Nos. 23-1512, -1513, -1514

IN THE

United States Court of Appeals for the Federal Circuit

ALIVECOR, INC.

Appellant,

v.

APPLE INC.,

Appellee.

On Appeal from the United States Patent and Trademark Office,
Patent Trial and Appeal Board
Nos. IPR2021-00970, IPR2021-00971, and IPR2021-00972

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CLAIM LANGUAGE AT ISSUE

U.S. Patent No. 9,572,499

1. A method of determining a presence of an arrhythmia of a first user, said method comprising

> sensing a heart rate of said first user with a heart rate sensor coupled to said first user;
>
> transmitting said heart rate of said first user to a mobile computing device, wherein said mobile computing device is configured to sense an electrocardiogram;
>
> determining, using said mobile computing device, a heart rate variability of said first user based on said heart rate of said first user;
>
> sensing an activity level of said first user with a motion sensor;
>
> comparing, using said mobile computing device, said heart rate variability of said first user to said activity level of said first user; and
>
> alerting said first user to sense an electrocardiogram of said first user, using said mobile computing device, in response to an irregularity in said heart rate variability of said first user.

7. The method of claim 1, further comprising determining a presence of said arrhythmia using a machine learning algorithm.

U.S. Patent No. 10,595,731

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 [electrocardiogram] 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.

3. The smart watch of claim 2, wherein to detect the presence of the arrhythmia, the processing device is configured to input the PPG data into a machine learning algorithm trained to detect arrhythmias.

U.S. Patent No. 10,638,941

1. A method of cardiac monitoring, comprising:

sensing an activity level of a user with a first sensor on a smartwatch worn by the user;

when the activity level is resting, sensing a heart rate parameter of the user with a second sensor on the smartwatch;

determining, by a processing device, that a discordance is present between the activity level value and the heart rate parameter;

based on the presence of the discordance, indicating to the user, using the smartwatch, a possibility of an arrhythmia being present; and

receiving electric signals of the user from an electrocardiogram sensor ("ECG") on the smartwatch to confirm a presence of the arrhythmia, wherein the ECG sensor comprises a first electrode and a second electrode.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 23-1512, -1513, -1514

Short Case Caption AliveCor, Inc. v. Apple Inc.

Filing Party/Entity Apple Inc.

Instructions:

1. Complete each section of the form and select none or N/A if appropriate.
2. Please enter only one item per box; attach additional pages as needed, and check the box to indicate such pages are attached.
3. In answering Sections 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance.
4. Please do not duplicate entries within Section 5.
5. Counsel must file an amended Certificate of Interest within seven days after any information on this form changes. Fed. Cir. R. 47.4(c).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 08/04/2023 Signature: /s/ Mark S. Davies

Name: Mark S. Davies

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☑ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☑ None/Not Applicable
Apple Inc.		

☐ Additional pages attached

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

☐ None/Not Applicable ☐ Additional pages attached

Fish & Richardson P.C.	Jeremy J. Monaldo	Ryan Chowdhury
Noah Graubart		

5. Related Cases. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

☑ Yes (file separate notice; see below) ☐ No ☐ N/A (amicus/movant)

If yes, concurrently file a separate Notice of Related Case Information that complies with Fed. Cir. R. 47.5(b). **Please do not duplicate information.** This separate Notice must only be filed with the first Certificate of Interest or, subsequently, if information changes during the pendency of the appeal. Fed. Cir. R. 47.5(b).

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

☑ None/Not Applicable ☐ Additional pages attached

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STATEMENT OF RELATED CASES

This appeal may affect or be affected by this Court's decision in *AliveCor, Inc. v. ITC*, No. 2023-1509, -1553, a consolidated appeal arising from a proceeding before the International Trade Commission ("Commission"). There, AliveCor asserted a subset of the same patent claims invalidated by the Patent Trial and Appeal Board here. The Court has designated this appeal and the Commission appeal as companion cases and directed that the appeals be assigned to the same merits panel. *See AliveCor, Inc. v. ITC*, No. 2023-1509, Order, Dkt. 25 (Fed. Cir. Apr. 25, 2023).

In addition, this appeal may affect district court litigation in which AliveCor has asserted against Apple the same patents at issue in this appeal. *See AliveCor, Inc. v. Apple Inc.*, No. 20-cv-1112 (W.D. Tex.). That litigation is stayed until the determination of the Commission investigation becomes final and the Commission proceedings are no longer subject to judicial review. *See id.*, Order, Dkt. 26 (W.D. Tex. May 6, 2021).

INTRODUCTION

The United States Patent and Trademark Office is "responsible for the granting and issuing of patents." *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1370 (2018) (quoting 35 U.S.C. § 2(a)(1)). "Sometimes, though, bad patents slip through" and the patent "was obvious all along." *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1353 (2018). To address this problem, Congress empowered the Patent Office, through the Patent Trial and Appeal Board ("Board"), to cancel "patent claims that were wrongly issued." *Oil States*, 138 S. Ct. at 1370-71 & n.1.

As Congress envisioned, Apple sought inter partes review of three AliveCor patents that should never have issued. Applying its expertise, the Board concluded that the portable cardiac-monitoring devices claimed by AliveCor were obvious. There was nothing new about combining photoplethysmography ("PPG") and electrocardiogram ("ECG") sensors on the same wearable device so the latter can confirm arrhythmias detected by the former, and nothing new about using known machine-learning algorithms in that process.

The Patent Office is the "lead agency in assessing … patentability." *Certain Unmanned Aerial Vehicles*, Inv. No. 337-TA-1133, Comm'n Op., 2020 WL 5407477, at *21 (Sept. 8, 2002) (citing *Fresenius USA, Inc. v. Baxter Int'l Inc.*, 721 F.3d 1330, 1344 (Fed. Cir. 2013)). Here, the Board properly determined that each claim is obvious.

Affirmance is warranted.

STATEMENT OF THE ISSUES

1. Skilled medical practitioners have long used wearable devices with PPG and ECG sensors to identify irregular heart conditions known as arrhythmias. Such devices use a simple PPG sensor to monitor for irregular heart rates. Then, as soon as an irregular heart rate is detected, the devices trigger collection and analysis of ECG data, the "gold standard" for confirming arrhythmias. The first question presented is whether the Board had substantial evidence to find obvious the independent claims of the '731 and '941 patents, where the claims refer to a portable device with an ECG sensor and a PPG sensor that is programmed to "detect, based on the PPG data, the presence of an arrhythmia" and then "confirm the presence of the arrhythmia based on the ECG data." Appx238 (26:26-46).

2. Skilled medical practitioners have also long used machine-learning algorithms to detect arrhythmias from heart data. The second question presented is whether the Board had substantial evidence to find that the prior art renders obvious the machine-learning claims of the '499 and '731 patents, where the claims refer to an unspecified machine-learning algorithm.

3. The third question presented is whether AliveCor's argument under 37 C.F.R. § 42.51(b)(1)(iii) is waived and, if not, whether the Board correctly reads its discovery regulation to refer to information inconsistent with a party's actual arguments.

STATEMENT OF THE CASE

Since the early 1900s, clinicians have used PPG and ECG data to detect and confirm heart conditions such as arrhythmias.

An arrhythmia is "a cardiac condition in which the electrical activity of the heart is irregular or is faster or slower than normal." Appx7434. "[A]rrhythmia is a common form of heart disease," Appx878, and is "one of the most obvious (if not the most obvious) types of 'irregular heart conditions.'" Appx3420-3421. Doctors have diagnosed arrhythmias "for millennia." Appx6237.

Atrial fibrillation is the "most common cardiac arrhythmia," with millions of Americans suffering from the condition. Appx3407 (quoting Appx226); Appx4073. Left untreated, atrial fibrillation can lead to "stroke, heart failure, hospitalization, and death." Appx4073. Atrial fibrillation and other potentially severe or fatal arrhythmias are often "intermittent," meaning their symptoms "come and go." Appx5419-5420; Appx4073; Appx 5426.

ECG is the "gold standard" for arrhythmia detection and diagnosis. Appx5861; Appx5819; Appx8466; *accord* Opening Brief ("OB") at 8. The ECG "was invented in 1906." Appx5425. It uses electrodes placed on the skin to measure electrical activity of the heart. Appx3409. ECG data is used to calculate heart-rate variability or "HRV"—"an important tool in cardiology to help diagnose various types of arrhythmia[s]." Appx3412-3413.

For decades, clinicians have also used PPG to detect arrhythmias and other heart conditions. Appx6235. PPG is also referred to as blood oxygen saturation, pulse oximeter, oximetry, or SpO_2. Appx3824; Appx3410; OB14 ("SpO_2 and PPG are interchangeable"). PPG is a "simple and ubiquitous technology" that was "developed in the 1930s for

monitoring blood volume changes in the micro vascular bed of tissue." Appx4129-4130. It works by shining light into the body and measuring the absorption rate of that light as blood flows through the blood vessels. Appx3410-3411; Appx6234-6235. PPG data is used to derive a patient's pulse and to form estimates of both heart rate and heart-rate variability. Appx3410-3411. PPG is one of the "most widespread method[s] used in clinical monitoring." Appx4130.

PPG is "simpler and easier to use" than ECG. Appx4116; *see* Appx3411; Appx4130. But the PPG "signal is susceptible to motion artifacts, which can impair the accuracy of the detected cardiac activity." Appx4130. And PPG does not detect as many heart parameters as ECG. Appx8138. PPG is therefore less effective than ECG in detecting certain arrhythmias like atrial fibrillation. Appx8138; Appx8472. Accordingly, clinicians have used ECG to "confirm or refute" a suspected arrhythmia detected by PPG "for at least the last 50 years." Appx6237-6238; Appx8137-8138; Appx7934; Appx3409-3410; Appx5851.

The prior art teaches a portable cardiac-monitoring device that combines PPG and ECG sensors to detect and confirm intermittent arrhythmias.

Since at least 2012, skilled practitioners have known that combining PPG and ECG sensors on a single wearable device improves identification of intermittent arrhythmias outside the hospital setting. A 2012 patent publication titled "Pulse Oximetry Measurement Triggering ECG Measurement" ("Shmueli") explains that arrhythmias and other irregular heart conditions are "typically" identified using ECG devices that are not worn continuously on the body. Appx3818; Appx3817-3848. If "the heart-related event is short enough," however, the patient may not "have the time to find an ECG device, to properly wire the device to the body and then take the ECG measurement." Appx3818.

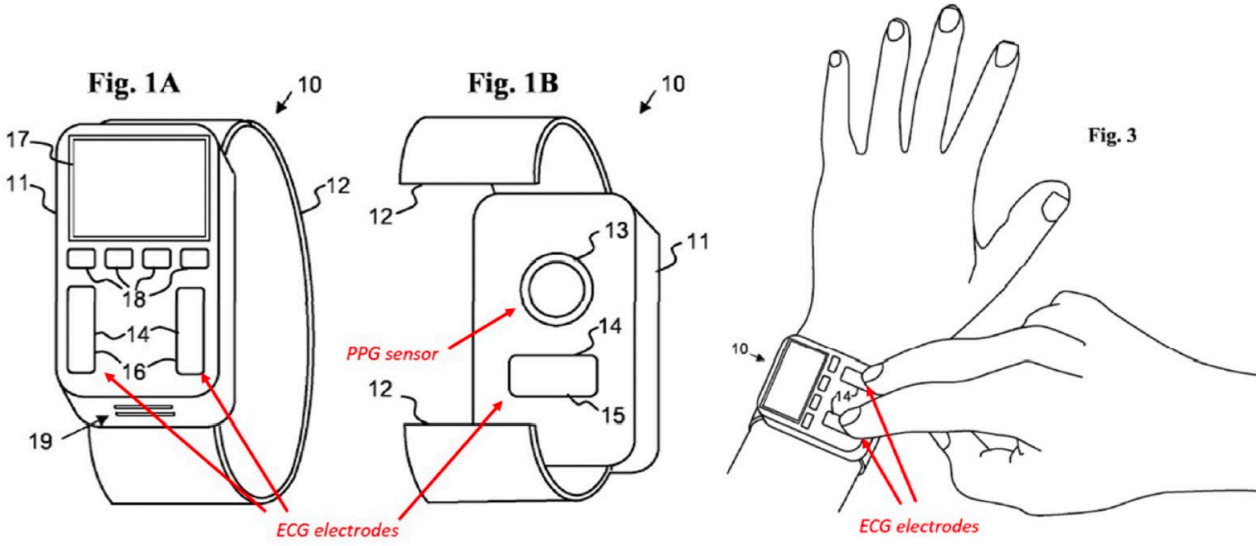
One "common solution" to this problem, Shmueli explains, is the "Holter" device—a small, portable ECG device that is "connected to the patient for typically 24 hours." Appx3818. But because Holter devices require "uncomfortable fixed wiring" and are connected to patients for only short periods of time, they are "inappropriate for monitoring infrequent events" of arrhythmia and other heart conditions.

Appx3819. And while less intrusive wearable PPG devices have long existed that could continuously detect arrhythmias, *see, e.g.*, Appx4116-4119; Appx6235; Appx4212-4213, as discussed, PPG was generally not as effective as ECG at detecting certain arrhythmias. Shmueli further notes that an earlier patent issued in 2009 "describes a wrist mounted device equipped with an ECG measuring device and a [PPG[1]] measuring device," but that it "does not teach interrelated measurements of ECG and [PPG]." Appx3825; *see* Appx5191-5208. Accordingly, Shmueli states that "it would be highly advantageous to have … a method and a system for measuring the ECG signal associated with an intermittent irregular heart-related event," Appx3819, that "enable[s] 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." Appx3825.

Shmueli "resolves this problem" by disclosing a wrist-mounted heart-monitoring device with both PPG and ECG sensors (shown below), "in which the [PPG] measurement is performed continuously

[1] Shmueli refers to PPG and SPO_2 "interchangeably." Appx3824; *see also* OB14.

and/or repeatedly, and the ECG measurement is triggered upon detection of an intermittent [arrhythmia]." Appx3825.



Appx3838-3839 (annotated).

Shmueli starts by measuring PPG data and then applying "detection parameters" to that data to "detect" an "irregular heart condition." Appx3828. Upon detection, Shmueli "notif[ies] the subject to perform an ECG," "initiat[es] ECG measurement," "notif[ies] the user [when] the ECG signal is detected," and begins recording the data. Appx3828-3829. The software then proceeds to "search for correlations between the [PPG] 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." Appx3830.

Shmueli indicates that its system preferably collects ECG and PPG data in tandem, but each type of data may also be collected in isolation. Appx3830-3831 ("ECG measurement is *preferably* performed while performing the [PPG] measurement (and vice-versa)" (emphasis added)). Once initiated, the ECG measurement continues "until it is stopped upon detecting … [a] stopping condition[]," such as "[t]he irregular heart condition has stopped" or "[t]he heart condition returned to normal." Appx3830-3831.

Shmueli also shows the use of a machine-learning algorithm in the arrhythmia identification process. A machine-learning algorithm is a computer software algorithm "capable of learning and/or adapting [its] structure (e.g., parameters) based on a set of observed data, with adaptation done by optimizing over an objective or cost function." Appx3413; Appx4670; *see* Appx5951 (machine learning is a "class of methods that allow machines to learn from data" and includes "very simple" techniques); Appx6570. Shmueli's software likewise: (a) learns/adapts its structure/parameters (it creates new detection parameters or modifies existing ones); (b) based on a set of observed data (correlations between ECG and PPG data); (c) with adaptation

done by optimizing over an objective (enhancing arrhythmia detection algorithms). Appx3830.

"Machine learning … ha[s] been the subject of tremendous interest in the biomedical community" for over a half-century. Appx4670-4697 (2006 article, discussing examples of machine learning dating to the 1960s). And skilled practitioners have been inputting heart data into machine-learning algorithms to improve arrhythmia identification for decades. *See* Appx3467-3468; Appx5912. In 1997, for instance, Yu Hen Hu and his colleagues published an article in the journal IEEE Transactions on Biomedical Engineering titled "A Patient-Adaptable ECG Beat Classifier Using a Mixture of Experts Approach" ("Hu 1997"). Appx4801; *see* Appx4801-4810. Hu 1997 discloses that using publicly available machine-learning algorithms trained on user-specific and population-level ECG data "significant[ly] … enhance[s]" "ECG beat classification," i.e., arrhythmia detection. Appx4801. Hu 1997 explains that its techniques "can be easily adapted to other automated patient monitoring algorithms and eventually support decentralized remote patient-monitoring systems." Appx4809.

In addition, an article published in 2012 by Qiao Li and his colleague, titled "Signal quality and data fusion for false alarm reduction in the intensive care unit" ("Li 2012"), discusses inputting PPG and ECG data into a machine-learning algorithm to improve arrhythmia identification by reducing false alarms. Appx3873; Appx3878; *see* Appx3873-3880. Li 2012 states that its techniques can "easily be adapted" and can "have a much wider impact to the general monitoring environment." Appx3880.

AliveCor's patents claim a portable cardiac-monitoring device that combines PPG and ECG sensors to detect and confirm intermittent arrhythmias.

Three of AliveCor's patents are relevant to this appeal: U.S. Patent Nos. 9,572,499, 10,595,731, and 10,638,941. The priority date for the '499 and '731 patents is no earlier than March 14, 2014, and the priority date for '941 patent is no earlier than May 13, 2015. Appx4 n.1; Appx59 n.1; Appx240.

The patents relate to systems, methods, and devices to "detect" or "determine" the presence of "arrhythmias." They use PPG (or "heart rate") data collected on the device as an initial screen for heart conditions, then "trigger[]" collection of ECG data on the device when

the PPG data indicates a potential problem. *E.g.*, Appx219 (Fig. 10); Appx255 (13:66-67).

As relevant here, every independent claim of the '731 and '941 patents also requires using the ECG data to "confirm" the arrhythmia on the device. *See* Appx873-874 (the "wearable device does a confirmation on the device"). Certain dependent claims of the '731 and '499 patents require use of an unspecified machine-learning algorithm to "detect" (or "determine") the presence of arrhythmias. Although the specification of the '941 patent also discusses machine learning, none of the '941 claims refer to machine learning.

The '731 and '941 patents start from the premise that arrhythmia is "typically diagnosed by taking an electrocardiogram (ECG)." Appx226 (1:52-53). They observe that existing, body-worn ECG-monitoring devices (like "Holter monitors") are "cumbersome for the patient," Appx250 (4:14-22), making them ill-suited for the long-term continuous monitoring needed to detect "intermittent arrhythmias"—which are not "always present in the patient." Appx249 (1:35-49); *see* Appx226 (1:60-2:7). The patents purport to improve detection of intermittent arrhythmias through devices (such as smartwatches) and

methods that combine (1) a PPG sensor that operates "continuously" and is used to initially "detect" the arrhythmia, with (2) an ECG sensor that is triggered to "confirm" the arrhythmia detection on the device. Appx249 (1:58-2:3); Appx257 (17:53-18:18); Appx226 (2:19-25, 2:39-64); Appx238 (26:27-46).

For example, Claim 1 of the '731 patent provides for a "smart watch" with a "photoplethysmography ('PPG') sensor" and an "ECG sensor" that is programmed to perform the following steps:

> 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.

Appx238 (26:27-46). Independent claim 17 recites the same process in the form of a method claim, Appx239 (27:42-50), and independent claim 25 recites a computer storage medium with "instructions that, when executed," perform the method. Appx239 (28:24-33).

Claims 1 and 12 of the '941 patent are similar, but they incorporate additional activity-level-related limitations that are not at issue in this appeal. Appx257 (17:2-17, 17:53-18:18).

The patents make clear that "detect[ing]" the arrhythmia using PPG data and "confirm[ing]" the arrhythmia using ECG data involve well-known techniques for PPG and ECG analysis. Appx248 (Fig. 7); Appx249-250 (1:58:2:9, 3:58-4:33); Appx226 (1:52-55). The patents also employ "commonly used" PPG sensors, Appx251 (5:15-23), "[v]arious" off-the-shelf "ECG monitoring or recording devices," Appx232 (13:26-28), and "available" smartwatches, Appx250 (4:59-62).

Several dependent claims of the '731 and '499 patents recite using a "machine learning algorithm" to "detect" or "determine" the presence of arrhythmias. Claims 3, 5-6, 19, and 21-22 of the '731 patent invoke an unspecified "machine learning algorithm" and then specify a particular type of data such as "PPG data" or "HRV data" that must be "input[ted]" into the algorithm. Claim 3 is representative:

> 3. The smart watch of claim 2, wherein to detect the presence of the arrhythmia, the processing device is configured to input the PPG data into a machine learning algorithm trained to detect arrhythmias.

Appx238 (26:53-56); *see* Appx238-239 (26:64-27:5, 28:1-4, 28:11-18).

Claims 7-9 and 17-19 of the '499 patent are even more general. For instance, Claim 7 reads:

> 7. The method of claim 1, further comprising determining a presence of said arrhythmia using a machine learning algorithm.

Appx206 (26:53-56); *see* Appx206-207 (26:57-67, 28:12-25).

The shared specification of the '731 and '499 patents states that "[a]ny number of machine learning algorithms or methods may be trained to identify … arrhythmias" and then provides a non-exclusive list of 11 algorithms such as "support vector machines," "neural network[s]," "or the like" that may be used. Appx230 (9:67-10:9); Appx198 (9:58-67). Each of the algorithms listed in the patents' shared specification had "already been known" as of the priority date of the patents. Appx5566.

AliveCor asserts its patents against Apple.

AliveCor has not offered a wearable cardiac-monitoring device for sale since 2019. *See Certain Wearable Elec. Devices*, Inv. No. 337-TA-1266, Initial Determination, 2022 WL 2981155, at *116 (June 27, 2022). Instead, it has litigated.

In 2020, AliveCor sued Apple in the Western District of Texas for allegedly infringing the '499, '731, and '941 patents. *AliveCor, Inc. v. Apple Inc.*, No. 20-cv-1112 (W.D. Tex.). That action is stayed.

In 2021, AliveCor initiated a proceeding before the International Trade Commission ("Commission"), again asserting infringement of the same three patents. Inv. No. 337-TA-1266. The Commission considered different prior art than the Board did here and found that Apple had presented a "strong" prima facie case of obviousness for all independent asserted claims and most dependent asserted claims. *See* Initial Determination, 2022 WL 2981155, at *49-66, 79-87, 100-05. Over the Chairman's dissent, the Commission found the patents nonobvious based on publicly available industry praise of AliveCor's asserted product and "not especially impressive" circumstantial evidence of purported copying. Comm'n Op., 2023 WL 372372, at *23-26 & n.29-30 (Jan. 20, 2023); Initial Determination, 2022 WL 2981155, at *64-66.

The Commission found no Section 337 violation with respect to the '499 patent. It found a violation with respect to the '941 and '731 patents, but suspended enforcement of its remedial orders pending this Court's review of the Board's decisions. Comm'n Op., 2023 WL 372372, at *51-52. Apple and AliveCor have filed appeals from the Commission's final determination.

Apple files petitions for inter partes review.

Several months after AliveCor initiated the Commission action, Apple filed petitions for inter partes review of the '499 patent (IPR2021-00970), the '731 patent (IPR2021-00971), and the '941 patent (IPR2021-00972).

As relevant here, Apple challenged the "confirm" claims of the '731 and '941 patents as obvious in light of Shmueli and a reference called "Osorio," which teaches motion-sensor related limitations not at issue here. Appx119; Appx59. Apple challenged the dependent machine-learning claims of the '731 and '499 patents as obvious over Shmueli and Osorio in view of Li 2012 (for the '731 claims) or Hu 1997 (for the '499 claims). Appx4; Appx59.

AliveCor disputed that the claims were obvious but did not raise any arguments relevant to secondary considerations of nonobviousness. *See* Appx889 (noting the absence of "any briefing on secondary considerations").

The Patent Trial And Appeal Board finds that the prior art references render obvious all claims of AliveCor's patents.

The Board found all claims unpatentable. Appx1-55; Appx56-115; Appx116-169. As relevant here, the Board found that: (1) Shmueli

renders obvious the '731 and '941 claim limitations involving "confirm[ing]" an arrhythmia using ECG data; and (2) Shmueli, Li 2012, and Hu 1997 each render obvious the machine-learning limitations of the dependent claims in the '731 and '499 patents.

First, the Board found that Shmueli teaches or suggests the use of ECG data to "confirm" the presence of an arrhythmia. Shmueli discloses confirming arrhythmias "directly through analysis of ECG data" because its improved arrhythmia identification system relies on "enabling ECG data [measurement] 'as soon as' an irregular heart condition is detected" by PPG data. Appx155-156 (quoting Appx3709); Appx94. The Board found that a skilled practitioner "would have found it obvious to use ECG" data—"undisputably the gold standard for detecting heart conditions"—"to confirm irregular heart conditions detected by [Shmueli's PPG] measurements." Appx153 (quoting Appx1915); Appx155. And the Board recognized multiple teachings in Shmueli that disclose or suggest analyzing the ECG data that the system collects. Appx155-158. For instance, Shmueli discloses embodiments in which the device uses only ECG data to determine the presence of a "stop condition," like the end of the arrhythmia. Appx157-

158. And "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." Appx157.

The Board also found that Shmueli teaches "indirectly" using ECG data to confirm arrhythmias through its disclosure of using correlations between ECG data and PPG data to improve the arrhythmia-detection parameters being applied to PPG data. Appx94; Appx156. As the Board explained, the claim limitations of the '941 and '731 patents "only require 'receiving' ECG data 'to confirm' arrhythmia, and thus, are broad enough to encompass confirmation with [PPG] data based on new parameters generated from analyzing ECG data." Appx156 (quoting Appx1917-1918).

Second, the Board found that Li 2012, Hu 1997, and Shmueli render obvious all the machine-learning claim elements of the '731 and '499 patents. For both patents, the Board considered the "general state of the art" and found "overwhelming evidence of the benefits and operability" of machine learning. Appx47-49 (quoting Appx706); *see* Appx43-44; Appx110. The Board further found that "those of ordinary skill in the art had" both an "interest and success in adapting machine

learning to various biomedical applications," Appx110, and that "machine learning algorithms were a well-known and popular technique to detect arrhythmia based on heart rate data." Appx47 (quoting Appx346).

The Board also found that the patents rely on machine-learning algorithms that were "all known in the art" and "provide[] no details about … how" the algorithm actually "works." Appx110 (citing Appx1371-1372; Appx5565; Appx5910-5912; Appx230 (10:3-9)); *see* Appx104 (observing that the patents discuss machine learning with a "high level of abstraction"). The Board "note[d] the testimony of Dr. Stultz," an expert in machine learning, "that a machine learning algorithm without specifics is nothing more than generic, functional language." Appx110 (citing Appx1372; Appx5912; Appx5907; Appx6281-6283; Appx6570).[2] Accordingly, the Board was "hard-pressed to find the addition of claim language reciting a generic machine

[2] Dr. Stultz was Apple's expert in the parallel proceedings before the Commission involving the same patents. AliveCor "cited lots of testimony from" Dr. Stultz in the Board proceedings, Appx883, and Apple in turn cited portions of Dr. Stultz's testimony in its replies.

learning algorithm element distinguishes" the claims "over the cited art." Appx110.

The Board also considered the testimony of Apple's expert, Dr. Chaitman, a "well-respected cardiologist with 'extensive experience working with tools for detecting cardiac conditions.'" Appx83 (quoting Appx1149). Dr. Chaitman is familiar with the use of machine-learning algorithms to detect arrhythmias and conducted a literature review on the subject. Appx8040; Appx849-851. And while Dr. Chaitman acknowledged he was not an expert in machine learning specifically, the Board found that machine-learning expertise was not a "prerequisite[] for qualifying a person of ordinary skill in the art for this proceeding," noting that AliveCor's expert, Dr. Efimov, also lacked any such expertise. Appx84.

Applying all this evidence along with the asserted prior art, the Board found that the machine-learning claim elements of the '731 and '499 patents would have been obvious in view of Shmueli (as to both the

'731 and the '499 claims[3]); Li 2012 (as to the '731 claims); and Hu 1997 (as to the '499 claims). Appx42-52; Appx104-111.

SUMMARY OF ARGUMENT

I. Substantial evidence supports the Board's factual finding that Shmueli renders obvious using ECG data to "confirm" an arrhythmia detected by PPG data, as all claims of the '731 and '941 patents require.

As the Board observed, Shmueli's system improves detection of irregular heart conditions by "trigger[ing]" ECG readings "as soon as" an irregular heart condition is detected using PPG data. ECG is known as the gold standard for identifying irregular heart conditions, and a skilled practitioner would find it obvious to analyze the ECG data Shmueli collects for that purpose. AliveCor insists Shmueli teaches collecting the ECG data and time-stamping it alongside the PPG data but does not teach analyzing the ECG data to see whether it confirms an arrhythmia detected by the PPG data. This reading ignores that Shmueli teaches ECG analysis of arrhythmias detected by PPG data.

[3] AliveCor agrees that the "arguments and analysis" regarding how Shmueli renders obvious the '731 machine-learning claim elements also apply to the '499 machine-learning claim elements. OB47 n.14; *see* OB25 (challenging obviousness as to "both patents").

This reading also defies common sense given the testimony from both experts that ECG data is typically used to confirm arrhythmias. Moreover, AliveCor has no meaningful answer to the Board's finding that Shmueli teaches use of ECG data to "confirm" the arrhythmia when it discloses that "correlations" between PPG and ECG data may be used to improve the arrhythmia-detection parameters applied to PPG data.

AliveCor complains that the Board's finding was improperly based on "conclusory" testimony from Apple's expert, Dr. Chaitman. But Dr. Chaitman's testimony—which buttressed the Board's independent analysis of Shmueli's disclosure—was not conclusory; it explained that a skilled practitioner would find it obvious to analyze Shmueli's ECG data to see whether it confirms the arrhythmia given the structure and purpose of Shmueli's system, as well as a skilled practitioner's background knowledge that ECG data is the gold standard for arrhythmia confirmation.

II. Substantial evidence supports the Board's conclusions that a skilled practitioner would have found obvious the machine-learning claims of the '731 and '499 patents. These claims recite using machine-

learning algorithms to detect arrhythmias based on various heart data. As the Board found, skilled practitioners have used machine-learning algorithms to improve arrhythmia detection based on heart data for decades, and each of the asserted prior art references teaches or suggests the use of machine learning to identify arrhythmias based on such data.

A. AliveCor again argues that the Board over-relied on Dr. Chaitman's expert testimony. Although Dr. Chaitman (like AliveCor's own expert) does not possess "advanced skills" in machine learning, he is familiar with attempts to detect arrhythmias using machine-learning algorithms and conducted an extensive literature review on the subject. And the Board appropriately found that no machine-learning expertise was required to testify as to the knowledge of a skilled practitioner. The patents are not focused on machine learning. They address machine-learning algorithms in only a handful of dependent claims that "provide[] no details about what that machine learning algorithm is or how it works." Appx110 (quoting Appx1371-1372). AliveCor effectively conceded that no machine-learning expertise was required, since its own expert freely admitted that he lacked any such expertise.

Moreover, the Board considered additional evidence that supports its obviousness finding, including numerous examples in the art applying machine learning to arrhythmia detection. The Board also credited the testimony of Dr. Stultz, an expert in machine learning, that the patents' generic machine-learning claim elements teach nothing new.

B. AliveCor argues that the Board articulated no supporting rationale for its finding that Shmueli's "search correlation" disclosure renders the '499 and '731 machine-learning claim elements obvious. But the Board gave multiple rationales. It explained that its finding was informed by the general state of the art, which demonstrated that skilled practitioners were interested in machine learning, aware of its benefits in arrhythmia detection, and knew that machine-learning algorithms could effectively correlate PPG and ECG data. The Board also adopted relevant portions of Apple's petition, which provided additional explanation for why a skilled practitioner would have understood both that Shmueli teaches machine learning and that using machine learning in this setting would be successful. AliveCor notes that Shmueli does not disclose inputting only PPG data into the machine-learning algorithm, but as discussed below, the Board correctly

held that neither patent's machine-learning claims are limited to PPG data.

C. AliveCor argues that Li 2012 does not render the '731 machine-learning claim elements obvious because the claims require a machine-learning algorithm trained to "detect" arrhythmias, whereas the Board found that Li 2012 teaches machine-learning algorithms trained to "confirm" arrhythmias. But a machine-learning algorithm trained to *confirm* an arrhythmia is necessarily also trained to *detect* that arrhythmia, because the arrhythmia cannot be confirmed without it also being detected. And, in any event, the Board also found that Li 2012 teaches machine-learning algorithms trained to *detect* arrhythmias. AliveCor also argues that the '731 claims require "PPG [data] alone" and that Li 2012 does not teach applying machine learning to PPG data alone. But the Board correctly held that the claims are not limited to PPG data. And, even if the claims were limited to PPG data, substantial evidence supports the Board's finding that Li 2012 renders the machine-learning claim elements obvious.

D. AliveCor argues that Hu 1997 is irrelevant to the '499 machine-learning claims because it teaches machine learning based on

ECG data while the '499 machine-learning claims are "drawn" to PPG data. But the Board correctly found that the '499 claims do not require PPG data at all. Even if the claims did require PPG data, substantial evidence supports the Board's finding that a skilled practitioner would have found it obvious to adapt Hu 1997's ECG-based machine learning to Shmueli's PPG data.

III. AliveCor ends its brief with a waived argument. AliveCor asserts for the first time on appeal that "routine discovery obligations" under 37 C.F.R. § 42.51(b)(1)(iii) required Apple to produce documents that were allegedly relevant to secondary considerations of nonobviousness. AliveCor did not raise this issue before the Board, and its suggestion that it could not do so without violating the Commission protective order is wrong—as shown by the fact that AliveCor is making the argument now, in a publicly filed document, with the same protective order in effect.

Section 42.51(b)(1)(iii) requires production of "information inconsistent with a position advanced by the party during the [inter partes review] proceeding." The Board has consistently interpreted § 42.51(b)(1)(iii) to cover information inconsistent with a party's actual

arguments, not all information potentially adverse to that party's case. Because neither party raised any secondary consideration argument before the Board, the secondary considerations documents at issue were not "inconsistent" with any argument a party advanced.

STANDARD OF REVIEW

"Obviousness is a question of law based on underlying facts." *Meiresonne v. Google, Inc.*, 849 F.3d 1379, 1382 (Fed. Cir. 2017). The Court reviews the Board's legal findings de novo and its factual findings for substantial evidence. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). The "scope and content of prior art" and the "differences between prior art and claims" are factual findings. *PAR Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1193 (Fed. Cir. 2014). So too, the "presence or absence of a motivation to combine references … is a pure question of fact." *In re Gartside*, 203 F.3d 1305, 1316 (Fed. Cir. 2000). "Decisions about credibility of witnesses and weight of evidence are committed to the sound discretion of the Board as the trier of fact." *Tiger Lily Ventures Ltd. v. Barclays Cap. Inc.*, 35 F.4th 1352, 1366 (Fed. Cir. 2022).

The Board's findings of fact are affirmed "if a reasonable mind might accept the evidence as sufficient to support the finding." *HP Inc. v. MPHJ Tech. Invs., LLC*, 817 F.3d 1339, 1343-44 (Fed. Cir. 2016).

The Court reviews any preserved discovery issue for abuse of discretion. *WesternGeco LLC v. Ion Geophysical Corp.*, 889 F.3d 1308, 1322 n.9 (Fed. Cir. 2018).

ARGUMENT

I. Shmueli Renders Obvious The "Confirm The Presence Of The Arrhythmia Based On The ECG Data" Claim Elements Of The '731 And '941 Patents.

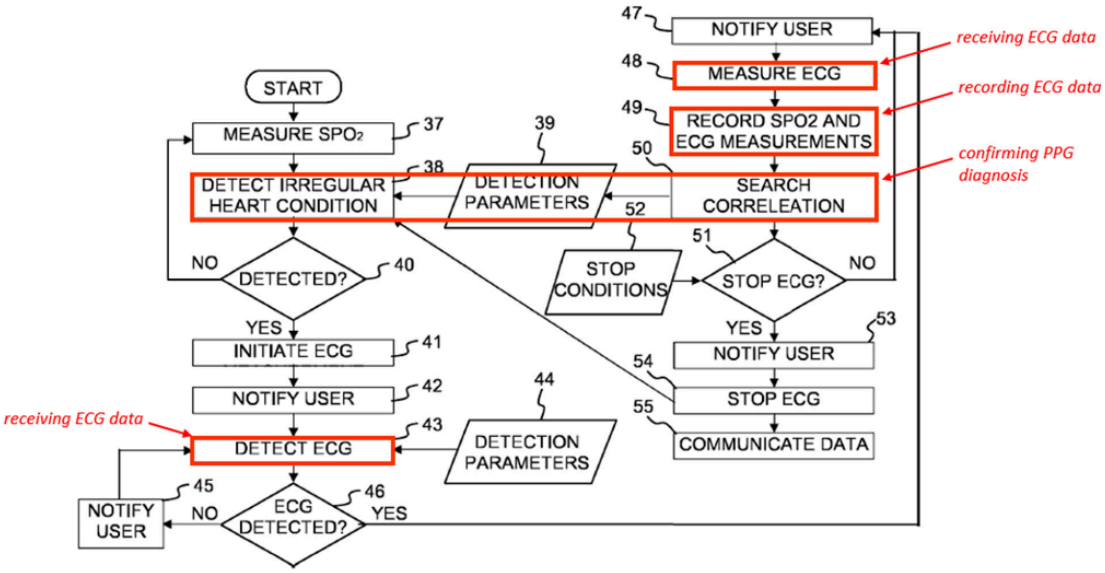
The Board correctly ruled that the Shmueli reference, in combination with other references, renders obvious the '731 and '941 claims. Each claim requires a processing device to detect a potential arrhythmia based on PPG data and then "confirm the presence of the arrhythmia based on the ECG data." Appx238-239; Appx257; *see also* Appx85 (giving "confirm" its ordinary meaning). But Shmueli already taught the public a (wrist-mounted) processing device that detects a potential arrhythmia based on PPG data and then confirms the presence of the arrhythmia based on the ECG data, as Apple's expert

explained. Appx94; Appx156; Appx3422-3423; Appx3462-3464. AliveCor misreads Shmueli.

A. Shmueli renders obvious "confirming" the arrhythmia using ECG data.

Like AliveCor's patents, Shmueli starts from the dual premises that irregular heart conditions are best detected using gold-standard ECG data and that the practical inconvenience of continuous ECG monitoring hinders detection of intermittent heart conditions. Appx3818-3819; Appx3825. Also like AliveCor's patents, Shmueli responds to this problem with a wrist-mounted system that first detects arrhythmia using PPG data and then collects ECG data to confirm the problem. Appx67; Appx823. The process of Shmueli's software is illustrated below:

Fig. 7



Appx3843 (Apple's annotations added in red); *see* Appx3458.

Figure 7 illustrates how Shmueli enhances detection of irregular heart conditions by using PPG data as a screen to determine when to initiate ECG measurement. The system first detects an irregular heart condition using PPG data (blocks 37 and 38). Appx91; Appx3825-3826; *see* Appx3824 (SpO_2 and PPG are "interchangeabl[e]"). "'[A]s soon as' an irregular heart condition is detected" by evaluating the PPG data, the device "triggers" the collection of ECG data (blocks 43, 48). Appx67 (quoting Appx3825); Appx91; Appx3833. The system then "identif[ies] a correlation between the [PPG] measurement and the ECG measurement, and us[es] the correlation in the step of detecting an

irregular heart condition from the [PPG] measurement" (blocks 50, 39). Appx3819-3820.

As Dr. Chaitman explained, a skilled practitioner would understand that this system "enables ECG data to be used to confirm the detection of the irregular heart condition using PPG data." Appx3709-3710 (also noting that the "correlation" step allows improved accuracy). In other words, a skilled practitioner—knowing that Shmueli uses PPG detection of an arrhythmia to trigger collection of ECG data and that ECG data is the gold standard for arrhythmia identification—would understand to use the collected ECG data for its traditional purpose: to confirm the presence of the suspected arrhythmia.

A skilled practitioner would also note several specific aspects of Shmueli's disclosure that teach using ECG data to confirm arrhythmias:

- **Collecting (and using) ECG data in isolation**: Shmueli teaches embodiments in which PPG measurement stops when ECG data collection begins. *See* Appx3829 (disclosing that when ECG measurement is initiated (element 41), "the [PPG] measurement (element 37) *preferably* continues" (emphasis added)). In such embodiments, ECG is the *only* measurement that can be used to perform subsequent operations, including confirming arrhythmias. Appx96; Appx157-158.

- **Stop conditions**: Shmueli teaches that ECG collection ends when "stop conditions" (like "the heart condition return[ing] to normal") are met. Appx3830 (identifying stop conditions); Appx96; Appx157-158. Figure 7 (above) shows that this process of stopping ECG collection (elements 51-54) happens after ECG and PPG data are correlated (element 50), indicating that ECG data is used in the stop-condition analysis.

- **"Further analysis"**: Shmueli discloses embodiments where "*further* analy[sis]" of "the recorded ECG measurement" can occur on a "remote server." Appx3831 (emphasis added). As the Board observed, this disclosure of "further" analysis "presupposes that the [ECG] data is first analyzed prior to transmission." Appx95; Appx157. And Shmueli does not suggest "analysis" of ECG data for any reason other than identifying arrhythmia.

- **On-device processing**: Shmueli describes Figure 7 as showing "a software program preferably *executed by the processor* of the … device." Appx3824 (emphasis added). This makes clear all analysis shown in Figure 7 "preferably occurs locally," not on a remote server. Appx95; Appx157.

Based on all this, the Board found that a skilled practitioner reviewing Shmueli—aware of the typical use of ECG data and Shmueli's goal of identifying irregular heart conditions—would "f[i]nd it obvious to use ECG, as taught by Shmueli, to confirm an irregular heart condition, such as an intermittently occurring arrhythmia." Appx155; Appx96; *see also* Appx823-826.

Moreover, Shmueli's disclosure of using ECG data to improve the detection parameters applied to the PPG data would constitute

"indirect[]" use of ECG data to "confirm" arrhythmia. Appx94; Appx156. As illustrated in Figure 7, Shmueli "search[es] for correlations between the [PPG] 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." Appx3830; *see* Appx3843. The ECG-enhanced detection algorithms are then applied to the PPG data to confirm whether an irregular heart condition is present. Appx3843; Appx3819-3820. This use of ECG data may happen in "real-time," Appx3830, and, like all of the steps in Figure 7, is "preferably executed by the processor of the wrist-mounted heart monitoring device." Appx3824.

In addition to its own analysis of Shmueli, the Board relied on the testimony of Dr. Chaitman. He explained that ECG is "conventional[ly]" used to diagnose cardiac arrhythmias, Appx3409-3410, and that a skilled practitioner would understand that Shmueli "contemplates using ECG data to confirm the initial [PPG] detection" because the reference begins by "criticiz[ing] other heart monitoring devices for 'not consider[ing] a requirement to enable a patient to perform ECG measurement as soon as an irregular heart activity

develops.'" Appx3423 (quoting Appx3825). Dr. Chaitman also testified that skilled practitioners would know to use Shmueli's ECG data for confirmation because Shmueli "enable[s] ECG measurements 'as soon as' an irregular heart condition is detected," and doing so would "improve[] detection accuracy." Appx3423 (quoting Appx3825).

The Board had much "more than a mere scintilla" of evidence, *In re Mouttet*, 686 F.3d 1322, 1331 (Fed. Cir. 2012), supporting its finding that Shmueli renders obvious the use of ECG data to confirm arrhythmias on the device. Appx94; Appx156.

B. AliveCor misreads Shmueli.

AliveCor fails to show that the Board's factual finding is unsupported by substantial evidence. AliveCor contends that Shmueli is too "vague" to teach a skilled practitioner that the ECG data collected by the system may be used to "confirm" the PPG-detected arrhythmia. OB51-55. According to AliveCor, a skilled practitioner would understand Shmueli only to disclose collecting ECG data, applying time stamps, and storing it—and would not understand it to analyze the collected ECG data in any way. OB51-53. These arguments misread Shmueli and ignore a skilled practitioner's "knowledge, creativity, and

common sense." *Fleming v. Cirrus Design Corp.*, 28 F.4th 1214, 1222-23 (Fed. Cir. 2022).

AliveCor wrongly says it is "undisputed" that the only part of Shmueli that could involve ECG analysis is the "correlation" of PPG and ECG data to create "detection parameters." OB51-53. But, as noted above (at 31-33), the Board also relied on other aspects of Shmueli's disclosure.

In any event, AliveCor's theory that the Shmueli "correlation" merely involves time-stamping the PPG and ECG data (without analyzing what the ECG data means), OB55-56, contradicts Shmueli's disclosure of a two-step process. Shmueli makes clear that "stamp[ing] with a time stamp" is part of a "recordation and storage" step that occurs *before* "the software program proceeds … to search for correlations between the [PPG] signal and the ECG signal to produce new detection parameters … to enhance the detection algorithms of the irregular heart conditions." Appx3830; Appx874. Figure 7 likewise illustrates "record [PPG] and ECG measurements" (element 49) as a step before "search correlations" (element 50). Appx3843.

AliveCor's argument that a skilled practitioner would understand Shmueli's "correlation" to time-stamp and store ECG data without analysis (while solely analyzing PPG data) also defies common sense. "Correlations" between gold-standard ECG data and the less-accurate PPG data would only "enhance" arrhythmia-detection algorithms, as Shmueli requires, if the system first knows whether the ECG data indicates arrhythmia. That is what would give the "correlation" with PPG data increased predictive value. Moreover, Shmueli's core insight is to improve arrhythmia identification by using PPG data as a screen to trigger collection of ECG data. Appx3819-3820; Appx3469-3471; Appx90. AliveCor is wrong that a skilled practitioner would require additional detail regarding Shmueli's "correlation" step to analyze the ECG data for the exact purpose for which it was collected. Appx92-94; Appx153-155. A skilled practitioner is "not an automaton," *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007), and a "reference must be considered not only for what it expressly teaches, but also for what it fairly suggests," *In re Burckel*, 592 F.2d 1175, 1179 (C.C.P.A. 1979).

AliveCor complains that nothing but "conclusory assumption" supports the Board's finding that Shmueli "indirectly" uses ECG data

"to confirm 'the presence of the arrhythmia.'" OB54. But the Board's finding is based on two explicit disclosures:

(1) Shmueli provides for arrhythmia "detection parameters" based in part on ECG data. Specifically, Shmueli uses "correlations between the [PPG] 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." Appx3830.

(2) Shmueli then "us[es]" the detection parameters produced by the "correlation [between PPG and ECG data] to detect[] an irregular heart condition from [PPG] measurement." Appx3829-3830; Appx3843; *see also* Appx3830 (noting that updating and applying detection parameters happens in "real-time").

As the Board recognized, identifying irregular heart conditions based on updated "detection parameters" constitutes "confirm[ing] the … arrhythmia based on … the ECG data" because the detection parameters themselves are based in part on ECG data. Appx94-95. AliveCor does not dispute that the claim language encompasses such use.

AliveCor also is wrong that the Board's conclusion rests on "conclusory" expert testimony that "cannot amount to substantial evidence." OB54-55. Expert testimony is proper to "shed light on what a skilled artisan would reasonably understand or infer from a prior art

reference." *Acoustic Tech., Inc. v. Itron Networked Sols., Inc.*, 949 F.3d 1366, 1373 (Fed. Cir. 2020). Dr. Chaitman's testimony offered detailed analysis of Shmueli's stated "goal[s]" as well as a skilled practitioner's background knowledge. *Id.* at 1372 (finding similar expert testimony non-conclusory); *see also* Appx3422-3423; Appx3461-3464; *Koninklijke Philips N.V. v. Google LLC,* 948 F.3d 1330, 1337-38 (Fed. Cir. 2020) (affirming reliance on expert testimony explaining skilled practitioner's understanding of reference to supply missing limitation). AliveCor does not dispute that Dr. Chaitman was qualified to offer this opinion.[4]

II. The Prior Art Renders Obvious The Machine-Learning Algorithm Claims.

Several dependent claims of the '499 and '731 patents recite using a "machine learning algorithm" to "detect" or "determine" arrhythmias. The Board found each of these claims obvious given that the claims invoke unspecified machine-learning algorithms; the benefits and ease of using machine-learning algorithms to improve arrhythmia detection were well known in the art; and the prior art references teach or

[4] The "concessions" AliveCor cites, OB54-55, merely reflect Dr. Chaitman agreeing that Shmueli describes updating detection parameters and does not describe "specific correlations" between PPG and ECG data. Appx7996-7997.

suggest using machine-learning algorithms to detect and confirm arrhythmias based on heart data. Appx42-52; Appx104-112. In finding the claims obvious, the Board considered the testimony of Dr. Chaitman. Appx83-84; Appx25-27. The Board also considered additional evidence of obviousness, including the patents' "high-level," "abstract[]" discussion of machine learning; numerous references that disclosed the successful use of machine learning to detect arrhythmias based on heart data; and the testimony of Dr. Stultz, an expert in machine learning, *see* Appx5885-5888, who explained that the patents' generic, functional machine-learning claims recite nothing inventive over what was known in the art. Appx43-44, Appx46-48 (citing, *e.g.*, Appx4655; Appx4660; Appx4077; Appx4088; Appx4641-4642; Appx6187; Appx6190); Appx104-105; Appx110 (citing, *e.g.*, Appx5912; Appx5907; Appx6281-6283; Appx6570; Appx6589-6590).

AliveCor principally argues that the Board should have given little weight to Dr. Chaitman's testimony. But the Board correctly found that Dr. Chaitman had the relevant expertise and, in any event, the Board considered additional evidence of obviousness. § II.A. AliveCor argues that the Board's obviousness findings "erroneously rely

on disclosures in the Li 2012, Hu 1997, and Shmueli references that have nothing to do with the requirements of the claims." OB35. AliveCor's arguments, however, rest on mischaracterizations of the claims and the Board's findings. § II.B-D.

A. The Board did not abuse its discretion in crediting Dr. Chaitman's testimony alongside extensive additional evidence demonstrating the obviousness of the machine-learning claims.

The Board properly found that Dr. Chaitman was "qualified to testify as to the understanding of a person of ordinary skill in the art." Appx84. The Board recognized that the patents involve "piecing together known technologies and … [known] analysis of cardiac data." Appx83 (quoting Appx843). "[O]ne of ordinary skill in the art with an understanding of cardiac monitoring technology" would therefore "understand how these types of data work, how they interplay and how the data could be processed on these devices." Appx83. As AliveCor concedes, Dr. Chaitman is "a well-respected cardiologist with 'extensive experience working with tools for detecting cardiac conditions.'" OB16-17.

AliveCor argues that Dr. Chaitman's testimony was "unreliable" because he is not an expert in machine learning and that, "without Dr.

Chaitman's testimony, there is no evidence whatsoever supporting the obviousness of the machine learning claims." OB31-32. Both premises are flawed. As the Board correctly found, machine-learning expertise was not necessary to testify as to the understanding of a skilled practitioner. § II.A.1. And, in any event, the Board considered extensive additional evidence—including the testimony of Dr. Stultz—demonstrating the obviousness of the machine-learning claims. § II.A.2.

1. The Board did not abuse its discretion in crediting Dr. Chaitman's testimony.

The Board appropriately exercised its discretion in crediting Dr. Chaitman's testimony, notwithstanding Dr. Chaitman's lack of "advanced skills" in machine learning. Appx84; *see Tiger Lily*, 35 F.4th at 1365-66 ("the Board's evidentiary rulings" are reviewed only "for abuse of discretion"). The Board found that, "although [machine-learning] 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." Appx83-84. AliveCor effectively conceded that no such expertise was required because, as the Board found, AliveCor's own expert, Dr. Efimov, lacked "advanced skills

in computer science, or more specifically, machine learning." Appx84; *see* Appx5565-5566 ("I never claimed that I'm an expert in machine learning.").

Neither party's Board expert had machine-learning expertise because the patents are not focused on machine learning.[5] The patents employ machine-learning algorithms in only a handful of dependent claims that, as the Board observed, "provide[] no details about what that machine learning algorithm is or how it works." Appx110 (quoting Appx705). Moreover, the factual disputes over the obviousness of the patents' machine-learning claims—such as which kinds of heart data a skilled practitioner would have found obvious to use in the algorithm—had nothing to do with any technical nuances about machine learning. *E.g.*, Appx46-48.

Dr. Chaitman was well qualified to testify about these questions given his familiarity with "attempt[s] to understand [arrhythmias] using machine-learning techniques" and his extensive literature review of "examples … of machine-learning techniques being used to detect"

[5] As detailed further below (at 45-46), the Board also credited the testimony of Apple's Commission expert, Dr. Stultz, who is an expert in machine learning.

arrhythmias before the priority date of the '731 and '499 patents. Appx8040; *see* Appx3413-3414; Appx3467-3468; Appx3527; Appx3529-3530; *Carnegie Mellon Univ. v. Marvell Tech. Grp., Ltd.*, 807 F.3d 1283, 1303 (Fed. Cir. 2015) ("Experts routinely rely upon other experts" or other facts or data "for expertise outside of their field." (citation omitted)).

AliveCor notes that Dr. Chaitman conceded that he was not intimately familiar with certain types of machine-learning algorithms like "support vector machines" and "neural networks." OB30-31. But AliveCor has no answer to the Board's finding that machine-learning expertise is not a "prerequisite[] for qualifying a person of ordinary skill in the art." Appx84. Indeed, the patents do not require any knowledge of "support vector machines" or "neural networks" at all; those algorithms are identified only in the joint specification's laundry list of "any number" of machine-learning algorithms that could be employed. Appx230 (9:67-10:9).

AliveCor also argues that Dr. Chaitman's testimony is "unreliable" because Dr. Stultz purportedly testified that clinicians are "skeptical of machine learning and would be hesitant to use it." OB32. But, as the

Board found, Appx49; Appx109 n.23, Dr. Stultz explained that this skepticism is "specific to deep learning"—one "very complex" type of machine learning—"not other areas within machine learning." Appx8291.[6] Dr. Stultz's acknowledgement of this skepticism of deep learning in no way undermines Dr. Chaitman's testimony that the patents' machine-learning claims are obvious, because the claims are not limited to deep-learning algorithms. *See* Appx230 (9:67-10:9) ("[a]ny number" of machine-learning algorithms may be used). On the contrary, Dr. Stultz explained—consistent with Dr. Chaitman's testimony—that "other types of machine learning methods … were being used" to detect arrhythmias "well before 2013," Appx8292-8293, and that the claims' use of machine learning "would have been obvious" to a skilled practitioner. Appx6304; Appx6374; *accord* Appx6282 ("Machine learning algorithms were conventional well before the … patent application existed, and the claims recite nothing about *how* the algorithm is trained."); Appx5911-5912 ("Machine learning using heart

[6] AliveCor's expert Dr. Efimov reiterated Dr. Stultz's testimony and cited one paper also noting skepticism of deep-learning algorithms. Appx7787 (citing Appx8287; Appx8498).

rate variability data had been described previously for arrhythmia detection.").

2. The Board considered extensive additional evidence of obviousness.

AliveCor is also wrong that "no evidence whatsoever" supports the Board's obviousness finding other than Dr. Chaitman's testimony. OB31. AliveCor overlooks a litany of additional evidence the Board considered, starting with the patents themselves. As the Board found, the claims "provide[] no details about what that machine learning algorithm is or how it works," and the joint specification broadly suggests that "any number" of a non-exclusive list of machine-learning algorithms could be used. Appx110 (quoting Appx705; Appx230 (9:67)). The Board further noted Dr. Efimov's observation that the "types of learning generically listed" in the specification "were all known in the art." Appx110 (citing Appx5565-5566). And it credited Dr. Stultz's testimony that the claims recite nothing inventive over what was known in the art because "a machine learning algorithm without specifics is nothing more than generic, functional language." Appx110 (citing Appx5907; Appx5912; Appx6281-6283; Appx6570; Appx6589-6590). Given all this, the Board found itself "hard-pressed to find the

addition of claim language reciting a generic machine learning algorithm element distinguishes" the machine-learning claims "over the cited art." Appx110.

The Board also considered and cited numerous additional articles and patents that, the Board found, establish "overwhelming evidence of the benefits and operability of machine learning," Appx49 (quoting Appx706); "support[] a finding that" skilled practitioners had "both interest and success in adapting machine learning to various biomedical applications," Appx110; and demonstrate "that 'machine learning algorithms were a well-known and popular technique to detect arrhythmia based on heart rate data.'" Appx47 (quoting Appx346); *see* Appx43-44 (reviewing evidence). As one "[r]epresentative" example of this "general state of the art," the Board highlighted a 2008 paper that teaches that inputting heart-rate variability data into a support vector machine classifier—one of the machine-learning algorithms listed in the patents' specification—can "effective[ly]" detect "cardiac arrhythmia[s]." Appx47 (quoting Appx4641-4642; Appx4647). And the Board considered the prior art references themselves, which each show the use

of machine-learning algorithms trained to detect arrhythmias based on heart data. Appx105-106; Appx44-51.

AliveCor ignores this evidence, asserting that Apple's machine-learning arguments "rest" on Dr. Chaitman's testimony and that, by adopting Apple's arguments, the Board "based its findings on the same evidence." OB30-31. That the Board agreed with Apple is not a basis for ignoring the additional evidence the Board expressly cited in reaching its obviousness conclusions. *See Outdry Techs. Corp. v. Geox S.p.A.*, 859 F.3d 1364, 1370 (Fed. Cir. 2017) ("The Board's reliance on [a party's] arguments does not undermine its otherwise adequate explanation."). Nor did Apple exclusively rely on Dr. Chaitman's testimony. As Apple explained, "[t]his is not a case where we're going out on a limb and rely on Dr. Chaitman's testimony alone. … [W]e're presenting the evidence and offering Dr. Chaitman's [testimony] to better our positions." Appx837. AliveCor selectively cites certain portions of Apple's petitions and replies that cite Dr. Chaitman's testimony (OB31) but ignores that those documents (as well as Dr. Chaitman's testimony) also cite the additional evidence the Board cited in reaching its obviousness conclusions. Appx1371-1379; Appx1000-

1006; *see* Appx3407-3408; Appx3413-3414; Appx3428-3429; Appx3467-3468; Appx3526-3527; Appx3190-3192; Appx3289-3301.

Of all the evidence the Board considered in addition to Dr. Chaitman's testimony, the only evidence that AliveCor addresses is the Board's citation to Dr. Stultz's testimony that the machine-learning claims recite only "generic, functional language." Appx110. AliveCor argues that this testimony is "irrelevant to obviousness" because it "relates to the Section 101 inquiry." OB34. But the § 101 and § 103 inquiries may "overlap." *See Berkheimer v. HP Inc.*, 881 F.3d 1360, 1368 (Fed. Cir. 2018) (quotation omitted). And Dr. Stultz's testimony that the claims recite only "generic, functional language" is relevant to the obviousness question here because, as the Board found, it further demonstrates that nothing about the claimed machine-learning algorithms "distinguishes [them] over the cited art." Appx110; *see* Appx5907 (testifying that the claims do not provide an "inventive concept … over what was known about machine learning algorithms" because "[a] machine learning algorithm with no specifics is a generic functional term").

AliveCor argues that "Dr. Stultz … necessarily could not have offered any opinion testimony regarding the prior art at issue in the" Board proceedings because Apple stipulated that it "would not seek resolution in … the ITC of any ground of invalidity that utilizes any of the prior art forming the part of any ground in any of the three [Board] proceedings." OB34 n.8. But the Board considered Dr. Stultz's testimony not as part of its analysis of the prior art, but rather as supporting its assessment that the claims' recitation of a "generic machine learning algorithm element" teaches the public nothing new. Appx110.

In re NuVasive, Inc., 842 F.3d 1376 (Fed. Cir. 2016) (cited at OB34), offers AliveCor no support. *NuVasive* held that expert testimony regarding "benefits recognized *after* the priority date" was irrelevant to obviousness, because that testimony did not address a skilled practitioner's knowledge and motivations "at the time of the invention." *Id.* at 1384. Here, in contrast, Dr. Stultz's testimony was relevant to what a skilled practitioner would have found obvious as of the priority date of the '499 and '731 patents. Appx5907; Appx5910-5912.

In any event, even if this Court disregarded *both* Dr. Stultz's and Dr. Chaitman's testimony, reversal would not be warranted "because substantial evidence otherwise supports the Board's conclusion." *Yeda Rsch. v. Mylan Pharms. Inc.*, 906 F.3d 1031, 1042 (Fed. Cir. 2018). As discussed above (at 46-47), the patents recite no technical details about machine learning, and the Board considered extensive additional evidence highlighting the advantages and ease of using machine-learning algorithms to detect arrhythmias based on heart data. The Board thus needed no expert testimony to conclude that the prior art references rendered the claims obvious. *See Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1079 (Fed. Cir. 2015).

B. The Board correctly found that Shmueli renders obvious the '731 and '499 machine-learning claim elements.

Shmueli teaches a software program that "search[es] for correlations between the [PPG] 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." Appx3830. Substantial evidence supports the Board's finding that this "search correlation" disclosure renders the '731 and

'499 patents' machine-learning claims obvious because "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 learning in "carrying out" Shmueli's "search correlation function." Appx111.

AliveCor argues that the "Board articulated no supporting rationale explaining why a [skilled practitioner] would have found machine learning obvious over Shmueli's search correlations." OB46. But the Board stated that its conclusion was based on the "state of the art as whole." Appx111. This "state of the art" includes evidence that "those of ordinary skill in the art had [] both interest and success in adapting machine learning to various biomedical applications" and arrhythmia detection in particular, Appx110 (citing, *e.g.*, Appx4669-4699; Appx3467; Appx3527; Appx104-105; Appx4641-4643), as well as evidence that "[u]sing machine learning to search for 'correlations' between [PPG] and ECG signals was … well known." Appx48 (quoting Appx713-714 (citing, *e.g.*, Appx6190)). This is "more than a mere scintilla" of evidence supporting the Board's finding. *Mouttet*, 686 F.3d at 1331.

Additionally, as AliveCor concedes, the Board "agree[d] with" Apple's position that Shmueli renders the challenged claims obvious. Appx111; OB46. In particular, the Board found that Apple had "present[ed] evidence that the ordinarily skilled artisan would have understood that [Shmueli's] 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." Appx106. A skilled practitioner would have understood Shmueli's search-correlation teaching to refer to a machine-learning algorithm, Apple explained, because of the correspondence between Shmueli's search-correlation disclosure and the agreed-upon definition of machine learning: "algorithms capable of learning and/or adapting their structure (e.g., parameters) based on a set of observed data." Appx1002 (citing Appx4670; Appx3529). Apple further explained that a skilled practitioner would have had success in applying machine learning this way, based on multiple references in the art showing that machine learning had been successfully applied to PPG and ECG data to improve arrhythmia detection. Appx1002 (citing Appx3529; Appx3878-3879; Appx4077; Appx4632); *see also, e.g.*, Appx4641-4642 (disclosing an

"effective cardiac arrhythmia classification" method that inputs ECG and heart-rate variability data into a machine-learning algorithm). The Board was entitled to rely on these "relevant portions of [Apple's] briefing that explain how the prior art discloses the relevant claim limitations." *Paice LLC v. Ford Motor Co.*, 881 F.3d 894, 905 (Fed. Cir. 2018).

Neither *NuVasive*, 842 F.3d at 1382-85, nor *Bowman Transportation, Inc. v. Arkansas-Best Freight System, Inc.*, 419 U.S. 281, 286 (1974) (cited at OB46), supports AliveCor's argument that the Board's reasoning was insufficient. In *NuVasive*, the Board never "expressly" "adopted" the party's arguments, nor would doing so have been sufficient because those arguments were "nothing more than conclusory statements." 842 F.3d at 1384. Moreover, as noted above (at 50), the only evidence the Board credited in *NuVasive*—testimony about "benefits recognized *after* the priority date" of the patent—was irrelevant to the obviousness issue. *Id.* Here, in contrast, the Board expressly adopted Apple's detailed explanation for why Shmueli renders machine learning obvious and credited relevant evidence about the general state of the art. And in *Bowman*, the Court *upheld* an agency

decision because, as here, it could "discern in the … opinion a rational basis for its treatment of the evidence." 419 U.S. at 290.

AliveCor argues that the Board impermissibly "rested" its obviousness finding only on the "conclusory" testimony of Dr. Chaitman. OB47-48. But, as discussed above (at 46-48), the Board did not solely consider Dr. Chaitman's testimony. And, in any event, Dr. Chaitman's testimony was anything but conclusory. He testified at length about both the definition of machine learning and the "known advantages" of applying machine learning to arrhythmia detection and explained why, given the correspondence between Shmueli's disclosure and the definition of machine learning, a skilled practitioner "would have found it obvious that" Shmueli's disclosure "covers machine learning." Appx3175; Appx3290-3292; *see* Appx3467-3468; Appx3527-3529. Dr. Chaitman also discussed multiple references supporting his assessment that a skilled practitioner would have expected to be successful in applying machine learning to Shmueli's teachings. Appx3529-3530.

AliveCor argues that "Shmueli still cannot render obvious the claims because Shmueli's search correlations are performed on ECG data, not PPG data." OB48. But Shmueli teaches "search[ing] for

correlations between the [PPG] signal and the ECG signal," thereby capturing PPG analysis. Appx3830. And, as discussed further below, the Board correctly found that neither the '499 nor the '731 claims require that the machine-learning algorithm be based on PPG data alone. Appx109-110; Appx50-51; *see* §§ II.C.2, II.D.1.

C. The Board correctly found that Li 2012 renders obvious the '731 machine-learning claim elements.

The machine-learning claim elements of the '731 patent recite "input[ting] the PPG data into a machine-learning algorithm trained to detect arrhythmias." *E.g.*, Appx238 (26:52-56). Li 2012 teaches that inputting ECG and PPG data into a machine-learning algorithm can aid arrhythmia detection by "minimiz[ing] false positives." Appx107; *see* Appx3873. Given Li 2012's teachings, the "generic" nature of the '731 claims, and the Board's finding that skilled artisans had "both interest and success in adapting machine learning to various biomedical applications," substantial evidence supports the Board's finding that Li 2012 renders obvious the '731 machine-learning claims. Appx110. AliveCor provides no persuasive reason to upset the Board's finding.

1. The Board correctly found that Li 2012's teachings to use machine-learning algorithms to confirm and detect arrhythmias render obvious the '731 machine-learning claim elements.

AliveCor argues that "the Board's determination that it would have been obvious to use machine learning for *confirmation*" is "legally erroneous" because the claims require "a machine learning algorithm trained to *detect* arrhythmias." OB36-37.

AliveCor's argument misses the mark because a machine-learning algorithm trained to confirm an arrhythmia is necessarily also trained to detect that arrhythmia. The word "confirm" means "give new assurance of the validity of: remove doubt about by authoritative act or indisputable fact." *Confirm*, Merriam-Webster Dictionary, https://tinyurl.com/347z4nyy. To "detect" is "to discover or determine the existence, presence, or fact." *Detect*, Merriam-Webster Dictionary, https://tinyurl.com/4rxv79r7. A child crossing the street cannot "remove doubt about" whether any cars are coming without also "determin[ing]" the "fact" that no cars are coming. So too, a machine-learning algorithm cannot confirm the presence of an arrhythmia without also detecting it. Indeed, AliveCor concedes that "there can be no confirmation" "without … the ability to detect an arrhythmia." OB53.

AliveCor accuses the Board of "conflat[ing]" the claims' detection and confirmation requirements. OB36-37. But, as AliveCor acknowledges (at OB38), the Board held that "'confirm' and 'confirming' are discrete requirements from 'detect.'" Appx85. The Board's finding that Li 2012's confirmation teachings render the machine-learning limitations obvious was consistent with this holding, because it recognizes that detecting an arrhythmia is a separate but necessary antecedent step to confirming that arrhythmia.

In any event, AliveCor's argument about Li 2012's "confirmation" teachings ignores that the Board also necessarily found that Li 2012's "detection" teachings render the machine-learning limitations obvious. The Board found that Li 2012 teaches using machine-learning algorithms to "detect[]" an arrhythmia by reducing false positives, because "'[f]alse positive reduction is simply a means of improving the accuracy of true positive detection.'" Appx107 (quoting Appx1374). AliveCor concedes that the claims are "directed to … using machine learning to improve detection," OB37, which is what the Board found Li 2012 teaches. Moreover, as discussed below (at 61), the Board rejected AliveCor's argument that a skilled practitioner "reading Li 2012 would

not expect that machine learning could have been adapted to detect arrhythmia[s] using only PPG data," as AliveCor asserted the claims require. Appx109. The Board's finding that Li 2012 discloses arrhythmia detection and its rejection of AliveCor's arguments show that the Board found the machine-learning limitations obvious based on Li 2012's detection teachings, in addition to its confirmation teachings. *See Paice*, 881 F.3d at 905 (affirming obviousness where the Board explained "how the prior art discloses the relevant claim limitation[]" and the "obviousness determinations flow[ed] directly from its rejection of [the patentee's contrary] arguments").

2. The Board correctly found that the '731 machine-learning claim elements are not limited to PPG data and that Li 2012 renders the claim elements obvious even if they were so limited.

AliveCor also argues that Li 2012 does not render the machine-learning limitations obvious because it does not teach using machine learning based on "PPG alone." OB38.

AliveCor's argument is beside the point, because the claims are not so limited. The claims refer to "input[ting] the PPG data into a machine-learning algorithm." Appx238 (26:52-56). The Board correctly found, however, that "[n]one of the claims … preclude ECG data (or any

other data used in Li 2012) from also being input into the algorithm." Appx109. In fact, the specification notes that "ECG data can be analyzed using a machine learning algorithm." Appx234 (17:43-44).[7]

AliveCor asserts that this PPG-only requirement "is evident by the claims' recitation that ECG data is used for another purpose—confirmation." OB39. But just because ECG data is used for one purpose does not mean it cannot be used for other purposes. Indeed, given that the patents use machine learning to "improve" arrhythmia detection, OB37, it would make no sense for them to exclude ECG data—the "gold standard" of arrhythmia detection. Appx5861.[8]

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[7] AliveCor suggests in a footnote that Apple's "obviousness theory required applying Li 2012's dataset to PPG only." OB41 n.11. That is incorrect. Apple and Dr. Chaitman both stated that Li 2012's dataset could be applied to "PPG data … and the ECG data." Appx1002-1003; Appx144; *see also* Appx49-50 (rejecting AliveCor's similar argument in the context of '499 obviousness analysis).

[8] AliveCor gets no support from the Commission's determination that "Amon," a prior art reference asserted in that proceeding, did not disclose the asserted '731 machine-learning claims. *Contra* OB38 n.10. Unlike Li 2012, Amon does not include PPG in its machine-learning algorithm at all (and the Commission failed to consider whether a skilled practitioner would have found it obvious to include PPG). Initial Determination, 2022 WL 2981155, at *81-82. The Commission never suggested that the claims require that *only* PPG be inputted into the algorithm, as AliveCor suggests.

In any event, the Board properly found that the claims would have been obvious even if they were limited to machine learning using PPG data alone. *See* Appx109. While Li 2012 applies a different kind of algorithm when analyzing just PPG data, it does not teach away from use of a machine-learning algorithm to analyze PPG data. On the contrary, as the Board found, "Li 2012's teaching … to 'keep the number of free parameters [i.e., data inputs] which we need to learn as low as possible'" and its "disclosure that its teachings 'could easily be adapted to other alarms in the ICU'" show that a skilled practitioner would have found it obvious to "adapt[] [Li 2012] to detect arrhythmia using only PPG data." Appx109 (quoting Appx3876; Appx3880).

AliveCor argues that the Board improperly credited "unsworn attorney argument" because Dr. Chaitman did not specifically address Li 2012's teachings about reducing the number of inputs and "easily" adapting its techniques. OB39-40. But "an obviousness case does not require expert testimony for every piece of the analysis," *Adapt Pharma Operations Ltd. v. Teva Pharmaceuticals USA, Inc.*, 25 F.4th 1354, 1368-69 (Fed. Cir. 2022), and the Board was well positioned to interpret for itself these "easily understandable" teachings of Li 2012, *Belden*, 805

F.3d at 1079. Moreover, as the Board found, machine learning had been "effective[ly]" used to detect arrhythmias based on heart rate variability data, Appx110 (quoting Appx4641), which "can be accurately determined based on either ECG … or PPG" data, Appx60 (quoting Appx3412)—further demonstrating that it would have been obvious to adapt Li 2012's machine-learning techniques to PPG data alone. *See* Appx3466-3467; Appx3528-3529; Appx3531; Appx3293-3294.

3. The Board correctly found that applying Li 2012 outside the hospital setting or to PPG data would not change its "principle of operation."

AliveCor argues that applying Li 2012's machine-learning algorithm outside "the ICU context" would change Li 2012's "principle of operation." OB40. But substantial evidence supports the Board's finding that a skilled practitioner "would immediately recognize the applicability of Li 2012's teachings to the development of a body-worn sensor" outside of the ICU setting. Appx109. Indeed, as the Board highlighted, Li 2012 discloses not only that its techniques "could easily be adapted to other alarms in the ICU" but also that they could "have a much wider impact to the general monitoring environment." Appx109 (quoting Appx3880). Applying Li 2012 to Shmueli's wearable sensor

would not change Li 2012's principle of operation because Li 2012 would continue to "operate 'on the same principles as before,'" i.e., improving arrhythmia detection using machine learning. *Mouttet*, 686 F.3d at 1332 (citation omitted). AliveCor offers no evidence to the contrary.

AliveCor also argues that removing ECG data would render Li 2012 "inoperable for its intended purpose." OB41. But even if the claims required the removal of ECG data (they do not), substantial evidence supports the Board's finding that this would not render Li 2012 inoperable. Appx108-109. As noted above, Li 2012 teaches that its techniques can "easily" be adapted to other settings, emphasizes the importance of reducing the number of inputs, and nowhere suggests that such a reduction would render it inoperable. *See* Appx3876; Appx3880. And the Board's finding that machine-learning algorithms were known to effectively detect arrhythmias based on inputs that can be derived solely from PPG data (HRV) further suggests that Li 2012's machine-learning algorithm, too, could be effectively applied without ECG data. Appx60; Appx110; *see* Appx3466-3467; Appx3528-3529; Appx3531; Appx3293-3294.

AliveCor notes Li 2012's teaching that removing a different kind of data—arterial blood pressure data—reduced false-alarm suppression for one kind of arrhythmia from roughly 30% to 20%. OB41. But this says nothing about whether removing *ECG data* would reduce Li 2012's efficacy. And, regardless, rendering Li 2012 somewhat less effective does not mean the system would be "inoperable" for detecting arrhythmias. *Arlington Indus., Inc. v. Bridgeport Fittings, Inc.*, 581 F. App'x 859, 866 (Fed. Cir. 2014) (combination not inoperable where it was still "at least functional"); *In re Urbanski*, 809 F.3d 1237, 1244 (Fed. Cir. 2016) (combination not "inoperable" because it requires "foregoing [a] benefit" taught by prior art).

AliveCor also notes that, "unlike PPG, ECG measurement techniques use the 'gold standard' tool—12 lead ECG, or Holter monitors and similar wearable or implantable devices." OB41 (emphasis omitted). Insofar as AliveCor suggests that Li 2012's principle of operation would be changed by applying it to data that is less effective than ECG for arrhythmia detection, AliveCor did not preserve the argument, and it is wrong. Li 2012's purpose is to use machine learning to *improve* arrhythmia detection. *See* Appx3873-

3878; Appx107. Applying Li 2012's teachings to improve the detection capacities of PPG data fulfills that purpose.

Neither case cited by AliveCor (at OB40) is to the contrary. In *Plas-Pak Industries, Inc. v. Sulzer Mixpac AG*, the proposed combination would "remove" the very "stop valves" that the prior art reference defined as "the invention." 600 F. App'x 755, 757-58 (Fed. Cir. 2015); *see Captioncall, L.L.C. v. Ultratec, Inc.*, IPR2015-00637, 2016 WL 5231958 (P.T.A.B. Sept. 7, 2016) ("the proposed modification" in *Plas-Pak* "would destroy the backflow functionality" and "remove the core component of the device"). Similarly, in *Application of Ratti*, the court found that the prior art "cannot function" under the proposed modification. 270 F.2d 810, 813 (C.C.P.A. 1959). Here, in contrast, there is no evidence that following Li 2012's suggestions to adapt its techniques and keep the number of inputs as low as possible would destroy its functionality.

D. The Board correctly found that Hu 1997 renders obvious the '499 machine-learning claim elements.

The '499 patent's machine-learning claim elements recite "determining a presence of said arrhythmia using a machine learning algorithm" and using "heart rate and heart rate variability data" from

the user and from other users in that process. Appx206-207 (26:54-67, 28:11-25). Hu 1997 teaches improving arrhythmia detection using machine-learning algorithms trained on user-specific and population-level ECG data. Appx4801. The Board correctly found that Hu 1997 renders obvious the machine-learning elements of the '499 claims by either (1) "applying Hu's machine learning to data including ECG data" or (2) "applying Hu's machine learning to data including PPG data but not ECG data." Appx45; Appx51-52.

1. The Board correctly found that Hu 1997's ECG teachings render obvious the machine-learning elements of the '499 claims.

The Board correctly found that Hu 1997's teachings regarding "determining a presence of arrhythmias using machine learning on ECG data" "satisfies the machine learning element of the claims." Appx51.

AliveCor argues that the Board "erroneously construed the machine-learning dependent claims of the '499 patent as not being drawn to PPG data." OB42. But the machine-learning claims specify only two general types of heart data that must be inputted into the algorithm—"heart rate and heart rate variability data." Appx206-207

(26:54-67, 28:11-25). The claims nowhere require that these inputs must be derived from PPG data. And the specification states that *either* PPG data *or* ECG data can be used to supply the "raw heart rate" data and "heart rate variability" data that the machine-learning algorithm analyzes. Appx197-198 (8:28-9:1).

AliveCor argues the '499 machine-learning claims require PPG data because they "call[] back to the independent claims' preamble recitation of determining a presence of an arrhythmia," and "it is only when" an arrhythmia's "presence is determined … that a user is alerted to take an ECG." OB42 (quotations omitted). But the preamble states that the "method of determining a presence of an arrhythmia" "compris[es]" each of six steps, including "alerting said first user to sense an electrocardiogram." Appx206 (26:20-39). Accordingly, as the Board found, the dependent machine-learning claims' reference to "determining a presence of said arrhythmia using a machine learning algorithm," Appx206 (26:54-56), "encompass[es] the application of machine learning to ECG data collected in response" to the step of alerting a user to sense an ECG. Appx50-51. For these reasons, AliveCor's assertion (at OB42) that the "heart rate sensor" recited in the

independent claims "refers to a PPG" sensor" is immaterial, because the machine-learning claims do not require that the heart data inputted into the algorithm be derived from that heart rate sensor. AliveCor notes that the claims do not *require* that the user take an ECG after being alerted to do so. OB43. But AliveCor identifies no reason why the user would not follow those instructions, thereby generating the ECG data analyzed by the machine-learning algorithm.

2. The Board correctly found that a skilled practitioner would be motivated to adapt Hu 1997's ECG teachings to Shmueli's PPG data.

Substantial evidence also supports the Board's findings that a skilled practitioner would have been motivated to apply "Hu 1997's machine-learning approach to Shmueli's PPG data" and could do so "with a reasonable expectation of success." Appx46-47.

AliveCor takes issue with the Board's motivation-to-combine analysis, accusing the Board of using "hindsight" because "neither Apple nor its expert explained why a [skilled practitioner] would have been motivated to use machine learning *with PPG*." OB43.

But Apple gave multiple, specific reasons why a skilled practitioner would have been motivated to apply Hu 1997's machine-

learning teachings to Shmueli's PPG data. Apple explained, for instance, that "Hu 1997 suggests applying machine learning to techniques like Shmueli's [PPG] cardiac monitoring," because it recognizes that "several arrhythmia[s] are potentially dangerous and life threatening, if not detected within a few seconds to a few minutes of its onset." Appx711 (quoting Appx4801). "With this recognition," Apple explained, "a POSITA would have been motivated to apply machine learning to … improve the accuracy of detecting arrhythmias using the [PPG] technology in Shmueli that enables detection within a few seconds to a few minutes of onset." Appx711. Apple also noted Hu 1997's teaching that machine learning offers several advantages for arrhythmia detection and explained that a skilled practitioner would have "even more reason to attempt to improve the accuracy of" Shmueli's "[PPG]-based arrhythmia detection with [Hu 1997's] machine learning," given "that [PPG]-based arrhythmia detection is less accurate than ECG-based arrhythmia detection." Appx710-711. Apple also highlighted Hu 1997's teachings that its machine-learning approach "can be easily adapted to *other automated patient monitoring algorithms* and eventually support decentralized *remote patient-*

monitoring systems." Appx711. Apple explained that a skilled practitioner "would have found it obvious to follow Hu 1997's suggestion[s] and apply its machine learning to" Shmueli's remote patient-monitoring device. Appx711.

The Board "adopted" these reasons in full. Appx46 (adopting "pages 18-25 of the Reply").

AliveCor argues that "Apple proposed and the Board adopted a vague, legally insufficient rationale for its combination that "would render every machine learning application obvious in every context." OB44-45. Not so. As discussed above (at 68-70), Apple articulated multiple specific reasons why a practitioner would have been motivated to apply Hu's machine learning to improve Shmueli's PPG-based arrhythmia detection in particular, and the Board adopted those reasons. For the same reasons, AliveCor is wrong that "Apple's reasoning … merely alleges that a [skilled practitioner] *could have* applied machine learning to PPG data." OB43-44 n.12. As discussed, Apple explained in detail why a skilled practitioner *would* have been motivated to do so.

AliveCor also argues that "applying Hu 1997's ECG-specific machine learning out of the ICU context, to the inferior PPG measurement tool," would alter its mode of operation. OB45. AliveCor did not preserve this argument, and it fails in any event. Hu 1997's disclosure that its techniques may be "easily adapted" to other algorithms and can "eventually support decentralized remote patient-monitoring systems" refutes any suggestion that applying those techniques to PPG data in Shmueli's remote monitoring setting would alter Hu 1997's purpose of improving arrhythmia detection using machine learning.

* * *

The Board correctly found that AliveCor's machine-learning claims taught the public nothing new. As a leading expert in cardiac-monitoring technology explained and extensive additional evidence showed, machine-learning algorithms to detect arrhythmias were widely used before the '731 and '499 patents issued, and the prior art of Shmueli, Li 2012, and Hu 1997 each teach or suggest inputting heart data into a machine-learning algorithm to detect arrhythmias, as the claims require. The patents recite only generic machine-learning

algorithms with no specifics that could in any way "distinguish[] [the claims] over the cited art." Appx110. The Board's findings that the machine-learning claims of the '731 and '499 patents are obvious should be affirmed.

III. AliveCor's "Routine Discovery" Argument Is Waived And Wrong.

As a last resort, AliveCor asks the Court to find in the first instance that Apple did not comply with "routine discovery" obligations. OB56-61. The argument is waived and wrong.

A. AliveCor waived this discovery dispute.

Section 42.51(b)(1)(iii) requires parties to produce, as "[r]outine discovery," all "information … inconsistent with a position advanced by the party during the [inter partes review] proceeding." 37 C.F.R. § 42.51(b)(1)(iii). AliveCor argues this provision imposed on Apple an obligation to produce documents concerning "secondary considerations," as such documents are "inconsistent" with Apple's position that the patents are obvious. OB57-58. AliveCor chose not to raise this discovery issue with the Board, with Apple, or with the Commission.

AliveCor did not raise this routine discovery issue to the Board, which would have enabled the Board to explain to AliveCor the proper

scope of "routine discovery." *See L'Oreal USA, Inc. v. Liqwd, Inc.*, PGR2017-00012, 2017 WL 4340409, at *5-6 (P.T.A.B. Sept. 27, 2017) (providing such guidance). AliveCor suggests (*see* OB59) that it could not raise the issue with the Board in light of the Commission protective order covering some of the secondary considerations documents. But AliveCor is raising the § 42.51(b)(1)(iii) argument now with the same protective order still in effect. *See* Appx8787-8813.

Nor did AliveCor raise the issue with Apple. *See BlackBerry Corp. v. Wi-Lan USA Inc.*, IPR2013-00126, 2013 WL 8695861 (P.T.A.B. Aug. 19, 2013) (instructing parties with doubt about routine discovery compliance to "communicate those concerns" to the other side). In the email exchange AliveCor references (at OB59), AliveCor asked Apple for its consent to use the documents and noted that, absent consent, it would seek Board permission to serve discovery requests. Appx8814-8818 (email exchange). At no point did AliveCor suggest that Apple was obligated to produce this discovery as "inconsistent" information. On the contrary, AliveCor's statement that it would "serve discovery" indicated that this was an "additional discovery" request under § 42.51(b)(2), not required "routine discovery" under § 42.51(b)(1).

AliveCor did not address this issue in the Commission investigation either. In the same email exchange described above, Apple noted that the protective order enabled AliveCor to seek an order from the Commission permitting use of the documents at the Board. Appx8814. Such an approach is common. *Compare*, *e.g.*, *Columbia Sportswear N. Am., Inc. v. Seirus Innovative Accessories, Inc.*, No. 3:15-cv-00064-HZ, 2017 WL 1217157, at *2-3 (D. Or. Apr. 3, 2017) (granting modification of protective order to allow use of materials in co-pending inter partes review proceeding). But AliveCor did not seek an order.

AliveCor instead chose to raise this "routine discovery" argument for the first time in its opening brief in this Court. The argument is waived. *NuVasive*, 842 F.3d at 1380-81; *Wood v. Milyard*, 566 U.S. 463, 472-74 (2012).[9]

[9] Should the Court find AliveCor's argument forfeited rather than waived, no "exceptional circumstances" justify excusing the forfeiture. *In re Google Tech. Holdings LLC,* 980 F.3d 858, 863 (Fed. Cir. 2020). AliveCor offers no valid reason for why it chose to raise this argument here and not before the Board. *Supra* 73-74. Moreover, this Court reviews the Board's discovery rulings only for abuse of discretion, *see WesternGeco LLC*, 889 F.3d at 1322 n.9, making AliveCor's untimely discovery dispute particularly inappropriate for this Court's de novo consideration.

B. AliveCor's expansive interpretation of Section 42.51(b)(1)(iii) is wrong.

The reason AliveCor did not raise § 42.51(b)(1)(iii) before now is transparent: the secondary considerations evidence AliveCor asserts Apple improperly "withheld," OB61, was not subject to "routine discovery." Apple did not raise secondary considerations in its petitions. AliveCor did not raise secondary considerations in its responses.[10] Thus, evidence related to secondary considerations was not "information inconsistent with a position advanced by [Apple] during the [inter partes review] proceeding," and Apple had no obligation to produce that information under § 42.51(b)(1)(iii). *See* Appx889 (APJ Cotta, observing that the parties did not raise secondary considerations); Appx893-894 (Apple's counsel confirming the same); Appx905-906 (AliveCor's counsel, in response, pointing solely to discussion of industry skepticism in motivation-to-combine context).

[10] In its secondary considerations arguments before the Commission, AliveCor relied heavily on its own confidential information (such as commercial data) and public information (such as a journal article supposedly showing industry praise). *See* Initial Determination, 2022 WL 2981155, at *64-65. AliveCor could have entered this material into the record in the Board proceedings. It did not.

AliveCor's suggestion that § 42.51(b)(1)(iii) imposes a sweeping obligation to produce all information that an opposing party could deem "inconsistent" with "obviousness," OB58, is inconsistent with the Board's interpretation of its rule. *See Am. Nat'l Mfg. v. Sleep No. Corp.*, 52 F.4th 1371, 1385 (Fed. Cir. 2022) ("We give deference to the Board's application of its own rules."). In *Garmin International, Inc. v. Cuozzo Speed Technologies LLC*, the Board rejected an effort to characterize discovery requests seeking secondary considerations evidence as "routine discovery" of "information inconsistent with positions … taken in the Petitions." IPR2012-00001, 2013 WL 11311697, at *1-2, *4-6 (Paper 26) (P.T.A.B. Mar. 5, 2013). In rejecting the request, the Board explained, "[r]outine discovery under 37 C.F.R. § 41.51(b)(1)(iii) is narrowly directed to specific information known to the responding party to be inconsistent with a position advanced by that party in the proceeding, and not broadly directed to any subject area in general within which the requesting party hopes to discover such inconsistent information." *Id.* at *2 (explaining that IPR discovery "is significantly different from the scope of discovery generally available under the Federal Rules of Civil Procedure").

The Board's Consolidated Trial Practice Guide confirms that the rule does not work the way AliveCor claims. The guide states: "[W]here a patent owner relies upon [the secondary consideration of] surprising and unexpected results to rebut an allegation of obviousness," § 42.51(b)(1)(iii) requires the patent owner to "provide the petitioner with non-privileged evidence that is inconsistent with the contention of unexpected properties." *Patent Trial and Appeal Board Consolidated Trial Practice Guide*, Nov. 2019 at (I)(F)(1)(a), page 23. This is incompatible with AliveCor's expansive reading of the rule, which would require the patent owner in the example to produce the secondary considerations evidence *regardless* of whether it advanced a secondary considerations argument before the Board.

The decisions AliveCor cites are consistent with the Board's "narrowly directed" understanding of its rule. *Garmin*, 2013 WL 11311697, at *2. In *Aker Biomarine AS v. Neptune Technologies & Bioressources Inc.*, the narrow question was whether the testimony was "inconsistent with [the patent owner's] position regarding the effect of the heating step on the crude krill oil product produced by [a prior art] process," not whether the testimony was inconsistent with the patent

owner's position on "obviousness." IPR2014-00003, 2014 WL 4987763 (P.T.A.B. Oct. 6, 2014). In *Spectrum Solutions LLC v. Longhorn Vaccines & Diagnostics, LLC*, the Board found that a patent owner violated § 42.51(b)(1)(iii) by selectively producing test results supporting its argument that a prior art compound does not kill pathogens, while withholding results from the same test showing that the compound did kill pathogens. IPR2021-00847, Paper 113, at 35-36, 48-49 (P.T.A.B. May 3, 2023). And *Becton* and *L'Oreal* note only that § 42.51(b)(1)(iii) requires a party to produce secondary considerations evidence that is "inconsistent" with secondary considerations arguments that party made before the Board—arguments that Apple did not make in this case. *See, e.g., Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 20, at 2-5 (P.T.A.B. Feb. 28, 2018); *L'Oreal*, 2017 WL 4340409, at *5-6.[11]

[11] Amicus MDMA cites no other authority suggesting that § 42.51(b)(1)(iii) or the "duty of candor" requires production of all information potentially inconsistent with "obviousness." *See* MDMA Br. 9-10. And while MDMA also argues that, as a policy matter, forums ruling on similar issues should have access to the same evidence, MDMA Br. 3-4, Congress deliberately narrowed IPR discovery to facilitate efficient agency action. *Garmin*, 2013 WL 11311697, at *2. AliveCor itself sought to prevent Board consideration of Apple's

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AliveCor's expansive interpretation of § 42.51(b)(1)(iii) is without support.

CONCLUSION

For the reasons above, the Court should affirm.

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evidence from the Commission proceeding. *See* Appx112. MDMA's complaint about "[s]trategic reliance on protective orders to withhold evidence," MDMA Br. 2, does not apply here since, protective order aside, the evidence was not covered by § 42.51(b)(1)(iii). Nor did AliveCor pursue ways to obtain the evidence consistent with the protective order.

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CERTIFICATE OF COMPLIANCE

The brief complies with the type-volume limitation of Fed. Cir. R. 32(b)(1) because this brief contains 13,989 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f) and Fed. Cir. R. 32(b)(2).

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