of time passes. Prelim. Resp. 35.

We do not agree that Petitioner conflates these limitations. Petitioner explains sufficiently how it contends Baker-1 teaches or suggests each of the "distinct limitations" of the claim. Specifically, Petitioner relies on Baker-1's SpO₂ and PR thresholds as teaching alarm activation thresholds, which indicate when an alarm "should be activated." Pet. 33; *see* Ex. 1003 ¶ 75; *supra* Section II.F.1.e). As Dr. Yanulis explains, "the time-integral algorithms of Baker-1 simply delay[] alarm activation once those thresholds are satisfied." Ex. 1003 ¶ 75. In other words, an indication of the alarm is delayed until the calculated integral value exceeds the integral threshold—so long as the SpO₂ or PR algorithms calculate an integral value within the integral threshold, the indication of the alarm is suspended. Pet. 34–38; *see supra* Section II.F.1.f) and II.F.1.g). Then, Baker-1's processor indicates the alarm when the calculated integral value exceeds the threshold, i.e., after passage of the integral-specific alarm suspension period of time. Pet. 39.

We determine that, on the record now before us, Petitioner's cited evidence sufficiently supports its contentions regarding this limitation.

i) Conclusion as to Claim 1

For the reasons discussed above, we determine that Petitioner has shown a reasonable likelihood of success in showing that claim 1 would have been obvious in view of Baker-1.

2. Independent claims 13 and 18

Independent claims 13 and 18 recite a method and system, respectively, and recite limitations similar to those of claim 1. ¹⁶ Petitioner relies on the same teachings of Baker for claims 13 and 18 as those discussed above for claim 1. *See* Pet. 43–48.

At this stage of the proceeding, Patent Owner does not present arguments separate from those discussed above with respect to claim 1. *See generally* Prelim. Resp.

For the same reasons discussed regarding claim 1, we determine that, on the record now before us, Petitioner's cited arguments and evidence sufficiently support its contentions regarding claims 13 and 18.

G. Asserted Obviousness over Baker-1 and Batchelder

Petitioner asserts that claims 1, 2, 6–9, 13–15, and 18–25 would have been obvious over Baker-1 and Batchelder. Pet. 49–56. As noted above, this asserted ground is "directed to a construction encompassing delays *before* an alarm is activated (i.e., pre-alarm delays)." *Id.* at 14.

Regarding independent claims 1, 13, and 18, as well as dependent claims 6–8, 14, 19, and 23–25, Petitioner argues that "[t]o the extent Baker-1 does not explicitly teach integral thresholds and SpO₂ and PR thresholds and integral thresholds can be adjusted by a user, thus resulting in different alarm suspension times"; Batchelder expressly teaches these limitations. *Id.* at 49. Specifically, Petitioner argues that Batchelder teaches adjusting SpO₂ thresholds in increments of 1% and SatSeconds thresholds in increments of

¹⁶ Claims 13 and 18 also recite a memory, and first and second parameter-specific alarms suspension periods.

25. *Id.* at 50 (citing Ex. 1006 ¶¶ 15, 16, 25, 26, 28, Figs. 4–8; Ex. 1003 ¶ 127). Petitioner argues that Batchelder teaches, "when SpO₂ or SatSeconds thresholds are adjusted, the amount of time it takes for the SatSeconds value to reach the threshold and sound an alarm (i.e., the alarm suspension) changes." *Id.* at 50–51 (citing Ex. 1006 ¶¶ 30–32, Figs. 5–8; Ex. 1003 ¶ 127).

Petitioner argues that "Batchelder merely represents common knowledge in the art or well-known prior art techniques." *Id.* at 50. Petitioner further argues that a person of ordinary skill in the art would have combined Baker-1 and Batchelder "because Batchelder expressly discloses that which Baker-1 implicitly teaches—a caregiver may adjust SpO₂ and PR thresholds and integral threshold, resulting in different alarm suspension time periods." *Id.* (citing Ex. 1003 ¶ 129).

Petitioner presents additional arguments and evidence regarding the limitations of several dependent claims. *Id.* at 52–56.

At this stage of the proceeding, Patent Owner does not present arguments separate from those discussed above with respect to Baker-1. *See generally* Prelim. Resp.

H. Asserted Obviousness over Baker-1, Batchelder, and Baker-2, with or without Hickle

Petitioner asserts that claims 1, 2, 6–9, 13–15, and 18–25 would have been obvious over Baker-1, Batchelder, and Baker-2. Pet. 57–59. Petitioner asserts that claims 3–5, 10–12, 16, and 17 would have been obvious over Baker-1, Batchelder, Baker-2, and Hickle. *Id.* at 60–63. As noted above, these asserted grounds of unpatentability are "directed to a construction

encompassing delays *before* an alarm is activated (i.e., pre-alarm delays)." Pet. 14.

Patent Owner argues that the addition of Baker-2 "does not meaningfully change" the calculation approach of Baker-1, and therefore the asserted combination does not teach the claimed invention. *See* Prelim. Resp. 36–43.

Petitioner presents this asserted ground, as an alternative, in the event that "the RE353 [patent] claims require *pre-set* 'parameter-specific alarm suspension periods of time." Pet. 57. Because we determine, on the record now before us, that the recited "alarm suspension period of time" need not be predetermined, fixed, or pre-set (*see supra* Section II.D.2), we do not address these grounds further for purposes of this Decision.

I. Asserted Obviousness over Saidara and Malangi, with or without Hickle

Petitioner asserts that claims 1, 2, 6–9, 13–15, and 18–25 would have been obvious over the combination of Saidara and Malangi. Pet. 63–83. Petitioner asserts that claims 3–5, 10–12, 14, 16, 17, and 24 would have been obvious over the combination of Saidara, Malangi, and Hickle. *Id.* at 83–87. As noted above, these asserted grounds are "directed to temporary suspension of active alarms (i.e., post-alarm suspensions)." *Id.* at 14.

Patent Owner argues Saidara and Malangi do not teach or suggest all features of the claimed system and that Petitioner fails to identify a reason to combine the references. Prelim. Resp. 42–53.

Petitioner asserts that Saidara teaches setting different alarm delays for hypoglycemia and hyperglycemia, and different severities of each condition. Pet. 65–66 (citing Ex. 1008 ¶¶ 128, 130, 132–133 Figs. 4D–4E;

Ex. 1003 ¶¶ 172–173). Petitioner further asserts that Saidara teaches applying the alarm delays to a wide variety of physiological characteristics, including measuring SpO₂. *Id.* at 65 (citing Ex. 1008 ¶¶ 60, 76; Ex. 1003 ¶ 173). In light of this teaching, Petitioner contends that a person of ordinary skill in the art would have been motivated to modify Saidara "to monitor additional physiological parameters and apply different alarm repeat delay periods to these parameters to provide more comprehensive data about a patient and to achieve the same predictable result," which Petitioner contends is "to prevent distraction to the caregiver from ongoing audible alarms or new alarms triggered by medical intervention, while also providing a caregiver with intermittent warnings corresponding to the severity of a continuing or worsening alarm condition that may require escalated medical intervention." *Id.* at 66–67 (citing Ex. 1003 ¶ 173).

Petitioner further asserts that "[t]o the extent Saidara does not disclose specific examples of alarm repeat delay periods for the identified additional monitored physiological characteristics, Malangi discloses a [blood pressure ('BP')] monitor including a noninvasive physiological sensor." *Id.* at 67 (citing Ex. 1010, Abstr., 1–3; Ex. 1003 ¶ 174). According to Petitioner, "Malangi teaches various BP measurements [that] have different silence times, with silence times correspond[ing] to the severity of the BP measurement." *Id.* at 67–68 (citing Ex. 1010, 6–7, 12–13, 18–20, 35; Ex. 1003 ¶¶ 175–176).

Petitioner asserts that "[b]oth Saidara and Malangi teach it was well-known to suspend active alarms for different physiological parameters, with different suspension time periods applying to different physiological parameters and corresponding to the severity of the monitored parameter."

Id. at 68 (citing Ex. 1003 ¶ 177). Petitioner further argues that "combining the teachings of Saidara with Malangi would have predictably measured both SpO₂ and BP and applied different alarm suspensions to those measured parameters according to the respective teachings of Saidara and Malangi." Id. at 69 (citing Ex. 1003 ¶ 178). Petitioner contends that a person of ordinary skill in the art would have been motivated to combine Saidara and Malangi as proposed in order "to comprehensively monitor a patient's health using a single monitor, and apply different alarm suspension periods corresponding to different parameters and 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." Id. at 68; see Ex. 1003 ¶ 177.

Patent Owner argues, *inter alia*, that Petitioner has not shown that a person of ordinary skill in the art would have combined Saidara and Malangi. Prelim. Resp. 43.

Patent Owner argues that Saidara teaches a single-parameter blood glucose monitor used by a patient to self-monitor glucose and deliver insulin. *Id.* at 43–46; *see also id.* at 45 (disputing that Saidara discloses oxygen saturation alarms). Patent Owner argues that Malangi, on the other hand, teaches a single-parameter blood pressure monitor operated by a caregiver or paramedic. *Id.* at 46–47.

In light of these purportedly disparate teachings, Patent Owner argues that Petitioner fails to offer a credible motivation to combine because "[t]hese references have different users (patient-user versus paramedic resuscitating a patient), different goals (improved patient self-treatment versus life-or-death resuscitation during war), and monitor different

physiological parameters (blood glucose versus blood pressure)." *Id.* at 49. Patent Owner argues that Petitioner's proposed modification would "fundamentally change[] Saidara's patient-used device." *Id.* at 48–50. (citing Pet. 68–69; Ex. 1003 ¶¶ 173, 177–178).

On the record now before us, we see merit in Patent Owner's argument. We agree with Patent Owner that Saidara and Malangi contemplate different users and different environments. *Id.* at 47–48. Saidara discloses a wristwatch-type monitor (Ex. 1008 ¶ 66) that may be worn by a patient in an outpatient or home use environment, "to provide for better treatment and control" of, e.g., glucose levels (*id.* ¶ 74). By contrast, Malangi discloses a paramedic or caregiver-operated infusion pump and blood pressure monitor to be used "during war and other critical situations." Ex. 1010, 1.

Given these differences, we are preliminarily unpersuaded by Petitioner's stated rationale for why an ordinarily skilled artisan would have been motivated to combine the teachings of Saidara and Malangi. For example, Petitioner asserts that modifying Saidara would have "prevent[ed] distraction to the caregiver from ongoing audible alarms or new alarms triggered by medical intervention, while also providing a caregiver with intermittent warnings corresponding to the severity of a continuing or worsening alarm condition that may require escalated medical intervention." Pet. 66–67 (citing Ex. 1003 ¶ 173). Similarly, Petitioner asserts that combining the teachings of Saidara and Malangi would have "ensure[d] a caregiver acknowledges the currency of alarms and can provide treatment without triggering additional alarms." *Id.* at 68 (citing Ex. 1003 ¶ 177). The pertinence of these benefits, however, is unclear because Saidara's monitor

is worn by a user at home, distant from any caregiver. Ex. 1008 ¶ 74. We recognize that Saidara discloses that information may be relayed from the monitor to a "medical professional and/or [a] related caregiver" and that the monitor may be used "under a physician's supervision." *Id.* ¶¶ 72, 74. Petitioner does not address persuasively, however, whether such remote caregivers would have been distracted by ongoing alarms or would have provided treatment without triggering additional alarms, as Petitioner alleges.

J. Word Count

In the Preliminary Response, Patent Owner raises an argument about "abbreviation and spacing tricks" used by Petitioner in order to satisfy the word count limit. Prelim. Resp. 2. In particular, Patent Owner points out the following "tricks": (1) the use of the abbreviation "EX1XXX" instead of "Ex 1xxx"; (2) the use of "Baker-1" and "Baker-2" instead of "Baker 1" and "Baker 2", respectively; and (3) omitting the full language of the claims from the arguments. *See id.* at 2 n.1. In the interest of fairness, Patent Owner may use these conventions in preparing its Patent Owner Response. The parties also may use these conventions for any other briefing in this proceeding (e.g., Reply, Sur-reply, Motions to Exclude).

III. CONCLUSION

For the reasons set forth above, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing with respect to at least one claim of the RE353 patent. We institute an *inter partes* review as set forth in the Order below.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–25 of U.S. Patent RE47,353 E is instituted with respect to all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), *inter partes* review of U.S. Patent RE47,353 E shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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