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Paper 42
Entered: December 6, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE, INC.,
Petitioner,

v.

ALIVECOR, INC.,
Patent Owner.

IPR2021-00971
Patent 10,595,731 B2

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

POLLOCK, *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 Moot
Patent Owner's Motion to Exclude Evidence
37 C.F.R. § 42.64

I. INTRODUCTION

A. Background

Apple, Inc. ("Petitioner") filed a Petition for an *inter partes* review of claims 1–30 of U.S. Patent No. 10,595,731 B2 (Ex. 1001, "the '731 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 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 '731 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 26, "PO Resp."); Petitioner filed a Reply to the Patent Owner Response (Paper 29, "Reply"); Patent Owner filed a (corrected) Sur-reply (Paper 36, "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 1–30 of the '731 patent. For the reasons discussed below, we hold that

Petitioner has demonstrated by a preponderance of the evidence that claims 1–30 are unpatentable.

B. Real Parties-in-Interest

Petitioner identifies itself, Apple Inc., as the real party-in-interest. Pet. 88. Patent Owner, identifies itself, AliveCor, Inc., as the real party-in-interest. Paper 6, 2.

C. Related Matters

According to Patent Owner:

> U.S. Patent No. 10,595,731 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 IPR2021-00972 (USP 10,638,941).

Paper 6, 2; *see* Pet. 88. We further note that the '731 patent at issue here is related by a chain of continuation applications to Application No. 14/730,122, which issued as U.S. Patent No. 9,572,499 ("the '499 patent"), challenged in IPR2021-00970. *See* Ex. 1001, code (63). As such, the '731 and '499 patents share substantially the same specification.

D. Priority Date of the '731 Patent

The '731 patent claims priority to, *inter alia*, a series of provisional applications filed between December 12, 2013, and June 19, 2014. Ex. 1001, code (60); *see* Prelim. Resp. 4; Pet. 2 & nn. 1–3. Petitioner contends that the claims of the '731 patent are not entitled the benefit of the earliest of those applications such that the critical date is March 14, 2014, the filing date of

provisional application No. 61/953,616. Pet. 2–3. Because Patent Owner does not contest this assertion, or the prior art status of any asserted reference, we need not determine whether the challenged claims are entitled to the benefit of the earliest filed provisional application. *See generally* Prelim. Resp. 4; PO Resp. 17, 19.

E. Asserted Grounds of Unpatentability

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

Ground	Claims Challenged	35 U.S.C §[1]	Reference(s)/Basis
1	1, 7, 12, 13, 16, 17, 23–26, 30	§ 103	Shmueli[2]
2	1, 2, 4, 7, 12–14, 16–18, 20, 23–26, 30	§ 103	Shmueli, Osorio[3]
3	3, 5, 6, 19, 21, 22	§ 103	Shmueli, Osorio, Li 2012[4]
4	8–11, 27–29	§ 103	Shmueli, Osorio, Kleiger[5]
5	15	§ 103	Shmueli, Osorio, Chan[6]

[1] The Leahy-Smith America Invents Act ("AIA") included revisions to 35 U.S.C. § 103 that became effective on March 16, 2013. Because we determine the priority date of the challenged claims is no earlier than the '731 patent's filing date of March 14, 2014 (*see infra*), we apply the AIA versions of the statutory bases for unpatentability.

[2] WO2012/140559, publ. Oct. 18, 2012. Ex. 1004.

[3] U.S. 2014/0275840, publ. Sept. 18, 2014. Ex. 1005.

[4] Li Q, Clifford GD, "*Signal quality and data fusion for false alarm reduction in the intensive care unit*," 45(6) J Electrocardiol. 596-603 (2012). ("Li" or "Li-2012") Ex. 1006.

[5] Kleiger RE, Stein PK, "*Bigger JT Jr. Heart rate variability: measurement and clinical utility*." 10(1) Ann Noninvasive Electrocardiol. 88–101 (2005). ("Kleiger") Ex. 1033.

[6] U.S. Pat. No. 7,894,888, issued Feb. 22, 2011. Ex. 1048.

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. Ex. 2001; Ex. 2016.

F. The '731 Patent and Relevant Background

The '731 patent relates to medical devices, systems, and methods for detecting cardiac conditions, including cardiac arrhythmias. Ex. 1001, 1:29–33, 2:17–25. In general:

> In response to the continuous measurement and recordation of the heart rate of the user, parameters such as heart rate (HR), heart rate variability (R-R variability or HRV), and heart rate turbulence (HRT) may be determined. These parameters and further parameters may be analyzed to detect and/or predict one or more of atrial fibrillation, tachycardia, bradycardia, bigeminy, trigeminy, or other cardiac conditions.

Id. at 2:57–64; *see id.* at 18:52–63 (Table 2, listing atrial fibrillation, sinus and supraventricular tachycardias, bradycardia, bigeminy, and trigemini among the types of arrhythmias).

According to Dr. Chaitman, "HRV analysis is an important tool in cardiology to help diagnose various types of arrhythmia." Ex. 1003 ¶ 35. "HRV is defined as the variation of RR intervals with respect to time and reflects beat-to-beat heart rate (HR) variability," and "can be accurately determined based on either ECG [electrocardiogram] data or PPG [photoplethysmography] data." *Id.* ¶¶ 35–36. "An R-R interval represents a time elapsed between successive R-waves of a QRS complex[7] of the ECG

[7] "[E]lectrical activity of the heart based on depolarization and repolarization of the atria and ventricles . . . typically show[s] up as five distinct waves on [an] ECG readout – P-wave, Q-wave, R-wave, S-wave, and T-wave." Ex. 1003 ¶ 29. "A QRS complex is a combination of the Q, R, and S waves

that occur between successive heart beats." *Id.* ¶ 29. "If the RR intervals over a time period are close to each other in value, then ventricular rhythm is understood to be 'regular.' In contrast, if there are significant variations in the RR intervals over a time period, then the ventricular rhythm is understood to be 'irregular.'" *Id.* ¶ 37 (citations omitted).

The Specification explains that during cardiac arrhythmia, "the electrical activity of the heart is irregular or is faster (tachycardia) or slower (bradycardia) than normal," and in some forms, "can cause cardiac arrest and even sudden cardiac death." Ex. 1001, 1:40–44. The '731 patent identifies atrial fibrillation as the most common form of cardiac arrhythmia—which occurs when electrical conduction through the atria of the heart is irregular, fast, and disorganized, leading to irregular activation of ventricles. *Id.* at 1:44–49. Although atrial fibrillation may cause no symptoms, it is associated with palpitations, shortness of breath, fainting, chest pain, congestive heart failure, as well as atrial clot formation, which can lead to clot migration and stroke. *Id.* at 1:44–51. "Atrial fibrillation is typically diagnosed by taking an electrocardiogram (ECG) of a subject, which shows a characteristic atrial fibrillation waveform." *Id.* at 1:52–54.

The Specification discloses body-worn devices for detecting the occurrence of arrhythmias using a combination of ECG and PPG electrodes. *See*, *e.g.*, claim 1. PPG, or photoplethysmography, uses an optical sensor to detect the fluctuation of blood flow, and can provide a measure of heart rate. *Id.* at 25:21–24. According to the Specification, fluctuations in heart rate not explained by changing activity levels may be interpreted as an advisory

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occurring in succession and represents the electrical impulse of a heartbeat as it spreads through the ventricles during ventricular depolarization." *Id.*

condition for recording an ECG, or electrocardiogram, which is a typical method for diagnosing episodes of arrhythmia. *Id.* at 1:52–54, 1:60–65, 25:1–35.

The collected data may also be analyzed using machine learning algorithms to, for example, determine appropriate trigger thresholds, detect and predict health conditions, or provide a heart health score. *See, e.g.*, *id.* at 3:43–4:16, 8:38–41, 9:8–11, 12:44–64. "The machine learning based algorithm(s) may allow software application(s) to identify patterns and/or features of the R-R interval data and/or the raw heart rate signals or data to predict and/or detect atrial fibrillation or other arrhythmias." *Id.* at 9:8–11. In particular,

> [a]ny number of machine learning algorithms or methods may be trained to identify atrial fibrillation or other conditions such as arrhythmias. These may include the use of decision tree learning such as with a random forest, association rule learning, artificial neural network, inductive logic programming, support vector machines, clustering, Bayesian networks, reinforcement learning, representation learning similarity and metric learning, sparse dictionary learning, or the like.

Id. at 9:66–10:9.

Figure 14, reproduced below, shows one embodiment of a body-worn device. *Id.* at 6:21–23.

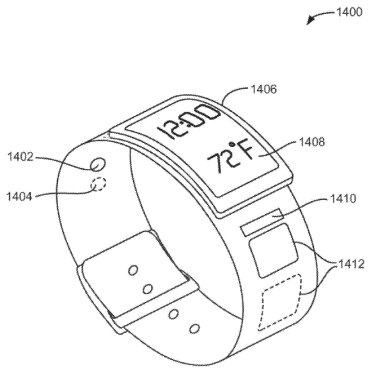


Figure 14, shows "smart watch 1400 which includes at least one heart rate monitor 1402 and at least one activity monitor 1404," such as an accelerometer. *Id.* at 24:66–25:1, 25:13–30. Analysis of signals from these monitors can be used to "determine if heart rate and activity measurements represent an advisory condition for recording an ECG," and trigger signals for recording an ECG if an advisory condition is detected. *Id.* at 25:1–12.

Figure 10, illustrated below, shows another embodiment involving a body-worn device. *Id.* at 6:3–5.

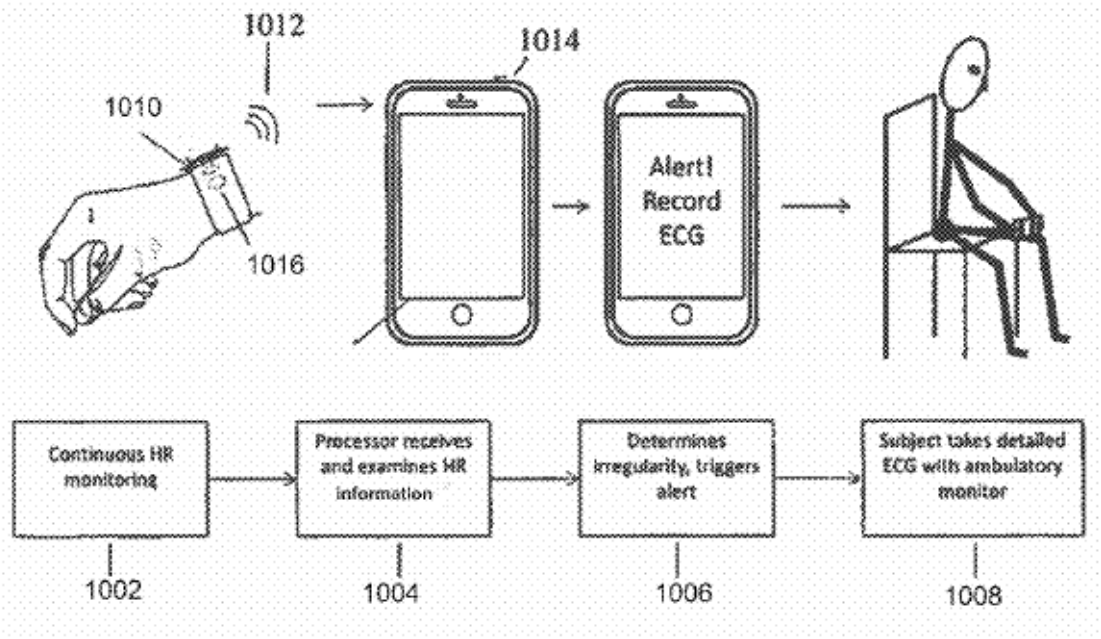


Figure 10 illustrates "a method for monitoring a subject to determine when to record an electrocardiogram (ECG)." *Id.* at 23:20–22. According to the Specification:

> In FIG. **10,** a subject is wearing a continuous heart rate monitor (configured as a watch **1010,** including electrodes **1016),** shown in step **1002.** The heart rate monitor transmits (wirelessly **1012)** heart rate information that is received by the smartphone **1018,** as shown in step **1004.** The smartphone includes a processor that may analyze the heart rate information **1004,** and when an irregularity is determined, may indicate **1006** to the subject that an ECG should be recorded.

Id. at 23:22–30. In some embodiments, the ECG device is "present in a smart watch band or a smart phone." *Id.* at 25:36–37. "The ECG, heart rate, and rhythm information can be displayed on the computer or smartphone, stored locally for later retrieval, and/or transmitted in real-time to a web server." *Id.* at 25:48–50.

G. Challenged Claims

Petitioner challenges claims 1–30, of which claims 1, 17, and 25 are independent. Of these, claim 1 recites:

> 1. A smart watch to detect the presence of an arrhythmia of a user, comprising:
>
> a processing device;
>
> a photoplethysmography ("PPG") sensor operatively coupled to the processing device;
>
> an ECG sensor, comprising two or more ECG electrodes, the ECG sensor operatively coupled to the processing device;
>
> a display operatively coupled to the processing device; and
>
> a memory, operatively coupled to the processing device, the memory having instructions stored thereon that, when executed by the processing device, cause the processing device to:
>
> receive PPG data from the PPG sensor;
>
> detect, based on the PPG data, the presence of an arrhythmia;
>
> receive ECG data from the ECG sensor; and
>
> confirm the presence of the arrhythmia based on the ECG data.

Independent claims 17 and 25 recite similar limitations but are respectively drawn to "[a] method to detect the presence of an arrhythmia of a user on a smart watch," and "non-transitory computer-readable storage medium including instructions."

Among the dependent claims, claims 2, 14, and 18 relate to the use of motion sensor (inertial) data; claims 4 and 20 relate to "determin[ing] heartrate variability ('HRV') data from the PPG data, and detect[ing], based on the HRV data, the presence of the arrhythmia"; claims 3, 5, 6, 19, 21, and 22 recite "a machine learning algorithm trained to detect arrhythmias"; and claim 15 recites a device "configured to display an ECG rhythm strip for the ECG data."

H. Overview of the Asserted References

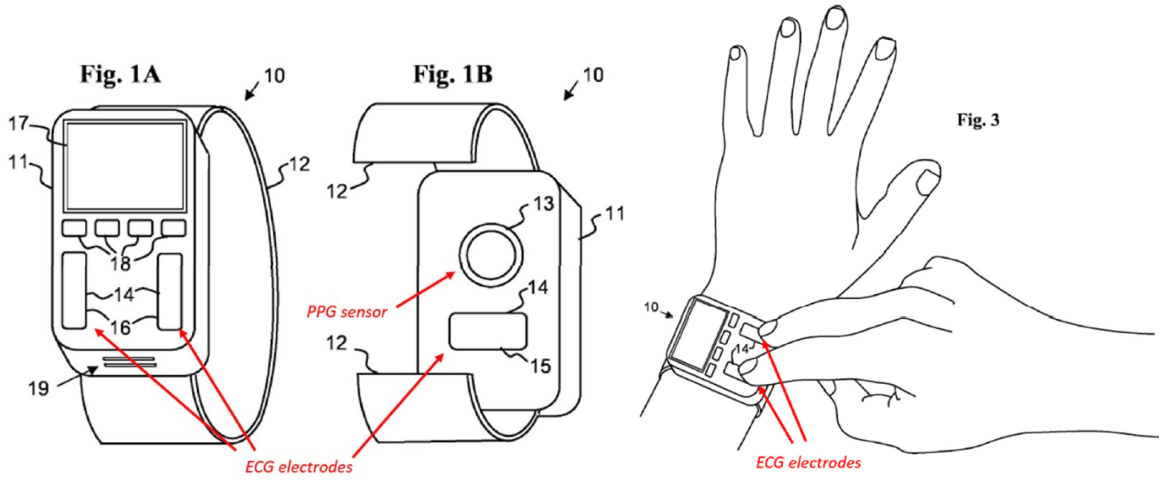
1) Shmueli (Exhibit 1004)

Shmueli, titled "Pulse Oximetry Measurement Triggering ECG Measurement," addresses "solutions . . . for monitoring infrequent events of irregular ECG." Ex. 1004, 2.[8] According to Shmueli, "[t]he present 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 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.*[9] Shmueli's Figures 1A, 1B, and 4, reproduced below, exemplify one embodiment (annotations by Petitioner in red):

[8] Throughout this opinion, we cite to the native pagination. For clarity with respect to citations to Shmueli, we understand the native pagination to be the numbers at the top of the page.

[9] 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.



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 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. Petitioner has also annotated Figure 1B with an arrow identifying PPG sensor 13. 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.

Id. 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:

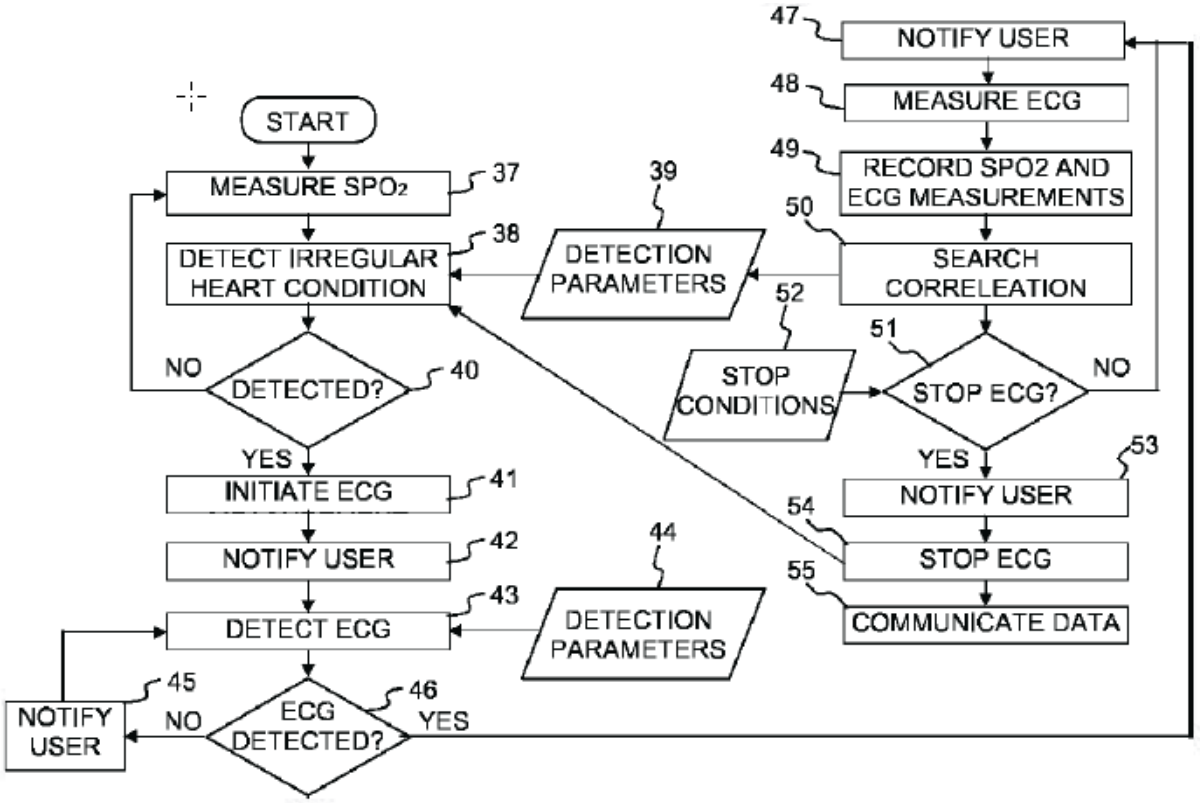
> The present invention resolves this problem by providing a combined oximetry and electrocardiogram measuring system and a method in which the oximetry measurement is performed continuously and/or repeatedly, and the ECG measurement is triggered upon detection of an intermittent irregular heart-related events without requiring the fixed wiring of the ECG device to the patient.

Id. Consistent with this disclosure, Shmueli claims:

> 1. A method for triggering measurement of electrocardiogram (ECG) signal of a subject, the method comprising the steps of:
>
> continuously measuring SpO2 at least one of a wrist and a finger of said subject;
>
> detecting an irregular heart condition from said SpO2 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.

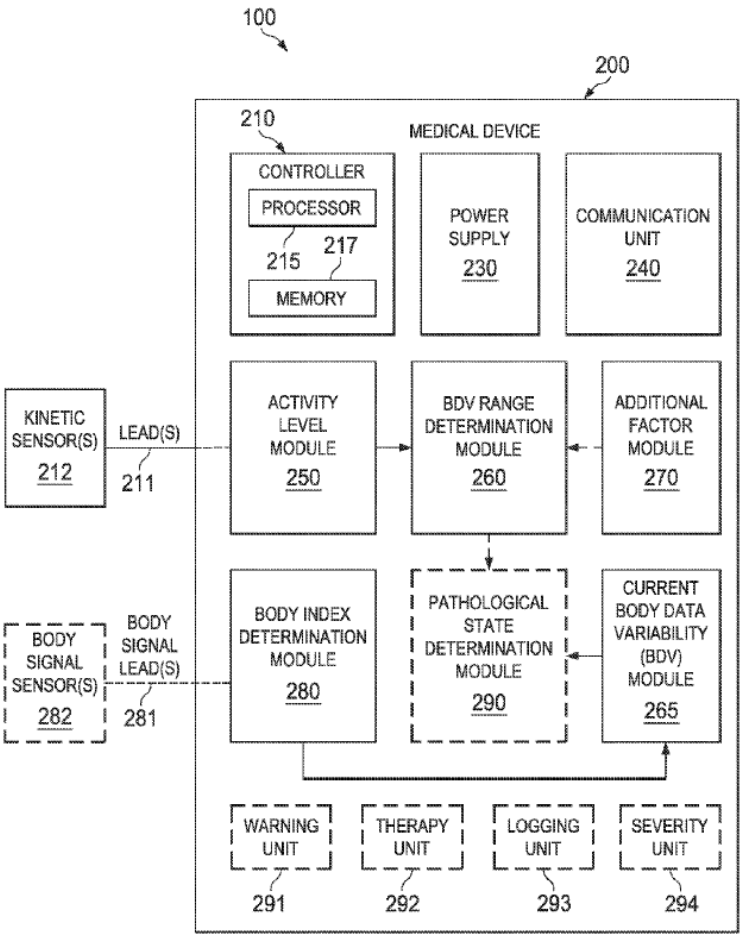


FIG. 1

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, 13, 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.

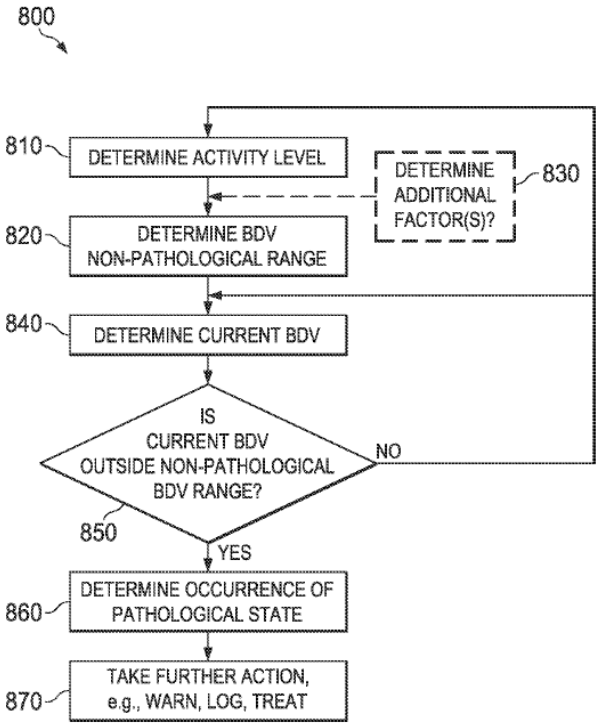


FIG. 8

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 CO2 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.

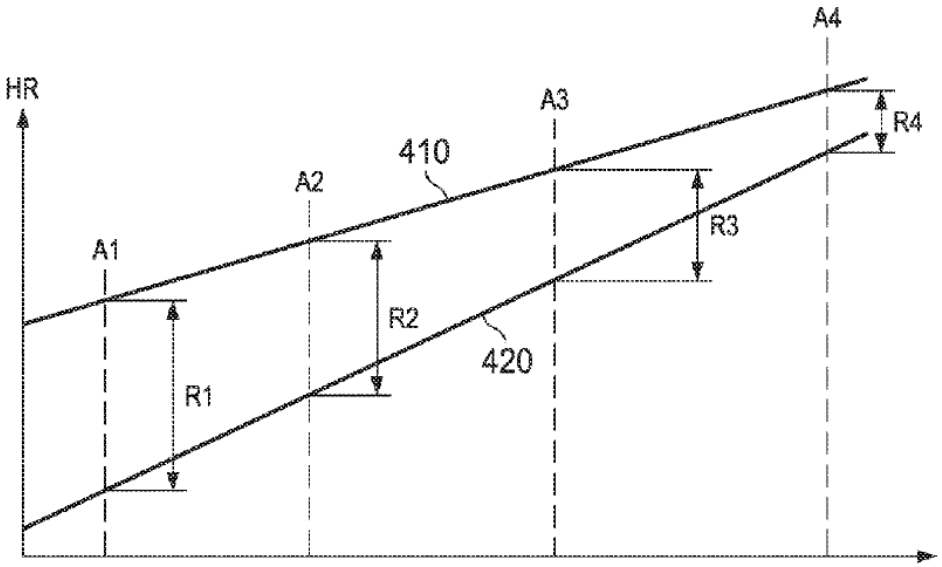


FIG. 4A

Figure 4A plots a patient's heart rate (HR) on the Y-axis and a patient's activity level on the X-axis. *Id.* 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.* at Fig. 4A. According to Osorio,

> the upper and lower bounds of the non-ictal[10] 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 seizure), for a particular activity level the patient's HRV should

[10] "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/.

> 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) Kleiger (Exhibit 1033)

Kleiger is a review article regarding the measurement and clinical utility of heart rate variability (HRV). Ex. 1033, Title. Kleiger discloses various methods for quantifying HRV including time domain, spectral or frequency domain, geometric, and nonlinear methods. *Id.* at 88. According to Kleiger:

> The greatest variation of heart rate occurs with circadian changes, particularly the difference between night and day heart rate, mediated by complex and poorly understood neurohormonal rhythms. Exercise and emotion also have profound effects on heart rate. Fluctuations in heart rate reflect autonomic modulation and have prognostic significance in pathological states.

Id. (internal citation numbers omitted).

> Long-term, usually 24-hour recordings, can be used to assess autonomic nervous responses during normal daily activities in health, disease, and in response to therapeutic interventions, e.g., exercise or drugs. RR interval variability is useful for assessing risk of cardiovascular death or arrhythmic events, especially when combined with other tests, e.g., left ventricular ejection fraction or ventricular arrhythmias.

Id. at Abstract.

4) Li 2012 (Exhibit 1006)

Li 2012 investigates algorithms for reducing cardiac monitor false alarms ("FA") in an intensive care setting. Ex. 1006, 1. Li 2012 explains that a lack of integration between different sensors results in frequent false alarms in intensive care units. *Id.* at Abstract. To reduce these false alarms, Li 2012

> present[s] a novel framework for FA reduction using a machine learning approach to combine up to 114 signal quality and physiological features extracted from the electrocardiogram, photoplethysmograph, and optionally the arterial blood pressure waveform. A machine learning algorithm was trained and evaluated on a database of 4107 expert-labeled life-threatening arrhythmias, from 182 separate ICU visits.

Id. According to Li 2012, the resulting algorithm reduced false alarms with without substantial suppression of true alarms. *Id.* at Abstract, 7, Table 6. For example, "[f]or the ventricular tachycardia alarms, the best FA [false alarm] suppression performance was 30.5% with a TA [true alarm] suppression rate below 1%." *Id.* at Abstract.

5) 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.

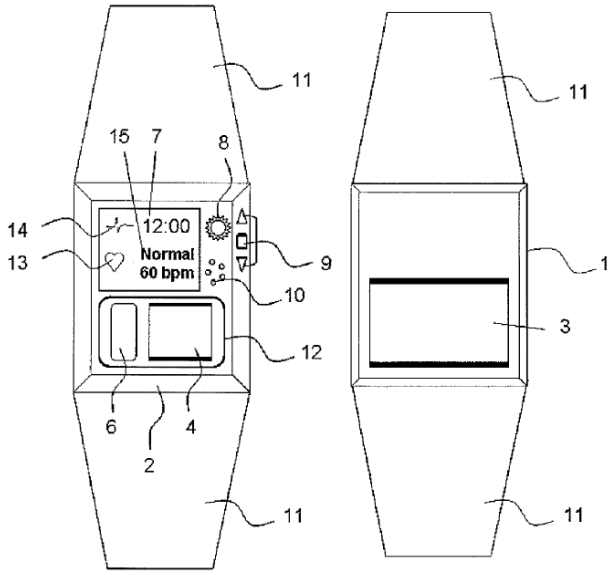


FIG.1A FIG.1B

Figures 1A and 1B, respectively, show the front and rear 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 time, heart rate, waveforms and any other information 61, such as activity level and temperature, if needed").

Chan Figure 2 is reproduced below.

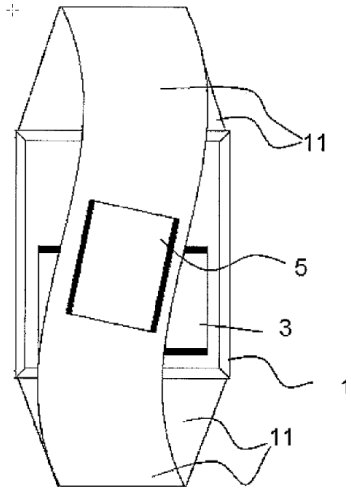


Figure 2 shows an embodiment of the three-lead ECG watch having a third lead 5 on the strap 11. *Id.* at 2:24–25, 3:1–4.

Chan Figure 3B is reproduced below.

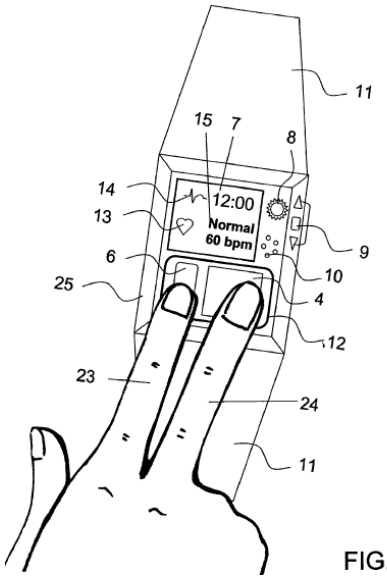


FIG.3B

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 Technology, 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 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).

Pet. 7–8. 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.* at 8.

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 ¶ 52). 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. 28 (arguing that "a cardiologist who is not an engineer lacks the necessary knowledge to develop a smartwatch with PPG or ECG sensors"); Sur-reply 24–25 (similar); *but see,* Tr. 39:20–40:12 (Petitioner 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 27–28. We further determined such a team in the context of the '731 patent might include specialists in electrical engineering, mechanical engineering, biomedical engineering, computer science, and cardiology. *Id.* at 28. With respect to the last of these, we noted that because the '731 patent "relates to methods and systems for managing health and disease such as cardiac diseases including arrhythmia and atrial fibrillation," it appeared reasonable that this hypothetical multidisciplinary team would include a cardiologist. *See id.* & n.10 (noting that the Kleiger reference is authored by a Ph.D. and two M.D.s); Ex. 1001, 1:29–33; *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. 29 (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 POSITAs," is well taken. 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. 28–31; 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 26–28. 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. *See, e.g.*, PO Resp. 28; Reply 27–38; Sur-reply 25; *see generally* Tr. 40:25–46:19, 55:2–56:13. Rather, 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 25 (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.

We also note that neither of the parties' experts possesses advanced skills in computer science, or more specifically, machine learning. *See generally* Tr. 43:21–46:17. In this respect, we find that although programming skills may be relevant to the implementation of certain of the challenged claims, they are not prerequisites for qualifying a person of ordinary skill in the art for this proceeding. *See id.* at 38:4–18.

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)).

Patent Owner notes that the ITC applied the plain and ordinary meaning to the terms "arrhythmia" and "confirm" or "confirming." PO Resp. 21 (citing Ex. 2010, 12–13). We understand "arrhythmia" as used in the context of the '731 patent refers to "a cardiac condition in which the electrical activity of the heart is irregular or is faster (tachychardia) or slower (bradycardia) than normal." *See id.* at 24–25 (quoting Ex. 1001, 1:40–42). This term does not appear to be in dispute. *See* 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 23 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 also asserts, and we agree, that "confirm" and "confirming" are discrete requirements from "detect" in claims 3, 5, 6, 19, 21, and 22. See *id.* at 25. Accepting these clarifications, we apply the plain and ordinary meaning to all claim terms.

D. Ground 1: Obviousness over Shmueli

As Ground 1, Petitioner challenges claims 1, 7, 12, 13, 16, 17, 23–26, and 30 as obvious over Shmueli. Pet. 8–39. Petitioner contends that Shmueli discloses or renders obvious each element of claims 1, 7, 12, 13, 16, 17, 23–26, and 30, and sets forth an element-by-element comparison of the asserted art to the challenged claims. Pet. 13–39. Patent Owner contends that Ground 1 fails because Petitioner has not shown that Shmueli teaches or suggests either 1) arrhythmia detection, or 2) the use of ECG data to confirm

the initial detection of an irregular heart condition using PPG data. PO. Resp. 42–47, 51–57; Sur-reply 6–16. We address the contested limitations below.

1) Arrhythmia Detection by Shmueli

Claim 1 requires a processing device to receive PPG data from a PPG sensor and "detect, based on the PPG data, the presence of an arrhythmia."[11] According to Petitioner, although Shmueli does not explicitly use the term arrhythmia, one of ordinary skill in the art reading Shmueli would have 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. 22–24; Ex. 1003 ¶¶ 47–51.

For the purpose of instituting trial, we determined that "one of ordinary skill in the art would have understood Shmueli's use of 'irregular heart condition' as referring to—or at a minimum, encompassing—arrhythmia, and, thus, disclosing the detection of arrhythmia." DI 33–34. As discussed below, the arguments and evidence adduced at trial confirm our initial understanding.

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. 42; *see* Ex. 2016 ¶ 73; Sur-reply 9–14 (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

[11] Although we focus on claim 1 for simplicity, independent claims 17 and 25 recite equivalent language.

in Shmueli." PO Resp. 43. Patent Owner argues, first, 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 44–45 (citing Ex. 1047, 1023; Ex. 2016 ¶ 69). Secondly, 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 45–46 (citing Ex. 2018, 62:9–21; Ex. 2017, 53:13–54:4, 54:13–55:12; Ex. 2016 ¶¶ 70–71; 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 CO2 content in the blood." PO Resp. 46 (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 a conclusion that Shmueli is not directed at arrhythmia detection. PO Resp. 46 (citing Ex. 2016 ¶ 72). Patent Owner's arguments are unavailing for substantially the reasons set forth at pages 3–11 of Petitioner's Reply and as discussed below.

We note, first, that Shmeli 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." Ex. 1004, 8. Collectively, these terms encompass two distinct functions—measurement of pulse and measurement of blood oxygen

content. As discussed below, both of these functions may be performed by a single device (a pulse oximeter).

In general terms, SpO_2 refers to the oxygen content of blood and PPG (photoplethysmography) measures pulse. *See* Ex. 1069, 81:8–13; Ex. 2001 ¶¶ 40–41. According to Dr. Efimov, a 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; Ex. 2016 ¶ 13; *see also* Ex. 2001 ¶ 40; Ex. 1003 ¶ 31. Unlike an SpO_2 sensor, PPG 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." *Id.*

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. 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, 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 8:11–13 ("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. The element of measuring SpO_2 (e.g. oxygen saturation in the blood).

Id. at 12:14–17, code (54) ("Pulse Oximetry Measurement Triggering ECG Measurement"); *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, 50; Ex. 1061, 16:54–58[12] ("The signal that is collected from the SpO2 sensor may also optionally be used for producing other heart related information . . . . such as heart rate, [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

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

"irregular heart condition" to refer to—or at a minimum, render obvious—arrhythmia, "one of the most obvious (if not the most obvious) types of "irregular heart condition[s]," as opposed to, for example, heart attack.[13] *See* Ex, 1003 ¶¶ 47–51, 72–73; *see also* Pet. 13; Reply 8; 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. 11, 20, 27–28, 33, 46 (citations omitted); 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."); Ex. 2016 ¶ 16 (same). [14] 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 SpO2/PPG so that the ECG can confirm whether or not the SpO2/PPG detection was accurate." Reply 2 (citing Pet. 12, 26–28; Ex. 1003 ¶¶ 51, 109–113; Ex. 1004, Abstract, 3:15–20, 9:21–29, 12:22–31, 14:16–29, 15:1–3, Fig. 7).

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[13] 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 9–14; Tr. 64:1–10, 73:18–74:6.

[14] Supporting its position that it was known to detect arrhythmia using PPG, Petitioner further points to Amano's disclosure of a wrist-worn device that uses pulse oximetry to detect arrhythmia. *See* Pet. 10, 24, Reply 10–11 (citing Ex. 1020, US Pat. No. 6,095,984); Ex. 1003 ¶ 27 (same). Patent Owner does not address this contention on the merits. *See* Sur-reply 2, 13.

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, 8; Ex. 1003 ¶¶ 29, 51, 104; 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 CO2 content in the blood." *See* PO Resp. 46 (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 teach or suggest a processing device to receive PPG data from a PPG sensor and "detect, based on the PPG data, the presence of an arrhythmia," as recited in independent claim 1.

2) Confirmation Using ECG Data

Claim 1 requires a processing device to receive ECG data from the ECG sensor and "confirm the presence of the arrhythmia based on the ECG data." Independent claims 17 and 25 recite similar language. As noted above, we find that Shmueli teaches or suggests detecting an irregular heart condition (arrhythmia) based on PPG data. Patent Owner argues that Ground 1 fails because Shmueli does not render obvious using ECG data to confirm

that initial detection. PO Resp. 51–57. We do not find Patent Owner's arguments availing for the reasons set forth in the Petition, the Reply, and as discussed below.

With reference to Shmueli's Figure 7 (which was reproduced and discussed *supra* § I.H.1), Petitioner presents several lines of evidence supporting its contention that Shmueli renders the confirmation step obvious. Pet. 26–29; Reply 13–17. 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 13. Focusing on the flow chart of Shmueli's Figure 7, Petitioner argues that that one of ordinary skill in the art

> would have found it obvious that the software at element 38 causes the processing device to detect, based on the PPG data, the presence of arrhythmia. APPLE-1003, ¶112. Thus, a POSITA would have understood that the software at element 50, element 39, and element 38 causes the processing device to confirm the presence of the arrhythmia based on the ECG data, by searching for correlations between the PPG and ECG data, modifying detection parameters, and confirming the presence of arrhythmia. APPLE-1003, ¶112. It is beneficial to confirm the presence of arrhythmia because it allows the user to make informed decisions regarding whether to seek further medical help. *Id*.

Pet. 27.

> Further with respect to Figure 7, Petitioner argues that,
>
> after the software confirms the detected arrhythmia at element 50, element 39, and element 38 by searching for correlations between the PPG and ECG data, the software proceeds to element 51 to determine a set of stop conditions (element 52), such as whether "***the irregular heart condition has stopped.***" APPLE-1004, 13:22-29. Shmueli discloses that, when the

> software program detects that "***the irregular heart condition has stopped***" (element 51), the software program notifies the user that the ECG measurement has stopped (element 53) and stops the ECG measurement (element 54). APPLE-1004, 13:22-29. A POSITA would have understood that determining whether "the irregular heart condition has stopped" also requires the software program to confirm the presence of arrhythmia using the ECG data. APPLE-1003, ¶113.

Pet. 28.

Patent Owner, however, contends that "the mere fact of taking an ECG following a PPG does not disclose 'confirming.'" PO Resp. 52 (citing Ex. 2016 ¶ 82). Rather, Patent Owner contends, Shmueli uses SpO_2 as the primary detection mechanism and merely *notifies* the user that an ECG measurement is required. *Id.* (citing Ex. 1004, 11–14). Addressing Petitioner's reliance on "Search Correlation" element 50, "Detection Parameters" element 39, and "Detect Irregular Heart Condition" element 38, Patent Owner argues that Shmueli does not explain what the correlations are. PO Resp. 53–54 (citing Ex. 1004, 13; Ex. 2016 ¶ 84). We do not find these arguments persuasive.

Despite the limited detail regarding its algorithm, the referenced passage in 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 disclosure that the process may be conducted "in real-time" for the purpose of "enhanc[ing]

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 14–15; Ex. 1004, Fig. 7, 14:16–21. In this respect we agree with Petitioner's assessment that the "Challenged Claims only require confirming presence of arrhythmia 'based on' ECG data, and thus, are broad enough to encompass confirming the presence of arrhythmia based on new parameters generated from analyzing the ECG data." Reply 16. As such, we agree with Petitioner that Shmueli teaches or suggests "analyz[ing] ECG data to detect (and confirm) irregular heart conditions." *Id.* at 15.

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 SpO2/PPG data; (2) measuring ECG data upon detecting an irregular heart condition; and (3) correlating SpO2/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 SpO2/PPG data).

Reply 16 (citing Pet. 12, 26–28; Ex. 1004, 12:22–15:3, Fig. 7).

We also note Shmueli's teaching that "[t]he SpO_2 measurement, the ECG measurement and their recordation and storage (elements 37, 47 and 49 respectively) are continued and performed in parallel until a stopping condition is met." Ex. 1004, 13. Conditions for stopping the ECG measurement include a determination that "[t]he irregular heart condition has stopped," at which point "the software program preferably notifies the user that the ECG measurement has stopped." *Id.* In sum, we agree with Petitioner that one of ordinary skill in the art would have understood that

determining whether "[t]he irregular heart condition has stopped," and notifying the user requires, as a predicate, that the software program confirm the presence of arrhythmia using the ECG data. Pet. 28 (emphasis omitted); Ex. 1003 ¶¶ 109–113.

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. 55–56 (citing e.g., Ex. 1004, 14; Ex. 2016 ¶ 87). We do not find these arguments availing. To the contrary, 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 17. 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. 56–57. We agree with Petitioner, however, that

> In Shmueli, when an irregular heart condition is detected and ECG measurement is initiated, the SpO2 measurement "***preferably*** continues," suggesting that the SpO2 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 16–17; *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 SpO2 measurement does not continue." *Id.* at 17.

3) Conclusion as to Ground 1

For the reasons set forth above, we find that Shmueli discloses or renders obvious the arrhythmia detection and confirmation elements of independent claims 1, 17, and 25. Patent Owner does not challenge any other element under 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, 7, 12, 13, 16, 17, 23–26, 30 are unpatentable as obvious in view of Shmueli.

E. Ground 2: Obviousness over Shmueli and Osorio

As Ground 2, Petitioner challenges claims 1, 2, 4, 7, 12–14, 16–18, 20, 23–26, and 30 as obvious over Shmueli in combination with Osorio. Pet. 39–67. Of these, claims 2, 4, 14, 18, and 20 recite a "motion sensor" (claims 2 and 4), "motion sensor data" (claims 18 and 20) or "inertial data of the user" (claim 14). Petitioner provides an element-by-element comparison of the asserted art to the challenged claims. *Id.* at 43–67. In short, Petitioner argues that "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. 43. As a marker for activity level, Petitioner points to Osorio as teaching to "determin[e] HRV from HR and using HRV to detect the pathological event." *Id.* at 43–44 (citing Ex. 1003 ¶ 152).

Patent Owner argues that Ground 2 fails for the reasons discussed with respect to Ground 1, which we find unavailing. *See* PO Resp. 42–47, 51–57; section II.D., above.

Patent Owner further contends that Ground 2 fails because Petitioner has not shown that 1) either Shmueli (discussed above) or Osorio teaches or suggests arrhythmia detection or 2) that one of ordinary skill would have been motivated to combine the teachings of Shmueli and Osorio. PO Resp. 47–51, 57–60. We discuss these additional arguments below.

1) 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 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 ¶ 54.

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. 47–51; Sur-reply 14–16; Tr. 56:16–57:23 (Patent Owner's counsel arguing that any change 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 2 relies on Osorio for arrhythmia detection, *per se*, it is invariably in combination with Shmueli. *See, e.g.*, Pet. 54–55 ("Osorio *also* discloses using heart rate data to determine arrhythmia") (emphasis added), 56 (same). 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, 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 11–13. 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 11–12 (citing Ex. 1005 ¶¶ 2, 27–31, 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 12–13. 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, 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, 50:17–22.[15]

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, 59:23–60:3 (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). It is undisputed that a cardiac arrhythmia is a type of pathological condition. Ex. 1003 ¶ 55; Ex. 2016 ¶ 75; Ex. 1069, 58:9–59:3. 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.

2) 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 POSITA would have found it obvious to improve Shmueli's method by considering activity level." Pet. 43 (citing, *e.g.*, Ex. 1003 ¶ 151). Petitioner further points to Osorio as evidencing 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

[15] We also note Dr. Efimov's testimony at deposition that Osorio and its claims were *focused* on a neurological pathological state—and his repeated refusal to squarely address whether they were *limited* to a neurological pathological state. *See id.* at 65:14–70:7.

Osorio's activity sensor and activity level analysis techniques into Shmueli's heart monitoring device . . . to improve the accuracy of detecting a pathological event (e.g., arrhythmia)," which would have "improved user satisfaction since the user would have been less bothered by false detections." *Id.* at 43–44, 54 (citing Ex. 1005 ¶ 29; Ex. 1003 ¶¶ 151–152, 167).

Petitioner similarly asserts that one of ordinary skill in the art "would have been motivated to incorporate Osorio's HRV analysis because it is less affected by noise" and, thus, "improve[] the pathological event detection capabilities compared to Shmueli's unmodified heart monitoring device." *Id.* at 48–50 (citing Ex. 1003 ¶¶ 159, 162; Ex. 1039, 52[16]). 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 ¶ 162. Petitioner further argues that one of ordinary skill in the art could have combined the teachings of Shmueli and Osorio with a reasonable expectation of success. Pet. 45–48.

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. 57–58; Sur-reply 16–17. As such, Patent Owner argues that 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

[16] 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.

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 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 POSITA would have been motivated to combine Shmueli and Osorio." PO Resp. 59–60 (citation omitted).

Patent Owner's arguments are unavailing for the reasons set forth on pages 17–18 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 condition. To the contrary, one of ordinary skill in the art would have understood Osorio's teachings applicable to "any pathological state," including arrythmia. *See e.g., id.* at 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. Reply 18 (citing Pet. 23–24; Ex. 1004, 13:9–17, Fig. 7).

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*. "[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: "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)," because, for example, "HRV analysis is more robust . . . and is less affected by noise." Pet. 30, 43–44, 48–49; *see generally* Ex. 1003 ¶¶ 151–167. Thus, even were Osorio ultimately limited to the detection of neurological events, Patent Owner's suggestion that these targeted improvements would render Shmueli's device inoperable for its intended purpose is unavailing.

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.

3) Conclusion as to Ground 2

For the reasons set forth above, we find that the combination of Shmueli and Osorio discloses or renders obvious the arrhythmia detection recited in independent claims 1, 17, and 25, and 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 element under Ground 2. Having reviewed the argument and evidence of record, we find that Petitioner has shown by a preponderance of the evidence that claims 1, 2, 4, 7, 12–14, 16–18, 20, 23–26, and 30 are unpatentable as obvious in view of Shmueli and Osorio.

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

As Ground 3, Petitioner challenges claims 3, 5, 6, 19, 21, and 22 as obvious over Shmueli, Osorio, and Li. Pet. 1, 67–73. Petitioner provides an element-by-element comparison of the asserted art to the challenged claims. *Id.* at 70–73.

Claims 3, 5, 6, 19, 21, and 22 recite inputting PPG or HRV data into a "machine learning algorithm trained to detect arrhythmias." Petitioner points to the '731 patent's high-level discussion of machine learning and disclosure that "[a]ny number of machine learning algorithms or methods may be trained to identify atrial fibrillation or other conditions such as arrhythmias." Pet. 67 (citing Ex. 1001, 9:55–10:11). Consistent with that high level of abstraction, Petitioner contends that "machine learning . . . focuses on algorithms capable of learning and/or adapting their structure (e.g.,

parameters) based on a set of observed data," and that such "algorithms were a well-known and popular technique to detect arrhythmia based on heart rate data." *Id.* at 67, 69 (citing Ex. 1003 ¶ 259; Ex. 1040, 1928;[17] Ex. 1041, 74;[18] Ex. 1042, 538;[19] Ex. 1003 ¶ 262); Tr. 28:14–35:22; *see also* Ex. 1042 (review of machine learning in biomedical applications).

Illustrative of the use of machine learning, Petitioner relies on Li as disclosing

> a machine learning algorithm to detect arrhythmia based on PPG and ECG data. APPLE-1006, Abstract. Li-2012 utilized a machine learning algorithm to combine up to 114 features extracted from PPG and ECG data. *Id.* Li-2012 demonstrates that its machine learning algorithm can reduce false alarm by more than 30% (29.84% on training, 30.46% on test data) with a true alarm suppression rate below 1%. APPLE-1006, p.7 and Table 6.

Pet. 67. Petitioner further argues that to detect arrhythmia, one of ordinary skill in the art would have been motivated to combine Shmueli and Osorio with machine learning given its many advantages including to "increase detection accuracy by reducing false alarms," as taught by Li. *Id.* at 67–68 (citing Ex. 1003 ¶¶ 258–265; Ex. 1042; Ex. 1006, Abstract); *see id.* at 70–72; Tr. 62:10–15; Reply 20.

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[17] Yaghouby and Ayatollahi, "*An arrhythmia classification method based on selected features of heart rate variability signal and support vector machine-based classifier*," Dössel O., Schlegel W.C. (eds) World Congress on Medical Physics and Biomedical Engineering, September 7–12, 2009, Munich, Germany, 25/4 IFMBE Proc.

[18] Dallali, et al., "*Integration of HRV, WT and neural networks for ECG arrhythmias classification*. 6 ARPN J. Eng'g. Applied Sci. 74-82 (2011).

[19] Sajda, "*Machine learning for detection and diagnosis of disease*," 8 Ann. Rev. Biomed. Eng. 537-65 (2006). Ex. 1042.

In addition to its reliance on Li, Petitioner argues that one of ordinary skill in the art would also have recognized Shmueli to disclose the use of machine language in the context of the software program diagramed in Shmueli's Figure 7. *Id.* at 68–69. In particular, Petitioner points to Shmueli's teaching that "after an ECG was measured, "the software program proceeds to element 50 to search for correlations between the SpO2 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***." *Id.* (citing Ex. 1004, 13:16–19). Petitioner presents evidence that the ordinarily skilled artisan would have understood that this disclosure refers to the use of machine learning, and would have had a reasonable expectation of success in using a machine learning to detect arrhythmia. *Id.* at 69 (citing Ex. 1042, 538; Ex. 1003 ¶ 262–263; Ex. 1006, 7, Tab. 6; Ex. 1012, Abstract; [20] Ex. 1038, Abstract;[21] Ex. 1039, Abstract).

Patent Owner argues that one of ordinary skill in the art would not have been motivated to combine Li 2012 with Shmueli and Osorio with a reasonable expectation of success. PO Resp. 60–65; Sur-reply 19–23.

Patent Owner first contends that Ground 3 fails because "while Li 2012 does describe machine learning, it does not describe using machine learning to detect arrhythmias," "makes no mention of arrythmias, and gives no disclosure on how machine learning could be applied to detecting

[20] Tsipouras et al., "*Automatic arrhythmia detection based on time and time—frequency analysis of heart rate variability*," 74 Computer Methods and Programs in Biomedicine 95–108 (2004).
[21] Tavassoli et al., Classification of cardiac arrhythmia with respect to ECG and HRV signal by genetic programming,) 3(1) Can. J. Art. Intel. Machine Learning Pattern Recognition 1–13 (2012).

arrythmias." PO Resp. 4, 60; *see* Sur-reply 21–22. Rather, Patent Owner argues, Li 2012 "takes in data in data from multiple sources, with over 100 variables, and weights those variables to its algorithm to reduce the [false alarm] rate of arrhythmias." *Id.* at 61. As such, Patent Owner argues, Li 2012 does not teach arrhythmia detection but "using machine learning to ***avoid*** incorrect arrhythmia detection," which is "the opposite of what the claims require." *Id.* at 62 (citing Ex. 2016 ¶ 98).

Patent Owner's arguments are unavailing for the reasons detailed in pages 21–23 of Petitioner's Reply. *See also* Tr. 32:20–33:12. In short, we agree with Petitioner that in disclosing the use of machine learning to minimize false positives, Li 2012 necessarily detects true positives. "[F]alse positive reduction is simply a means of improving the accuracy of true positive detection" because "labeling the alarms as true (arrhythmia detected) and false requires distinguishing arrhythmia from non-arrhythmia." Reply 21 (citing Ex. 1006, 2, 4, 6, Tables 4–7; Pet. 67). In practice, Li 2012's system "only detects an arrhythmia when the machine learning algorithms accept it as a true arrhythmia." *Id*. at 22 (citing Ex. 1006, 2–4, 7–8).

Patent Owner further argues that the Li 2012 machine learning framework is based on "'114 variables . . . [that] were extracted from ***ECG, ABP [arterial blood pressure], PPG, and SpO2*** signals." Ex. 1006, 4. Pointing to Petitioner's statement that the combination of Li 2012, Shmueli, and Osorio, would result in a device that "would 'detect[] arrhythmia using a machine learning algorithm based on the PPG data, heart rate, HRV, motion sensor data, and activity level," Patent Owner argues Petitioner's combination "would disregard at least ECG and ABP data." PO Resp. 63–64

(citing Pet. 68, 69; Ex. 2017, 129:11–13). Patent Owner contends that, "Li 2012 provides no disclosure of any machine learning utilizing only one (PPG) of four signals (PPG, ECG, ABP, SpO2) and Petitioner provides no explanation how the Li 2012 machine learning algorithm could be adapted to work exclusively with PPG data." PO Resp. 63–64 (citing Ex. 2016, ¶ 100).

Patent Owner explains that "Li 2012 understood that certain measurements are not always available, such as the ABP measurement." PO Resp. 64 (citing Ex. 1006, 7). Patent Owner argues that a comparison of Tables 6 and 7 of Li 2012 show the results using all measurements, and results excluding ABP data, respectively. *Id.* According to Patent Owner, "[w]hen ABP is excluded, FA suppression decreases from a maximum of 30.46% to a maximum of 20.75%—a 50% reduction." *Id.*, (citing Ex. 1006, Table 6, 7, Ex. 2017, 127:3–128:9). Patent Owner reasons that

> because Petitioner's proposed Shmueli-Osorio-Li 2012 combination would require Li 2012 to operate using only a small fraction of its ECG, PPG, ABP, and SpO2 dataset, in the face of Li 2012's disclosure that removing even one set of variables—from the ABP sensor—causes a significant reduction in Li 2012's effectiveness, Petitioner's proposed combination renders Li 2012 inoperable for its intended purpose.

PO Resp. 64–65 (citing, e.g., Ex. 2016 ¶¶ 101–102).

Patent Owner's arguments are unavailing for essentially reasons detailed in pages 23–25 of Petitioner's Reply.[22] As an initial matter, we look

[22] Petitioner does not persuade us, however, that Li 2012's citation to Li and Clifford involves a machine learning, rather than rule-based, heuristic algorithm. *See* Reply 23 (citing Ex. 1006, 3, reference 14); Ex. 2017, 109:20–24; Tr. 82:21–83:9, 85:23–86:7. Although Li and Clifford is titled "Dynamic time warping and machine learning for signal quality assessment of pulsatile signals," Li 2012 describes its teaching as "using . . . Dynamic

to the plain language of claims 3, 5, 6, 19, 21, and 22, which require the input of at least PPG or HRV data into a machine learning algorithm. Claim 5, for example, recites a processing device . . . configured to input the HRV data into a machine learning algorithm trained to detect arrhythmias." None of the claims challenged under Ground 3 preclude ECG data (or any other data used in Li 2012) from also being input into the algorithm.

With respect to Patent Owner's argument that one of ordinary skill in the art reading Li 2012 would not expect that machine learning could have been adapted to detect arrhythmia using only PPG data, we note Li 2012's teaching that to "keep the number of free parameters which we need to learn as low as possible." Ex. 1003, 4. We also note Li 2012's disclosure that its teachings "could easily be adapted to other alarms in the ICU and have a much wider impact to the general monitoring environment." *Id.* at 8. We do not find persuasive Patent Owner's counsel's argument that Li 2012's "machine-learning algorithm is completely inapplicable to the patents at hand i[n] that it's about an in-clinic setting where you're hooked up to all kinds of devices." *See* Tr. 104:1–10. To the contrary, we find that one of ordinary skill in the art would immediately recognize the applicability of Li 2012's teachings to the development of a body-worn sensor such as disclosed in Shmueli.[23]

Time Warping (DTW), multiple-template matching, and a heuristic fusion algorithm," and as including a function to "heuristically to classify each beat." *Cf.* Ex. 1006, 3 and reference 14.

[23] Patent Owner also argues that clinicians and patients may have difficulty trusting "black box" machine learning applications. PO Resp. 65. To the extent this concern has any applicability here, Petitioner reasonably explains that Patent Owner's "'black box' comment applies to deep learning, not to all machine learning." *See* Reply 20; Ex. 1082, 211:10–217:8.

Our findings are informed by the general state of art. The record supports a finding that those of ordinary skill in the art had a both interest and success in adapting machine learning to various biomedical applications. *See* PO Resp. 65; s*ee e.g.*, Ex. 1042 (reviewing machine learning models and applications in the biomedical sciences); Ex. 1002 ¶¶ 117, 259. Asl for example, "presents an effective cardiac arrhythmia classification algorithm" based on HRV data and employing the support vector machine (SVM) classifier— "a machine-learning technique which has established itself as a powerful tool in many classification problems." Ex. 1039, Abstract, 47.

We also note the testimony of Dr. Stultz, Petitioner's expert before the ITC, that a machine learning algorithm without specifics is nothing more than generic, functional language. *See* Reply 19 (citing, e.g., Ex. 1072, 1086:1–6, 1081:11–16; Ex, 1081, 74–76; Ex. 1082, 34:1–35:17; 113–115). As Petitioner points out, although claims 3, 5, 6, 19, 21, and 22 recite "a machine learning algorithm," the '731 patent "provide[s] no details about what that machine learning algorithm is or how it works." Reply 18–19 (citing Ex. 1001, 5:15–19, 9:63-10:9). Despite this lack of guidance, the Specification teaches that "[a]ny number of machine learning algorithms or methods may be trained to identify atrial fibrillation or other conditions such as arrhythmias." Ex. 1001, 9:67–10:3. Moreover, the record indicates that the types of learning generically listed in the '731 patent were all known in the art. Reply 19 (citing Ex. 1069, 169:10–170:14; Ex. 1072, 1084:18–1086:6); *see, e.g.*, Ex. 1001, 10:3–9). We are hard-pressed to find the addition of claim language reciting a generic machine learning algorithm element distinguishes claims 3, 5, 6, 19, 21, and 22 over the cited art.

Considering all the art and argument of record, and the level of ordinary skill in the art, we agree with Petitioner that "after an ECG is measured, it would have been obvious to confirm arrhythmia detection using a machine learning algorithm based on the PPG data, motion sensor data, and/or ECG data." *See* Reply 25 (citing Pet., 68–70; Ex. 1003 ¶¶ 262–265).

Patent Owner also opposes Petitioner's alternative argument, that one of ordinary skill in the art would have understood element 50 of Shmueli's Figure 7, as referring to the use of machine learning. PO Resp. 65–67. Sur-reply 24. In particular, Patent Owner argues that the "detection parameters" referenced in connection with element 50 do not evidence machine learning, but exemplify "a rule-based algorithm," which is the antithesis of machine learning. PO Resp. 65–67 (citing Ex. 2016 ¶¶ 104–105; Ex. 2017, 109:20–24); Sur-reply 24 (citing Ex. 2016 ¶¶ 86–90).

Considering the state of the art as a whole (discussed above), we agree with Petitioner that one of ordinary skill in the art would have understood that Shmueli disclosed the use of machine learning, or would have found it obvious to employ machine language in carrying out the "search correlation" function of Figure 7, step 50.

G. Grounds 4–5: Obviousness over Shmueli and Osorio further in view of Kleiger, or Chan

As Ground 4, Petitioner challenges claims 8–11 and 27–29 as obvious over Shmueli, Osorio and Kleiger; as Ground 5, Petitioner challenges claim 15 as obvious over Shmueli and Chan, with or without Osorio. Pet. 1, 73–81. Petitioner provides an element-by-element comparison of the asserted art to the challenged claims. *Id.* Patent Owner presents no arguments with respect to Grounds 4 and 5 that have not been discussed above. *See* PO Resp. 29–60 (consolidating arguments). Having reviewed the argument and evidence of

record, we find that Petitioner has shown by a preponderance of the evidence that claims 8–11 and 27–29 are unpatentable as obvious over Shmueli, Osorio and Kleiger, and that claim 15 is unpatentable as obvious in view of Shmueli, Osorio and Chan.

III. PATENT OWNER'S MOTION TO EXCLUDE

Patent Owner moved to exclude Petitioner's Exhibits 1060–1068 and 1072–1085. *See* Mot. 1. Patent Owner withdrew its motion at oral argument with respect to Exhibits 1072, 1073, 1075, and 1082. Tr. 78:19–79:16, 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. 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 activity" to indicate arrhythmia. *See* Reply 8–9; Sur-reply 3; *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 1–30 are unpatentable under § 103 as obvious in view of Shmueli alone or in combinations with Osorio, Li 2012, Kleiger, and/or Chan as summarized below:[24]

Claims	35 U.S.C. §	Reference(s)	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1, 7, 12, 13, 16, 17, 23–26, 30	103	Shmueli	1, 7, 12, 13, 16, 17, 23–26, 30	
1, 2, 4, 7, 12–14, 16–18, 20, 23–26, 30	103	Shmueli, Osorio	1, 2, 4, 7, 12–14, 16–18, 20, 23–26, 30	
3, 5, 6, 19, 21, 22	103	Shmueli, Osorio, Li 2012	3, 5, 6, 19, 21, 22	
8–11, 27–29	103	Shmueli, Osorio, Kleiger	8–11, 27–29	
15	103	Shmueli, Osorio, Chan	15	
Overall Outcome			1–30	

[24] 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 1–30 of the '731 patent are held to be unpatentable;

FURTHER ORDERED that Patent Owner's Motion to Exclude Evidence is denied with respect to Exhibit 1061, and otherwise 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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