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Paper 43
Date: December 6, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE, INC.,
Petitioner,

v.

ALIVECOR, INC.,
Patent Owner.

IPR2021-00972
Patent 10,638,941 B2

Before ROBERT A. POLLOCK, ERIC C. JESCHKE, and DAVID COTTA, *Administrative Patent Judges*.

COTTA, *Administrative Patent Judge*.

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

Denying In-Part and Dismissing In-Part as Dismissing Patent Owner's Motion to Exclude Evidence as Moot
37 C.F.R. § 42.64

I. INTRODUCTION

A. Background

Apple, Inc. ("Petitioner") filed a Petition for an *inter partes* review of claims 1–23 of U.S. Patent No. 10,638,941 B2 (Ex. 1001, "the '941 patent"). Paper 2 ("Pet."). AliveCor, Inc. ("Patent Owner") timely filed a Preliminary Response. Paper 6 ("Prelim. Resp."). Petitioner further filed an authorized Reply to the Preliminary Response (Paper 7); Patent Owner filed a responsive Sur-reply (Paper 8). Taking into account the arguments and evidence presented, we determined that the information presented in the Petition established that there was a reasonable likelihood that Petitioner would prevail in demonstrating unpatentability of at least one challenged claim of the '941 patent, and we instituted this *inter partes* review as to all challenged claims. Paper 10 ("DI").

After institution, Patent Owner filed a Patent Owner Response (Paper 27, "PO Resp."); Petitioner filed a Reply to the Patent Owner Response (Paper 29, "Reply"); Patent Owner filed a (corrected) Sur-reply (Paper 35, "PO Sur-reply").

Patent Owner also filed a motion to exclude (Paper 34, "Mot."); Petitioner opposed the motion (Paper 36, "Opp. Mot."); and Patent Owner filed a reply in support of its motion (Paper 38, "Reply Mot.").

An oral hearing was held on September 14, 2022, and a transcript of the hearing is included in the record. Paper 41 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6. This decision is a Final Written Decision under 35 U.S.C. § 318(a) as to the patentability of claims

1–23 of the '941 patent. For the reasons discussed below, we hold that Petitioner has demonstrated by a preponderance of the evidence that claims 1–23 are unpatentable.

B. Real Parties-in-Interest

Petitioner identifies itself, Apple Inc., as the real party-in-interest. Pet. 84. Patent Owner, identifies itself, AliveCor, Inc., as the real party-in-interest. Paper 4, 2.

C. Related Matters

According to Patent Owner:

> U.S. Patent No. 10,638,941 has been asserted by Patent Owner against Petitioner in *AliveCor, Inc. v. Apple, Inc.*, Case No. 6:20-cv-01112-ADA, filed in the United States District Court for the Western District of Texas, and in Investigation No. 337-TA-1266 before the International Trade Commission, *In the Matter of Certain Wearable Electronic Devices with ECG Functionality and Components Thereof*. Apple also filed IPR petitions against the other patents asserted in those actions: IPR2021-00970 (USP 9,572,499) and IPR2021-00971 (USP 10,595,731).

Paper 6, 2; *see* Pet. 84.

D. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability (Pet. 1):

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1, 5, 7–9, 11, 12, 16, 18–20, 22, 23	103[1]	Shmueli,[2] Osorio[3]
2–4, 6, 13–15, 17	103	Shmueli, Osorio, Lee-2013[4]
10, 21	103	Shmueli, Osorio, Chan[5]

In support of its patentability challenge, Petitioner relies on, *inter alia*, the Declaration of Dr. Bernard R. Chaitman, M.D. Ex. 1003. Patent Owner similarly relies on the Declarations of Dr. Igor Efimov, Ph.D. Exs. 2001 and 2016.

E. Technological Background

Electrocardiography measures "the electrical activity of the heart, which can be indicative of various heart diseases." Ex. 1003 ¶ 28 (Chaitman Decl.). "In conventional clinical practice, [electrocardiography] and telemetry are used at a hospital to diagnose cardiac arrhythmias." *Id.* ¶ 30.

An electrocardiogram ("ECG") represents "electrical activity of the heart based on depolarization and repolarization of the atria and ventricles, which typically show up as five distinct waves on [an] ECG readout –

[1] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), amended 35 U.S.C. §§ 102 and 103. Based on the filing date of the '941 patent, we apply the AIA versions of §§ 102 and 103.
[2] Shmueli et al., WO 2012/140559 A1, published Oct. 18, 2012, (Ex. 1004, "Shmueli").
[3] Osorio, U.S. Patent Publication No. 2014/0275840 A1, published Sept. 18, 2014, (Ex. 1005, "Osorio").
[4] Jinseok Lee et al., *Atrial Fibrillation Detection using a Smart Phone*, 15:1 INT'L. J. OF BIOELECTROMAGNETISM 26–29 (2013) (Ex. 1011, "Lee-2013").
[5] Chan et al., U.S. Patent No. 7,894,888 B2, issued Feb. 22, 2011 (Ex. 1048, "Chan").

P-wave, Q-wave, R-wave, S-wave, and T-wave." *Id.* ¶ 29. "An R-R interval represents a time elapsed between successive R-waves of a QRS complex[6] of the ECG that occur between successive heart beats." *Id.* "If [the] R-R interval durations over a time period are close to one another in value, then ventricular rhythm is understood to be 'regular.' In contrast, if there are significant variations in the R-R interval durations over a time period, then the ventricular rhythm is understood to be 'irregular.'" *Id.* ¶ 29 (internal citations omitted).

"Photoplethysmography (PPG) is a simple noninvasive optical technique" that uses a "light source to illuminate subcutaneous tissue and a photo detector with spectral characteristics matching those of the light source" to "monitor[] beat-to-beat relative blood volume changes in the microvascular bed of peripheral tissues." *Id.* ¶ 31. According to Dr. Chaitman, "the information derived from RR intervals of ECG can also be derived from the pulse period of a PPG reading." *Id.* ¶ 32. PPG is "sometimes . . . referred to as blood oxygen saturation, pulse oximeter, oximetry, and SpO2." *Id.* ¶ 31.

Heart rate variability ("HRV") is defined as "the variation of RR intervals with respect to time and reflects beat-to-beat heart rate (HR) variability." *Id.* ¶ 34. It "can be accurately determined based on either ECG data or PPG data." *Id.* ¶ 35. With respect to the former, this involves measuring RR intervals. *Id.* ¶ 29. According to Dr. Chaitman, "HRV

[6] "A QRS complex is a combination of the Q, R, and S waves occurring in succession and represents the electrical impulse of a heartbeat as it spreads through the ventricles during ventricular depolarization." Ex. 1003 ¶ 29.

analysis is an important tool in cardiology to help diagnose various types of arrhythmia." *Id.* ¶ 34.

F. The '941 Patent

The '941 patent discloses that "[i]rregular heartbeats and arrhythmias are associated with significant morbidity and mortality in patients." Ex. 1001, 1:17–18. According to the '941 patent, "[n]on-invasive cardiac monitoring is useful in diagnosing cardiac arrhythmia." *Id.* at 1:21–22. In furtherance of this use, the '941 patent discloses "systems, devices, and methods for cardiac monitoring," including, for example "portable computing devices such as smartphones, smartwatches, laptops, and tablet computers." *Id.* at 1:26–30.

The '941 patent explains that "certain parameter values may be conveniently sensed continuously such as, for example, heart rate and activity level, and analyzed to predict or determine the presence of an arrhythmia." *Id.* at 1:58–61. For example, the '941 patent describes analyzing heart rate and activity level and identifying discordance between these two parameters to determine the presence or the future onset of an arrhythmia. *Id.* at 1:61–66. If the presence or the future onset of an arrhythmia is identified, an electrocardiogram (ECG) may be initiated. *Id.* at 2:1–3.

Figure 7 of the '941 patent is reproduced below.

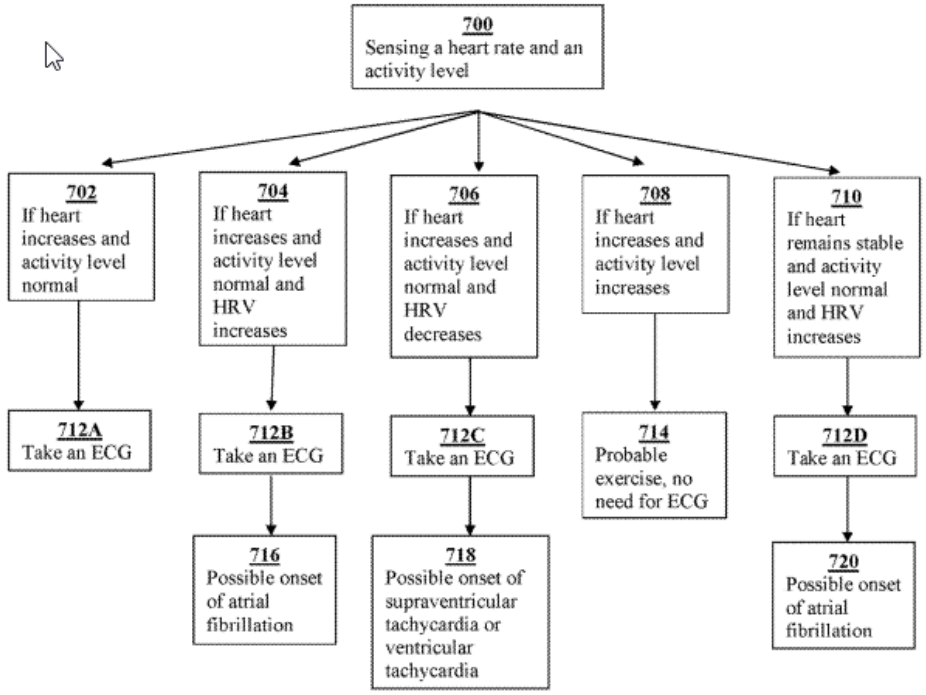


FIG. 7

Figure 7 schematically depicts "an algorithm for discordance monitoring." *Id.* at 3:53–54. The '941 patent explains that a heart rate and an activity level are sensed in step 700. *Id.* at 14:49–51. The '941 patent describes sensing an activity level with a gyroscope or an accelerometer and sensing heart rate using "light based or other commonly used heart rate sensors." *Id.* at 14:51–54. Figure 7 depicts various possible outcomes from the sensing of heart rate and activity level. *Id.* at Fig. 7, elements 702, 704, 706, 708, 710. For example, in step 702, the sensors detect "an increased heart rate . . . together with a normal or resting activity level." *Id.* at 14:59–60. This result is identified as a "discordance [that] may indicate the presence of an arrhythmia." *Id.* at 14:59–66. "As such, an ECG is caused to be sensed in step 712A." *Id.* at 14:66–67. Steps 704, 706, 708, and 710 depict other

potential outcomes from the sensing of heart rate and activity level as well as the actions taken for each potential outcome. *Id.* at 15:22–58.

G. Challenged Claims

The '941 patent includes twenty-three claims. All of those are challenged here. Pet. 1. Claims 1 and 12 are the only independent claims. Claim 1 is illustrative of the claims challenged in this Petition and reads as follows:

> 1. A method of cardiac monitoring, comprising:
> sensing an activity level of a user with a first sensor on a smartwatch worn by the user;
> when the activity level is resting, sensing a heart rate parameter of the user with a second sensor on the smartwatch;
> determining, by a processing device, that a discordance is present between the activity level value and the heart rate parameter;
> based on the presence of the discordance, indicating to the user, using the smartwatch, a possibility of an arrhythmia being present; and
> receiving electric signals of the user from an electrocardiogram sensor ("ECG") on the smartwatch to confirm a presence of the arrhythmia, wherein the ECG sensor comprises a first electrode and a second electrode.

Ex. 1001, 17:2–18.

H. Overview of the Asserted References

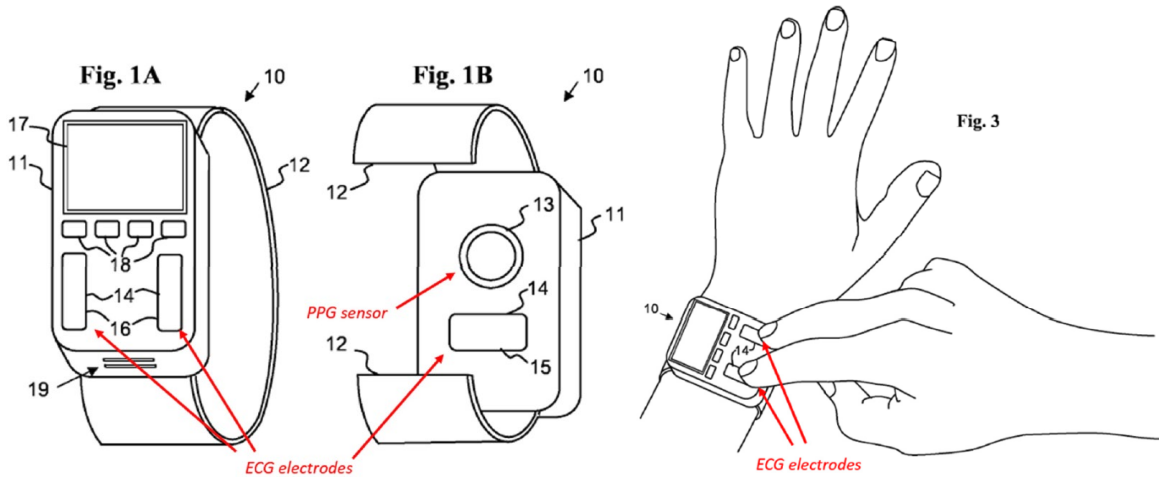
1) Shmueli (Exhibit 1004)

Shmueli, titled "Pulse Oximetry Measurement Triggering ECG Measurement," addresses "solutions . . . for monitoring infrequent events of irregular ECG." Ex. 1004, 2.[7] According to Shmueli, "[t]he present

[7] Throughout this decision, we refer to native pagination wherever it is available. For clarity with respect to citations to Shmueli, we understand the native pagination to be the numbers at the top of the page.

invention preferably performs measurements of intermittent irregular heart-related events without requiring the fixed wiring of the ECG device to the patient." *Id.* at 8.

Shmueli's discloses body-worn cardiac monitoring devices "equipped with two types of sensing devices: an oximetry (SpO_2) measuring unit and an ECG measuring unit." *Id.* at 9.[8] Shmueli's Figures 1A, 1B, and 3, reproduced below, exemplify one embodiment (annotations by Petitioner in red):



Pet. 12. Figures 1A, 1B, and 3 show three views of a wrist-mount heart monitoring device having three ECG electrodes 14 and a PPG sensor 13. Ex. 1004, 6, 9–10. Figure 1A shows two of the ECG electrodes, 14/16, on the face of the device. *Id.* at 9. Figure 1B shows a third ECG electrode, 14/15, along with PPG sensor 13, of the back of the device. *Id.* Figure 3 shows the device as worn on a patient's wrist, with PPG sensor 13 and ECG

[8] As used by Shmueli, "the terms 'oxygen saturation in the blood', 'blood oxygen saturation', 'pulse oximeter', oximetry, SpO_2, and photoplethysmography have the same meaning and may be used interchangeably, except for those places where a difference between such terms is described." *Id.* at 7; *see* Tr. 6:22–7:12, 73:18–21, 95:7–11.

electrode 14/15 in contact with the patient's left wrist and ECG electrodes 14/16 in contact with two fingers of the patient's right hand. *Id.* Petitioner annotates each of Figures 1A, 1B, and 3 with arrows identifying the ECG electrodes. Pet. 12. Petitioner has also annotated Figure 1B with an arrow identifying PPG sensor 13. *Id.* In connection with these devices, Shmueli discloses

> a method for triggering measurement of electrocardiogram (ECG) signal of a subject, the method including the steps of: continuously measuring SpO2 at least one of a wrist and a finger of the subject, detecting an irregular heart condition from the SpO2 measurement, notifying the subject to perform an ECG measurement, and initiating ECG measurement at least partially at the wrist.

Ex. 1004. at 2; *see* Abstract.

Shmueli explains that "[d]eriving heart beat rate from oximetry, as well as other artifacts of the heart activity and blood flow, is . . . known in the art," as are various body-worn oximetry devices. *Id.* at 8. Shmueli further explains that the use of oximetry in combination with ECG measurements is also known in the art. *Id.* Shmueli states, for example, that "US patent No. 7,598,878 (Goldreich) describes a wrist mounted device equipped with an ECG measuring device and a SpO_2 measuring device." *Id.* However, Shmueli, notes "Goldreich does not teach interrelated measurements of ECG and SpO_2" and, thus, does not "enable a patient to perform ECG measurement as soon as an irregular heart activity develops and without requiring the ECG to be constantly wired to the patient." *Id.* According to Shmueli:

> The present invention resolves this problem by providing a combined oximetry and electrocardiogram measuring system and a method in which the oximetry measurement is performed continuously and/or repeatedly, and the ECG measurement is

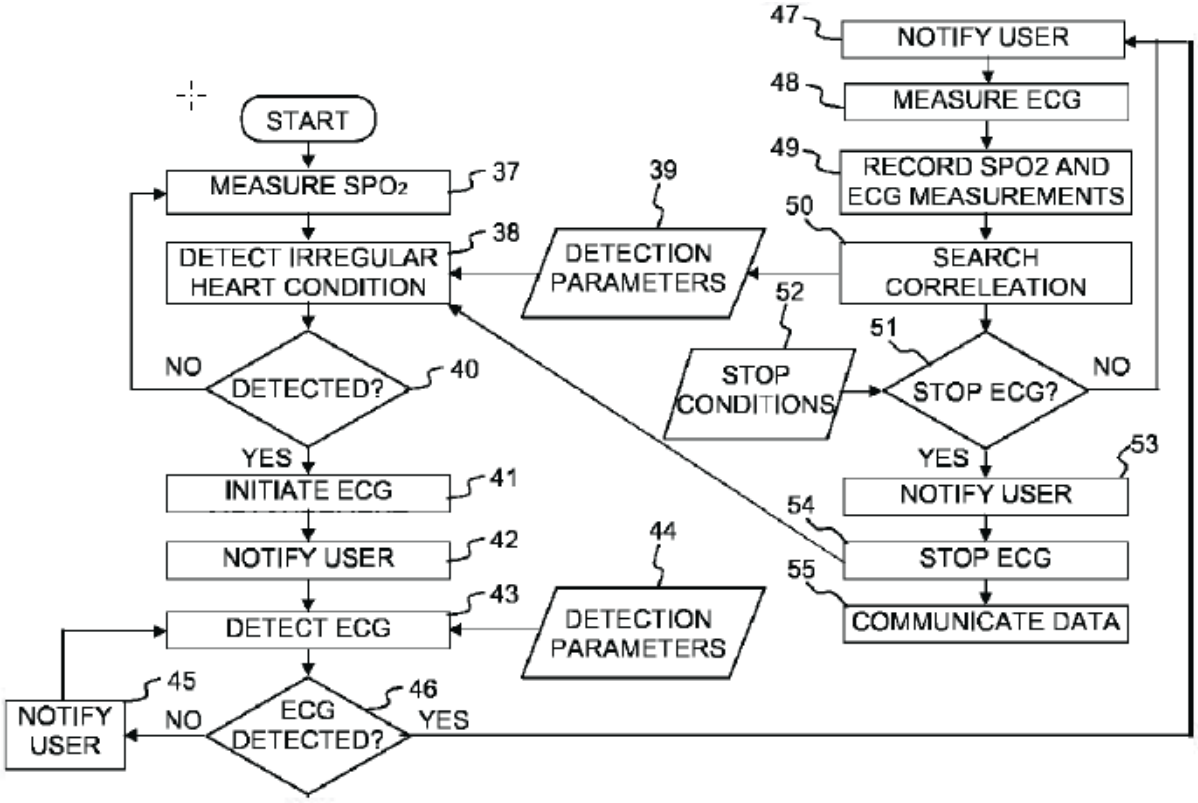
> triggered upon detection of an intermittent irregular heart-related events without requiring the fixed wiring of the ECG device to the patient.

Id. Consistent with this disclosure, Shmueli's claims:

> 1. A method for triggering measurement of electrocardiogram (ECG) signal of a subject, the method comprising the steps of:
>
> continuously measuring SpO_2 at least one of a wrist and a finger of said subject;
>
> detecting an irregular heart condition from said SpO_2 measurement;
>
> notifying said subject to perform an ECG measurement; and
>
> initiating ECG measurement at least partially at said wrist.

Id. at 16.

Shmueli Figure 7 is reproduced below:



"Fig. 7 is a simplified flow chart of a software program preferably executed by the processor of the wrist-mounted heart monitoring device." *Id.* at 7; *see*

also id. at 12–13 (further describing the steps of the software program illustrated in Figure 7).

2) Osorio (Exhibit 1005)

Osorio, titled "Pathological State Detection Using Dynamically Determined Body Data Variability Range Values," "relates to medical device systems and methods capable of detecting a pathological body state of a patient, which may include epileptic seizures, and responding to the same." Ex. 1005 ¶ 2. Although broadly referencing "a pathological body state," Osorio repeatedly exemplifies such conditions in terms of detecting epileptic events. *See*, *e.g.*, *id.* ¶ 37 (referencing values that may "be indicative of a certain pathological state (e.g., epileptic seizure)"), ¶ 46 ("In one embodiment, the pathological state is an epileptic event, e.g., an epileptic seizure."), ¶ 56 ("HRV range may be taken as an indication of an occurrence of a pathological state, e.g., an epileptic seizure"), ¶ 66 ("The dynamic relationship between non-pathological HRVs and activity levels may be exploited to detect pathological states such as epileptic seizures").

Consistent with the broad disclosure and narrow exemplification in the body of its specification, Osorio's claim 1 is directed to "[a] method for detecting a pathological body state of a patient," whereas claim 7 limits the pathological state to an epileptic event. *Id.* at claim 1, claim 7; *also compare id.* at claim 14, *with* claim 17 (similarly limiting a pathological state to an epileptic event).

According to Osorio, the disclosed methods, systems, and related devices, detect a pathological state of a patient by determining when a body data variability value, or "BDV," is outside of a "value range," and where the threshold levels of that range vary in response to the patient's physical

activity (measured by, e.g., an accelerometer) or mental/emotional state. *See, e.g.*, *id.* at code (57), ¶¶ 3–8, 28, 33, 35. In this respect, Osorio states that "false negative and false positive detections of pathological events may be reduced by dynamically determining pathological or non-pathological ranges for particular body indices based on activity type and level or other variables (e.g., environmental conditions)." *Id.* ¶ 36.

Osorio's Figure 1 is reproduced below.

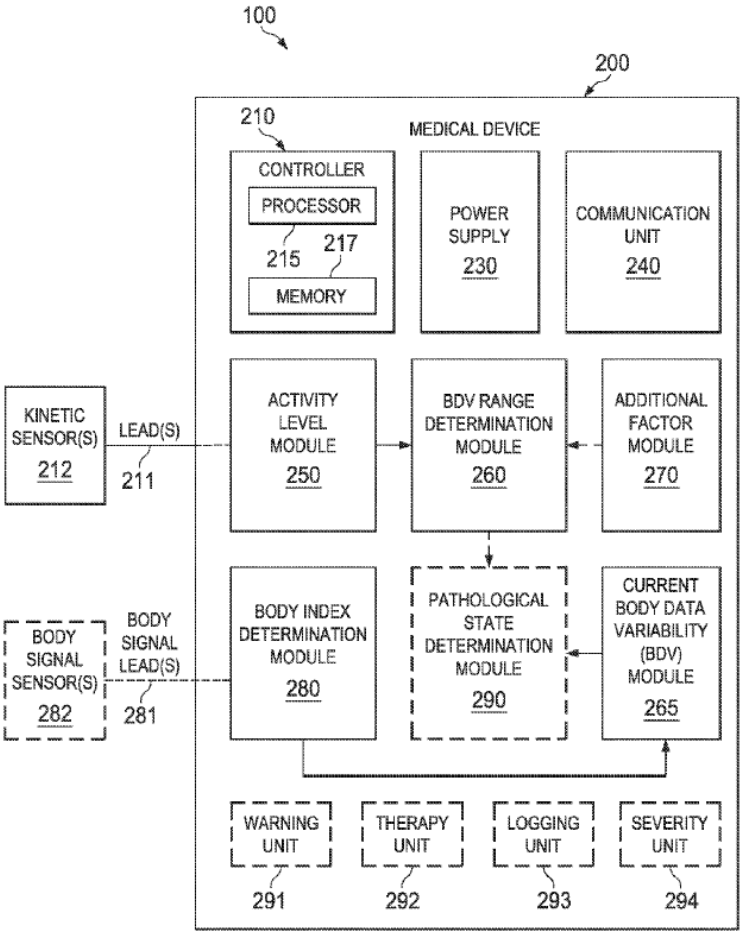


FIG. 1

Figure 1 shows a schematic representation of medical device system 100, including kinetic sensor(s) 212 and body signal sensor(s) 282 connected to medical device 200 by leads 211 and 281, respectively. *Id.* ¶ 33. "[A]ctivity

sensor(s) 212 may each be configured to collect at least one signal from a patient relating to an activity level of the patient," and include, for example, an accelerometer, an inclinometer, a gyroscope, or an ergometer. *Id.* Figure 1 also shows a current body data variability (BDV) module 265, which may "may comprise an O_2 saturation variability (O2SV) module 330 configured to determine O2SV from O_2 saturation data," and "an HRV module 310 configured to determine HRV from heart rate data." *Id.* ¶¶ 10, 53, Fig. 2C. Osorio discloses that "medical device system 100 may be fully or partially implanted, or alternatively may be fully external." *Id.* ¶ 33.

Figure 8, reproduced below, shows one embodiment of Osorio's monitoring method.

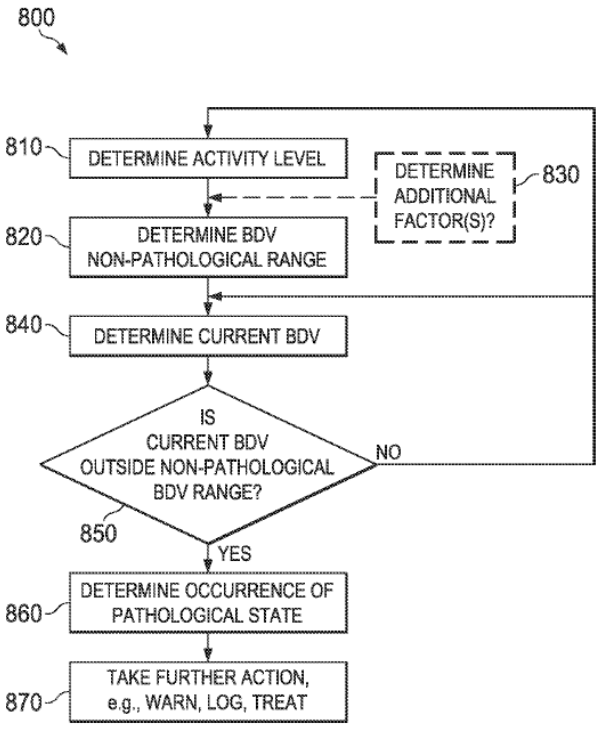


FIG. 8

Figure 8 shows that an activity level is determined at 810, and a non-pathological BDV range is determined at 820 based on the activity level. *Id.* ¶ 77. A current BDV is determined at 840 and compared to the non-

pathological BDV range at 850. *Id.* ¶ 78. If the current BDV is outside the non-pathological range, then a pathological state is determined at 860 and a further action, such as warning, treating, or logging the occurrence and/or severity of the pathological state, is taken at 870. *Id.*

According to Osorio, body indices that may be the subject of BDV monitoring include:

> heart rhythm variability, a heart rate variability (HRV), a respiratory rate variability (RRV), a blood pressure variability (BPV), a respiratory rhythm variability, respiratory sinus arrhythmia, end tidal CO_2 concentration variability, power variability at a certain neurological index frequency band (e.g., beta), an EKG morphology variability, a heart rate pattern variability, an electrodermal variability (e.g., a skin resistivity variability or a skin conductivity variability), a pupillary diameter variability, a blood oxygen saturation variability, a kinetic activity variability, a cognitive activity variability, arterial pH variability, venous pH variability, arterial-venous pH difference variability, a lactic acid concentration variability, a cortisol level variability, or a catecholamine level variability.

Id. ¶ 43; *see also id.* ¶ 42 (similar) ¶¶ 45–46 (monitoring heart rate for episodes of tachycardia and bradycardia). "In one embodiment, the severity [of a pathological state] may be measured by a magnitude and/or duration of a pathological state such as a seizure, a type of autonomic change associated with the pathological state (e.g., changes in heart rate, breathing rate, brain electrical activity, the emergence of one or more cardiac arrhythmias, etc.)." *Id.* ¶ 71.

With respect to HRV, in particular, Osorio teaches: "By monitoring the patient's activity level, HR, and HRV, it is possible to determine when the patient's HRV falls outside the non-pathological ranges as the patient's activity levels change over time." *Id.* ¶ 66. Osorio's Figure 4A, reproduced

below, shows heart rate variability as a function of activity level. *See id.* ¶ 58.

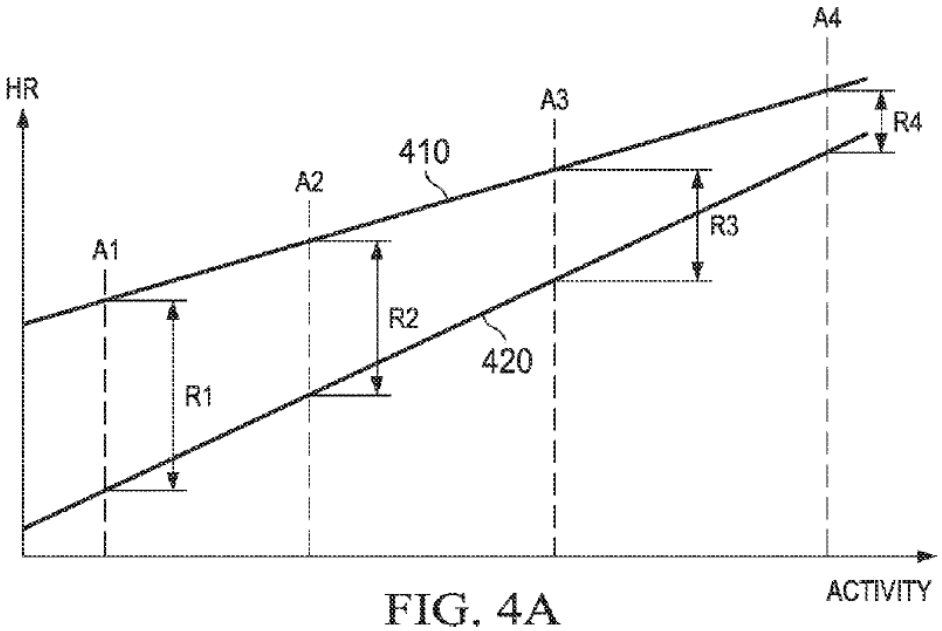


FIG. 4A

Figure 4A plots a patient's heart rate (HR) on the Y-axis and a patient's activity level on the X-axis. *Id.* at Fig. 4A. Markers A1 though A4 represent increasing activity from a sleep state (A1) through vigorous activity (A4). *Id.* Boundary lines 410 and 420, respectively, represent the upper and lower limits of non-pathological heart rate, and include representative ranges R1 through R4. *Id.* According to Osorio,

> the upper and lower bounds of the non-ictal[9] HR region increase as activity level increases (e.g., from a sleep state to a resting, awake state) and reach their highest values for strenuous exertion. In addition, the width of the non-pathological HR ranges narrows as activity levels and heart rates increase, which is consistent with the known reduction in HRV at high levels of exertion. When the patient is in a non-pathological state (e.g., when an epileptic patient is not having a

[9] "Ictal" refers to the active, middle stage of a seizure and corresponds with intense electrical brain activity. *See* https://epilepsyfoundation.org.au/understanding-epilepsy/seizures/seizure-phases/.

> seizure), for a particular activity level the patient's HRV should fall within a non-pathological HRV range associated with that activity level.

Id. ¶ 58.

Osorio further presents Figure 11 as "depict[ing] pathological and non-pathological BDV (e.g., HRV) value ranges." *Id.* ¶¶ 23, 91. In this illustration, Osorio shows that HRV values falling below 0.5 bpm and above 4 bpm are always pathological when activity level is low (e.g., resting or walking), whereas intermediate HRV values (0.5–4 bpm) may be pathological when considered in light of the patient's activity level. *Id*. Osorio further notes that the boundaries between normal and pathological may be adjusted based on an individual's physiology. "For example, in an epilepsy patient also suffering from tachycardia, and having base resting heart rate of 100-110 bpm, a decline in heart rate to 70 bpm may be indicative of a seizure slowing down the heart rate, even though a heart rate of 70 bpm is generally 'normal' across a typical population." *Id.* ¶ 45.

3) Lee-2013 (Exhibit 1011)

Lee-2013, titled "Atrial Fibrillation Detection Using a Smart Phone," discloses a study to assess whether "an iPhone 4s can be used to detect atrial fibrillation (AF) based on its ability to record a pulsatile PPG signal from a fingertip using the built-in camera lens." Ex. 1011, 26.

Lee-2013 teaches that atrial fibrillation is the "most common sustained arrhythmia," with "[o]ver 3 million Americans" diagnosed. *Id.* According to Lee-2013, there is a "pressing need to develop methods for accurate AF detection and monitoring in order to improve patient care and reduce healthcare costs." *Id.* In response to this need, the authors of Lee-2013 developed "a smartphone application to measure pulsatile time series

and then use this data to detect AF real-time." *Id.* Lee-2013's study concluded that "AF can be accurately detected from pulsatile signals in the fingertip using the camera of an iPhone 4s." *Id.* at 29.

4) Chan (Exhibit 1048)

Chan discloses:

> A wristwatch worn by a user for measuring a three-lead ECG [that] includes three electrodes placed separately on the front, either side, and back or strap thereof. The wristwatch further includes an electrode panel having the electrode on the front or either side of the watch, sensing elements, pressure, infrared or impedance detectors, and circuits. The electrode panel is capable of sensing the contact or press of fingers to trigger the ECG measuring. While the electrode in the back-side of the watch contacts the hand wearing the watch, the electrode and electrode panel on the front or either side of the watch are pressed by fingers from the other hand, and the electrode in the strap contacts the abdomen or left leg simultaneously. Thus, a three-lead ECG can be measured. ECG data can be transmitted to a personal or hospital computer by wireless networks or flash memory.

Ex. 1048, Abstract.

Chan's figures 1A and 1B, reproduced below, show an embodiment of the disclosed three-lead ECG wristwatch.

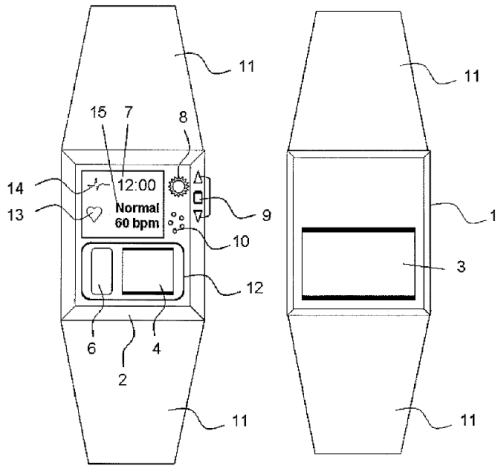


FIG.1A FIG.1B

Figures 1A and 1B, respectively, show the front and back views of a three-lead ECG wristwatch. *Id.* at 2:21–22. Figure 1A shows ECG electrode 4, sensing element 6 (which can detect "pressure, impedance or infrared for recognizing the contact or press made by fingers to initiate an ECG measurement"), and display 7, which may be an LCD. *Id.* at 2:44–56. Display 7 can display text (e.g., time, heart rate, and, condition (normal vs arrhythmia) as well as "graph/animation, for an event reminding 13 and ECG waveforms 14." *Id*. at 2:56–59; *see also id.* at 4:56–59 (stating, with reference to Figure 7, that "display 57 can show users 59 time, heart rate, waveforms and any other information 61, such as activity level and temperature, if needed").

Chan Figure 2 is reproduced below.

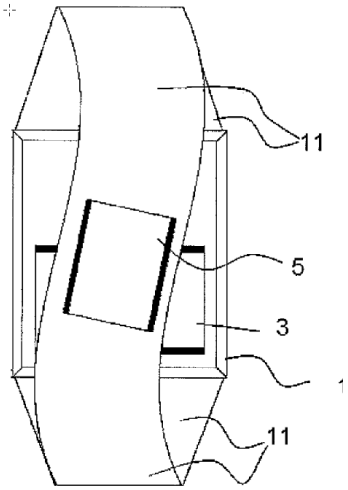


Figure 2 shows an embodiment of the three-lead ECG watch having a third lead 5 on the strap 11. *Id.* at 2:24–25, 3:1–4.

Chan Figure 3B is reproduced below.

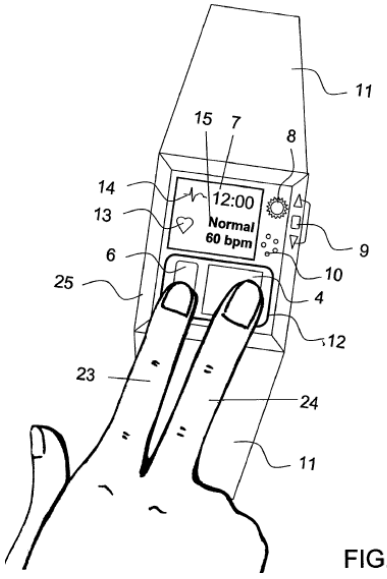


FIG.3B

Figure 3B "demonstrate[s] how to place the wristwatch to make electrodes be contacted by both hands." *Id.* at 2:26–28, 3:5–22.

II. ANALYSIS

A. Legal Standards

"In an IPR, 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 (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).

In *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), the Supreme Court reaffirmed the framework for determining obviousness set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The *KSR* Court summarized the four factual inquiries set forth in *Graham* (383 U.S. at 17–18) that are applied in determining whether a claim is unpatentable as obvious under 35 U.S.C. § 103 as follows: (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the art; and (4) considering objective evidence indicating obviousness or non-obviousness, if present. *KSR*, 550 U.S. at 406.

"[W]hen a patent 'simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious." *Id.* at 417 (quoting *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 282 (1976)). But in analyzing the obviousness of a combination of prior art elements, it can also be important to identify a reason that would have prompted one of skill

in the art "to combine . . . known elements in the fashion claimed by the patent at issue." *Id.* at 418. A precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *Id.* Rather, "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.* at 420. Accordingly, a party that petitions the Board for a determination of unpatentability based on obviousness must show that "a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (quotations and citations omitted). Under the proper inquiry, "obviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success." *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007).

B. Level of Ordinary Skill in the Art

In determining the level of skill in the art, we consider the type of problems encountered in the art, the prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. *See Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986); *see also Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1011 (Fed. Cir. 1983).

Petitioner asserts that a person of ordinary skill in the art would have been someone with

> at least a combination of [a] Bachelor's Degree (or a similar Master's Degree, or higher degree) in an academic area emphasizing health science, or a related field, and two or more years of work experience with cardiac monitoring technologies (e.g., as a cardiologist).

Ex. 1003 ¶ 10 (Dr. Chaitman testimony defining the POSA based on his "knowledge and experience in the field and [his] review of the '941 patent and file history") (cited at Pet. 10 n.3). Petitioner further contends that "[a]dditional education or industry experience may compensate for a deficit in one of the other aspects of the requirements stated above." *Id.*

In its Preliminary Response, Patent Owner took the position that one of ordinary skill in the art would have had "specialized engineering skills" including "a degree in biomedical or electrical engineering (or an equivalent), and/or extensive experience working with tools for detecting cardiac conditions." Prelim. Resp. 9 (citing Ex. 2001 ¶¶ 51–53). Although Patent Owner does not expressly define the person of ordinary skill in the art post-institution, it appears to argue that such a person would have an engineering degree or comparable experience. *See* PO Resp. 26 (arguing that "a cardiologist who is not an engineer 'lacks the necessary knowledge to develop a smartwatch with PPG or ECG sensors'"); Sur-reply 21 (similar); *but see* Tr. 39:20–40:12 (arguing that Patent Owner waived its opportunity to propose a definition).

In our Institution Decision, we noted that

> the research and development of medical devices is often the work of a multidisciplinary team, and courts and tribunals have frequently identified the hypothetical person of ordinary skill as a composite or team of individuals with complementary backgrounds and skills. *See, e.g.*, *AstraZeneca Pharm. LP v. Anchen Pharm., Inc.*, 2012 WL 1065458, at *19, *22 (D.N.J. Mar. 29, 2012), *aff'd*, 498 F. App'x 999 (Fed. Cir. 2013)

(collecting cases); *Apotex Inc. v. Novartis AG*, IPR2017-00854, Paper 109 at 10–11 (PTAB July 11, 2018) (collecting cases).

DI 25. We further determined such a team in the context of the '941 patent might include specialists in electrical engineering, mechanical engineering, biomedical engineering, computer science, and cardiology. *Id.* With respect to the last of these, we noted that because the '941 patent "relate[s] to, e.g., 'methods of cardiac monitoring" to "confirm a presence of [an] arrhythmia" it appeared reasonable that this hypothetical multidisciplinary team would include a cardiologist. *Id.* at 26 & n.9 (noting that the Lee-2013 reference is authored by a group comprised of three people Department of Biomedical Engineering at Worcester Polytechnic Institute, and two people from the Department of Medicine at the University of Massachusetts, Worcester); Ex. 1001, 1:30–33; *see also* Tr. 39:5–19 (Petitioner arguing that prior art Exhibits 1021, 1033, 1036, 1076–1078, 2024, and 2029 evidence "teams of people, medical doctors, cardiologists working together with engineers").

Patent Owner argues that we should reject our originally proposed definition in light of, for example, Petitioner's proposed definition before the ITC, which required an engineering background and "at least two years of relevant work experience designing wearable devices and/or sensors for measuring physiological signals." PO Resp. 27 (citing Ex. 2004, 6). As noted at oral argument, however, Patent Owner truncates the full extent of Petitioner's ITC definition, which further states that "a hypothetical person of ordinary skill in the art could also be a person with a medical degree (MD or DO) and with at least two years of work experience using biomedical sensors and/or analyzing their data (in the context of industry, in biomedical academic research, or in practice treating patients)." Ex. 2004, 6; Tr. 40:13–41:10. Patent Owner's assertion that our originally proposed definition,

would "classify all cardiologists as [persons of ordinary skill in the art]," is well taken. PO Resp. 25. Accordingly, we apply the following modified definition, which is consistent with Petitioner's representation before the ITC. For the purpose of this proceeding, a person of ordinary skill in the art may be a member of an interdisciplinary team including persons with backgrounds in electrical engineering, mechanical engineering, biomedical engineering, computer science, and/or cardiology, and having at least two years of relevant work experience designing, using, or analyzing data from, cardiac monitoring devices.

The parties' dispute regarding the definition of one of ordinary skill in the art relates to Dr. Chaitman's alleged lack of "specialized engineering skills," and the bases for Dr. Efimov's opinions on the meaning of "medical technology at-issue in this proceeding, such as 'irregular heart condition' and 'pathological state.'" *See e.g.*, PO Resp. 27–29; Reply 27–28. Neither party has sought to exclude expert testimony in this proceeding, and the arguments bear on the amount of weight we should accord the opinions of either expert. *See e.g.*, Tr. 49:22–52:21.

As discussed in our Institution Decision, Dr. Chaitman is a well-respected cardiologist with "extensive experience working with tools for detecting cardiac conditions," who would qualify as one of ordinary skill in the art even under Patent Owner's then-proposed definition. *See* DI 24–26. Despite Patent Owner's subsequent position that the ordinarily skilled artisan should have an engineering degree and "design experience" in developing wearable cardiac sensors, the arguments and evidence adduced at trial do not alter our initial determination regarding Dr. Chaitman's qualification to testify. DI 24–26 (our initial determination); PO Resp. 25–

29; Reply 27–28; Sur-reply 21–23; *see generally* Tr. 40:25–46:19. In this respect we agree with Petitioner's argument in support of Dr. Chaitman's qualifications, that this proceeding involves "piecing together known technologies and . . . the analysis of cardiac data" including PPG data, ECG data and activity level. Tr. 38:4–18. Thus, one of ordinary skill in the art with an understanding of cardiac monitoring technology "would understand how these types of data work, how they interplay and how the data could be processed on these devices." *Id.*

Dr. Efimov has extensive experience in the design of cardiac monitoring and related technologies, but Petitioner asserts that he "is unable to offer credible testimony on the meaning of [relevant] medical terminology," because he is not a doctor. Reply 28; Sur-reply 22 (arguing that "Dr. Efimov is a recognized expert in the field of clinical cardiac electrophysiology"). Considering the totality of Dr. Efimov's background, including extensive work on the physiology, diagnostics, and therapy of cardiac arrhythmias, we do not adopt Petitioner's position. *See*, *e.g.*, Ex. 2001 ¶¶ 2–15.

In light of the above, we determine that Dr. Chaitman and Dr. Efimov are both qualified to testify as to the understanding of a person of ordinary skill in the art, we, nevertheless, consider the weight of both parties' experts on a particular topic in light of the strengths and weaknesses of their respective background.

C. Claim Construction

We interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b). Under this standard, we construe the claim

"in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.* "[W]e need only construe terms 'that are in controversy, 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) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

Petitioner offers a construction for the claim term "discordance," proposing that it should be construed to mean "when a first sensed parameter value would not be expected to coincide with a second sensed parameter value." Pet. 8–10. Patent Owner does not propose a competing construction and, in the ITC Investigation, proposed "[n]o construction required" for the term "discordance." Ex. 2009, 4. Having reviewed the evidence and argument of record, we determine that we do not need to construe the term "discordance" in order to resolve this dispute. *See Vivid Techs.*, 200 F.3d at 803 ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.").

Patent Owner identifies the term "arrhythmia" and the phrase "confirm the presence of arrhythmia" as needing construction. PO Resp. 22. For the term "arrhythmia," Patent Owner represents that during the ITC proceeding both parties "agreed" that a person of ordinary skill in the art would understand the term arrhythmia to be "a cardiac condition in which the electrical activity of the heart is irregular or is fast[er] or slower than normal." *Id.* at 23. Patent Owner cites intrinsic and extrinsic evidence supporting this construction and proposes that we adopt it here. *Id.* at

23–24. Petitioner does not address Patent Owner's proposed construction. *See generally* Reply; Tr. 21:18-22:3 ("[Board]: . . . Patent Owner raised the issue of claim construction for the term arrhythmia. Is there any dispute there? [Petitioner's counsel]: Honestly, Your Honor, we considered that -- put a lot of energy into considering it. We don't believe so."); *see also* Tr. 53:24–54:2 ("[Board]: . . . Your claim construction of arrhythmia is merely a matter of precision and clarification rather than a contested point; is that correct? [Patent Owner's counsel]: I believe that's largely correct.").

Patent Owner's proposed construction is consistent with the intrinsic and extrinsic evidence. *See e.g.*, Ex. 1047 (medical dictionary defining arrhythmias as "[a]n abnormal rate or rhythm of the heartbeat" caused by "a disturbance in the electrical impulses within the heart"); Ex. 1001, 4:4 ("Heart function is also measured in terms of regularity of rhythm. . . . When there is an abnormality of rhythm, the condition is typically referred to as an arrhythmia."). Although it is not clear that the term is in dispute, for clarity, we understand the term "arrhythmia" as used in the context of the '941 patent to mean: a cardiac condition in which the electrical activity of the heart is irregular or is faster (tachycardia) or slower (bradycardia) than normal.

As for the phrase "confirming the presence of arrhythmia," Patent Owner contends that this term should be given its plain meaning. PO Resp. 22. Petitioner does not address construction of this phrase (*see generally* Reply), and we do not see any need to construe it here. *See Vivid Techs.*, 200 F.3d at 803.

D. Ground 1: Obviousness over Shmueli

As Ground 1, Petitioner asserts that claims 1, 5, 7–9, 11, 12, 16, 18–20, 22, and 23 are unpatentable as obvious over the combination of Shmueli and Osorio. Pet. 11–65; *see id.* at 31–53 (claim 1), 54–60 (claims depending from claim 1), 60–63 (claim 12), 63–65 (claims depending from claim 12). Petitioner contends that the combination of Shmueli and Osorio discloses or renders obvious each element of claims 1, 5, 7–9, 11, 12, 16, 18–20, 22, and 23, and sets forth an element-by-element comparison of the asserted art to the challenged claims. Pet. 31–65. According to Petitioner, "Shmueli's wrist-mounted heart monitoring device detects an irregular heart condition (arrhythmia) based on PPG and ECG measurements" but "does not expressly account for a user's activity level." Pet. 20. Petitioner contends that it was "well-known that activity level is related to HR and HRV." *Id.* (citing evidence). Petitioner then points to Osorio as evidence of the "benefits (e.g., improved accuracy, reliability, and reduced false detection) of using activity level to detect an irregular heart condition." *Id.* (citing Ex. 1005 ¶¶ 29, 36). Petitioner contends that in view of these benefits, a person of ordinary skill in the art "would have been motivated to incorporate Osorio's activity sensor and activity level analysis techniques into Shmueli's heart monitoring device." *Id.* (citing Ex. 1005 ¶ 29; Ex. 1003 ¶ 69).

Petitioner contends that the person of ordinary skill in the art would have incorporated two specific teachings from Osorio in a modified version of Shmueli's device: "(i) using activity level monitoring to improve the accuracy of detecting a pathological event (e.g., arrhythmia), and (ii) determining HRV from HR and using HRV to detect the pathological event (e.g., arrhythmia)." *Id.*

Patent Owner contends that Ground 1 fails because 1) Petitioner has not shown that either Shmueli or Osorio teaches or suggests arrhythmia detection, 2) Petitioner has not shown that Shmueli renders obvious the use of ECG data to confirm the initial detection of an irregular heart condition using PPG data, and 3) Petitioner has not shown that a person of ordinary skill in the art would have been motivated to combine Shmueli and Osorio. PO. Resp. 39–56; Sur-reply 10–19. We address the contested matters below.

1) Arrhythmia Detection by Shmueli

Claim 1 requires "indicating to the user, . . . a possibility of an arrhythmia being present." Ex. 1001, 17:11–13. Claim 12, the only other independent claim, includes a similar limitation. *Id.* at 18:14–16. Although Shmueli does not explicitly use the term arrhythmia, it does disclose "detecting an irregular heart condition" using both PPG and ECG data. *See e.g.*, Ex. 1004, Abstract. Petitioner cites the testimony of Dr. Chaitman that arrhythmia is "one of the most obvious (if not the most obvious) types of 'irregular heart condition' that can be determined using PPG and ECG data." Ex. 1003 ¶ 55 (citing Ex. 1016, 6081, Ex. 1020, Abstract, 44:29–32, Ex. 1011, Abstract). Thus, according to Petitioner, a person of ordinary skill would have understood and/or found it obvious that the text "Detect Irregular Heart Condition," in element 38 of Shmueli's Figure 7, refers to detecting the presence of arrhythmia based on PPG data. *See* Pet. 14–15; Ex. 1003 ¶ 56–57.

Patent Owner argues that Ground 1 fails because Shmueli's reference to irregular heart conditions refers instead to "conditions traditionally detected using SpO_2 monitoring, such as heart attacks or acute heart failure." PO Resp. 39; *see* Ex. 2016 ¶ 61; Sur-reply 10–14 (more narrowly focusing on heart attack detection). Patent Owner raises three arguments supporting

its contention that "while an arrhythmia might be an irregular heart condition in the abstract, it cannot be an 'irregular heart condition' as that phrase is used in Shmueli." PO Resp. 40. First, Patent Owner argues that "Shmueli could be referring to practically any heart condition that includes an irregular heart condition . . . including: heart attack, angina pectoris, cardiomyopathy, congenital heart disease, . . . coronary heart disease, and heart-valve defect." *Id.* at 41–42 (citing Ex. 1047, 1023); *see also* Ex. 2016 ¶ 62. Second, Patent Owner argues that one of ordinary skill in the art would not understand Shmueli to refer to arrhythmias because "pulse oximetry was a well-known diagnostic tool for conditions affecting blood oxygen levels including cardiac conditions such as heart attacks" but "PPG was a 'sub-optimal' tool for measuring arrhythmias." *Id.* at 43 (citing Ex. 2018, 62:9–21; Ex. 2017, 53:13–54:4, Ex. 2016 ¶ 64; Ex. 2025). Third, Patent Owner points to Shmueli's disclosure that "instead of, or in addition to, the oximetry (SpO_2) measuring unit[,] the heart monitoring device may include a unit for measuring CO_2 content in the blood." PO Resp. 44 (citing Ex. 1004, 9); Sur-reply 13–14. According to Patent Owner, because CO_2 levels are "not used for arrhythmia detection but ***can*** be used to detect heart attacks or acute heart failure," Shmueli's disclosure of using CO_2 measurements "supports the conclusion that Shmueli is not directed at arrhythmia detection." PO Resp. 44 (citing Ex. 2016 ¶ 65). Patent Owner's arguments are unavailing for substantially the reasons set forth at pages 3–15 of Petitioner's Reply and as discussed below.

In general terms, SpO_2 refers to the oxygen content of blood and PPG (photoplethysmography) measures pulse.[10] *See* Ex. 1069, 81:8–13; Ex. 2001 ¶¶ 40–41. According to Dr. Efimov, an SpO_2 sensor detects changes in the color of blood (indicative of degree of oxygenation) using infra-red and red light emitting diodes; PPG (photoplethysmography) on the other hand, measures changes in reflected light as blood vessels pulsate with every heartbeat. Ex. 1069, 79:17–83:20; *see also* Ex. 2001 ¶ 40; Ex. 1003 ¶ 31. Unlike an SpO_2 sensor, PPG can, but does not necessarily require, that the light source is in the infra-red and red portion of the spectrum. Ex. 1069, 79:20–80:24, 83:15–16. But by combining the necessary sensors and using infra-red/red light emitting diodes, their features can be combined in a single device able to perform pulse oximetry, which measures both pulse rate and oxygen levels. *See id.* at 83:4–85:2 ("[T]his combination is an oximeter.").

Patent Owner, supported by the testimony of Dr. Efimov, focuses on Shmueli's reference to SpO_2, for example, in element 37 of Shmueli's figure 7. Taken strictly at face value, the instruction of element 37 to "Measure SPO_2" refers to the measurement of blood oxygen content, which, Patent Owner argues, may be used for monitoring signs of heart attack, but not arrhythmias. *See* PO Resp. 44–45; Tr. 62:1–10, 70:18–71:1, 73:18–74:6. But as Petitioner points out, Shmueli is not focused solely on monitoring blood oxygen content. *See, e.g.*, Reply 4–6; Ex. 1004, Title. We note in particular, that in describing the operation of Figure 7, Shmueli teaches that "the software program starts in element 37 by measuring SpO_2." Ex. 1004,

[10] As noted above, Shmueli discloses that "the terms 'oxygen saturation in the blood', 'blood oxygen saturation', 'pulse oximeter', oximetry, SpO_2, and photoplethysmography have the same meaning and may be used interchangeably." *See* Ex. 1004, 8.

12:9–10. Although Shmueli states that element 37 measures "oxygen saturation in the blood," it further states that the measurement is preferably executed using oximetry—which, as noted above, can measure pulse rate in addition to blood oxygen content. *See id.* at 12:10–13; *see also id.* at 8 ("Deriving heart beat rate from oximetry, as well as other artifacts of the heart activity and blood flow, is . . . known in the art."). Consistent with its title highlighting the use of "Pulse Oximetry Measurement," Shmueli states:

> The software program proceeds to element 38 to derive from the SpO_2 measurement physiological parameters such as pulse rate, pulse amplitude, pulse shape, rate of blood flow, etc. Then, the software program scans the derived physiological parameters to detect various irregularities of the heart condition.

Id. at 12:14–17; *see* Ex. 1069, 84:18–25.

Dr. Efimov tacitly admits that the above passage discloses that the "Measure SpO_2" command of Shmueli's element 37 measures pulse rate, amplitude and shape, thus, indicating the PPG functionality. Ex. 1069, 119:20–120:13. This type of heart rate data can be used to detect arrythmia. *See* Ex. 1069, 84:4–25, 120:6–13, 121:2–122:6; Ex. 2017, 90:5–12; Ex. 1003 ¶¶ 26–27, 31–32, 54, 56; Ex. 1061, 16:54–58[11] ("The signal that is collected from the SpO2 sensor may also optionally be used for producing other heart related information . . . such as heart rate, PWTT [pulse wave transit time], irregularity of heart rate etc.").

Accepting that the embodiment of Shmueli's Figure 7 was capable of detecting arrythmia using SpO_2/PPG data, we adopt Dr. Chaitman's reasoning that one of ordinary skill would have understood Shmueli's "irregular heart condition" to refer to—or at a minimum, render obvious—

[11] Goldreich, US 7,598,878 B2, issued Oct. 6, 2009.

arrhythmia, "one of the most obvious (if not the most obvious) types of 'irregular heart condition[s],'" as opposed to, for example, heart attack.[12] *See* Ex, 1003 ¶¶ 49–57; *see also* Pet. 13–15; Reply 3–9; Ex. 2016 ¶ 3; Tr. 15:9–12, 73:6–74:6.

Patent Owner also argues that, whereas ECG is the "gold standard" for arrythmia detection, "PPG was a 'sub-optimal' tool for measuring arrhythmias." *See* PO Resp. 25, 43; *see also id.* at 9–10, 25–26, 31; Ex. 2001 ¶ 41 (Dr. Efimov's statement that "PPG monitoring is reliable in measurements of oxygen saturation and average heart rate, but historically has been found to be less reliable in detecting arrhythmias, especially atrial arrhythmias. Compared to the traditional ECG data, heart rate estimation is more challenging based on the PPG-signal."); Ex. 2016 ¶ 16 (similar). But this is precisely the point of Shmueli, which combines the ease of use of the PPG sensor with a less convenient, but confirmatory, ECG. As stated by Petitioner, "Shmueli instructs a user to take an ECG when a problem is identified by SpO_2/PPG so that the ECG can confirm whether or not the SpO_2/PPG detection was accurate." Reply 2 (citing Pet. 15, 53; Ex. 1003 ¶¶ 57, 121; Ex. 1004, Abstract, 3:15–20, 9:21–29, 12:22–31, 14:16–29, Fig. 7). As Shmueli explains, this provides the benefit of "enabl[ing] a patient to perform ECG measurement as soon as an irregular heart activity develops and without requiring the ECG to be constantly wired to the patient," as with the more cumbersome implanted, tethered, or Holter devices. Ex. 1004, 2–3,

[12] Although Patent Owner argues that Shmueli's use of "irregular heart condition" potentially encompasses many conditions, we note that some of these (e.g., heart-valve defects, and congenital heart defects) are chronic conditions, and thus, not pertinent to Shmueli's detection of episodic events. Rather than attempt to parse the relevance of each, we focus on heart attack, as does Patent Owner. *See* Sur-reply 10–14; Tr. 64:1–10, 73:18–74:6.

8; Ex. 1003 ¶ 57; Ex. 2016 ¶ 7 ("Clinically, AFib is diagnosed by cardiologists using gold standard tool – 12 lead ECG, or Holter monitors and similar wearable or implantable devices.").

We also do not find persuasive Patent Owner's argument regarding Shmueli's disclosure that "instead of, or in addition to, the oximetry (SpO_2) measuring unit[,] the heart monitoring device may include a unit for measuring CO_2 content in the blood." *See* PO Resp. 44 (citing Ex. 1004, 9). Shmueli is relevant "for all that it teaches," and its brief reference to alternative embodiments does not change our understanding of either Figure 7 or Shmueli as a whole. *See In re Mouttet*, 686 F.3d 1322, 1331 (Fed. Cir. 2012).

In light of the above, and all the evidence adduced at trial, we agree with Petitioner that one of ordinary skill in the art would have understood Shmueli to disclose or render obvious a method of cardiac monitoring comprising "indicating to the user, . . . a possibility of an arrhythmia being present," as recited in independent claim 1[13]

2) *Arrhythmia Detection by Osorio*

Osorio discloses medical device systems and methods for detecting a pathological state of a patient by determining when a body data variability value, or "BDV," is outside of a "value range," and where the threshold levels of that range vary in response to the patient's physical activity level (measured by, e.g., an accelerometer), sleep/wake state, or other mental/emotional condition. *See* Ex. 1005, Abstract, ¶¶ 3–8, 28, 33, 35, 48, Fig. 4. Osorio states that "false negative and false positive detections of pathological events may be reduced by dynamically determining

[13] As noted above, independent claim 12 includes similar language.

pathological or non-pathological ranges for particular body indices based on activity type and level or other variables (e.g., environmental conditions)." *Id.* ¶ 36. Osorio discloses that among the body indices subject to BDV monitoring are "heart rhythm variability," "heart rate variability (HRV)," changes in heart rate, including tachycardia and bradycardia, and "the emergence of one or more cardiac arrhythmias." *Id*. ¶¶ 42, 43, 45, 46, 71; Ex. 1069, 61:13–16; Ex. 1003 ¶ 60.

Patent Owner argues that we should discount Osorio's express teachings to monitor heart rate for episodes of tachycardia, bradycardia, or other cardiac arrhythmias because the underlying "pathological state" at issue in Osorio is epilepsy, rather than arrhythmia. *See* PO Resp. 45–48; Sur-reply 14–16; Tr. 56:16–57:23 (Patent Owner's counsel arguing that any changes in heartbeat mentioned in Osorio are "in the context of a neurological condition"). Patent Owner's arguments are unavailing for a number of reasons.

First, to the extent Ground 1 relies on Osorio for arrhythmia detection, *per se*, it is invariably in combination with Shmueli. *See e.g.*, Pet. 20–31. Because we determine that Shmueli discloses or renders obvious arrhythmia detection, it is not necessary that we also find that disclosure in Osorio. *See* Section II.D.1, above.

Second, for essentially the reasons set forth in Petitioner's Reply, we do not read Osorio's "pathological state" as limited to neurological conditions. *See* Reply 15–18. We do not dispute that Osorio largely focuses on a particular neurological condition—epilepsy—as an exemplary pathological state. As noted by Petitioner, however, Osorio, consistently employs "permissive language to indicate that its teaching for epileptic

seizures are merely exemplary," and its five-paragraph introduction to the invention does not once mention epilepsy. Reply 15–16 (citing Ex. 1005 ¶¶ 2, 37, 46); *see also* Ex. 1005 ¶¶ 56, 57. Illustrative of Osorio's broad usage of pathological state, the reference discloses that "[a]n occurrence of *any pathological state* that may be associated with a body signal outside a non-pathological BDV range provided by analysis of the patient's activity level may be determined by the pathological state occurrence module." Ex. 1005 ¶ 44 (emphasis added).

We also agree with Petitioner that one of ordinary skill reading Osorio, including its claims, would also understand that its teachings are not limited to epilepsy. *See* Reply 16–17. In particular, Osorio's claim 1 is directed to "[a] method for detecting a pathological body state of a patient," whereas claim 7 limits the pathological state to an epileptic event. The same relationship is seen with claims 14 and 17 (limiting a pathological state of claim 14 to an epileptic event). Patent Owner's argument that the broader "pathological body state" recited in claims 1 and 14 should be limited to neurological states (Sur-Reply 15), is not consistent with our reading of Osorio's specification. To the contrary, our understanding of Osorio is consistent with Dr. Efimov's admission that one of ordinary skill in the art would, in general, understand pathological state to include arrhythmia. Ex. 1069, 51:17–52:10.

Third, even were we to read Osorio as narrowly drawn to the detection of epilepsy as Patent Owner urges, the reference, nonetheless, contains repeated teachings to monitor heart rate and heart rate variability for signs of arrhythmia. *See* Ex. 1005 ¶¶ 42, 43, 45, 46, 71; Ex. 1069, 58:9–59:3; (Dr. Efimov's agreement that Osorio discloses determining the

severity of a neurologic condition based, at least in part, on the identification of cardiac arrhythmia), 61:13–62:7 (Dr. Efimov's testimony that Osorio uses identification of cardiac arrhythmia to diagnosis a neurological pathological state). It is undisputed that a cardiac arrhythmia is a type of pathological condition. Ex. 1003 ¶ 61; Ex. 1069, 50:17–51:10. Patent Owner provides no persuasive explanation of why we should ignore Osorio's express teachings relating to the detection of cardiac arrhythmias, merely because Osorio also implicates them in detecting the pathological condition of epilepsy.

3) Confirmation Using ECG Data

Claim 1 requires "receiving electric signals of the user from an electrocardiogram sensor ('ECG') on the smartwatch to confirm a presence of the arrhythmia." Ex. 1001, 17:14–16. Independent claim 12 includes similar language. *Id.* at 18:18–19. As noted above, we find that Shmueli teaches or suggests "indicating . . . a possibility of an arrhythmia being present" based on PPG data. *See supra* § II.D.1. Patent Owner argues that "Petitioner relies exclusively on Shmueli for this 'confirm' limitation'" and that Ground 1 fails because Shmueli does not render obvious using ECG data to confirm that initial detection. PO Resp. 48–54. We do not find Patent Owner's arguments availing for the reasons set forth in the Petition, the Reply, and as discussed below.

Petitioner presents several lines of evidence supporting its contention that Shmueli renders the confirmation step obvious. Pet. 51–53; Reply 18–20. Petitioner argues, for example, "ECG is undisputedly the gold standard for detecting heart conditions, which makes it obvious that Shmueli's ECG measurements are used to confirm irregular heart conditions detected by its SpO_2/PPG measurements." Reply 18. Focusing on the flow chart of

Shmueli's Figure 7 (which was reproduced and discussed *supra* § I.H.1), Petitioner argues:

> A [person of ordinary skill in the art] would have understood and/or found obvious that the monitoring technique shown in Shmueli's Figure 7 contemplates using ECG data to confirm the initial detection of an irregular heart condition using PPG data. APPLE-1004, 8:24-29. This is because Shmueli criticizes other heart monitoring devices for "not consider[ing] a requirement to enable a patient to perform ECG measurement as soon as an irregular heart activity develops and without requiring the ECG to be constantly wired to the patient." *Id.*, 8:21-24. A [person of ordinary skill in the art] would have recognized that Shmueli's focus on enabling ECG measurements "as soon as" an irregular heart condition is detected enables ECG data to be used to confirm the detection of the irregular heart condition using PPG data, thereby improving detection accuracy compared to prior art heart monitoring devices. APPLE-1004, 13:16-21; APPLE-1003, ¶57.

Pet. 15; *see also id.* at 53.

Patent Owner, however, contends that "the mere fact of taking an ECG following a PPG does not discloses 'confirming.'" PO Resp. 49 (citing Ex. 2016 ¶ 74). Rather, Patent Owner contends, "***all*** detection of irregular heart conditions in Shmueli is by SpO_2 measurement" and Shmueli merely *notifies* the user that an ECG measurement is required. *Id.* at 49–50 (citing Ex. 1004, 11–14). Patent Owner notes that Petitioner incorrectly annotates Figure 7 to include the language "alerting said first user to sense an electrocardiogram," which language appears in the related '499 patent, but not in the challenged '941 patent. *Id.* at 51. According to Patent Owner, Petitioner has provided "no evidence that Figure 7 of Shmueli teaches 'confirm[ing] the presence of' an arrhythmia" and, "[i]n any case, Shmueli does not disclose 'confirming.'" *Id.* at 51 (citing Ex. 2016 ¶ 75). We do not find these arguments persuasive.

Shmueli sought to address a problem that prior art monitoring devices did not "enable a patient to perform ECG measurement as soon as an irregular heart activity develops and without requiring the ECG to be constantly wired to the patient." Ex. 1004, 8:21–32, 13:16–21. Shmueli addressed this problem by providing "a combined oximetry and electrocardiogram measuring system . . . in which the oximetry measurement is performed continuously and/or repeatedly, and the ECG measurement is triggered upon detection of an intermittent irregular heart-related event." *Id.* at 8:24-30. We do not agree with Patent Owner that Shmueli's improvement over the prior art was only to "provid[e] an ECG that does not have to be 'constantly wired to the patient.'" Pet. 49. Rather, we agree with Dr. Chaitman that Shmueli "improves detection accuracy compared to prior art heart monitoring devices" by "enabling ECG data 'as soon as' an irregular heart condition is detected," which allows "ECG data to be used to confirm the detection of the irregular heart condition using PPG data." Ex. 1003 ¶ 121. We thus credit Dr. Chaitman's testimony that the person of ordinary skill in the art would have found it obvious to use ECG, as taught by Shmueli, to confirm an irregular heart condition, such as an intermittently occurring arrhythmia. *Id.*

In addition, with reference to Figure 7, Shmueli explains that "the software program proceeds to element 50 to search for correlations between the SpO_2 signal and the ECG signal to produce new detection parameters, or modify existing detection parameters, so as to enhance the detection algorithms of the irregular heart conditions." Ex. 1004, 13. Shmueli further discloses that "[s]earching for correlation (element 50) can be executed in real-time (together with elements 37, 47 and 49) or later after the ECG

measurement is concluded." *Id.* Considering the relationship between elements 38, 39, and 50, and Shmueli's disclosures that the process may be conducted "in real-time" and that the process "enhance[s] detection algorithms of the irregular heart conditions," we agree with Petitioner that Figure 7 of Shmueli shows that the "ECG analysis (element 50) leads to new detection parameters (element 39) used for more accurate detection of the irregular heart condition (element 38) with SpO_2/PPG data." *See* Reply 20; Ex. 1004, Fig. 7, 13:16–21. In this respect we agree with Petitioner's assessment that the "Challenged Claims only require 'receiving' ECG data 'to confirm' arrhythmia, and thus, are broad enough to encompass confirmation with SpO_2/PPG data based on new parameters generated from analyzing ECG data." Reply 20–21. As such, we agree with Petitioner that Shmueli teaches or suggests "analyz[ing] ECG data to detect (and confirm) irregular heart conditions." *Id.* at 20.

In sum, we agree with Petitioner's characterization of how Shmueli confirms the presence of an irregular heart condition, such as arrhythmia:

> Shmueli works as follows: (1) continuously measuring SpO_2/PPG data; (2) measuring ECG data upon detecting an irregular heart condition; and (3) correlating SpO_2/PPG and ECG data to confirm presence of the irregular heart condition (directly through analysis of ECG data or indirectly through updates to detection parameters used for assessment of SpO_2/PPG data).

Reply 21 (citing Ex. 1003 ¶¶ 57, 121; Ex. 1004, 12:22–15:3, Fig. 7).

Patent Owner also argues that Shmueli's "ECG data is merely measured and stored" and that any "ECG analysis is performed off the device, after the data is sent to a remote server." PO Resp. 52 (citing e.g., Ex. 1004, 11–14; Ex. 2016 ¶ 78; 2017, 93:1–13). We do not find these arguments persuasive. Shmueli states that "the wrist-mounted heart

monitoring device preferably transmits to the remote server the collected data, such as the recorded ECG measurement," whereupon the "remote server preferably *further analyzes*" collected ECG data. *See* Ex. 1004, 14 (emphasis added). Shmueli's disclosure that ECG data may be transmitted to a remote server for *further* analysis presupposes that the data is first analyzed prior to transmission in this embodiment. In addition, Shmueli describes the embodiment represented in Figure 7 as "a simplified flow chart of a software program *preferably executed by the processor of the wrist-mounted heart monitoring device*." Ex. 1004, 7:6–7 (emphasis added). As such, the confirmation step embodied in elements 38, 39, and 50 preferably occurs locally. *See* Reply 23. Shmueli's teaching that, in a subsequent step, "[a]fter concluding the ECG measurement (element 54) the software program preferably proceeds to element 55 to communicate with a remote server," also indicates that the steps of confirming the presence of arrhythmia and stopping the ECG measurement may occur locally, and prior to communication with any remote server. *See* Ex. 1004, 14.

Patent Owner further argues that the ECG data is not involved in the confirming step because Shmueli's sole stop condition for the ECG measurement occurs when the SpO_2 sensor no longer detects an irregular heart condition. *See* PO Resp. 53. We agree with Petitioner, however, that Shmueli discloses that

> when an irregular heart condition is detected (element 40) and ECG measurement is initiated (element 41), the SpO_2 measurement (element 37) "***preferably*** continues," suggesting that the SpO_2 measurement may stop in some embodiments. APPLE-1004, 13:19-22. In these embodiments where SpO2 measurement has stopped, ECG is the only measurement that can be used to perform the operations described by Shmueli,

> including determining whether "the irregular heart condition has stopped." APPLE-1004, 14:22-29.

Reply 22; *see also* Tr. 19:21–21:2 (highlighting the relationship between element 54 ("Stop ECG") and element 38 ("Detect Irregular Heart Condition" using SPO_2/PPG). Considering the argument and evidence of record, we agree with Petitioner that, with respect to the stop condition, "Shmueli renders obvious 'confirmation' of the irregular heart condition based on ECG data" based its disclosure of "embodiments where the SpO_2 measurement does not continue." *Id.* at 22.

4) Reasons to Combine Shmueli and Osorio

Relying on the testimony of Dr. Chaitman, Petitioner argues that "it was well-known that activity level is related to HR and HRV and a [person of ordinary skill in the art] would have found it obvious to improve Shmueli's method by considering activity level." Pet. 20 (citing, *e.g.*, Ex. 1003 ¶ 69). Petitioner further points to Osorio as evidencing the benefits of using activity level to detect an irregular heart condition (e.g., improved accuracy, reliability, and reduced false detection). *Id.* (citing Ex. 1005 ¶¶ 29, 36). Accordingly, Petitioner contends, one of ordinary skill in the art "would have been motivated to incorporate Osorio's activity sensor and activity level analysis techniques into Shmueli's heart monitoring device." *Id.* (citing Ex. 1003 ¶ 69). Doing so would "improve[] the accuracy of detecting a pathological event (e.g., arrhythmia)" (*id.* (citing Ex. 1003 ¶ 70)), "resulting in improved user satisfaction since the user would have been less bothered by false detections." *Id.* at 31 (citing Ex. 1003 ¶84).

Petitioner similarly asserts that one of ordinary skill in the art "would have been motivated to incorporate Osorio's HRV analysis because processing HRV from R-R intervals of an ECG signal was known to be less

affected by noise compared to processing morphological features of the ECG signal." *Id.* at 25–26. According to Petitioner, a person of ordinary skill would have implemented this modification by incorporating Osorio's software modules into Shmueli's device, thus, "improv[ing] the pathological event detection capabilities compared to Shmueli's unmodified heart monitoring device." *Id.* at 26–28 (citing Ex. 1003 ¶¶ 78–81; Ex. 1005 ¶¶ 43, 53, 55, 56, 65, 66, 80; Ex. 1039, 52[14]). Supporting Petitioner's position, Dr. Chaitman testifies that one of ordinary skill in the art would have understood that modifying Shmueli's device to use Osorio's HRV analysis would have improved the detection of certain arrhythmias, particularly atrial fibrillation. *See* Ex. 1003 ¶ 80. Petitioner further argues that one of ordinary skill in the art would have found it obvious to combine the teachings of Shmueli and Osorio with a reasonable expectation of success. Pet. 24–25.

Patent Owner argues that one of ordinary skill in the art would not have been motivated to combine Shmueli with Osorio because the two references are directed to different problems: Shmueli to detecting heart conditions, and Osorio to detecting epileptic seizures. PO Resp. 54–56; Sur-reply 16–17. As such, Patent Owner argues, combining the two references would improperly change the basic principles under which the prior art was designed to operate or render the prior art inoperable for its intended purpose. *See* PO Resp. 59; Sur-reply 16–17 (citing, e.g., *Adidas AG v. Nike Inc.*, 963 F.3d 1355, 1359 (Fed. Cir. 2020) and *Nichia Corp v. Everlight Ams., Inc.,* 855 F.3d 1328, 1340 (Fed. Cir. 2017)). Patent Owner further

[14] Asl and Setarehdan, "*Support vector machine-based arrhythmia classification using reduced features of heart rate variability signal*," 44(1) Artif. Intell. Med. 51–64 (2008), Ex. 1039.

argues that, absent a finding that Osorio discloses detecting arrhythmias, "there can be no finding of obviousness, because with no arrhythmia detection there is no argument that a [person of ordinary skill in the art] would have been motivated to combine Shmueli and Osorio." PO Resp. 56 (citation omitted).

Patent Owner's arguments are unavailing for the reasons set forth on pages 23–25 of Petitioner's Reply, which we adopt in full. In short, Osorio relates to medical device systems and methods capable of detecting a pathological body state of a patient. Ex. 1005 ¶ 2. As discussed above, we do not read Osorio as limiting "pathological state" to epilepsy or other neurological conditions. To the contrary, one of ordinary skill in the art would have understood Osorio's teachings to be applicable to "any pathological state," including arrythmia. *See e.g.*, *id.* ¶ 44. As such, the references are not directed to different problems as Patent Owner urges.

Further, even if one of ordinary skill in the art were to read Osorio as limited to the detection neurological events such as epilepsy, Osorio contains express teachings to monitor heart rate and heart rate variability for signs of arrhythmia. *See* Ex. 1005 ¶¶ 42, 43, 45, 46, 71; Ex. 1069, 58:23–59:3; 61:13–62–7. Whether Osorio's detection of arrhythmias is viewed as a stand-alone goal, or as data for use in monitoring for epileptic seizures, does not materially affect the analysis. "Because Shmueli already renders arrhythmia detection obvious and Osorio motivates use of activity tracking to improve detection of any heart-related pathological conditions," including arrhythmias, it is irrelevant whether Osorio's ultimate goal is the detection of neurological events. *See* Reply 24.

With respect to Patent Owner's reliance on *Adidas*, it is well established that a finding of obviousness does not require that all features of a secondary reference are "bodily incorporated into the structure of the primary reference." *In re Keller*, 642 F.2d 413, 425 (CCPA 1981). "Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *Id*. (citation omitted). "[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." *KSR*, 550 U.S. at 417. In the present case, we do not understand Petitioner to argue for the wholesale incorporation of Osorio into Shmueli's device. Rather, Petitioner more narrowly argues that one of ordinary skill in the art would find it obvious to incorporate two elements of Osorio into Shmueli's device: "(i) using activity level monitoring to improve the accuracy of detecting a pathological event (e.g., arrhythmia), and (ii) determining HRV from HR and using HRV to detect the pathological event (e.g., arrhythmia)." Pet. 20. Thus, even were Osorio ultimately limited to the detection of neurological events, we find unavailing Patent Owner's suggestion that these targeted improvements would render Shmueli's device inoperable for its intended purpose.

In view of the above, and all the argument and evidence adduced at trial, Petitioner has established sufficiently that one of ordinary skill in the art would have been motivated to combine Shmueli and Osorio with a reasonable expectation of success in arriving at the claimed invention.

5) Conclusion as to Ground 1

For the reasons set forth above, we find that the combination of Shmueli and Osorio discloses or renders obvious the arrhythmia detection

and confirmation recited in the challenged claims. We also find that one of ordinary skill in the art would have been motivated to combine the cited references with a reasonable expectation of success in arriving at the challenged claims. Patent Owner does not specifically challenge any other aspect of Petitioner's showing with respect to Ground 1. Having reviewed the argument and evidence of record, we find that Petitioner has shown by a preponderance of the evidence that claims 1, 5, 7–9, 11, 12, 16, 18–20, 22, and 23 are unpatentable as obvious in view of Shmueli and Osorio.

E. Ground 2: Obviousness over Shmueli, Osorio, and Lee-2013

Petitioner challenges claims 2–4, 6, 13–15, and 17 as obvious over the combination of Shmueli, Osorio, and Lee-2013. Pet. 65–72. Petitioner contends that the combination of Shmueli, Osorio, and Lee-2013 discloses or renders obvious each element of claims 2–4, 6, 13–15, and 17, and sets forth an element-by-element comparison of the asserted art to the challenged claims. Pet. 68–72; *see also id.* at 31–53 (for elements of independent claim 1) and 60–63 (for elements of independent claim 12). Claims 2–4 and 6 depend from claim 1 while claims 13–15 and 17 depend from claim 12. Claims 2–4 and 13–15 additionally recite, *inter alia*, that the arrhythmia is atrial fibrillation. Claim 6 and 17 additionally recite that the arrhythmia is selected from a group comprising three different arrhythmias, one of which is AF.

According to Petitioner, "Shmueli and Osorio each describe[] techniques for generally detecting arrhythmias, but do not address detection of specific types of arrhythmias, such as AF." Pet. 66. Petitioner contends that "AF detection was well-known by the Critical Date, as demonstrated by Lee-2013." *Id.* Petitioner contends that the person of ordinary skill "would

have been motivated to incorporate Lee-2013's AF detection techniques into the Shmueli-Osorio device . . . since Lee-2013 teaches that '[a]trial fibrillation is the most common sustained arrhythmia'" and "incorporating AF detection into the Shmueli-Osorio device [would] provide[] a new capability for classifying an arrhythmia." *Id.* (citing Ex. 1011, 26; Ex. 1003 ¶ 152). Petitioner asserts that a person of ordinary skill in the art would have had "a reasonable expectation of success in implementing the Shmueli-Osorio-Lee-2013 device since the combination involves using a well-known diagnostic technique (detecting AF) using well-known data (PPG data, which is disclosed in each reference) and well-known statistical techniques for AF assessment (RMSSD, ShE, SampE)." *Id.* at 67–68 (citing Ex. 1003 ¶ 154; Ex. 1011, Abstract; Ex. 1004, 11:16–18).

Patent Owner argues that Lee-2013 teaches to use a smartphone camera to detect PPG and expressly teaches that this is advantageous because it "does not involve a separate ECG sensor and instead employs built-in hardware," making it "cost-effective" and "novel." PO Resp. 56–57 (quoting Ex. 2017, 29). According to Patent Owner, the person of ordinary skill in the art "would not have been motivated to incorporate Lee 2013 into a device including an ECG sensor in the face of a clear disclosure that the benefit of Lee 2013 is derived from not using such a sensor." *Id.* at 57 (citing Ex. 2016 ¶ 86). In addition, Patent Owner argues that Lee-2013 discloses detecting AF using PPG data while the claims require using an ECG to confirm the presence of arrhythmia. Patent Owner asserts that Petitioner "does not even argue that any of the prior art discloses confirming [AF] using ECG data." *Id.*

1) Detecting and Confirming Atrial Fibrillation

The evidence of record supports that there are 8 kinds of arrhythmia, of which atrial fibrillation is the most common. Ex. 1016, 6080 ("There are 8 kinds of arrhythmia according to the Minnesota code that is widely used in the clinical field"); Ex. 1011, 26 (Lee-2013, disclosing that "[a]trial fibrillation is the most common sustained arrhythmia"); Ex. 1069, 23:5–9 (Dr. Efimov's testimony agreeing that "atrial fibrillation is the most common cardiac arrhythmia present"). We agree with, and credit, the testimony of Dr. Chaitman that, "[g]iven the prominence of AF, a [person of ordinary skill in the art] would have recognized that incorporating AF detection into the Shmueli-Osorio device provides a new capability for classifying an arrhythmia as AF" and "been motivated to incorporate Lee-2013's AF detection techniques into the Shmueli-Osorio device." Ex. 1003 ¶ 152. We further agree with Dr. Chaitman that the combined Shmueli-Osorio-Lee-2013 device would provide an improvement over Lee-2013's technique because it provides wrist-mounted detection "without requiring the user to carry a separate mobile device" and because it "improves the accuracy of AF detection provided be Lee-2013 alone since the Shmueli-Osorio-Lee-2013 device uses ECG data to confirm AF detection based on PPG data." *Id.* ¶¶ 152, 153.

We recognize that Lee-2013 touts that its application is "novel and cost effective" because it "does not involve a separate ECG sensor and instead employs built-in hardware." Ex. 1011, 29. But, we do not interpret this disclosure as teaching away from the use of ECG sensors because it does not disparage ECG sensors, particularly where the ECG sensor is part of the built-in hardware, as in Shmueli, rather than a separate device. Ex. 1004, Fig. 4 (Figures 1A, 1B of Shmueli, showing a wrist-mount heart

monitoring device having three ECG electrodes 14 and a PPG sensor 13); *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1364 (Fed. Cir. 2006) ("We will not read into a reference a teaching away from a process where no such language exists."). Nor does this disclosure diminish the motivation to combine Lee-2013 with Shmueli and Osorio because the benefits of the combination (a new capacity in the Shmueli-Osorio device for classifying arrhythmia as AF and improved accuracy of AF detection as compared to Lee-2013 alone) can be obtained without compromising the benefit of Lee-2013 – that it does not "involve a *separate* ECG sensor." Ex. 1011, 29 (emphasis added). Specifically, AF can be detected using the built-in PPG sensor already present in Shmueli. *See* Ex. 1003 ¶ 154 (discussing implementation of the proposed Shmueli-Osorio-Lee-2013 device).

As for Patent Owner's argument that the prior art does not disclose confirming AF using an ECG, we find that the evidence of record supports that such confirmation would have been obvious. Dr. Chaitman testifies that using "ECG data to confirm AF detection based on PPG data" would "improve[] the accuracy of AF detection provided by Lee-2013 alone." Ex. 1003 ¶ 153; *see also* Pet. 67. This testimony is consistent with the evidence that ECG is better at detecting arrhythmia than PPG and, absent persuasive evidence to the contrary, we credit it. *See* PO Resp. 25–26 ("In the clinical setting, there is no dispute that even today, ECG is the gold standard while PPG is a suboptimal replacement"). The evidence of record thus supports 1) that AF is the most common form of arrhythmia, 2) that it was known to use a single device comprising both ECG and PPG sensors to detect a possible arrhythmia (using PPG) and confirm the presence of

arrhythmia (using ECG), and 3) that using ECG data to confirm AF detected using PPG data improves the accuracy of AF detection as compared to a system that uses only PPG data. Accordingly, we agree with Petitioner that it would have been obvious to detect a possible arrhythmia using PPG and confirm the presence of arrhythmia using ECG, wherein the arrhythmia is the most common form of arrhythmia, atrial fibrillation. *KSR*, 550 U.S. at 421 ("A person of ordinary skill is also a person of ordinary creativity, not an automaton.").

2) Conclusion as to Ground 2

For the reasons set forth above, we find that the combination of Shmueli, Osorio, and Lee-2013 discloses or renders obvious the method of claim 1 and the smartwatch of claim 12, wherein the arrythmia is atrial fibrillation. We also find that one of ordinary skill in the art would have been motivated to combine the cited references with a reasonable expectation of arriving at the challenged claims. Patent Owner does not specifically challenge any other aspect of Petitioner's showing with respect to Ground 2, other than arguing that Ground 2 fails for the same reasons it argues that Ground 1 fails. *See* PO Resp. 39–56 (consolidating arguments). For the reasons discussed *supra* § II.D, we are not persuaded by Patent Owner's arguments that Ground 1 fails. Having reviewed the argument and evidence of record, we find that Petitioner has shown by a preponderance of the evidence that claims 2–4, 6, 13–15, and 17 are unpatentable as obvious in view of Shmueli, Osorio, and Lee-2013.

F. Ground 3: Obviousness over Shmueli, Osorio, and Chan

As Ground 3, Petitioner challenges claims 10 and 21 as obvious over Shmueli, Osorio, and Chan. Pet. 72–77. Petitioner provides an element-by-

element comparison of the asserted art to the challenged claims. *Id.* Patent Owner presents no arguments with respect to Ground 3 that have not been discussed above. *See* PO Resp. 39–56 (consolidating arguments). Having reviewed the argument and evidence of record, we find that Petitioner has shown by a preponderance of the evidence that claims 10 and 21 are unpatentable as obvious over Shmueli, Osorio, and Chan.

III. PATENT OWNER'S MOTION TO EXCLUDE

Patent Owner moved to exclude Petitioner's Exhibits 1060–1068, and 1072–1085. Mot. 1. Patent Owner withdrew its motion at oral argument with respect to Exhibits 1072, 1073, 1075, and 1082. Tr. 78:19–79:15–16, 99:18–23. Of the remaining exhibits, we cite herein only to Exhibit 1061.

Patent Owner challenges Exhibit 1061 as "new evidence . . . not properly raised in Reply." Mot. 1; Sur-reply 3. Patent Owner's argument is unavailing. Petitioner properly employed it in the Reply in responding to Patent Owner's argument that one of ordinary skill in the art would not understand Shmueli's recitation of "irregular heart condition" to indicate arrhythmia. *See* Reply 10–11; *see also* Pet. vi (listing Ex. 1061); *Anacor Pharm., Inc. v. Iancu*, 889 F.3d 1372, 1380–81 (Fed. Cir. 2018) (stating that a "petitioner in an inter partes review proceeding may introduce new evidence after the petition stage if the evidence is a legitimate reply to evidence introduced by the patent owner"). We, therefore, deny the motion with respect to Exhibit 1061.

Because we do not specifically rely on any other challenged exhibit, we dismiss that portion of Patent Owner's motion as moot.

IV. CONCLUSION

Petitioner has shown, by a preponderance of the evidence, that claims 1–23 are unpatentable under § 103 as obvious in view of combinations of Shmueli, Osorio, Lee-2013, and Chan as summarized below:[15]

Claims	35 U.S.C. §	Reference(s) /Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1, 5, 7–9, 11, 12, 16, 18–20, 22, 23	103	Shmueli, Osorio	1, 5, 7–9, 11, 12, 16, 18–20, 22, 23	
2–4, 6, 13–15, 17	103	Shmueli, Osorio, Lee-2013	2–4, 6, 13–15, 17	
10, 21	103	Shmueli, Osorio, Chan	10, 21	
Overall Outcome			1–23	

[15] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this Decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding. See* 84 Fed. Reg. 16654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

V. ORDER

ORDERED, that claims 1–23 of the '941 patent are held to be unpatentable;

FURTHER ORDERED that Patent Owner's Motion to Exclude Evidence is dismissed as moot;

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

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