Paper 37 Entered: January 17, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CAREFUSION CORPORATION, Petitioner,

v.

BAXTER INTERNATIONAL, INC., Patent Owner.

Case IPR2016-01460 Patent 5,764,034

Before ROBERT J. WEINSCHENK, TIMOTHY J. GOODSON, and AMANDA F. WIEKER, *Administrative Patent Judges*.

WIEKER, Administrative Patent Judge.

FINAL WRITTEN DECISION 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

CareFusion Corporation ("Petitioner") filed a Petition (Paper 1, "Pet.") requesting an *inter partes* review of claims 1–4 and 9–12 of U.S. Patent No. 5,764,034 (Ex. 1001, "the '034 patent"). Baxter International, Inc. ("Patent Owner") filed a Preliminary Response (Paper 7, "Prelim. Resp.") to the Petition. We instituted an *inter partes* review of challenged claims 1–4 based on the asserted ground of obviousness under 35 U.S.C. § 103(a)¹ over the combined teachings of Layman² and Gargano³. Paper 10 ("Dec. on Inst."), 27; Paper 15 ("Dec. on Reh'g"), 7.

After institution, Patent Owner filed a Response (Paper 22, "PO Resp.") to the Petition, and Petitioner filed a Reply (Paper 23, "Pet. Reply") to the Response. A consolidated oral hearing with IPR2016-01463 was held on October 17, 2017, and a transcript of the hearing is included in the record. Paper 36 ("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 shown by a preponderance of the evidence that challenged claims 1–4 of the '034 patent are unpatentable.

¹ The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, which was enacted on September 16, 2011, made amendments to 35 U.S.C. §§ 102, 103. AIA § 3(b), (c). Those amendments became effective eighteen months later on March 16, 2013. *Id.* at § 3(n). Because the application from which the '034 patent issued was filed before March 16, 2013, any citations herein to 35 U.S.C. § 103 are to its pre-AIA version.

² U.S. Patent No. 5,712,795 (issued Jan. 27, 1998) (Ex. 1004).

³ U.S. Patent No. 5,814,015 (issued Sept. 29, 1998) (Ex. 1005).

A. Related Matters

According to the parties, the '034 patent is at issue in the following proceeding: *Baxter Int'l, Inc. v. CareFusion Corp.*, No. 1:15-cv-9986 (N.D. Ill.). Pet. 1–2; Paper 4, 1. According to Patent Owner, the '034 patent also is involved in PTAB proceeding IPR2017-00202. Paper 9, 1.

B. The '034 Patent

The '034 patent discloses a battery gauge for an infusion pump that "provides an estimate of the amount of time left on the battery by monitoring not only the voltage . . . but also the amount of current flowing from the battery." Ex. 1001, 2:12–25. Figure 11 is reproduced below.

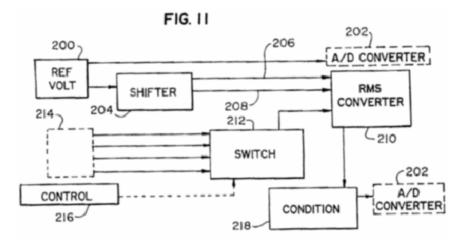


Figure 11 depicts a block diagram of the battery gauge circuit. *Id.* at 2:47–49. Control circuit 216 controls switch 212 to select the voltage or current range 214 to be measured, e.g., high-voltage, low-voltage, high-current, or low-current. *Id.* at 9:38–42, 10:55–56. The selected signal is sent to RMS converter 210 and conditioning circuit 218, before being input to A/D (analog-to-digital) converter 202 of a slave microprocessor for analysis. *Id.* at 9:43–47. Reference voltage 200 is also sent to RMS converter 210 and A/D converter 202. *Id.* at 9:25–28, Fig. 11. Additionally, a coarse voltage signal (not shown) is supplied to the slave microprocessor. *Id.* at 11:13–23.

These signals are used to generate visual and audible indicators of battery status. *Id.* at 5:12–18, 5:35–37, 8:26–39, 11:39–41. For example, a "Battery Alarm occurs when the battery voltage falls below a critically determined value," e.g., 10.8 volts. *Id.* at 11:46–49, 13:21–30, Fig. 14 (step 14). A "Battery Alert is generated when less than a predetermined time is left until the Alarm is generated," e.g., 30 minutes. *Id.* at 11:43–46, 13:36–52, 14:50–56, Fig. 14 (step 17).

C. Illustrative Claim

Challenged claim 1 is independent. Ex. 1001, 15:36–50. Challenged claims 2–4 depend directly from independent claim 1. *Id.* at 15:51–59. Claim 1, reproduced below, is illustrative:

- 1. An infusion pump comprising:
- a pump drive mechanism for applying the pumping action to a liquid for infusion in a patent;
 - a battery for powering the pump drive mechanism;
- a circuit which monitors the voltage and current from the battery;
- a circuit responsive to the monitoring circuit which determines the remaining time of charge in the battery;
- a battery alarm which occurs when the remaining time of charge in the battery is below a predetermined level;
- a battery low alert which occurs when the remaining time of charge in the battery is below a predetermined level but above the battery alarm level; and

display means for displaying the remaining time of charge in the battery.

Id. at 15:36–50.

II. ANALYSIS

A. Claim Interpretation

The parties agree that the '034 patent has expired. Pet. 7, 13–14; PO Resp. 8. "The Board construes claims of an expired patent in accordance with *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc)." Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc., 853 F.3d 1272, 1279 (Fed. Cir. 2017). Accordingly, the "words of a claim 'are generally given their ordinary and customary meaning" as understood by a person of ordinary skill in the art at the time of the invention. *Phillips*, 415 F.3d at 1312 (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)). "In determining the meaning of the disputed claim limitation[s], we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence." DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., 469 F.3d 1005, 1014 (Fed. Cir. 2006). "[T]he 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." Phillips, 415 F.3d at 1315 (quoting Vitronics, 90 F.3d at 1582). Extrinsic evidence is "less significant than the intrinsic record in determining the legally operative meaning of claim language." *Id.* at 1317 (internal quotation marks omitted).

1. "a circuit responsive to the monitoring circuit which determines the remaining time of charge in the battery"

In the Decision on Institution, we addressed Petitioner's proposed construction of this phrase, which appears in challenged claim 1. Dec. on Inst. 6–8; Ex. 1001, 15:42–43. In their post-institution papers, Petitioner and Patent Owner maintain their positions as originally set forth in the Petition

and Preliminary Response, but do not provide additional argument or evidence. Pet. Reply 4; PO Resp. 9–13.

Specifically, Petitioner contends that this phrase should be construed as "a circuit that determines the remaining time of charge in the battery based on both the monitored voltage and monitored current." Pet. 15; Pet. Reply 4. Patent Owner argues that Petitioner's construction improperly limits claim 1, which does not recite that both voltage and current are used in determining the remaining time of charge, and that further construction of this limitation is not necessary. Prelim. Resp. 6–10; PO Resp. 9–13.

In light of the full record developed during trial, we agree with Patent Owner that Petitioner's construction is improperly limiting. PO Resp. 9–13; Dec. on Inst. 8. Challenged claim 1 does not specify how the circuit determines the remaining time of charge, other than to require it "respon[d] to the monitoring circuit." Ex. 1001, 15:42–43. By contrast, claim 9 explicitly limits the determination by stating, "determining *from the voltage and the current* the remaining time of charge." *Id.* at 16:32–33 (emphasis added). We will not, through claim construction, import limitations into claim 1 that are not recited. *See, e.g., U.S. v. Telectronics, Inc.*, 857 F.2d 778, 783–784 (Fed. Cir. 1988) ("There is presumed to be a difference in meaning and scope when different words or phrases are used in separate claims. . . . 'Where some claims are broad and others narrow, the narrow claim limitations cannot be read into the broad.") (citations omitted).

The '034 patent Specification supports this interpretation. For example, the remaining time of charge is determined, in the first instance, from "current drain and amp/hours remaining" and, separately, in the second instance, from "true RMS voltage." Ex. 1001, 13:36–57, Fig. 14 (at 15, 18).

Petitioner's citations to the prosecution history do not compel a different conclusion. Pet. 15. The cited portions indicate only that voltage and current "are monitored and utilized as inputs to determine the amount of charge remaining." Ex. 1002, APP0140, APP0178 (same). However, that voltage and current are "utilized as inputs" does not require that they both be utilized as inputs *together*, as Petitioner's argument assumes.

Thus, we maintain the construction set forth in the Decision on Institution, and conclude that "a circuit responsive to the monitoring circuit which determines the remaining time of charge in the battery" does not require that the remaining time of charge be determined "based on both the monitored voltage and monitored current," as Petitioner proposes. No further construction is required. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

2. "display means," "means for sampling," and "means for alternatively sampling"

In the Decision on Institution, we considered Petitioner's proposed constructions of these limitations. Based upon a review of the entirety of the '034 patent, we construed these claim limitations as follows:

Claim Term	Construction
"display means"	Subject to 35 U.S.C. § 112 ¶ 6, the recited function is "displaying the remaining time of charge in the battery" and the corresponding structure is an LCD
"means for sampling"	Subject to 35 U.S.C. § 112 ¶ 6, the recited function is "sampling the voltage and the current of the battery" and the corresponding structure is an analog-to-digital converter

"means for alternatively sampling"	Subject to 35 U.S.C. § 112 ¶ 6, the recited function is recited function is "alternatively sampling the voltage of the battery and the current from the battery" and the corresponding structure
	is a switch that selects among analog inputs such as voltage and current, and an analog-to-digital converter

Dec. on Inst. 8–11.

In its Response, Patent Owner argues that these limitations are "not germane to Patent Owner's evidence and arguments" and, therefore, construction is not necessary. PO Resp. 14. Petitioner responds that construction of these limitations is necessary because these limitations are written in means-plus-function format. Pet. Reply. 4–5.

These limitations recite the term "means" and, as such, we presume they invoke 35 U.S.C. § 112 ¶ 6. See Williamson v. Citrix Online, LLC, 792 F.3d 1339, 1348–49 (Fed. Cir. 2015) (en banc in relevant part) ("'[U]se of the word 'means' creates a presumption that § 112, ¶ 6 applies.""). Accordingly, we agree with Petitioner that construction of these limitations is necessary in order to apply properly the asserted prior art to the relevant claim limitations. See Fresenius USA, Inc. v. Baxter Int'l, Inc., 582 F.3d 1288, 1299–1300 (Fed. Cir. 2009) ("It is firmly established in our precedent that a structural analysis is required when means-plus-function limitations are at issue; a functional analysis alone will not suffice.").

In their post-institution papers, neither party provides evidence or argument to support a different construction of these limitations.

Accordingly, we discern no reason to address or alter our initial construction of these limitations for the purposes of this Final Written Decision.

B. Obviousness over the Combined Teachings of Layman and Gargano

Petitioner contends that claims 1–4 of the '034 patent are unpatentable under 35 U.S.C. § 103(a) over Layman and Gargano. Pet. 19–37. Petitioner explains how the combined teachings of Layman and Gargano purportedly account for the subject matter of the challenged claims, and provides reasoning as to why one of ordinary skill in the art would have found it obvious to combine their respective teachings. *Id.* Petitioner relies on the Declaration of Dr. Yangming Xu (the "Xu Declaration," Ex. 1003) to support its positions. *Id.*

In its Patent Owner Response, Patent Owner presents a number of arguments with respect to challenged claim 1. PO Resp. 14–53. Patent Owner relies upon two Declarations of Mr. Warren Heim (the "First Heim Declaration," Ex. 2001; the "Second Heim Declaration," Ex. 2006) to support its positions. *Id*.

We begin our analysis with the principles of law that generally apply to a ground based on obviousness, followed by an assessment of the level of skill in the art. We then provide a brief overview of Layman and Gargano, and address the parties' contentions with respect to the challenged claims.

1. Principles of Law

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

(Fed. Cir. 2015).

factual determinations, including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness.

"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). The burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378

Graham v. John Deere Co., 383 U.S. 1, 17–18 (1966).

We analyze this asserted ground with these principles in mind.

2. Level of Ordinary Skill in the Art

Petitioner relies on the Xu Declaration and contends that a person of ordinary skill in the art of the '034 patent would have had "education and research/industry experience in biomedical engineering and at least 2 years' experience designing hardware, software and/or firmware for electrical devices in the biomedical industry." Pet. 10–11 (citing Ex. 1003 ¶ 8). According to Petitioner, someone with such education and experience would have been familiar with the battery-monitoring features relevant to the '034 patent. Pet. Reply. 3–4 (citing Ex. 2005, 75:3–9, 75:13–16).

Patent Owner relies on the First Heim Declaration and contends that such a person would have had "an engineering degree and at least six years' experience designing medical devices using electronics and electromechanical components (*e.g.*, infusion pumps) powered by batteries." PO Resp. 7–8 (citing Ex. 2001 ¶¶ 43–44).

Primarily, the parties' assessments of the skill level of a person of ordinary skill in the art differ in that Patent Owner contends that such a person would have had six years of experience designing medical devices, instead of two years of experience, and further contends that this experience would relate specifically to medical devices that are powered by batteries. Compare PO Resp. 7-8, with Pet. 10-11. Based on our review of the '034 patent, the types of problems and solutions described in the '034 patent and in the applied prior art, and the testimony of Dr. Xu and Mr. Heim, we determine that Petitioner's assessment of the skill level of a person of ordinary skill in the art is most consistent with this evidence. Specifically, the '034 patent and the asserted prior art relate to various different aspects of infusion pump technology, including processing, power management (by both external and internal battery sources), device display, and infusion pumping. See generally Ex. 1001; Ex. 1004; Ex. 1005. In light of these broad disclosures, we conclude that the appropriate level of skill in the art is not as narrow or specialized as Patent Owner proposes. We note that our conclusions herein would not differ under either party's assessment.

3. Overview of Layman (Ex. 1004)

Layman is a U.S. Patent titled "Power Management System," which discloses a power management system for an infusion pump. Ex. 1004, [54], [57]. Layman's Figure 2 is reproduced below.

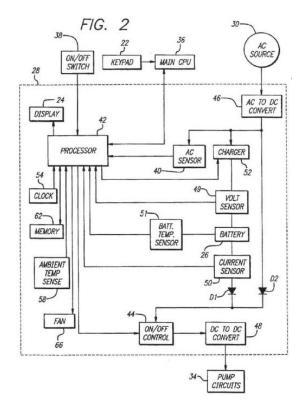


Figure 2 depicts a block diagram of power management system 28, which includes processor 42, battery 26, voltage sensor 49, and current sensor 50. *Id.* at 3:41–42, 4:54–58. Layman explains that the amount of time remaining on the battery (the "run-time") is determined "based on the amount of charge remaining in the battery and the present current draw from the battery," and is depicted on a display in fifteen minute increments. *Id.* at 2:4–5, 7:15–27, 10:38–42, Fig. 3. Layman also discloses that audible and visual alarms indicate low battery voltage levels. *Id.* at 10:52–59 (e.g., 12.1 V remaining).

4. Overview of Gargano (Ex. 1005)

Gargano is a U.S. Patent titled "Infusion Pump For At Least One Syringe," which discloses an infusion pump that provides feedback warnings and alarms. Ex. 1005, [54], [57]. Gargano discloses that the pump displays continuously the remaining life of the pump battery. *Id.* at 2:17–23, 7:36–37. Gargano also discloses that "warnings" are provided to indicate when,

e.g., 30 minutes of battery life remain. *Id.* at 19:50–20:8 (disclosing 15 minute and 30 minute warnings), Figs. 60–61. Additionally, a "battery alarm" indicates when 5 minutes of battery life remain (*id.* at 20:9–15, Fig. 62) and a "battery depleted" alarm indicates when battery life is expended (*id.* at 20:16–19, Fig. 62).

5. *Claim 1*

Petitioner contends that the combined teachings of Layman and Gargano would have rendered claim 1 obvious to a person of ordinary skill in the art. Pet. 19–37. Specifically, Petitioner contends that Layman discloses a pump with a pump drive mechanism, a battery, a circuit which monitors the voltage and current, a circuit responsive to the monitoring circuit which determines the remaining time of charge in the battery, and display means. *Id.* at 24–28, 33–34. Petitioner relies on Gargano's disclosure of warnings and alarms that indicate remaining battery time (*id.* at 30–33) and concludes that it would have been obvious to incorporate Gargano's warnings and alarms into Layman's pump (*id.* at 22–23).

a. "An infusion pump"

Claim 1 recites "[a]n infusion pump." Ex. 1001, 15:36. We are persuaded by Petitioner's contention, which Patent Owner does not dispute, that Layman discloses this limitation. Pet. 24. Specifically, Layman discloses "medical infusion pump 10." Ex. 1004, 3:60–63.

b. "a pump drive mechanism for applying the pumping action to a liquid for infusion in a patent"

Claim 1 recites "a pump drive mechanism" Ex. 1001, 15:37–38. We are persuaded by Petitioner's contention, which Patent Owner does not dispute, that Layman discloses this limitation. Pet. 24. Specifically,

Layman discloses "drive mechanism 18... forces fluid from the reservoir to the patient." Ex. 1004, 3:63–4:1, Fig. 1.

c. "a battery for powering the pump drive mechanism"

Claim 1 recites "a battery for powering the pump drive mechanism."

Ex. 1001, 15:39. We are persuaded by Petitioner's contention, which Patent Owner does not dispute, that Layman discloses this limitation. Pet. 25.

Specifically, Layman discloses battery 26 and power management system 28, which "controls the pump 10 to operate . . . on battery power if external power is not available." Ex. 1004, 4:3–9, Figs. 1–2.

d. "a circuit which monitors the voltage and current from the battery" Claim 1 recites "a circuit which monitors the voltage and current from the battery." Ex. 1001, 15:40–41. We are persuaded by Petitioner's contention, which Patent Owner does not dispute, that Layman discloses this limitation. Pet. 25–27. Specifically, Layman discloses that "power management system 28 closely monitors the battery 26 voltage, current, and temperature by means of the battery voltage sensor 49, battery current sensor 50, and battery temperature sensor 51." Ex. 1004, 4:54–58, 7:21–26, 11:3–5, Fig. 2.

e. "a circuit responsive to the monitoring circuit which determines the remaining time of charge in the battery"

Claim 1 recites "a circuit responsive to the monitoring circuit which determines the remaining time of charge in the battery." Ex. 1001, 15:42–43. We are persuaded by Petitioner's contention, which Patent Owner does not dispute, that Layman discloses this limitation. Pet. 27–28; Tr. 38:7–8 ("Layman determines the remaining time of charge."). Specifically, Layman discloses that "the amount of time that the battery can run the pump before

the battery becomes discharged" is determined "based on the amount of charge remaining in the battery and the present current draw from the battery," which may be provided by current sensor 50. Ex. 1004, 7:15–27, 2:4–5, 2:64–65; *see also supra* Section II.A.1.

f. "display means for displaying the remaining time of charge in the battery"

Claim 1 recites "display means," subject to 35 U.S.C. § 112 ¶ 6, for which we construed the recited function as "displaying the remaining time of charge in the battery" and the corresponding structure as an LCD. Ex. 1001, 15:49–50; *see supra* Section II.A.2. We are persuaded by Petitioner's contention, which Patent Owner does not dispute, that Layman discloses this limitation. Pet. 33–34. Specifically, Layman discloses that "liquid crystal display 24 may be used to display the run time." Ex. 1004, 8:14–15; *see also id.* at 3:25–26, 10:38–52, Fig. 3.

g. "a battery alarm which occurs when the remaining time of charge in the battery is below a predetermined level" and "a battery low alert which occurs when the remaining time of charge in the battery is below a predetermined level but above the battery alarm level"

Claim 1 recites (1) "a battery alarm" that "occurs when the remaining time of charge in the battery is below a predetermined level," and (2) "a battery low alert" that "occurs when the remaining time of charge in the battery is below a predetermined level but above the battery alarm level." Ex. 1001, 15:44–48.

Petitioner relies on Gargano's disclosure of warnings and alarms that indicate remaining battery time (Pet. 30–33) and contends that it would have been obvious to incorporate Gargano's warnings and alarms into Layman's pump (*id.* at 22–23).

Specifically, Petitioner contends that Gargano provides "an alarm and alert based on the remaining time of charge in the battery." Pet. 21–22 (identifying alarms that occur when five minutes remain and when the battery is depleted), 29–32 (identifying alarms that occur when thirty, fifteen, and five minutes remain). We are persuaded by this contention. Gargano discloses a syringe pump that includes battery 58 and software that "provides a continuous indication of remaining battery life on the [pump] display." Ex. 1005, 2:21–23, 7:7–8, 7:32–37. Gargano also discloses "first degree warnings" that occur when, e.g., 30 minutes of battery life remain. *Id.* at 20:4, Fig. 60 (audible alarm beeps twice; status message displays). Gargano discloses "second degree warnings" that occur when, e.g., 15 minutes of battery life remain. *Id.* at 20:5–8, Fig. 61 (audible alarm beeps continuously, but may be silenced; status message displays). And finally, Gargano discloses "recoverable alarms" that occur when, e.g., 5 minutes of battery life remain, as well as "non-recoverable alarms" that occur when, e.g., a battery is depleted. *Id.* at 20:9–15 (for recoverable alarm, alarm screen displays in red), 20:16–19 (for non-recoverable alarm, a system fault occurs), Fig. 62 (for recoverable alarm, audible alarm beeps continuously and may not be silenced, and pump stops running; for non-recoverable alarm, audible alarm cannot be silenced for two minutes and user must power off the pump).

Patent Owner argues that although "Gargano disclose[s] various battery warning messages and alarms, including a warning message of the number of minutes of battery remaining," Gargano does not specify "how these warnings or alarms are generated, including what actually triggers" them. PO Resp. 29–30; *see also id.* at 25–26. According to Patent Owner,

Gargano discloses a battery management circuit that determines remaining battery life *and* remaining voltage, and a person of ordinary skill in the art would not have understood that Gargano's warnings and alarms are "based on the remaining time of charge as required by claim 1." *Id.* at 30–31. Patent Owner relies on Mr. Heim's testimony that such a person instead would have been motivated to trigger Gargano's warnings and alarms based on remaining *charge*. *Id.* at 31–32 (citing Ex. 2006 ¶¶ 69-70, 72–74).

We have considered Patent Owner's argument and evidence; however, we are persuaded by Petitioner's contentions regarding Gargano. Contrary to Patent Owner's argument, the plain language of claim 1 does not recite what "triggers" the claimed alarm and alert. Rather, claim 1 recites that the alarm and alert "occur[] when the remaining time of charge in the battery is below a predetermined level " Ex. 1001, 15:44–48 (emphasis added). In other words, the claim defines the temporal relationship between the alarm/alert and the predetermined level of remaining time of charge, i.e., they "occur[] when . . . ," but the claim does not define what actually triggers the alarm and alert. Accordingly, Patent Owner's argument is not commensurate with the claim scope and is unpersuasive. Of relevance to the actual claim scope, Patent Owner does not dispute that Gargano's warnings and alarms "occur[] when the remaining time of charge in the battery is below" a series of predetermined levels. PO Resp. 29–30 ("Patent Owner acknowledges that FIGS. 60–62 of Gargano disclose various battery warning messages and alarms, including a warning message of the number of minutes of battery remaining."); Tr. 39:8–10 ("Gargano shows a battery alarm that occurs when -- however it's calculated, there's an -- there's a certain amount of time remaining."); Ex. 2006 ¶ 74 (declarant testimony that

"[s]imply stating that an alarm occurs when five minutes of battery remain is not adequate to inform a person of ordinary skill in the art how the alarm was implemented"); see also Pet. Reply 12.

During the oral hearing, Patent Owner argued that it had not briefed the issue of whether the "occurs when" language requires that the remaining time of charge trigger the claimed alarm and alert because the parties agree that the claim requires a specific "triggering" element. Tr. 27:14–19, 28:5– 7. Patent Owner's argument is not persuasive. Patent Owner was on notice of the plain language of its claims and had ample opportunity during this proceeding to propose that "occur when" be construed to require a "triggering" component that is absent in its plain verbiage. Patent Owner did not do so. In the Preliminary Response, Patent Owner neither proposed this language for construction nor presented arguments directed to its application against the prior art. See generally Prelim. Resp. Likewise, in the Patent Owner Response, Patent Owner again chose not to propose this claim language for construction. Moreover, during oral argument, Petitioner stated that it did not agree that the claim language requires a "triggering" component. Tr. 50:10–16 ("No, we did not agree that the claim language says anything other than what the claim language says. Yes, we have used the word 'trigger,' because triggering based on a time of charge remaining is certainly sufficient to meet the claim language. It is not required. . . . [T]he claim language simply requires alerts and alarms occurring when there is a time of charge remaining, and Gargano certainly teaches that.").

As such, we decline to rewrite claim 1 to require a "triggering" component that is not recited. *See*, *e.g.*, Ex. 1001, 8:30–35, 11:43–52 ("is generated when"; "occurs when"); Ex. 1002, APP0204 (the Examiner's

Reasons for Allowance stating, "the [p]rior art of record does not disclose or suggest the battery alarm *when* the time of charge left on a battery is below a predetermined level," but not discussing what triggers the alarm) (emphasis added); *see also Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) ("Even 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'.").⁴

h. Rationale to Combine

Petitioner contends that it would have been obvious to a person of ordinary skill in the art to have "combine[d] the infusion pump system of Layman with the specific alarms and alert features of the Gargano infusion pump." Pet. 22. Petitioner provides several rationales for this modification. First, Petitioner contends that Layman and Gargano are directed to similar pump systems, each with battery monitoring capabilities. *Id.* According to Petitioner, "design and development engineers . . . look to devices that include similar features and functionality," and the proposed combination merely combines well-understood elements in predictable ways to yield

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⁴ Patent Owner also argues that Layman does not disclose the alarm and alert limitations of claim 1. PO Resp. 20–25, 28–29. According to Patent Owner, despite determining run time, Layman provides alarms based on battery voltage instead of time. *Id.* at 21, 24. According to Mr. Heim, this was consistent with the state of the art. *Id.* at 24–25; Ex. 2006 ¶¶ 54–56. We are unpersuaded by this argument because the Petition does not rely on Layman to satisfy the "alarm" and "alert" limitations. *See* Pet. 21–22 (relying on Gargano); *see also* Tr. 8:8–9 (discussing Layman's bar graph that displays time and stating, "CareFusion has not asked the Board, not in the petition, not in the reply, to institute based on Layman alone."); Paper 26, 1–2; Paper 27, 1.

predictable results. *Id.* Additionally, Petitioner contends that the proposed modification would have been obvious because it "is merely a substitution of one known element for another to obtain predictable results," and combining battery monitoring functionality from other electronic devices "would have been '[u]se of [a] known technique to improve similar devices in the same way." *Id.* at 23 (citing MPEP § 2143).⁵

In response, Patent Owner argues that the Petition fails to set forth a sufficient rationale for the proposed modification. PO Resp. 32–53. First, Patent Owner argues that the Petition's contentions rest upon conclusory attorney argument and are not supported by evidence. *Id.* at 33–35. Second, Patent Owner contends that the Petition shows only that Layman and Gargano are analogous art, without providing a reason why one of ordinary skill in the art would have found it obvious to combine them. *Id.* at 35–38, 47–50 ("could" have combined is not sufficient). Third, Patent Owner argues that Petitioner cites "general principles from case law and the M.P.E.P.," without citing any evidence and without articulating how the law applies to the proposed combination. *Id.* at 38. Moreover, Patent Owner contends that the proposed modification would have been detrimental to Layman's performance and safety. *Id.* at 40–45.6

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⁵ We are not persuaded by Petitioner's contentions regarding a corporate merger that combined "different infusion systems into one integrated product." *Id.* at 23. This generalized argument and cited evidence is divorced from the specific modification proposed here, which is based on the combined teachings of Layman and Gargano. Ex. 1003 ¶¶ 4−5; Tr. 18:16–20:22; *see also* PO Resp. 45–47.

⁶ Patent Owner also argues that Petitioner's declarant, Dr. Xu, provides conclusory testimony, does not understand the law of obviousness, and is unqualified to testify regarding battery monitoring and alerts. PO Resp. 47–53 (citing Ex. 1003 ¶ 18); but see Pet. Reply 20–22. Because we do not rely

We have considered the parties' positions and the cited evidence, and we are persuaded by Petitioner. We agree that "Layman and Gargano are each directed to an infusion pump system with battery life monitoring functionality." Pet. 22. Layman discloses a pump that displays remaining battery life and provides alarms to indicate when the remaining battery *charge* reaches predetermined levels, e.g., 12.1, 11.45, or 10.25 volts. Ex. 1004, 3:60–63, 10:38–49, 10:53–59. Similarly, Gargano discloses a pump that displays remaining battery life and provides warnings and alarms to indicate when the remaining battery *life*, i.e., time of charge, reaches predetermined levels, e.g., 30, 15, or 5 minutes. Ex. 1005, 1:7–8, 2:21–23, 7:32–38, 20:9–15.

We acknowledge Patent Owner's arguments that it is insufficient to merely demonstrate that prior art references are analogous and to provide general principles of case law as a rationale to combine. PO Resp. 35–41. However, in this case, the Petition and the evidence cited therein do more. Specifically, Layman itself teaches that the techniques disclosed by Layman and Gargano for indicating battery status—namely, indicating remaining charge and indicating remaining time—are interrelated. Layman states, "[a]s discussed previously, it is desirable to indicate to the pump operator the amount of time the battery can run the pump before the battery becomes

on Dr. Xu's testimony regarding the "alarm" and "alert" limitations, this argument is moot. Nonetheless, we note that Dr. Xu holds a Ph.D. in Robotics and Biomedical Engineering from Massachusetts Institute of Technology, has extensive experience as a Principle Engineer and Software Engineer, and has worked on the design and development of "processor-controlled electronic devices in the biomedical industry," including "the design and development of battery-related functionality and features for electronic devices, particularly as related to CareFusion's products." Ex. 1003 ¶¶ 1–3; see also Ex. 2005, 53:7–55:16; Pet. Reply 20–22.

discharged." Ex. 1004, 7:15–17 (cited at Pet. 27). In explaining the desirability of an indicator of time, Layman explains that although it may be "beneficial to be able to determine how much *charge* remains in a battery, *it is more beneficial to determine the amount of time* or 'run-time' remaining in the battery." *Id.* at 1:44–46 (emphases added). According to Layman, warning the pump operator about remaining run-time, as opposed to remaining charge, is more effective in informing the operator about when to expect an abrupt end to battery power. *Id.* at 1:44–62.

Although Layman achieves this goal through a *display* that indicates remaining run-time, Layman's express disclosure of the benefit of timebased indicators supports the Petition's contention that combining Gargano's warnings and alarms, which occur when remaining battery *time* is below predetermined levels, into Layman's pump "would have been '[u]se of [a] known technique to improve similar devices in the same way." Pet. 23. As taught by Layman, such a modification would improve Layman's pump by providing an alternate indication of battery capacity, e.g., warnings and alarms provided in units of time, which allow the pump operator to expect when an abrupt end of battery power will occur. Ex. 1004, 1:44–62. As such, we are not persuaded by Patent Owner's argument that the Petition lacks supporting evidence (PO Resp. 33–35, 38), merely demonstrates that the references are analogous art without providing a reason why a person of ordinary skill in the art would have combined them (*id.* at 35–38, 47–50),⁷ or fails to articulate how the law applies to the combination (*id.* at 38–41).

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⁷ This asserted ground of unpatentability differs from those referenced in Patent Owner's Response, for which we determined the Petition failed to present a sufficient rationale. PO Resp. 37–38 (citing Dec. on Reh'g 5). With respect to grounds involving LTC1325 (Ex. 1007) and EDN

We also have considered Patent Owner's argument that the proposed modification would have been detrimental to Layman's performance and safety. PO Resp. 41–45. According to Patent Owner, Layman's choice to (1) display remaining battery time, and (2) provide alarms based on remaining battery *charge* "provide[s] redundant and independent systems to reduce the likelihood of depletion of the battery without adequate warning in the life-critical infusion pump." *Id.* at 42 (citing Ex. 2006 ¶¶ 77–79). Patent Owner relies on the testimony of its declarant, Mr. Heim, to argue that if Layman's displayed estimate of run-time was inaccurate, the separate charge-based alarm would provide an independent safeguard to alert the pump operator of battery depletion. *Id.* 42–45 (citing Ex. 2001 ¶¶ 45–46; Ex. 2006 ¶¶ 43–46, 53, 57–61, 80). Accordingly, Patent Owner contends that a person of ordinary skill in the art "would be discouraged from relying upon the run time calculation in Layman to trigger low battery alarms and alerts instead of the conventional battery voltage measurement since it would have been understood that the run time calculation could be inaccurate for a host of reasons." *Id.* at 45 (emphasis added).

We have considered the cited testimony of Mr. Heim but conclude that it, and Patent Owner's arguments, are not responsive to the Petition. Specifically, Patent Owner's position rests on the assumption that time-

⁽Ex. 1006), we determined that the Petition failed to identify the "specific 'battery monitoring functionality and features'... upon which Petitioner relies," as well as the "readily understood' motivations that would have led a person of ordinary skill in the art to modify the Layman and Gargano pump with unspecified features" of LTC1325 and EDN. Dec. on Reh'g 4, 6–7. Here, by contrast, the Petition specifically explains that the combination involves modifying Layman's pump to include Gargano's "specific alarms and alert features" to "improve similar devices in the same way." Pet. 22–23.

indicating alarms, as taught by Gargano, must replace or substitute for the charge-indicating alarms disclosed by Layman. PO Resp. 41–45; see also Ex. 2006 ¶¶ 78–80. Replacement or substitution, however, is not required by the proposed combination. Although the Petition references "substitution" of one known element for another," Pet. 23, the Petition also repeatedly contemplates that the prior art teachings would have been combined. For example, the Petition states clearly that one skilled in the art would have been motivated to "combine the infusion pump system of Layman" with Gargano's time-indicating alarms, and also explains that a person of ordinary skill would have found it obvious "to incorporate the teachings of both systems and provide various methods of alerting the user of the remaining time of battery life, such as based on the remaining time of charge." Id. at 22 (emphases added), 23 (obvious to "combine battery monitoring functionality from other electronic devices" to improve similar devices in the same way), 29–30 (claim chart relying on features of both Layman and Gargano); see also Pet. Reply 18–19.8 Patent Owner's argument is not responsive to this modification in which Gargano's warnings and alarms are "combine[d]" with Layman's pump, to "provide various methods of alerting the user of the remaining time of battery life." *Id.* at 22.

i. Secondary Considerations

Patent Owner also argues that "a number of available patents filed shortly before the '034 Patent . . . objectively demonstrate that the

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⁸ We do not agree with Patent Owner's contention that Petitioner's reply argument exceeds the proper scope. *See* Paper 26, 2. Petitioner's argument responds directly to Patent Owner's Response (PO Resp. 41–45) and is supported by arguments made in the Petition (Pet. 22–23). Paper 27, 1–2.

conventional wisdom at the time of the filing of the '034 Patent was to monitor the battery voltage and to trigger any low battery alarms or alerts in an infusion pump based on a low battery voltage measurement." PO Resp. 16–20 (citing Ex. 2006 ¶¶ 47–52). According to Patent Owner, this shows that the '034 patent proceeded contrary to accepted wisdom and demonstrates non-obviousness. *Id.* at 20.

We are unpersuaded by this argument. As discussed above, Layman, which also was filed prior to the '034 patent, expressly discloses the benefit of using indicators of remaining battery run-time to warn an operator of the impending depletion of battery life. See, e.g., Ex. 1004, [22], 1:41–62. Moreover, Gargano, also filed prior to the '034 patent, expressly discloses battery warnings and alarms that occur when remaining battery time reaches predetermined levels. Ex. 1005, [22], 19:50-20:19. Accordingly, we are not persuaded that the '034 patent proceeded contrary to conventional wisdom. See Pet. Reply 18 ("That [cited prior art] evidence in no way addresses or contradicts the two prior art references (Layman and Gargano) asserted in the Petition, each of which disclose notifying the user based on remaining battery runtime."). Finally, as discussed in Section II.B.5.g supra, the challenged claims do not recite what actually triggers the claimed alarms and alerts. As such, Patent Owner's purported evidence showing that conventional wisdom "trigger[ed] any low battery alarms" based on voltage is not commensurate with the scope of the challenged claims, and is unpersuasive.

j. Summary

Accordingly, based on the entirety of the record before us, we determine that Petitioner has shown by a preponderance of the evidence that claim 1 would have been obvious to a person of ordinary skill in the art.

6. Claim 2

Claim 2 recites that the monitoring circuit includes "means for sampling . . .," subject to 35 U.S.C. § 112 ¶ 6, for which we construed the recited function as "sampling the voltage and the current of the battery" and the corresponding structure as an analog-to-digital converter. Ex. 1001, 15:51–53; see supra Section II.A.2.

Petitioner contends that Layman's teachings satisfy this claim because Layman discloses a voltage sample rate of five seconds and "inherently discloses sampling the battery current, because battery current sensor 50 provides a signal to processor 42 (inherently a digital signal) that is representative of the (inherently analog) battery current," and "[c]onverting analog signals to digital values inherently requires sampling the analog signals and an analog-to-digital converter." Pet. 34–35. Petitioner also contends that sampling voltage and current would have been obvious. *Id.* In the Patent Owner Response, Patent Owner does not dispute Petitioner's contentions regarding claim 2.

We are persuaded by Petitioner's contentions. First, Layman specifies that voltage is monitored at a "sample rate of five seconds." Ex. 1004, 7:12–14. Second, Layman discloses that "the actual current leaving the battery can be directly measured by an electrical circuit." *Id.* at 7:20–39. Although Layman does not specify a sample rate for this direct current measurement, the evidence of record supports Petitioner's contention that this current

signal inherently is sampled and converted into digital form with an analog-to-digital converter. Pet. 35. Specifically, Petitioner's contention that processor 42 receives digital signals is supported by Layman's disclosure of a Toshiba four-bit CMOS micro-controller (TMP 47C446). Ex. 1004, 4:28–32; Pet. 34–35. Additionally, Petitioner's Exhibit 1008, a prior art publication titled "Electronic Analog-to-Digital Converters," explains that analog-to-digital converters are used to convert continuous analog representations, e.g., voltage signals, into discrete, digital form. Ex. 1008, APP0398; *see also id.* at APP0399 (disclosing use of analog-to-digital converters for current) (cited at Pet. 11). Exhibit 1008 explains that conversion requires an analog-to-digital converter to sample the analog signal, perform quantization and encoding, and output a digital signal. *Id.* at APP0402. We find this evidence persuasive.

Accordingly, we determine that Petitioner has shown by a preponderance of evidence that Layman inherently includes an analog-to-digital converter that samples voltage and current from the battery.

7. *Claim 3*

Claim 3 recites that the monitoring circuit includes "means for alternatively sampling . . .," subject to 35 U.S.C. § 112 ¶ 6, for which we construed the recited function as "alternatively sampling the voltage of the battery and the current from the battery" and the corresponding structure as a switch that selects among analog inputs such as voltage and current, and an analog-to-digital converter. Ex. 1001, 15:54–56; *see supra* Section II.A.2.

Petitioner contends that Layman's teachings satisfy this claim, stating that "because the same digital circuit cannot process two signals simultaneously, Layman inherently teaches that the processor alternates

between sampling the voltage signal and the current signal," and, "even if it were not inherent, it would at most have been an obvious design choice for the processor 42 to alternate between sampling the various inputs being fed to it." Pet. 36–37 (internal citations omitted) (citing Ex. 1003 ¶ 16). In the Patent Owner Response, Patent Owner does not dispute Petitioner's contentions regarding claim 3.

We are persuaded by Petitioner's contentions. As discussed above regarding claim 2, Petitioner has shown that Layman inherently discloses "means for sampling" voltage and current. The Petition's contention that a single circuit cannot process two signals simultaneously is supported by the Xu Declaration. Dr. Xu states:

[S]uch a person [of ordinary skill in the art] would have known and easily understood that a single analog-to-digital converter channel cannot sample two analog signals simultaneously. Rather, such a circuit samples the signals one at a time. As such, some sort of switch or addressing device would have been used to direct the circuit to sample the correct signal at the proper time.

See Ex. 1003 ¶ 16. According to Dr. Xu, this would have been a "basic engineering and physics principle[]" that "would have been readily apparent to a person of ordinary skill and experience." *Id.* We credit Dr. Xu's testimony on this issue, especially in light of the lack of contrary evidence in the Patent Owner Response.

In light of this evidence, we determine that Petitioner has shown by a preponderance of the evidence that Layman inherently discloses an analog-to-digital converter, as discussed regarding claim 2, and a switch to sample alternatively between voltage and current. Alternatively, we are persuaded by Petitioner's contention that it would have been obvious to a person of

ordinary skill in the art to utilize a switch to alternatively sample in this manner, to enable "the circuit to sample the correct signal at the proper time," as explained by Dr. Xu. Ex. 1003 ¶ 16.

8. Claim 4

Claim 4 recites "a battery low alert which occurs when the battery charge is below a predetermined level." Ex. 1001, 15:57–59.

Petitioner contends that Layman's teachings satisfy this claim because Layman discloses "multiple low battery warnings and alarms that are provided when the battery voltage reaches predetermined levels." Pet. 37, 29–32 (citing Ex. 1004, 10:38–49, 10:53–59, Fig. 3). In the Patent Owner Response, Patent Owner does not dispute Petitioner's contentions regarding claim 4.

We are persuaded by Petitioner's contentions. Layman discloses "audible and visual alarms," which occur when the battery voltage charge reaches predetermined levels, e.g., 12.1 volts, 11.45 volts, or 10.25 volts. Ex. 1004, 10:53–59. As discussed in Section II.B.5.h, *see supra*, in the proposed combination, Gargano's warnings and alarms that occur when the remaining battery *time* is below predetermined levels would be combined with Layman's existing alarms that occur when remaining *charge* is below predetermined levels. *See*, *e.g.*, Pet. 22–23.

Accordingly, we determine that Petitioner has shown by a preponderance of evidence that Layman discloses the claimed alert.

9. Summary

For the reasons discussed above, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–4 of the '034 patent

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would have been obvious over the combined teachings of Layman and Gargano.

III. CONCLUSION

Petitioner has shown by a preponderance of the evidence that claims 1–4 of the '034 patent are unpatentable.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–4 of the '034 patent are shown unpatentable; 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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