No. 23-1553

IN THE
United States Court of Appeals for the Federal Circuit

APPLE INC.,

Appellant,

v.

INTERNATIONAL TRADE COMMISSION

Appellee.

On Appeal from the United States International Trade Commission
Inv. No. 337-TA-1266

NON-CONFIDENTIAL OPENING BRIEF OF APPELLANT APPLE INC.

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CLAIM LANGUAGE AT ISSUE

U.S. Patent No. 10,638,941 – Claim 12

12. A smartwatch, comprising

a processor;

a first sensor configured to sense an activity level value of a user, wherein the first sensor is coupled to the processor;

a photoplethysmogram ("PPG") sensor configured to sense a heart rate parameter of the user when the activity level value is resting, wherein the PPG sensor is coupled to the processor;

an electrocardiogram ("ECG") sensor configured to sense electrical signals of a heart, wherein the ECG sensor comprises a first electrode and a second electrode, and wherein the ECG sensor is coupled to the processor; and

a non-transitory computer readable storage medium encoded with a computer program including instructions executable by the processor to cause the processor to:

determine if a discordance is present between the activity level value of the user and the heart rate parameter of the user;

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

receive electric signals of the user from the ECG sensor to confirm the presence of the arrhythmia.

U.S. Patent No. 10,595,731 – Claim 1

1. A smart watch to detect the presence of an arrhythmia of a user, comprising:

a processing device;

a photoplethysmography ("PPG") sensor operatively coupled to the processing device;

an ECG sensor, comprising two or more ECG electrodes, the ECG sensor operatively coupled to the processing device;

a display operatively coupled to the processing device; and

a memory, operatively coupled to the processing device, the memory having instructions stored thereon that, when executed by the processing device, cause the processing device to:

receive PPG data from the PPG sensor;

detect, based on the PPG data, the presence of an arrhythmia;

receive ECG data from the ECG sensor; and

confirm the presence of the arrhythmia based on the ECG data.

U.S. Patent No. 9,572,499 – Dependent Claim 16

11. A system for determining the presence of an arrhythmia of a first user, comprising

a heart rate sensor coupled to said first user;

a mobile computing device comprising a processor, wherein said mobile computing device is coupled to said heart rate sensor, and wherein said mobile computing device is configured to sense an electrocardiogram of said first user; and

a motion sensor

a non-transitory computer readable medium encoded with a computer program including instructions executable by said processor to cause said processor to receive a heart rate of said first user from said heart rate sensor, sense an activity level of said first user from said motion sensor, determine a heart rate variability of said first user based on said heart rate of said first user, compare and [sic] activity level of said first user to said heart

rate variability of said first user, and alert said first user to record an electrocardiogram using said mobile computing device.

16. The system of claim 11, wherein said mobile computing device comprises a smartwatch.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 23-1553

Short Case Caption Apple Inc. v. International Trade Commission

Filing Party/Entity Apple Inc.

Instructions:

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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.
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Date: 04/17/2023

Signature: /s/ Melanie L. Bostwick

Name: Melanie L. Bostwick

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

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

Attachment

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).

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CERTIFICATE OF COMPLIANCE

Statement Regarding Confidential Material Omitted

Pursuant to Federal Circuit Rule 25.1(e) and the Protective Order issued in the ITC on May 26, 2021, and amended on August 18, 2021, two versions of this brief are being filed with the Court: a confidential version that notes the material marked confidential, and a non-confidential version containing appropriate redactions. In the non-confidential version of this brief, confidential material has been deleted on pages 16-17, 27, 32-34, and 36-44. The general nature of the deleted material is confidential business information of AliveCor, Inc., regarding its finances, product information, and agreements with a third party not involved in this litigation.

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STATEMENT OF RELATED CASES

Complainant AliveCor, Inc., has noticed an appeal from the same underlying proceeding before the International Trade Commission. That appeal is pending before this Court as No. 23-1509. Both AliveCor and Apple have sought consolidation of Appeal No. 23-1509 with this appeal, and Apple has asked for this appeal to be designated as lead in the consolidated appeal so that Apple can self-expedite its briefing. Those motions remain unresolved. As Apple explained in its motion, Dkt. 10 at 7, it is filing this opening brief within one week of the Commission providing the certified list for this appeal. Should the Court subsequently grant Apple's consolidation motion, Apple would file an identical opening brief in the consolidated appeal.

This appeal may affect or be affected by AliveCor's pending appeal from the Patent Trial and Appeal Board's decisions holding all claims of AliveCor's asserted patents unpatentable. *See AliveCor, Inc. v. Apple Inc.*, Nos. 23-1512, -1513, -1514.

In addition, this appeal may affect the pending 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 pending resolution of the Commission Investigation. *See id.*, Order, Dkt. 26 (May 6, 2021).

INTRODUCTION

According to Apple's customers, the Apple Watch has saved lives—"[l]iterally, not figuratively," as one customer took pains to point out. Appx1616-1617. With multiple FDA-cleared cardiac-monitoring functions—among many other industry-leading health and wellness features—the Apple Watches at issue are helping users both manage known conditions and discover potential problems that warrant a doctor visit. Millions of American consumers have activated these features on their Apple Watches. And many more stand to benefit, as researchers at renowned institutions across the country are investigating how Apple Watch can be used to do even more to improve health.

These benefits to the American public are now in jeopardy, however, because of the International Trade Commission's ruling that these Apple Watches infringe two patents held by a company that long since stopped offering a product protected by those patents. That ruling would be bad enough if the Commission's bases for finding a Section 337 violation were valid. That is because the Commission is meant to protect American industry and the public interest, not just to serve as an alternative forum for patent assertion. The Commission wields the

extreme authority to exclude products from importation, but only for the purpose of protecting American innovation—and only after considering the effects of exclusion on public health, competition, and consumers.

But the Commission not only abdicated that critical responsibility. It also found a protectable domestic "industry" based on a product that AliveCor abandoned years before filing its complaint; the Commission made this finding despite recognizing that AliveCor submitted unreliable evidence and intentionally declined to satisfy its burden to link its expenditures with the patents or protected articles. It found infringement only by ignoring the plain claim language. And it allowed admittedly shaky evidence of secondary considerations to outweigh a strong showing of obviousness. It even issued an exclusion order—albeit in a suspended state—after the Patent Trial and Appeal Board held AliveCor's asserted patents invalid as obvious based on a separate set of prior art from the one the Commission considered.

The Commission's exclusionary authority is a powerful remedy meant to protect American industry from unfair importation practices. That is not this case. One American company is providing

groundbreaking products that improve consumers' lives. Another American company is wielding invalid patents without offering any comparable product of its own. The Court should reverse.

STATEMENT OF JURISDICTION

The Commission had jurisdiction of the underlying Investigation pursuant to 19 U.S.C. § 1337(b)(1). The Commission issued a Final Determination on December 22, 2022, finding a violation of Section 337 based on the '941 and '731 patents but no violation based on the '499 patent. Appx1-89. The Commission's decision as to the '499 patent became final upon issuance; AliveCor timely filed a petition for review of that decision on February 7, 2023. No. 23-1509, Dkt. 1. The Commission's decision as to the '941 and '731 patents became final one day after the presidential review period closed with no action from the President, on February 21, 2023. 19 U.S.C. § 1337(j)(4); *see* Appx2797-2798. Apple timely filed a petition for review of that decision on February 22, 2023. Dkt. 1. This Court has jurisdiction pursuant to 28 U.S.C. § 1295(a)(6) and 19 U.S.C. § 1337(c).

STATEMENT OF THE ISSUES

1. Whether the Commission erred in finding an existing domestic industry in AliveCor's long-discontinued KardiaBand product based on a modest amount of research and development spending that no witness attempted to link to the asserted patents and which mostly related to products that the Commission found were not part of the domestic industry.

2. Whether the Commission erred in concluding that the accused Apple Watches infringe patent claims requiring a smartwatch processor that uses ECG data to "confirm … the arrhythmia" first detected by PPG data, despite the undisputed fact that Apple Watch's ECG and PPG-based features are wholly separate and do not interact, as required by Apple's FDA clearances.

3. Whether the Commission erred in upholding certain dependent patent claims by ignoring record evidence, and whether the Commission erred in concluding that admittedly weak evidence of secondary considerations outweighed Apple's strong showing of prima facie obviousness.

4. Whether the Commission properly issued sweeping remedial orders directed at a U.S. company's innovative product that can improve health and save lives, particularly when the complainant offers no competing product.

STATEMENT OF THE CASE

Apple Designs The Apple Watch, Including Several Features That Help Users Detect And Manage Potentially Fatal Cardiac Conditions.

Apple, headquartered in Cupertino, California, designs and markets personal consumer devices. Appx713-714. This case involves the Apple Watch, a "revolutionary product" first announced in 2014 that has "grown to become the world's most popular smartwatch." Appx10127; Appx2631. Like every Apple product, Apple Watch is designed with one of Apple's "core principles" in mind: "a commitment to improve users' lives by developing the world's best technology." Appx1502. Consistent with that goal, since the first model debuted in 2015, Apple Watch has offered consumers a suite of "comprehensive health and fitness apps that can help people lead healthier lives." Appx10126-10127. Among many other features, these apps can help consumers monitor their cardiac health.

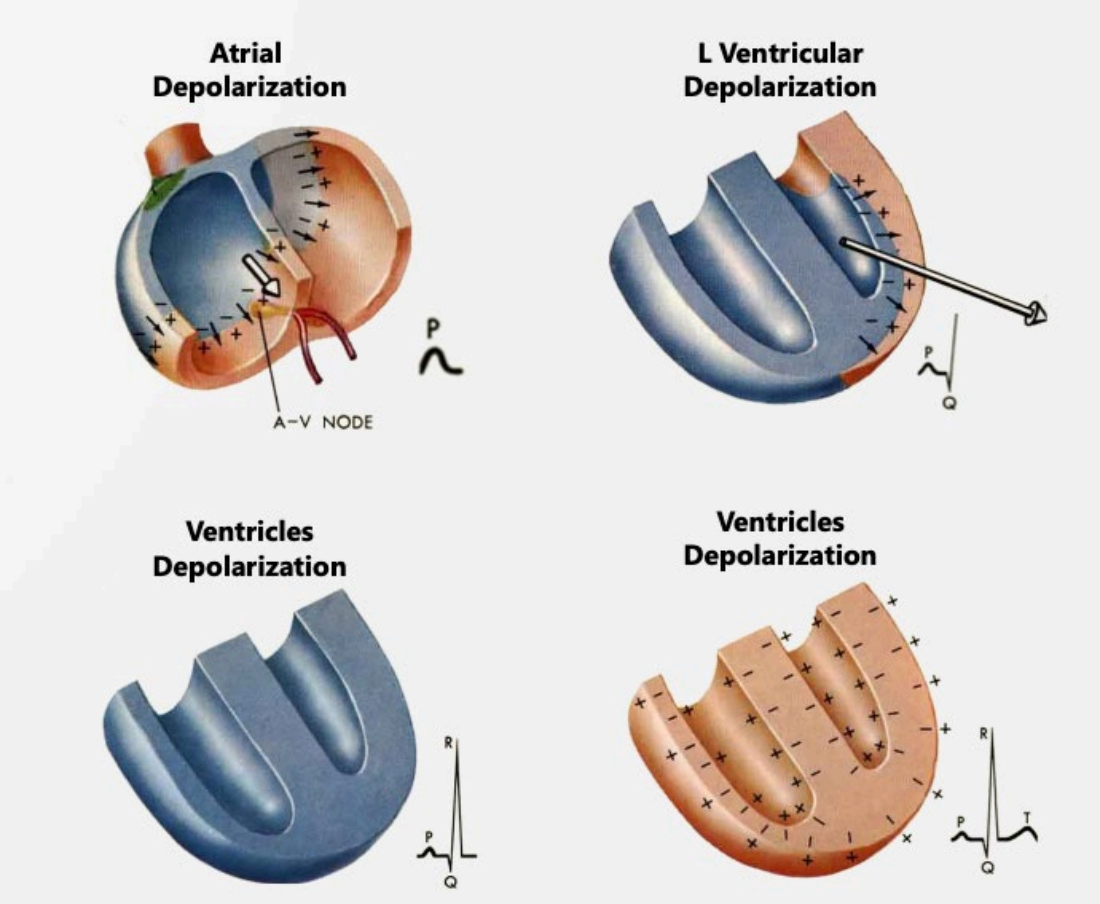
Even before the first release of Apple Watch, Apple was working on this technology. Appx12005-12006; Appx12206; Appx30738-30741. The earliest Watch models contained a feature known as "Background Heart Rate," which uses an infrared PPG sensor—short for "photoplethysmogram"—to measure a user's heart rate throughout the day and, for example, allows users to track heart rate during workouts. Appx30746-30747; Appx30751-30752. PPG sensors shine light into the body and measure the absorption rate of that light as blood flows through the blood vessels. Appx716. This measurement can be used to determine a patient's pulse and to derive estimates of both heart rate and heart-rate variability. Appx497-498.

Beginning with the Series 3 model released in 2017, Apple Watch has also included the "High Heart Rate Notification" feature, or "HHRN." Appx12206; Appx30744-30745. If the Background Heart Rate measurement exceeds a user-set threshold while the user seems to be inactive (as measured by the Watch's accelerometer), HHRN triggers a higher-powered green-light PPG sensor to obtain a higher-fidelity measurement of heart rate. Appx722; Appx30752-30753; Appx10824-10826. If this process confirms the high heart rate, the user receives a

notification that their heart rate is above the preset threshold even though they appear to be inactive. Appx11734-11737; Appx30753.

Appx12056.

With the release of Apple Watch Series 4 in 2018, and following "clinical evaluation trials" and a "regulatory clearance process," Apple accomplished its long-held goal of including ECG ("electrocardiogram") capability. Appx30739-30745; Appx12016-12028. An electrocardiogram uses electrodes placed on the skin to measure the electrical flow that causes the heart muscle to contract and pump blood through the four chambers in an orderly way. Appx716. The normal process by which this electrical flow (also called "depolarization") occurs—and the corresponding ECG measurement—is depicted below:

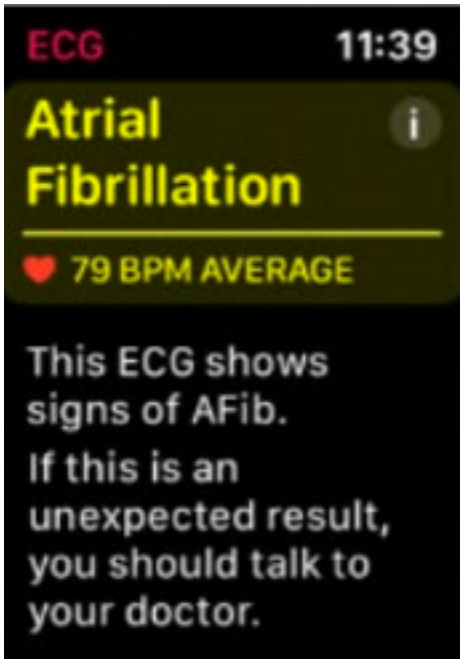


Appx12114. The P wave (top left) corresponds to current flow that depolarizes the atria (causing contraction), while the "QRS complex"—reflected in the spike shown in the bottom graphics—corresponds to current flow that depolarizes the ventricles (again causing contraction). Appx31065-31068. An ECG can reveal abnormal electrical activity (or "arrhythmias") in the heart, such as a fast heart rate (called tachycardia) or an irregular heart rhythm such as atrial flutter or atrial fibrillation. Appx12115; Appx31068-31069; Appx30105. Atrial fibrillation is "the most common serious arrhythmia," affecting many

millions of individuals. Appx30050. The ECG, first developed in the early twentieth century, has been used since that time to assist in detecting and diagnosing atrial fibrillation. Appx30048-30053.

Since Series 4, Apple Watch has included two electrodes—one in the digital crown and one on the underside of the Watch—that allow a user to acquire an ECG signal. Appx724; Appx11466. And, since a software update in December 2018, Apple Watches with these electrodes have included the ECG app, which received FDA clearance as a novel form of "Software as a Medical Device." Appx11738-11747; Appx11726-11727. When a user launches it, the ECG app prompts the user to hold their finger on the digital crown, as shown below in instructions provided by the user's iPhone:

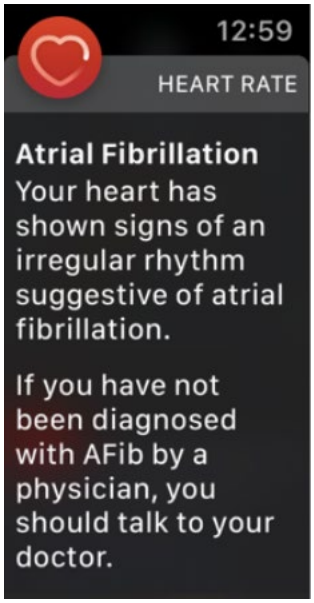
Appx11750. The electrical sensors then acquire ECG signals, which are visually represented on the Watch face. Appx725. The ECG app analyzes the acquired data and tells the user whether it shows a sinus rhythm (that is, normal), a low or high heart rate, atrial fibrillation, atrial fibrillation with high heart rate, or "inconclusive" due to a "poor recording." Appx725; Appx30766-30767. If the notification indicates atrial fibrillation, the user will be advised to "talk to your doctor" if this is "an unexpected result":

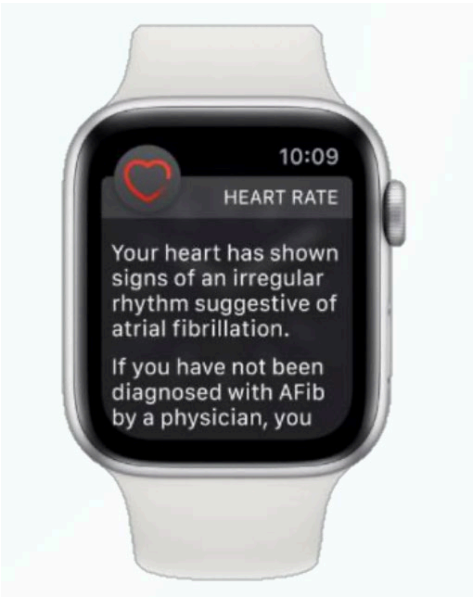


Appx11421. A doctor may then use a more sophisticated ECG to determine if a diagnosis of atrial fibrillation (or any other disorder) is appropriate. Appx31073-31074.

When it released the ECG app, Apple also released another feature known as Irregular Rhythm Notification, or "IRN." Appx30756-30759; Appx12206. IRN received its own separate FDA clearance as novel Software as a Medical Device. Appx11730-11733. IRN is available on Apple Watch models that predate the Series 4 model because it relies on the PPG sensor, not the ECG sensors. Appx722; Appx30756; Appx30762. When the Watch's accelerometer shows the user is sufficiently still, IRN triggers the higher-fidelity green-light

PPG sensor to take a tachogram—a precisely measured list of heartbeats—and analyzes the data to assess whether the rhythm appears to be normal or irregular. Appx30757-30758. If IRN detects an irregularity, it will request more frequent tachograms to collect more data. Appx723-724; Appx30758-30759. After a certain number of irregular tachograms, IRN will notify the user that their "heart has shown signs of irregular rhythm suggestive of atrial fibrillation" and to "talk to [their] doctor" if they have not previously been diagnosed with this condition. Appx724; Appx11819.





Appx11897; Appx12048.

More than 10 million Americans have IRN activated on their Apple Watches, and a similar number have the ECG app enabled.

Appx1509. Each feature can proactively alert users to possible cardiovascular conditions that might otherwise go undetected. Appx1507. Early detection of atrial fibrillation is especially critical; this potentially fatal condition affects millions of Americans but is often asymptomatic or only sporadically symptomatic until a major health event, such as a stroke, occurs. Appx1462; Appx30050. Apple has received many letters from users who credit their Apple Watch features with meaningfully improving, or even saving, their lives. Appx1508.

AliveCor Develops But Then Abandons The KardiaBand, An Apple Watch Accessory.

AliveCor, the complainant in this case, is a California-based company. Appx30044; Appx11672. AliveCor develops and sells personal ECG devices for users who need to monitor their cardiac health. Its first commercial product was the KardiaMobile, which received FDA clearance in 2012. Appx30062. The KardiaMobile, pictured below, is a standalone device with ECG sensors combined with a smartphone app that analyzes ECG data to detect atrial fibrillation.

Appx11673. The original KardiaMobile, along with a newer version that provides more views of the heart's rhythm and a card version that is the shape and size of a credit card, are AliveCor's current commercial products. Appx30100. But KardiaMobile is not at issue in this case. Appx30160-30161.

Instead, this case involves AliveCor's long-discontinued product, KardiaBand. Introduced after it received FDA clearance in November 2017, KardiaBand was an accessory designed to be used with Apple Watch Series 1, 2, or 3. Appx912-913; Appx30083; Appx30131. A user could exchange the Apple Watch band for the KardiaBand, which contained built-in ECG sensors, as shown below:

Appx11676 (annotations added). Using the sensors on the band and an app (also sold by AliveCor) running on the Watch, users could take an ECG. Appx751; Appx912-913. AliveCor's "KardiaApp" also contained a feature known as SmartRhythm, which placed the Watch into "workout mode," triggering the high-power, green-light PPG sensor in the Apple Watch to monitor heart rate (while relying on Apple Watch's accelerometer to detect activity levels). Appx751-753; Appx11769. If SmartRhythm detected a discordance between the user's activity level and heart-rate data, it would prompt the user to take an ECG using the KardiaBand. Appx30065.

AliveCor stopped marketing KardiaBand and discontinued SmartRhythm in August 2019. Appx30085; Appx30136; Appx30675-

30676. According to AliveCor, it made this decision because of changes to the Apple Watch operating system that happened in December 2018. Appx1375; Appx12207. Apple had updated the algorithms that process PPG signals and output heart-rate data for exercise sessions, resulting in "substantially better accuracy." Appx30748-30749. Third-party apps continued to have access to the "same type of workout mode heart rate data after the change," and multiple third-party apps continue to offer ECG or heart rate-related functions. Appx30749-30750. Nonetheless, AliveCor chose not to update its SmartRhythm software to work with the improved output. Appx30134-30136.

AliveCor instead "pivoted" to building its own device that would not rely on Apple Watch. Appx30085-30086. AliveCor intends for this "[redacted]" to be a [redacted] by [redacted] for [redacted]. Appx30093. The [redacted] is not yet on the market. At the time AliveCor filed its complaint, the device "did not exist in any hardware-sense." Appx245. Even by the time of expert discovery, "[redacted]." Appx153-154; *see* Appx1241-1242.

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In addition, around the time it initiated this litigation, AliveCor contracted with [redacted] a [redacted], to [redacted] a product consisting of an [redacted] smartwatch with PPG, motion, and ECG sensors to monitor heart activity and alert users to potential arrhythmias. Appx30384-30385; Appx10106; Appx10120-10125; Appx11982-11983. At that time, [redacted] a [redacted] [redacted] for other [redacted] to [redacted]. Appx30091; Appx10108-10119. AliveCor later [redacted] and [redacted] it with [redacted] Appx30482-30486; Appx154-157; *compare* Appx11795, *with* Appx11796. But neither AliveCor nor [redacted] has [redacted] any [redacted] to [redacted] the [redacted], nor have they begun discussions with [redacted] related to the product. Appx756; Appx31013; Appx30156; Appx10508; Appx10519.

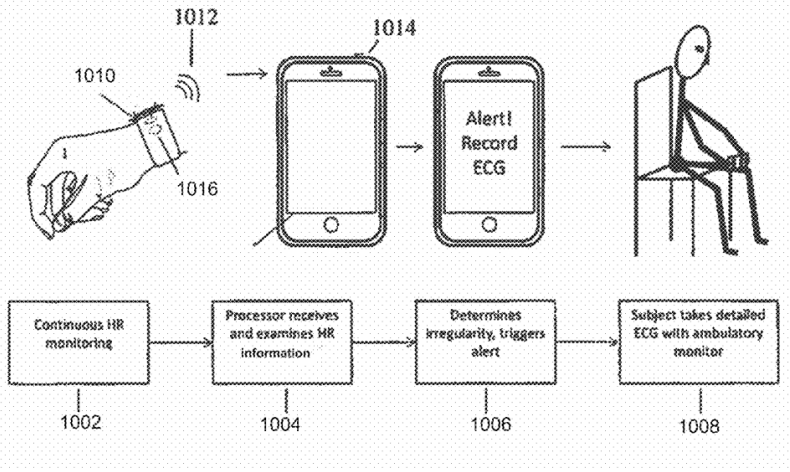
AliveCor Sues Apple For Patent Infringement In District Court And The International Trade Commission.

AliveCor has received several patents related to cardiac-monitoring technology. The patents at issue here stem from two provisional applications, one filed in December 2013 and one filed in May 2015. Appx109. Through a series of continuation applications, the earlier provisional led to two of the asserted patents: U.S. Patent No.

9,572,499, which issued in February 2017; and U.S. Patent No. 10,595,731, which issued in March 2020. Appx10001-10040; Appx10041-10073. The later provisional, also through a series of continuation applications, led to asserted U.S. Patent No. 10,638,941, which issued in May 2020. Appx10074-10092.

The '499 and '731 patents are titled "Methods and Systems for Arrhythmia Tracking and Scoring." Their shared specification focuses on tracking a user's cardiac health and providing recommendations for improvement. Appx10042. The data is captured by "[a] portable computing device or an accessory thereof," such as a commercially available wearable device, which measures and analyzes physiological signals such as a user's heart rate. Appx10060 2:30-41 (mentioning Google Glass and the Samsung Galaxy Gear smartwatch as examples). The specification also contemplates an ECG sensor. Appx10061 4:57-58. And it describes how the system may provide "[t]riggers or alerts" to the user "in response to the measured physiological signals," which may "notify the user to take corrective steps … or monitor other vital signs or physiological parameters." Appx10062 5:19-23. Figure 10, reproduced below, "shows an exemplary method for monitoring a

subject to determine when to record an electrocardiogram (ECG)" in response to the heart-rate monitoring data, Appx10062 6:3-5:



Appx10053.

Unasserted claim 11 of the '499 patent recites a generic system that determines whether a user's heart rate is mismatched with their activity level and suggests taking an ECG. Appx10039 27:5-24. Asserted dependent claims 16 and 17 add, respectively, that part of the system "comprises a smartwatch" and that the system uses a generic "machine learning algorithm." Appx10039 28:9-13.

Claim 1 of the '731 patent is directed to a smartwatch that performs a similar function:

> 1. A smart watch to detect the presence of an arrhythmia of a user, comprising:
>
> a processing device;

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

Appx10072 26:27-46.

The specification of the later '941 patent is focused more specifically on "Discordance Monitoring"—that is, using a wearable device to monitor cardiac activity and "determin[e] if a discordance is present between" the user's activity level and their heart rate (or heart-rate variability). Appx10084 2:10-21. The specification does not propose any new wearable but instead refers to existing products, including "smartwatches made available by manufacture[r]s such as, for example, Apple." Appx10085 4:60-62. The invention incorporates

"commonly used heart rate sensors" and applies known correlations between heart-rate values and activity levels to determine if a potential arrhythmia is present and, if so, take an ECG to "confirm" or "not confirm" "the presence of an arrhythmia … which was indicated by" the discordance. Appx10083 (Fig. 7); Appx10090 14:1-8.

Claim 12 of the '941 patent recites a smartwatch with components and functionality quite similar to that claimed by the '731 patent:

> 12. A smartwatch, comprising
>
> a processor;
>
> a first sensor configured to sense an activity level value of a user, wherein the first sensor is coupled to the processor;
>
> a photoplethysmogram ("PPG") sensor configured to sense a heart rate parameter of the user when the activity level value is resting, wherein the PPG sensor is coupled to the processor;
>
> an electrocardiogram ("ECG") sensor configured to sense electrical signals of a heart, wherein the ECG sensor comprises a first electrode and a second electrode, and wherein the ECG sensor is coupled to the processor; and
>
> a non-transitory computer readable storage medium encoded with a computer program including instructions executable by the processor to cause the processor to:
>
> determine if a discordance is present between the activity level value of the user and the heart rate parameter of the user;

> based on the presence of the discordance, indicate to the user a possibility of an arrhythmia being present; and
>
> receive electric signals of the user from the ECG sensor to confirm the presence of the arrhythmia.

Appx10092 17:53-18:18.

In December 2020, AliveCor sued Apple in the Western District of Texas, asserting infringement of the '941, '731, and '499 patents. *See AliveCor, Inc. v. Apple Inc.*, No. 20-cv-1112 (W.D. Tex.). In April 2021, AliveCor filed a complaint with the Commission making the same assertions and seeking to exclude the Apple Watch from importation into the United States. Appx363-395. The district court litigation is stayed pending resolution of the Commission proceeding. *See* Appx1220.

The Administrative Law Judge Finds A Violation With Respect To Two Of The Three Asserted Patents.

An Administrative Law Judge issued an Initial Determination finding a violation of 19 U.S.C. § 1337(a)(1)(B)(i) with respect to the '731 and '941 patents but finding no violation with respect to the '499 patent. Appx293-294.

The ALJ found that AliveCor met the critical threshold of showing a domestic industry in articles protected by the patent, despite

acknowledging that the analysis it used to reach that conclusion was "troubling." Appx288-289. Although AliveCor's KardiaBand product was discontinued in 2019, the ALJ in 2022 found an existing domestic industry related to that product. And, despite rejecting most of AliveCor's evidence as "not reliable," Appx264, the ALJ seized on two tabs of a single spreadsheet showing "payments made to R&D contractors," which were not limited to the KardiaBand but were accompanied by "at least some description of the activity behind each cost that *suggests* a nexus to sensors, circuitry, and housing structure" of a device. Appx281. Even though "no [AliveCor] witness explained any of these projects or relationships, and [AliveCor's expert] Dr. Akemann made clear he conducted no analysis on nexus," the ALJ "accepted" these expenses simply because Apple—the party that did not bear the burden of proof—did not have its expert opine on a lack of nexus. Appx282.

The ALJ reached a split outcome on infringement. As to the '499 patent, the ALJ found no infringement because the Apple Watch does not alert a user to record an ECG, as the asserted claims require. AliveCor accused IRN of performing this function when it alerts users

to potential signs of atrial fibrillation. But, as found by the ALJ and shown in the image above (at 12), "[t]his is not an alert for the user to take an ECG; it is an alert for the user to see their doctor." Appx243.

As to the '731 and '941 patents, however, the ALJ was willing to draw a link between IRN and the ECG app. It is undisputed that the HHRN and IRN features are completely separate from the ECG app; indeed, this separation is mandated by Apple's FDA clearance. *See* Appx30891-30894; Appx12065 (Dr. Picard explaining that Apple doesn't "have clearance to link ECG with IRN"). The apps use different data from different sensors; furthermore, HHRN and IRN run in the background while the ECG app operates only if the user opens it. Appx30768-30769; Appx30891-30892; Appx30894-30896; Appx30463-30464; Appx1106-1110. If a user receives a notification from HHRN or IRN, it is up to the user—not the device—to decide what to do with that information. Yet the ALJ found that the accused Apple Watches meet the '941 and '731 claim limitations requiring executable instructions that "detect" "an arrhythmia" and then "confirm" "the arrhythmia." The ALJ found infringement based on the simple fact that an Apple Watch user can both receive a PPG-based notification and take an ECG

reading, and that both operations may detect an arrhythmia, whether or not it is the same arrhythmia. Appx148-150; Appx213-214.

As to validity, the ALJ rejected Apple's § 103 challenge despite finding that Apple had shown a prima facie case of obviousness for most of the asserted claims (including all independent claims). The ALJ agreed that a 2004 article disclosed (or rendered obvious) a smartwatch with all the requisite hardware and functionality recited in the patents' independent claims, and that most of the dependent claims were also disclosed in the prior art. Appx177-203. But the ALJ found this "strong" showing overcome by secondary considerations. The ALJ found significant "the mere fact that a peer-reviewed medical journal published a laudatory article" on the KardiaBand, "even if the article's specific focus was on only one of its functions"—and even though the article's lead author was an AliveCor advisory board member. Appx200. The ALJ also gave some weight to the KardiaBand's "commercial success," despite acknowledging that its "profitability is not clear." Appx201. And the ALJ found that documents reflecting Apple's awareness of AliveCor products other than the KardiaBand, along with Apple's comparisons of its ECG app to the KardiaBand's

ECG functionality in its FDA submission, "point[ed] circumstantially to copying by Apple" despite being "not exactly a smoking gun." Appx202.

The Commission Affirms The Finding Of A Violation Despite AliveCor's Patents Being Held Unpatentable By The PTO.

Both parties petitioned for review of the Initial Determination. Relevant to Apple's appeal, the Commission determined to review the ALJ's findings regarding obviousness and the economic prong of the domestic-industry requirement. Appx94-98.

The Commission ultimately agreed with the ALJ's overall conclusions—that there is a violation of Section 337 with respect to the '941 and '731 patents but not with respect to the '499 patent—but modified some of the reasoning behind those conclusions. Appx3. The Commission, over the Chairman's dissent, affirmed the ruling that secondary considerations overcome the prima facie case of obviousness, though it excluded commercial success from the analysis. Appx44-45.

As to economic domestic industry, the Commission agreed that AliveCor had shown this critical requirement satisfied based on the lone spreadsheet of payments to outside contractors for research and development. Appx18-19. While the Commission elsewhere recognized that any expenses needed to be tied to KardiaBand—the only domestic-

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industry product—it inexplicably considered all $[Dollar amount redacted] in payments despite most of that amount undisputedly relating to AliveCor's other products in development. Appx19; *see* Appx271-272; Appx281-282; Appx1224-1226; Appx11927. And it found that amount substantial based simply on the fact that, according to the Commission, AliveCor spent more domestically on these contractors than it did on contractors outside the United States. Appx21-22.

Finally, the Commission decided to issue a limited exclusion order and a cease and desist order directed to the accused Apple Watches. Appx49-52. The Commission acknowledged the public-interest concerns raised by Apple and several third parties, including the "numerous ongoing studies related to heart diseases using the Apple Watch," as well as the "health, wellness, and safety features" the Apple Watch provides to consumers. Appx70-71. The Commission discounted the first effect by suggesting that the studies, which are still enrolling participants, would not need any additional Apple Watches. Appx71. As to consumer use, the Commission concluded that "suitable alternatives are available," such as wearing two different devices (one for heart-rate notifications and one for ECG functionality) or using a

fitness tracker lacking most smartwatch functionality. Appx72-73. The Commission further took the unusual step of requiring a bond for Apple Watches that enter during the presidential review period, despite the ALJ's recommendation that no bond should issue because AliveCor, which does not have a practicing product, faces no competitive harm. Appx82-83. According to the Commission's unelaborated reasoning, "Apple is at least partially responsible for AliveCor currently not having a viable product." Appx83.

The Commission did agree to suspend its remedial orders, however. While this Investigation was proceeding, Apple sought inter partes review of the three asserted patents before the Patent Trial and Appeal Board. A few weeks before the Commission issued its Final Determination, the Board issued Final Written Decisions finding all claims of all three patents unpatentable as obvious, based on separate prior art from that considered in the Commission proceeding. Appx86. Consistent with its past practice, the Commission "suspend[ed] enforcement of [its] remedial orders pending final resolution" of those proceedings. Appx86.

Both Apple and AliveCor filed notices of appeal from the Commission's decision. AliveCor's appeals from the Board decisions are also pending.

SUMMARY OF ARGUMENT

This Court should reverse the Commission's finding of a Section 337 violation and entry of remedial orders for four independent reasons.

First, the Commission erred in finding a domestic industry by plucking a snippet of data from the wealth of unreliable evidence AliveCor submitted and making conclusory assertions about that data with no record support. The lone domestic-industry product is the long-defunct KardiaBand, yet most of the cited expenditures indisputably were not related to that product. Furthermore, AliveCor expressly declined to even try to meet its burden of demonstrating a nexus between the expenditures and asserted patents. And, even apart from these fatal defects, the total expenditures represented only a tiny fraction of AliveCor's revenues, and the Commission's only basis for deeming them "substantial" is plainly wrong.

Second, the Commission erred in finding infringement by ignoring the plain meaning of the asserted claims, which require the ECG sensor

to "confirm… the arrhythmia" first detected by the PPG sensor, not simply detect a potential arrhythmia that may or may not be connected to the first. Under the correct construction, the accused Apple Watches do not infringe because, as required under their FDA clearances, the ECG and PPG-based features operate separately, and neither "confirms" what the other has detected.

Third, the Commission erroneously held that AliveCor's patent claims are not obvious. It upheld a handful of dependent patent claims only after misconstruing the teachings of the prior art, glossing over record evidence and AliveCor's admissions, and ignoring what would have been obvious to a skilled artisan. And, despite finding that Apple made a strong showing of prima facie obviousness as to most of the claims, the Commission deemed this showing outweighed by industry praise directed at non-patented features of KardiaBand and purported circumstantial evidence of copying that the Commission conceded was "not especially impressive."

Finally, even accepting its flawed finding of a violation, the Commission abused its discretion in issuing remedial orders despite overwhelming evidence that exclusion of the accused Watches will risk

lives and disrupt critical medical research—harms that no other available product can adequately prevent.

STANDARD OF REVIEW

"[T]his court reviews the Commission's legal determinations de novo and its factual findings for substantial evidence." *Gen. Protecht Grp., Inc. v. ITC*, 619 F.3d 1303, 1306 (Fed. Cir. 2010). "The question whether a complainant has satisfied the domestic industry requirement typically presents issues of both law and fact." *John Mezzalingua Assocs., Inc. v. ITC*, 660 F.3d 1322, 1327 (Fed. Cir. 2011). "Claim construction is ultimately an issue of law," *Techtronic Indus. Co. v. ITC*, 944 F.3d 901, 906 (Fed. Cir. 2019), while infringement is a factual determination, *Cisco Sys., Inc. v. ITC*, 873 F.3d 1354, 1361 (Fed. Cir. 2017). "Obviousness is a question of law based on underlying findings of fact." *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1237 (Fed. Cir. 2010). The Commission's issuance of a remedy must be set aside if it is "legally erroneous, arbitrary and capricious, or constitutes an abuse of discretion." *Fuji Photo Film Co. v. ITC*, 386 F.3d 1095, 1106 (Fed. Cir. 2004).

ARGUMENT

I. There Is No Section 337 Violation Because AliveCor Failed To Prove The Existence Of A Domestic Industry.

The Commission is not merely an alternative forum to an Article III district court. It is "fundamentally a trade forum, not an intellectual property forum." *Mezzalingua*, 660 F.3d at 1328. To obtain the injunctive relief provided by Section 337, therefore, a complainant in a patent dispute bears the burden of proving not just patent infringement but "the existence of a domestic industry 'relating to the articles protected by the patent.'" *Microsoft Corp. v. ITC*, 731 F.3d 1354, 1361 (Fed. Cir. 2013) (quoting 19 U.S.C. § 1337(a)(2)-(3)); *see Mezzalingua*, 660 F.3d at 1331 (complainant bears "burden of proof"). A complainant may satisfy this burden by showing that such an industry either "exists" or "is in the process of being established." 19 U.S.C. § 1337(a)(2).

The Commission rightly rejected AliveCor's attempt to show that a domestic industry "is in the process of being established" based on the Confidential product information [redacted] or Confidential product information [redacted], given AliveCor's lack of progress and "unclear" future intent for developing them. Appx11; Appx289-293. And it likewise rejected AliveCor's attempt to show an

existing domestic industry in the discontinued KardiaBand based on investments in plant and equipment or employment of labor and capital. Appx11; *see* 19 U.S.C. § 1337(a)(3)(A)-(B). AliveCor's evidence of such an industry was "not reliable." Appx264. According to the Commission, AliveCor failed to show how its activities related to the only "existing" product—KardiaBand—as opposed to the [redacted] or [redacted] products. Appx264-265. And the numbers AliveCor offered were compiled by its founder, Dr. Albert, "solely from memory." Appx266. Despite consulting no documents or other people, Dr. Albert generated percentages for how much time thirteen different employees spent on the KardiaBand project over five years. Appx267. The Commission rightly concluded there was "more reason to doubt than to trust this critical allocation." Appx268; *see also* Appx277-281; Appx16-17.

Confidential product information

Confidential product information

But the Commission nonetheless went out of its way to find a domestic industry—a finding it has made in 80% of recent patent-based investigations.[1] The Commission plucked two tabs of data from a

[1] Jonathan J. Engler et al., *Domestic Industry Alive and Well at ITC* (Feb. 1, 2022), https://tinyurl.com/DIAliveAndWell.

spreadsheet to find that $[redacted] in "payments made to R&D contractors," Appx281, somehow amounted to "substantial investment" in exploiting the asserted patents through "engineering, research and development, or licensing," 19 U.S.C. § 1337(a)(3)(C). *See* Appx17; Appx11709-11725; Appx11654; Appx11655.

The Commission reached that conclusion through a patchwork of logical errors and evidentiary gap-filling that cannot withstand scrutiny. No witness testified about the contents of these spreadsheet tabs. Appx281-282; Appx16-17. And the $[redacted] of payments drawn from these tabs includes more than $[redacted] that plainly relate to [redacted], not KardiaBand. *Infra* Part I.A. The Commission further found that these research and development expenses related to the asserted patents, even while acknowledging that AliveCor intentionally refused to demonstrate that link. *Infra* Part I.B. And it determined that $[redacted], over five years, amounts to a "substantial" investment for a company whose revenues across the same five-year period totaled $[redacted]. Appx11929 (Total Revenue, 2016 through 2020). *Infra* Part I.C.

If that is enough to constitute a domestic industry, then this statutory requirement is essentially meaningless. The Commission becomes just another patent-litigation forum—though a forum with extensive remedial powers unchecked by the limits applicable in district court. This Court should not permit the kind of clear statutory overreach that AliveCor invited and the Commission undertook in this case.

A. The Commission erred in crediting expenditures unrelated to any "articles protected by the patent."

Whatever statutory path a complainant takes to satisfy the domestic-industry requirement, there is one common denominator: the investments must relate to "articles protected by the patent." *InterDigital Commc'ns, LLC v. ITC*, 707 F.3d 1295, 1298 (Fed. Cir. 2013); *see also* Appx12 n.16; *Certain Integrated Circuit Chips*, Inv. No. 337-TA-859, Comm'n Op., 2014 WL 12796437, at *27 (Aug. 22, 2014). The Commission recognized that the only qualifying "articles" are AliveCor's former product, the so-called KardiaBand "system."[2] *See,*

[2] The Commission used this "system" terminology because AliveCor's KardiaBand accessory and associated software do not, by themselves, practice the asserted patent claims. Appx152-157; Appx214-215;

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e.g., Appx19 n.17 (noting that the "DI product for each of the three asserted patents is the [KardiaBand System]").

But the vast majority of the expenditures the Commission relied on were instead directed to the [Confidential product information redacted]—which "ha[s] not been shown to practice any of the asserted patents at the time of the complaint." Appx264; *see also* Appx153, Appx245 (deeming it "essentially undisputed" that [Confidential product information redacted] "did not exist in any hardware-sense at the time of the complaint"). Of the $[Dollar amount redacted] in research and development contractor expenses that the Commission credited, $[Dollar amount redacted] was associated with [Confidential product information redacted]. *See* Appx281-282; Appx1224-1225; Appx11927. These expenditures on potential future products cannot be said to relate to a domestic industry that "exists," as the Commission found. And the Commission's rationale for treating them that way is neither sufficient under the statute nor supported by any evidence. The Commission simply stated, without citation, that AliveCor's "continuing R&D investments" in

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Appx245. To satisfy the "technical prong" of the domestic-industry requirement, the Commission had to include the Apple Watch as part of AliveCor's "domestic industry" articles. *See* Appx111.

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potential future products somehow "benefit [KardiaBand system] users." Appx17; *see also* Appx16.

The Commission did not explain how research into the Confidential product information [redacted], a potential product that still does not exist, could benefit any remaining users of the KardiaBand, a product discontinued years before AliveCor filed its complaint. The cases it cited for support involved very different circumstances. Appx16. In one, the Commission credited pre-complaint investments in a marine sonar module that had since been discontinued because the complainant showed significant continuing investments in *that product*, including ongoing technical-support and warranty-service spending. *Certain Marine Sonar Imaging Devices*, Inv. No. 337-TA-921, Comm'n Op., 2016 WL 10987364, at *38 (Jan. 6, 2016). Similarly, this Court has credited an ATM manufacturer's pre-complaint research and development expenditures on a module that provided one of the patented features; those investments were directly linked to ongoing expenditures in servicing ATMs containing that module and the complainant's continued

installation of that module "in an increasing number of ATMs." *Hyosung TNS Inc. v. ITC*, 926 F.3d 1353, 1361-62 (Fed. Cir. 2019).[3]

But the issue here is not simply that AliveCor's spending happened before the complaint was filed. It is that most of AliveCor's research and development spending related to something other than the domestic-industry product. And the statute requires that qualifying investments be made "with respect to the articles protected by the patent." 19 U.S.C. § 1337(a)(3). For that reason, the Commission's seeming attempt to analogize this case to *Marine Sonar* by citing AliveCor's ongoing customer-service expenditures is irrelevant. *See* Appx17. Even if that limited spending could justify counting pre-complaint spending on KardiaBand,[4] it does not justify counting pre-complaint spending on other products that are not part of the relevant domestic industry.

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[3] *Hyosung* did not, as the Commission claimed, involve a "discontinued" product. Appx16. Nor did *Hyosung* "affirm[]"—or even cite—the Commission's *Marine Sonar* decision. Appx16 (representing otherwise).

[4] Only $[redacted] (Dollar amount) of the customer-service tickets were linked to KardiaBand. Appx274.

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The Commission adhered to this statutory requirement—and properly excluded the $[Dollar amount] linked to [Confidential product information]—when it analyzed whether AliveCor had shown "significant employment of labor or capital" under § 1337(a)(3)(B). The ALJ found that "removing [Confidential product information] investment is proper" and so limited AliveCor's spend on "contractor R&D amounts" to $[Dollar amount] for 2017 and $[Dollar amount] for 2018. Appx271-272. The Commission accepted these calculations for purposes of subsection (B). Appx23. But it took the opposite approach under subsection (C), *including* the exact same $[Dollar amount] in [Confidential product information] payments that it properly *excluded* in analyzing subsection (B).

There is no basis for this inconsistent treatment, and the Commission did not even attempt to offer one. *See, e.g.*, *LePage's 2000, Inc. v. Postal Regulatory Comm'n*, 642 F.3d 225, 232 (D.C. Cir. 2011) ("The Commission does not explain how it can read the same evidence differently when applied to different aspects of the same program."); *Colo. Interstate Gas Co. v. FERC*, 850 F.2d 769, 774 (D.C. Cir. 1988) (dissimilar treatment of identical cases "seems the quintessence of arbitrariness and caprice"); *see also* Appx1240-1242. On the contrary, it took pains to "clarify" that the articles requirement "applies with

respect to subsections (A), (B), and (C)." Appx12 n.16. Yet more than two-thirds of the expenditures the Commission counted toward the subsection (C) showing do not relate to any such "articles."

With those expenditures removed, AliveCor's research and development expenses creditable under subsection (C) would total only Dollar amount $[redacted]. But even that amount cannot be counted, given the separate error discussed below.

B. The Commission erred in crediting expenditures that bore no nexus to the asserted patents.

A complainant attempting to establish a domestic industry under subsection (C) must prove not only that this industry "relat[es] to the articles protected by the patent," but also that the investments reflect "exploitation" of the patent. 19 U.S.C. § 1337(a)(2), (3)(C). As the Commission put it, this additional requirement obligates complainants to show a "nexus between the claimed investments and the asserted patents." Appx12 n.16.

But AliveCor did not even attempt to show that this nexus existed for any of the Dollar amount $[redacted] in research and development expenses that supported the Commission's domestic-industry finding. Indeed, as the ALJ observed, AliveCor's expert "made clear he conducted no analysis

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on nexus." Appx282; *see also* Appx30720 ("I'm making an assumption that that part of the requirement will be met."). And "no [AliveCor] witness explained any of the[] projects or relationships" listed in the spreadsheet tabs. Appx282. The descriptions in the document do not make the link self-evident. Many refer broadly to "Confidential product information [redacted]" "Confidential product information [redacted]" "[redacted]" or "Confidential product information [redacted]." Appx11717-11718. Some descriptions suggest the absence of any link, describing expenses related to Confidential product information [redacted], for example, or Confidential product information [redacted]. Appx11717-11718.

The Commission nonetheless "inferred" that a nexus existed. Appx18. It did so by attributing to the ALJ a finding that "the contractor expenditures are directed to the sensors, circuitry, and the housing structure of the AliveCor wristbands, *i.e.*, the KardiaBands." Appx18 (citing Appx11709-11725, Appx11654, Appx281-282). But there was no such finding; the ALJ stated only that the descriptions in the spreadsheet "*suggest[]* a nexus to sensors, circuitry, and housing structure." Appx281. The only support for that statement, moreover, was a cut-and-paste of an unexplained subset of spreadsheet rows. Appx282.

AliveCor bore the burden of showing a nexus between its contractor payments and its asserted patents. *See Integrated Circuit Chips*, 2014 WL 12796437, at *29 (complainant must "shoulder its burden to establish the nexus requirement"); *cf. Motorola Mobility, LLC v. ITC*, 737 F.3d 1345, 1351 (Fed. Cir. 2013) (complainant "must prove" domestic industry requirement). Instead, AliveCor presented a spreadsheet with no testimony to link the $[Dollar amount redacted] worth of payments in that document to any "exploitation" of the asserted patents. 19 U.S.C. § 1337(a)(3)(C). And the ALJ found a nexus because Apple—the party that did not have the burden of proof—did not have its own expert "opine that any of these expenses have *no nexus* to the Asserted Claims." Appx282 (emphasis added). That was error. AliveCor's failure to link its investments to the asserted patents should have led to a finding that no domestic industry exists.

C. The Commission erred in finding AliveCor's qualifying expenditures were "substantial."

For the reasons discussed above, the Commission had no basis to find any investment in a relevant domestic industry. At most, however, the proper amount that could have been counted under subsection (C) was the $[Dollar amount redacted] in "contractor R&D" made in 2017 and 2018, when

KardiaBand was still offered. Appx271-272. AliveCor did not argue—and the Commission could not have found—that those amounts would qualify as "substantial investment" in exploiting the asserted patents. If the Court believes that $[Dollar amount redacted] is the correct number, therefore, a remand is required at a minimum for the Commission to determine whether that figure amounts to "substantial" investment.

But no remand is necessary. Even if the Commission's $[Dollar amount redacted] figure were correct, it was error to find that the total amount was a substantial investment. The Commission purported to find otherwise by comparing the $[Dollar amount redacted] that AliveCor spent on domestic contractor payments from 2016 through 2020 to the $[Dollar amount redacted] it spent during the same period on payments to non-U.S. contractors. Appx21-22 ("[A] comparison of the domestic contractor expenses to the foreign contractor expenses shows that the domestic expenditure is substantial."). The Commission's reasoning is obviously flawed. The question is not whether AliveCor spent relatively more domestically than it did overseas on one expense category. The question is whether AliveCor's qualifying domestic expenditures are themselves substantial. Under the Commission's reasoning, a domestic industry would exist if a

company spent $500 domestically over a five-year period, simply because it spent only $100 in foreign investments over the same period. That is plainly incorrect.

The Commission offered no other basis for finding $[Dollar amount] sufficient to show a "substantial investment" in domestic exploitation of AliveCor's patents. Nor could such a finding be supported by the record when these expenditures represent roughly [Financial information]% of AliveCor's revenues for the same period. Appx11929. The Commission's finding of a domestic industry should be reversed.

II. There Is No Section 337 Violation Because AliveCor Has Not Shown Infringement Of Valid Patent Claims.

A. Under the proper claim construction, Apple does not infringe.

Every asserted patent claim requires a smartwatch with executable instructions that cause a processor to "confirm the presence" of an arrhythmia based on data from an ECG sensor. Appx10092 18:18; Appx10072 26:45. The Commission construed "arrhythmia" as "a cardiac condition in which the electrical activity of the heart is irregular or is faster or slower than normal." Appx127. In the '731 patent claims, "the arrhythmia" being confirmed by the ECG is "an arrhythmia" that

has first been "detect[ed]" based on "data from the PPG sensor." Appx10072 26:42-45. In the '941 patent claims, the processor first determines that a "discordance" is present between the user's activity level and heart rate; then "indicate[s] to the user a possibility of an arrhythmia being present"; and finally "confirm[s] the presence of the arrhythmia" using the ECG sensor. Appx10092 18:12-18.

Apple's products do not operate as the claims contemplate. Consistent with Apple's FDA clearances, the PPG and ECG functionalities are wholly separate features that do not interact with each other and, indeed, physically cannot operate at the same time. Appx30672. The accused Apple Watch features relying on the PPG sensor run in the background. The ECG app uses the ECG sensor only when the user affirmatively requests it. But the Commission found infringement. It did so by essentially reading the word "confirm" out of the patent claims. But every relevant claim-construction consideration requires a connection between "an arrhythmia" that is first detected (or indicated) and "the arrhythmia" that is "confirmed." The Commission held otherwise, construing the terms to "not require a comparison of the ECG sensor results" to the "discordance determination" in the '941

patent or the "PPG data" in the '731 patent. Appx127; Appx207; *see* Appx6 (Commission determined not to review this issue). That ruling defies ordinary claim-construction principles and deprives the claim term "confirm" of any independent meaning. *Infra* Part II.A.1. Under the correct construction, moreover, it is indisputable that the accused Apple Watches do not infringe. *Infra* Part II.A.2. The Court should reverse the Commission's claim construction and its resulting infringement finding.

1. The claims require that the processor use ECG data to "confirm … the arrhythmia" first detected by the PPG sensor.

The Commission committed two related errors in construing the "confirm" terms: (1) equating "confirming" the arrhythmia with merely "detecting" an arrhythmia; and (2) requiring no correlation between the PPG and ECG results. Appx327-328; Appx330-332; Appx127-136; Appx149-150; Appx207-211; Appx94-98. Under the Commission's construction, any standalone device that has PPG notifications and ECG capability would fall within the claims. Appx148; Appx150.

"Confirm" is not a technical or confusing term. It is widely and uniformly understood to require a connection or comparison between

two things. A person schedules an appointment with their physician; the doctor's office calls to "confirm" that same appointment. A scientist posits a hypothesis, then performs an experiment to "confirm" whether real-world evidence supports that hypothesis. A person places a food-delivery order, and the restaurant "confirms" that the items requested are available. When something is "confirmed," in other words, it is verified. *See* Appx436-439; Appx441-443. That plain meaning of "confirm" is also the meaning supported by the claim language, the specification, and the stated purpose behind the claimed inventions. Appx436-439; Appx441-443. The Commission's construction conflicts with this meaning and finds no support in the record.

The claim language uses different verbs when describing the different roles of the PPG and ECG data. In the '731 patent claims, for example, the processor must first "detect, based on the PPG data, the presence of an arrhythmia" before it can "confirm the presence of the arrhythmia based on the ECG data." Appx10072 26:42-46. "Confirm" and "detect" must have different meanings to give effect to each term. *See CAE Screenplates Inc. v. Heinrich Fiedler GmbH & Co. KG*, 224 F.3d 1308, 1317 (Fed. Cir. 2000) ("In the absence of any evidence to the

contrary, we must presume that the use of these different terms in the claims connotes different meanings.").[5]

Similarly, claim 12 of the '941 patent recites first "determin[ing]" if there is a discordance between the user's activity level and heart rate (relying on the PPG signals), "indicat[ing]" to the user "a possibility of an arrhythmia" based on that determination, then using "the ECG sensor to confirm the presence of the arrhythmia." Appx10092 18:12-18. Not only does this claim again use different verbs to describe the respective roles of the PPG and ECG data, it also demonstrates the link between them. Just like the scientist described above, the smartwatch of claim 12 posits a hypothesis (a possible arrhythmia) and then uses ECG data as the experiment to confirm that hypothesis. If the claims did not require any relation between the possible arrhythmia and the arrhythmia shown on the ECG, as the Commission concluded, it would make no sense to use the word "confirm."

[5] Indeed, AliveCor agreed before the Patent Trial and Appeal Board that "confirm" and "detect" are "discrete requirements." *Apple Inc. v. AliveCor, Inc.*, IPR2021-00971, Paper 42 at 30 (P.T.A.B. Dec. 6, 2022).

Other aspects of the claim language likewise make clear that the PPG and ECG sensors are collecting data about the same arrhythmia. Claim 12 of the '941 patent and claim 1 of the '731 patent recite first determining or detecting "an" arrhythmia via the PPG readings and then confirming "the" arrhythmia via the ECG reading. Appx10092 18:12-18; Appx10072 26:42-46. "The" arrhythmia being confirmed by the ECG reading must therefore be the same arrhythmia that was just detected through the PPG readings. *See Wi-Lan, Inc. v. Apple Inc.*, 811 F.3d 455, 462 (Fed. Cir. 2016) ("Subsequent use of the definite articles 'the' or 'said' in a claim refers back to the same term recited earlier in the claim.").

The patent specifications confirm this correlation between the PPG and ECG readings. For example, the '941 patent specification explains that an ECG is recorded "when a user is given an indication that an intermittent arrhythmia is occurring" from the PPG readings. Appx10085 4:27-32; *see also* Appx10086 5:8-11 ("The one or more continuously sensed parameters of the user of such a technology … are then used to indicate to the user to use a device or system to sense an ECG."); Appx10088 9:23-37 (detailing example PPG reading that would

trigger an ECG); Appx10083 (Fig. 7) (directing user to "[t]ake an ECG" based on received PPG signals or, upon detecting typical heart patterns, indicating "no need for ECG"). The '731 patent specification similarly describes, for example, "monitoring a subject" by tracking heart-rate data "to determine when to record an [ECG]." Appx10053 (Fig. 10); Appx10062 6:3-5; *see also, e.g.*, Appx10071 23:20-30 ("The smartphone includes a processor that may analyze the heart rate information [from the heart-rate monitor] and when an irregularity is determined, may indicate … to the subject that an ECG should be recorded."). The Commission's narrow focus on the specifications' failure to use the term "confirm" in these descriptions missed the more important point that, substantively, that is what the specifications are describing. *See* Appx128-136.

The specifications similarly refute the Commission's interpretation of the claims to cover, for example, first detecting atrial fibrillation with PPG data and then detecting tachycardia with the ECG data. Appx327. The specifications, like the claim language, make clear that "confirmation" refers to verifying the same arrhythmia that was previously detected. *See, e.g.*, Appx10091 15:27-32 ("this particular

discordance may be indicative of the presence of atrial fibrillation and it should be confirmed with the ECG"); Appx10091 15:55-59 ("atrial fibrillation may be present and it should be confirmed with the ECG"); Appx10091 15:39-43 ("supraventricular tachycardia may be present and it should be confirmed with the ECG").

Indeed, that is the stated purpose of having both types of sensor in the claimed inventions. As the patent specifications describe, "intermittent arrhythmias"—like atrial fibrillation—"do not always present," such that diagnosing these arrhythmias "may be difficult" because "it is not practical to be prepared to apply one of the aforementioned diagnostic modalities at the exact time that an individual experiences an intermittent arrhythmia." Appx10084 1:35-53. The patents purport to address this problem by monitoring certain parameters (such as heart rate and activity level) "continuously" and, if a possible arrhythmia is detected, "an electrocardiogram may be caused to be sensed." Appx10084 1:58-2:3; Appx10060 2:39-64; Appx10061-10062 4:57-5:10. In other words, the data from the PPG sensor is what alerts the user to what they otherwise wouldn't know: that they might be experiencing a dangerous arrhythmia, and they should take an ECG

reading to confirm. *See also* Appx30292-30293 (AliveCor's expert describing "the core part of the invention" as using the PPG to "measure[] heart rate and heart rate parameters in the background" and, "[i]f you happen to identify irregularities," "provide a trigger to the user to take an ECG"). If the sensors' functions did not need to be correlated, it would defeat the purpose of using PPG data to know when to take an ECG.

The Commission's claim construction failed to reflect the ordinary meaning of "confirm" as used in the patents. The Court should instead adopt Apple's construction and require the ECG to confirm the particular arrhythmia detected by the PPG sensor. Appx737.

2. Under the proper construction of the "confirm" terms, Apple cannot infringe.

Under the proper construction of the "confirm" terms, the Apple Watch cannot infringe the asserted claims. The Commission found otherwise because Apple's HHRN and IRN features can indicate a potential arrhythmia to a user, while the ECG app can independently indicate a potential arrhythmia to the user. *See* Appx146-150; Appx935-937. That is not enough to infringe.

The claims require that "instructions" stored on and executed by the device's processor perform the "confirm[ing]." Appx10092 18:9-18; Appx10072 26:38-46. At most, the Commission identified the possibility that *a user* of an Apple Watch might make a mental comparison of two independent readings. Appx149-150; Appx213-214. That does not satisfy the claims.

There is no dispute about how the accused technology works. HHRN, IRN, and the ECG app are separate functions that do not interact with each other. HHRN and IRN each rely separately on the Background Heart Rate data from the PPG sensor. Appx30307-30309; Appx30312-30314. If HHRN detects a heart rate above a user-set threshold, or if IRN detects an irregular heart rhythm, each feature provides a notification to the user of that finding. The notifications do not refer to ECG at all, let alone Apple's ECG app. Appx30307-30309; Appx30312-30314. They certainly do not prompt the user to take an ECG or cause the Watch to initiate the ECG app. It is undisputed that nothing in the Apple Watch source code triggers an ECG recording based on results from the PPG readings (either HHRN or IRN). *See* Appx30463-30464 (AliveCor's expert); Appx30892 (Apple's expert).

The ECG app, meanwhile, operates only when the user affirmatively opens it and affirmatively takes a reading for 30 seconds. Appx30766. It does not use any data or input from the PPG sensor, HHRN, or IRN. Appx30462-30464; Appx30763; Appx30766-30769. The ECG app relies solely on its own detection of electrical activity of the heart to determine whether atrial fibrillation may be present. Appx11249-11324; Appx11325-11401; Appx30891-30892; Appx30894-30896; Appx30859-30860. It is incapable of comparing this detected data with the readings taken from the PPG sensor and processed by HHRN and IRN. The ECG app therefore does not "confirm" any previously detected arrhythmia. Indeed, Apple originally considered providing this kind of functionality, but determined it was not "an additive experience," particularly given the "really excellent" results Apple achieved with IRN alone. Appx30769-30770. In the configuration Apple chose, moreover, it would violate the separate FDA clearances for IRN and ECG app to "link those two features" in any way. Appx30780-30781.

There are therefore no "instructions" on the Apple Watch processor that "confirm" the presence of an arrhythmia as the claims

require. The Commission observed that an Apple Watch user theoretically could decide to take an ECG shortly after receiving an HHRN or IRN notification. Appx149-150; Appx213-214. But even in that situation, the user is simply receiving two different readings of cardiac data; the ECG reading on the Watch does not "confirm" anything about the initial reading. There is no substantial evidence to support a finding of infringement under the correct claim construction.

B. The exceedingly weak evidence of secondary considerations cannot overcome Apple's showing of obviousness.

The Commission found that Apple demonstrated a "strong" prima facie case of obviousness for all independent claims and most dependent claims of the asserted patents. Appx203; Appx232. But it upheld the validity of a handful of dependent claims based on minor additions that are rendered obvious by the prior art. More troublingly, the Commission concluded, based on admittedly tenuous evidence of industry praise and alleged copying, that secondary considerations somehow outweighed Apple's strong showing. The Commission's conclusion of non-obviousness is contrary to law and unsupported by substantial evidence.

1. The Commission erred in concluding that Apple failed to show prima facie obviousness as to a handful of dependent claims.

The Commission found that AMON, a 2004 IEEE paper describing a "wearable medical monitoring and alert system targeting high-risk cardiac/respiratory patients," disclosed or rendered obvious the hardware components and software functionalities of the smartwatch recited in independent claims 12 of the '941 patent and 1 of the '731 patent. Appx11966-11978; *see* Appx178-188; Appx232.

But it held that Apple failed to show how the prior art disclosed or rendered obvious the limitations of three sets of dependent claims that make only minor additions to the limitations found to be met by the prior art: (a) an ECG rhythm strip display ('941 claim 21 and '731 claim 15); (b) a machine-learning algorithm ('731 claims 3 and 5); or (c) specific types of mathematical analysis of PPG-based heart-rate variability data ('731 claims 9-10). The Commission's analysis misconstrued the teachings of the prior art, ignored AliveCor's own admissions, and narrowly focused on the literal disclosure of the prior art, rather than what would have been obvious to a person of ordinary skill.

ECG rhythm strip display claims. Claim 21 of the '941 patent and claim 15 of the '731 patent each recite that the processor in the claimed smartwatch can "display an ECG rhythm strip from" the electrical signals sensed by the ECG. Appx10092 18:46-48; Appx10073 27:36-38. The Commission agreed that AMON discloses a smartwatch with a processor that measures ECG signals and a "screen" that "display[s]" results. Appx182; Appx184-185; Appx198. But it nevertheless concluded that AMON does not disclose "display[ing] an ECG rhythm strip" based on its ECG analysis. Appx198.

AMON expressly depicts a "sample" ECG rhythm strip created using the AMON device:

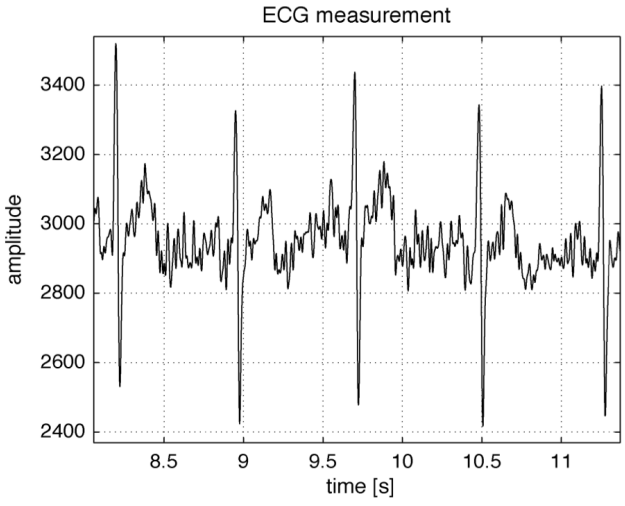

Fig. 4. AMON one lead ECG sample measurement: A digital bandpass filter [0.015 40]Hz has been applied to reduce noise. Heart rate, QT interval and QRS duration can be detected.

Appx11969. That device, pictured below, plainly includes a display, as the article explains:

Appx11967. And AMON describes using the device to provide "real-time feedback to the user." Appx11967; *see* Appx31129; Appx31141-31142; Appx12171-12172. AliveCor's expert conceded that any standard ECG device in the prior art would "create[]" a digital cardiac rhythm strip. Appx31296-31297. AMON is no exception.

The Commission's reasoning focused narrowly on AMON's Figure 4, and it inexplicably concluded that the depiction is merely a "rhythm strip created for publication." Appx198. But AMON describes Figure 4 as the output of the device. Appx11969; Appx31129. And the Commission's cursory conclusion that there was no identifiable "benefit for the processor to drive" a display showing a rhythm strip, Appx199, is

bizarre. The whole point of taking an ECG is to produce this kind of display, as underscored by Apple and AliveCor's experts' mutual testimony that ECG devices have been creating digital rhythm strips for many years, so that physicians can use the data to diagnose heart problems. *See* Appx31088; Appx31296-31297. A skilled practitioner seeking to accomplish AMON's goals of ensuring that high-risk cardiac patients' heart "problems will be detected in time," Appx11966, would at the very least have found it obvious to use AMON to display ECG rhythm strips.

Machine-learning claims. Claims 3 and 5 of the '731 patent recite, respectively, inputting "PPG data" and "HRV [heart-rate variability] data" into "a machine learning algorithm trained to detect arrhythmias." Appx10072 26:53-56, 26:64-67. The Commission agreed that AMON expressly discloses "employ[ing] a … machine learning algorithm" that "improve[s] [AMON's] detection" of "a number of medical parameters," which are then used to determine when the user is experiencing an arrhythmia. Appx183-184 (quotation marks omitted); Appx11969; Appx11971. But the Commission focused on the fact that, in AMON, only ECG inputs are fed into the algorithm, and

the algorithm is intended to help "determin[e] what the signals are," not "determin[e] whether the signals are" an arrhythmia. Appx224-227.

In both respects, the Commission improperly focused solely on what is literally stated in AMON. The obviousness analysis "*requires* an assessment of the … background knowledge possessed by a person having ordinary skill in the art." *Koninklijke Philips N.V. v. Google LLC*, 948 F.3d 1330, 1337 (Fed. Cir. 2020) (quotation marks omitted). As Apple's expert, Dr. Stultz, testified, machine learning is simply "a class of methods that allow machines to learn from data." Appx31137; *see also* Appx10064 9:67-10:3 (acknowledging that "[a]ny number of machine learning algorithms … may be trained to identify … arrhythmias"). Dr. Stultz discussed the algorithm disclosed in AMON and provided his opinion that claims 3 and 5 would have been rendered obvious. Appx31136-31138; *see also* Appx12184-12188. And AliveCor's expert, Dr. Efimov, agreed that even years before the '731 patent's 2013 priority date, machine-learning techniques to classify arrhythmias from PPG and heart-rate variability data were known. Appx31299-31300; *see* Appx11985-11998 (2008 paper disclosing machine-learning

algorithms using heart-rate variability data derived from PPG to identify atrial fibrillation).

The Commission faulted Apple for supposedly "not argu[ing]" that claims 3 and 5 would have been obvious in view of the "knowledge of a skilled artisan." Appx226-227. That is incorrect. Apple expressly argued that AMON discloses or "renders obvious" to a skilled artisan "all of the '731 patent's Asserted Claims," Appx806; *accord* Appx811, and Apple specifically highlighted Dr. Stultz's testimony that this artisan would have been "well-aware" of "concepts fundamental to the claimed limitations of all of the Asserted Patents," including machine-learning algorithms using PPG and heart-rate variability data to detect arrhythmias. Appx772-773; *see also* Appx1153.

Mathematical analysis claims. Claims 9 and 10 of the '731 patent recite specific "features" that the smartwatch processor will extract from PPG data to detect an arrhythmia. Claim 9 specifies that these features "comprise a nonlinear transform of R-R ratio or R-R ratio statistics with an adaptive weighting factor." Appx10073 27:14-16. Claim 10 specifies that the features "are features of an HRV [heart-rate variability] signal analyzed geometrically." Appx10073 27:17-19. As

the '731 patent acknowledges, both methods of analysis were "known in the art." Appx10063-10064 8:64-9:2. Yet the Commission found these claims non-obvious because the particular prior-art references Apple cited—AMON as well as the Almen reference, a patent published in 2005—do not expressly disclose these same specific modes of analysis. Appx166; Appx229-231; *see* Appx11930-11965.

This was error. The Commission acknowledged that AMON in view of Almen "discloses measurement of HRV" from PPG data. Appx229; *see* Appx194. A skilled artisan would have found it obvious to modify these devices to "supply[] [these] missing claim limitation[s]," particularly given the '731 patent's "binding" admission that nonlinear and geometric means of measuring PPG-derived heart rate variability signals were known. *Qualcomm Inc. v. Apple Inc.*, 24 F.4th 1367, 1375-76 (Fed. Cir. 2022). Apple's expert additionally explained why a person of ordinary skill would have been motivated to use these "off-the-shelf methods" to accomplish AMON and Almen's teachings, in light of their utility in accomplishing the "hard part" of calculating heart rates—"determining the R-R distances." Appx31140-31141. The Commission's

finding of non-obviousness is contrary to law and unsupported by substantial evidence.

2. The Commission erred in concluding that extraordinarily weak secondary considerations "overcome" Apple's strong prima facie showing of obviousness.

Factors such as commercial success or industry praise, "without invention[,] will not make patentability." *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 283 (1976) (citation omitted). Apple made a "strong" prima facie case of obviousness. Appx203; Appx232. Because even "strong objective evidence" of non-obviousness cannot overcome a strong showing of obviousness, AliveCor would have needed an extremely strong showing of secondary considerations to preserve its patents' validity. *Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1472 (Fed. Cir. 1997). AliveCor did not and cannot meet that burden.

The Commission rightly deemed AliveCor's evidence of commercial success "weak" and did not consider it in the final analysis. Appx44. The remaining secondary considerations cited by the Commission amounted to (1) industry praise (authored in part by AliveCor affiliates) that was "not … unqualified" and not focused on the patented technology, and (2) "circumstantial[]" evidence that was "not

especially impressive" yet somehow suggested that Apple copied AliveCor by implementing technology it had been working on for years before the KardiaBand existed. Appx200-203. Yet the Commission concluded (over Chairman Johanson's dissent) that this paltry showing somehow outweighed Apple's strong showing that AliveCor's patents contributed nothing new. Appx44 n.29; Appx47 n.30.

The Commission's conclusion cannot be upheld. There is no substantial evidence to support a finding of any relevant industry praise or copying. And, even accepting those findings, the secondary considerations here do not come close to outweighing Apple's showing of obviousness.

Alleged Praise. "While praise in the industry for a patented invention, and specifically praise from a competitor tends to indicate that the invention was not obvious, self-serving statements from researchers about their own work do not have the same reliability." *In re Cree, Inc.*, 818 F.3d 694, 702 (Fed. Cir. 2016) (quotation omitted). But the Commission's finding of supposed industry praise for AliveCor's invention was based heavily on such self-serving statements.

The Commission gave the most weight to a 2018 article in a medical journal praising the accuracy of KardiaBand's ECG algorithm for detecting atrial fibrillation. Appx11644-11651; *see* Appx200-203. The Commission deemed this article "impressive" and "unusual," Appx200, Appx203, ignoring the fact that the lead author was "on the advisory board of Alive[C]or." Appx11630. Similarly, the doctor quoted in another article the Commission relied on "helped test the KardiaBand"—and the article otherwise relies heavily on information provided by AliveCor's then-CEO. Appx11632-11636.

Furthermore, as the Commission itself "[a]dmitted[]," AliveCor's examples of industry praise "generally focus on the ECG function" of KardiaBand and its associated software. Appx200. What the industry found praise-worthy was, for example, the "ease and accuracy of the ECG recordings." Appx11629-11630; *see also* Appx11999-12004; Appx11633; Appx11644-11651. But AliveCor's asserted patents make no claims to improved ECG sensors or ECG analysis techniques. *See* Appx187 (AliveCor's patent offers no "information on how to achieve" reliable ECG measurements and "effectively assumes such devices are ordinary"); Appx10235 ("ECG watches [existed] since the early 1990s").

The claimed features of the invention—such as the PPG and activity sensors on the Apple Watch, discordance detection, or arrhythmia notifications—are mentioned in only a few documents and are not the focus of the alleged praise. *See* Appx11999-12004 (describing SmartRhythm as "kind of neat" but mainly criticizing the feature); Appx11632-11636 (including single quote from doctor who tested KardiaBand describing SmartRhythm as "important"). AliveCor "failed to connect the evidence of industry praise to the novel elements of the claims," and the Commission should not have relied on this evidence to defeat Apple's strong showing of obviousness. *S. Ala. Med. Sci. Found. v. Gnosis S.P.A.*, 808 F.3d 823, 827 (Fed. Cir. 2015).

Alleged copying. The Commission found that AliveCor's "evidence of copying is not especially impressive" and "not exactly a smoking gun." Appx202-203. That was an understatement.

"[C]opying requires evidence of efforts to replicate a specific product." *Wyers*, 616 F.3d at 1246. But the bulk of the evidence—all of which the Commission deemed circumstantial, Appx202—is irrelevant because it predates the public release of the KardiaBand in November 2017—the earliest date Apple had access to any product found to

practice the asserted claims. Although AliveCor publicly disclosed a prototype of the KardiaBand at a 2015 conference, that prototype concededly did not have the SmartRhythm software necessary to practice the claims. *See* Appx30131. And none of the documents cited by the Commission indicate that Apple had access to a version of the KardiaBand with SmartRhythm before its public release. Some of those documents plainly refer to AliveCor's earlier products—not KardiaBand. Appx11653; Appx11524. And the others cannot provide even circumstantial evidence of Apple trying to copy AliveCor's product. *See* Appx11652; Appx11485; Appx11492. That Apple employees may have been benchmarking Apple Watch's ECG functions against a non-practicing prototype of KardiaBand (or other AliveCor products altogether) cannot show copying of the patented invention. *See Liqwd, Inc. v. L'Oreal USA, Inc.*, 941 F.3d 1133, 1137 (Fed. Cir. 2019) (copying "requires … access to" a specific product or work that discloses the asserted claims) (citation omitted)); *Extang Corp. v. Truck Accessories Grp., LLC*, No. CV 19-923 (KAJ), 2022 WL 607868, at *2 (D. Del. Feb. 18, 2022) (Jordan, J.) ("[b]enchmarking is a common practice" that is "not inherently suspect").

The only post-November 2017 evidence that the Commission credited does not show copying either. In an FDA submission, Apple described the software component of the KardiaBand as the "product most similar" to Apple's ECG app. Appx11578-11579; Appx11606; Appx11626. But "similarities between an issued patent and an accused product do not, on their own, establish copying." *Liqwd*, 941 F.3d at 1137. Moreover, the KardiaBand is only one among many "ECG products" cited in Apple's submissions, which further explain that "ECG devices are not novel" and cite "[k]ey differences" between AliveCor's product and Apple's. Appx11626-11627; Appx11578-11579.

There is, therefore, no evidence of copying at all. And the evidence the Commission cited certainly cannot be called substantial when compared against the extensive evidence showing that Apple independently began its effort to develop an ECG sensor, PPG sensor, and related software for its smartwatch in 2012, well before the filing date of any of AliveCor's patent applications and five years before the KardiaBand's release. *See, e.g.*, Appx30738-30743; Appx12029; Appx12206. While the Commission observed that Apple "'shelved' an attempt to put an ECG on the first versions of the Apple Watch,"

Appx202, it made no finding—and there is no evidence suggesting—that Apple "shelved" its ECG development due to technical challenges. On the contrary, the record shows that Apple chose to "backburner" its ECG development due to "*regulatory* challenges" with placing an ECG sensor in the Apple Watch. Appx11038-11039; *see also* Appx30745 (describing regulatory approval schedule for ECG features). A company's decision to assign a "low priority" to development of a product is not evidence that it tried and failed to develop that product. *Vandenberg v. Dairy Equip. Co.*, 740 F.2d 1560, 1567 (Fed. Cir. 1984).

Weight of secondary considerations. Even assuming the Commission correctly found evidence of both industry praise and copying, that evidence still cannot outweigh Apple's "strong" showing of obviousness. *See Wyers*, 616 F.3d at 1246. "Obviousness is ultimately a legal determination, and a strong showing of obviousness may stand even in the face of considerable evidence of secondary considerations." *ZUP, LLC v. Nash Mfg., Inc.*, 896 F.3d 1365, 1374 (Fed. Cir. 2018) (quotation omitted).

Here, nearly every claim limitation is expressly disclosed by a single prior-art reference, and the few that are not would have been

obvious to a skilled practitioner. Given this uniquely "strong" showing of obviousness, Appx203; Appx232; Appx44 n.29; Appx47 n.30, it would take exceedingly powerful secondary evidence to establish non-obviousness. *See, e.g.*, *Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007) (even "substantial evidence of commercial success, praise, and long-felt need" was "inadequate" to establish non-obviousness, "given the strength of the prima facie obviousness showing").

That high bar is not met here. Copying is, at best, "only equivocal evidence of non-obviousness in the absence of more compelling objective indicia of other secondary considerations." *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1380 (Fed. Cir. 2000). And the copying evidence here is "not especially impressive," Appx203; it shows, at most, that Apple was aware of AliveCor's product and contrasted it with the Apple Watch. The Commission gave the industry praise evidence more credence than it did copying, Appx203, but still found nothing about that praise that could be considered so exceptional that it could outweigh the strong showing of obviousness. The Commission's conclusion of non-obviousness cannot stand.

III. Because Exclusion Of The Apple Watch Will Risk Lives And Jeopardize Critical Research, The Commission Should Not Have Issued A Remedy.

Even if the statutory requirements for a Section 337 violation were met, the Commission should not have excluded the accused Apple Watches from importation. This extraordinary relief is not supposed to be automatic. Before entering it, the Commission must first "consider[] the effect of such [order] upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers." 19 U.S.C. § 1337(d), (f). Congress instructed the Commission not to issue a remedy if doing so "would have a greater adverse impact" on these "public interest factors" "than would be gained by protecting the patent holder." *Certain Fluidized Supporting Apparatus*, Inv. No. 337-TA-182/188, Comm'n Op., 1984 WL 63741, at *2 (Oct. 1984).

The Commission has long since abdicated its statutory obligation to protect the American public, not just patent owners. The Commission purports to give the public interest "overriding consideration[] in the administration of" Section 337. *Certain*

Microfluidic Devices, Inv. No. 337-TA-1068, Comm'n Op., 2020 WL 225020, at *15 n.25 (Jan. 10, 2020) (quoting S. Rep. No. 93-1298, at 197 (1974)). But while the Commission has found a Section 337 violation in hundreds of cases, it has declined to exclude products found to infringe "in only three investigations"—most recently in 1984. *Spansion, Inc. v. ITC*, 629 F.3d 1331, 1360 (Fed. Cir. 2010). For nearly four decades—and particularly in the 17 years since the Supreme Court's *eBay* decision—the Commission's willingness to rubber-stamp injunctive relief has fostered patent holders' use of Section 337 to achieve holdup. *See, e.g.*, Colleen V. Chien & Mark A. Lemley, *Patent Holdup, The ITC, And The Public Interest*, 98 Cornell L. Rev. 1, 2, 39-40 (2012). Apple is just the latest U.S. company facing exclusion of an innovative product that offers an array of benefits to American consumers, based on patents that—even if valid and infringed—cover only one specific feature of that product, asserted by a patent holder who does not offer the marketplace a competing product.

Apple recognizes that this Court reviews the Commission's public-interest analysis deferentially. *Spansion*, 629 F.3d at 1358. But this case falls into the precise category that the Commission has previously

held warrants withholding of its injunctive remedies: the Apple Watch is "necessary for something socially important," including "human health," and "no other supplier could meet demand in a commercially reasonable time period" if an exclusion order issues. *Chien*, *supra*, at 20.

Yet the Commission refused to withhold its remedial orders. Appx52-82. Amidst an analysis beset with arbitrary and capricious reasoning, two errors stand out. First, the Commission arbitrarily concluded—contrary to all record evidence—that there are other available products that can remedy the serious health harms that will be caused by exclusion. And second, the Commission arbitrarily decided—again without any record basis—that the numerous ongoing and planned research studies involving Apple Watches will not be jeopardized by exclusion. The Court is "bound to reverse" the Commission's entry of remedial orders because the agency "failed to consider an important aspect of the problem" and "offered an explanation for its decision that runs counter to the evidence before the agency." *Saad v. S.E.C.*, 718 F.3d 904, 910-11 (D.C. Cir. 2013) (quoting *Motor Vehicle Mfgs. Assoc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S.

29, 43 (1983)); *see In re Vivint, Inc.*, 14 F.4th 1342, 1351 (Fed. Cir. 2021) (agency abuses its discretion when the "record … contains no evidence on which the [agency] could rationally base its decision").

A. The Commission arbitrarily concluded that other products can remedy the serious health harms that will result from exclusion.

The accused Apple Watches provide profound health and wellness benefits directly to consumers. Tens of thousands of current Apple Watch users receive irregular heart rhythm notifications or atrial fibrillation warnings from their Apple Watch's heart-health monitoring features each day, Appx1509, and Apple has received over 300 unsolicited testimonials from users detailing how Apple Watches with these features have "saved their lives." Appx1508; *see, e.g.*, Appx1645-1646 ("Thanks to Apple, I'm awake, alive, and breathing better than ever. The Apple Watch saved my life."); *see, e.g.*, Appx1586 ("Apple Watch literally saved my life."); Appx1612-1613 ("thank you for saving my life."); Appx1616 ("My apple watch saved my life. Literally, not figuratively."). Apple Watch provides an especially valuable benefit to users who are unaware they have a cardiac condition but happen to purchase a Watch for its other industry-leading features. As one

cardiologist explained, "[m]any of these patients[']" heart conditions "would have either been diagnosed much later or missed altogether without an Apple Watch." Appx1380-1382.

The public-interest analysis must consider whether other products can replace the benefits offered by the accused product. *See Certain Pers. Data Devices*, Inv. No. 337-TA-710, Comm'n Op., 2011 WL 12488979, at *39 (Dec. 29, 2011). Any such product must (a) be a comparable wearable device; (b) include features equivalent to ECG, IRN, and HHRN; and (c) have FDA clearance for both its ECG and IRN-equivalent features. As Apple explained in its briefing to the Commission, there is no such product. *See* Appx1476-1479, Appx2769-2777.

The Commission concluded that a two-device solution—in which consumers must purchase both "wearable devices that have IRN and HHRN functionality" and "portable ECG devices"—represents "a reasonable alternative" to the Apple Watch. Appx73. But many users who are likely to benefit from the heart-health features of Apple Watch—users who are unaware they have a heart condition—are unlikely to have any reason to purchase a separate ECG monitor. *See*

Appx2719-2720; Appx1387-1388; Appx12007-12008; Appx1380-1381. The Commission had no answer to this problem. It simply cited AliveCor's position "that a combination of portable devices can readily replace the infringing Apple Watches" and offered an unexplained endorsement of "these comments." Appx73.

The Commission even suggested that consumers might replace the accused Apple Watches by pairing an Apple Watch SE—which does not contain an ECG sensor—with AliveCor's defunct KardiaBand. Appx75. It is undisputed that the KardiaBand has not been on the market for more than four years. Yet the Commission suggested that Apple should somehow "chang[e] its software to again allow compatibility" with this non-existent product—a business decision that, even if feasible, would have wide-reaching effects on Apple and other third-party developers. Appx75-76 n.39.

The Commission's unfounded suggestions did not stop there. It also reasoned that FDA clearance would be *optional* for an alternative product's ECG and IRN-equivalent functionality. Appx73-74. The FDA would surely be surprised to hear this view, given that its own regulations impose Class II controls over any "photoplethysmography

[PPG] analysis software device for over-the-counter use" and any "electrocardiograph software device for over-the-counter use." 21 C.F.R. §§ 870.2790, 870.2345. To receive FDA clearance, a device must undergo extensive clinical testing and validation, ensuring the device's accuracy. *See* Appx1523; Appx1572-1575. Non-FDA-cleared devices that purport to measure cardiac activity such as irregular rhythms may be "inaccurate" and "may lead to ill-advised decisions about medications and treatment." Appx1391 (StopAfib.org); *see also* Appx1562. The Commission missed the fact that the law requires FDA clearance, and it offered no basis to question the importance of FDA clearance in ensuring accuracy (apart from characterizing StopAfib.org's comments as mere "general admonition[s]," Appx74).

Perhaps recognizing that its hypothetical alternatives of one rogue device or two separate devices lacked any shred of record support, the Commission offered a fallback. It suggested that FitBit's Charge 5 and Sense 2—the only other products in the record with FDA-cleared ECG and IRN-equivalent functionality—are adequate alternatives. Appx74-75. But, as Apple explained, there is "a fundamental mismatch in what Apple's and Fitbit's products do and why people buy them." Appx1478.

The Fitbit devices have a "narrow" focus on fitness, Appx2777; neither offers features available on Apple Watches such as voice-assist, two-way calling and messaging, music storage, or access to third-party apps. Appx2776-2777; Appx1478. The Commission arbitrarily ignored this evidence. *See* Appx75 (wrongly concluding that Apple provided "no evidence" for its assertions). And its suggestion that Apple "concede[d]" that these products "are alternatives" (Appx74) is simply untrue. Apple told the Commission: "Sense and Charge 5 would fail to compensate for the significant harm to the public health and welfare that exclusion of Apple Watch would cause." Appx1478; *see also* Appx2776-2777.

Even if an adequate alternative to Apple Watch did exist, however, ongoing supply chain issues and other logistical constraints—combined with the tremendous volume of Apple Watches subject to exclusion—would make it impossible for any other manufacturer to replace the excluded products "within a commercially reasonable length of time." *Certain Automatic Crankpin Grinders*, Inv. No. 337-TA-60, Comm'n Op., 0079 WL 419349, at *10 (Dec. 1979); *see* Appx1479-1483; Appx2777-2778. Indeed, Fitbit and Samsung—the second- and third-most popular smartwatch manufacturers in the United States—would

need to rapidly increase their production of ECG-enabled devices by 2000% and 375%, respectively, to replace the sudden shortfall of accused Apple Watches. Appx2712; Appx2716-2717; Appx2638-2639; Appx2778. Under current conditions, even Apple would be able to achieve only a 10% increase in Watch production capacity within one year. *See* Appx1582-1583. The notion that other manufacturers could achieve 40 or 200 times that increase in even less time is simply not credible.

The Commission faulted Apple for failing to provide information about Fitbit and Samsung's "manufacturing capabilit[ies]." Appx75-76. Yet the Commission prevented Apple from obtaining that confidential information by refusing Apple's request to delegate consideration of the public interest to the ALJ, Appx398, which was the only way Apple could have served third-party subpoenas to those companies, *see* 19 C.F.R. § 210.32. The Commission itself could have sought out such information in complying with its obligation to protect the public interest. *See* 19 C.F.R. § 201.9 (authorizing Commission to "employ any means authorized by law" to "obtain[] information necessary to carry out its functions and duties"). Instead it blamed Apple.

The Commission also reasoned that, because 10 million Apple Watch users have activated IRN and ECG and roughly 6 million Americans currently have atrial fibrillation, most or all individuals with atrial fibrillation must "have already purchased and activated IRN and ECG on their Apple watches" or other devices. Appx78. The Commission's logic is deeply flawed. The U.S. population numbers in the 300 millions. Roughly 2.5 million Americans do not know they have atrial fibrillation, Appx1394, and many millions more will develop atrial fibrillation through the life of the exclusion order. There is not a shred of support for concluding that most or all of these individuals are among the Apple Watch users who already have access to the features that could save their lives.

B. The Commission arbitrarily concluded that research studies involving the accused Apple Watches will not be jeopardized by exclusion.

"[S]cientific research … is precisely the kind of activity intended by Congress to be included when it required the Commission to consider the effect of a remedy on the public health and welfare." *Certain Inclined-Field Acceleration Tubes*, Inv. No. 337-TA-67, Comm'n Op., 0080 WL 594319, at *11 (Dec. 1980). And the Apple Watch is a critical

part of multiple ongoing and planned research studies that have the potential to "revolutionize" the management of atrial fibrillation and other medical conditions. Appx1381-1382; *see also* Appx1401-1402; Appx1512-1514. For example, the REACT-AF study is a seven-year, $37 million government-funded research trial set to begin in spring 2023. This trial is designed to determine if Apple Watch's heart-monitoring features can help cardiac patients minimize the amount of time they need to take potentially dangerous blood-thinning medications. *See* Appx1381-1382; Appx1513. In another ongoing study, the Mayo Clinic is enrolling 1,000,000 participants to assess the potential of the accused Apple Watches to detect unknown and asymptomatic diseases. *See* Appx1512-1513; Appx1401-1402.

In the words of a lead investigator on REACT-AF, "high impact studies like ours which involve the use of Apple Watch would simply not be conducted" if the accused Apple Watches are excluded, resulting in a "devastating impact on clinical care and clinical science." Appx1381-1382; *see also, e.g.*, Appx1403; Appx1391; Appx1408. The Commission nevertheless concluded that *not a single study* will be adversely affected by exclusion of the accused Apple Watches. Its sole reason: "Apple does

not contend that [ongoing] studies need additional Apple Watches for additional participants, much less quantify that need." Appx71. That is false. Apple specifically asserted that exclusion would harm "ongoing studies that are recruiting" now and in the future, and it quantified those needs. Appx1470; *see* Appx2781-2782. Participants who join ongoing and planned Apple Watch studies will require Apple Watches that are under the cloud of the Commission's remedial orders.

The Commission had no basis to conclude that all this critical and publicly supported research will be "unaffected" by exclusion. Appx71.

CONCLUSION

For the foregoing reasons, the Court should reverse the Commission's finding of a Section 337 violation.

April 17, 2023

Respectfully submitted,

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ADDENDUM

Commission Opinion, filed December 22, 2022 ..... Appx1

Notice of Commission Final Determination Finding a Violation of Section 337, filed December 22, 2022 ..... Appx90

Notice of Commission Determination to Review in Part a Final Initial Determination Finding a Violation of Section 337, filed September 22, 2022 ..... Appx94

Initial Determination on Violation of Section 337 and Recommended Determination on Remedy and Bond, filed June 27, 2022 ..... Appx99

Order No. 12: Construing the Terms of the Asserted Claims of the Patents at Issue, filed November 4, 2021 ..... Appx305

JX-1: U.S. Patent No. 9,572,499 .....Appx10001

JX-2: U.S. Patent No. 10,595,731 .....Appx10041

JX-3: U.S. Patent No. 10,638,941 .....Appx10074

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of	
CERTAIN WEARABLE ELECTRONIC DEVICES WITH ECG FUNCTIONALITY AND COMPONENTS THEREOF	**Investigation No. 337-TA-1266**

COMMISSION OPINION

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I. INTRODUCTION

On September 22, 2022, the Commission determined to review in part the final initial determination ("ID") issued by the presiding administrative law judge ("ALJ") on June 27, 2022. 87 Fed. Reg. 58819-21 (Sept. 28, 2022). On review, the Commission has determined to affirm, with modifications, the ID's finding that there has been a violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337. Having found a violation of section 337, the Commission has determined to issue a limited exclusion order and a cease and desist order as set forth below. The Commission finds that the public interest does not preclude the issuance of remedial orders. The Commission has determined that a bond in the amount of $2 per imported article is required for infringing products imported during the period of Presidential review.[1] The Commission, however, has determined to suspend enforcement of the orders, including the bond provision, pending final resolution of the U.S. Patent and Trademark Office, Patent Trial and Appeal Board's ("PTAB") Final Written Decisions finding all asserted patent claims unpatentable. *See Apple, Inc. v. AliveCor, Inc.*, IPR2021-00970, Patent 9,572,499, Final Written Decision Determining All Challenged Claims Unpatentable (Dec. 6, 2022); *Apple, Inc. v. AliveCor, Inc.*, IPR2021-00971, Patent 10,595,731, Final Written Decision Determining All Challenged Claims Unpatentable (Dec. 6, 2022); *Apple, Inc. v. AliveCor, Inc.*, IPR2021-00972, Patent 10,638,941, Final Written Decision Determining All Challenged Claims Unpatentable (Dec. 6, 2022) (collectively, "Final Written Decisions" or "FWDs").

This opinion sets forth the Commission's reasoning in support of that determination. The Commission adopts the remainder of the ID that is not inconsistent with this opinion.

[1] Commissioners Schmidtlein and Stayin disagree with the Commission's determination regarding the amount of the bond required for infringing products imported during the period of Presidential review as provided in section (V)(D) of the Commission's Opinion concerning bond. *See infra* note 41.

II. BACKGROUND

A. Procedural History

On May 26, 2021, the Commission instituted this investigation based on a complaint filed by AliveCor, Inc. of Mountain View, California ("AliveCor" or "ALC"). 86 Fed. Reg. 28382 (May 26, 2021). The complaint, as supplemented, alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain wearable electronic devices with ECG[2] functionality and components thereof by reason of infringement of one or more of claims 1-30 of U.S. Patent No. 10,595,731 ("the '731 patent"); claims 1-23 of U.S. Patent No. 10,638,941 ("the '941 patent"); and claims 1-4, 6-14, 16-20 of U.S. Patent No. 9,572,499 ("the '499 patent"). *Id.* The Commission's notice of investigation named Apple Inc. of Cupertino, California ("Apple") as the sole respondent. The Office of Unfair Import Investigations ("OUII") is named as a party in this investigation. *Id.*

On February 23, 2022, the ALJ issued an initial determination granting AliveCor's motion to terminate the investigation as to (1) claims 1-4, 6-14, and 18-20 of the '499 patent; (2) claims 2, 4, 6, 7, 11, 13, 14, and 17-30 of the '731 patent; and (3) claims 1-11, 14, 15, 17, and 18 of the '941 patent based upon withdrawal of allegations from the complaint as to those claims. Order No. 16 (Feb. 23, 2022), *unreviewed by* Notice (Mar. 18, 2022).

The ALJ held an evidentiary hearing from March 28-April 1, 2022, and received post-hearing briefs thereafter.

[2] ECG stands for electrocardiogram.

On June 27, 2022, the ALJ issued the final initial determination ("ID"), finding a violation of section 337 as to the '941 and '731 patents, and no violation as to the '499 patent.[3] The ID found that the parties do not contest personal jurisdiction, and that the Commission has *in rem* jurisdiction over the accused products. ID at 18. The ID further found that the importation requirement under 19 U.S.C. § 1337(a)(1)(B) is satisfied. *Id.* (citing CX-0904C (Apple stipulating that it imports the accused products into the United States)). Regarding the '941 patent, the ID found that AliveCor has proven infringement of the asserted claims, claims 12, 13, 19, and 20-23, and that Apple failed to show that any of the asserted claims are invalid. *Id.* at 30-45, 60-98, 187-88. For the '731 patent, the ID found that AliveCor has proven infringement of the asserted claims, claims 1, 3, 5, 8-10, 12, 15, and 16, but that Apple has proven that claims 1, 8, 12, and 16 are invalid for obviousness. *Id.* at 105-108, 113-127, 188. For the '499 patent, the ID found that AliveCor failed to prove infringement of the asserted claims, claims 16 and 17, and that claim 17 is invalid for lack of patentable subject matter under 35 U.S.C. § 101. *Id.* at 129-138, 140-152, 188. Finally, the ID found that AliveCor has proven the existence of a domestic industry that practices the asserted patents as required by 19 U.S.C. § 1337(a)(2). *Id.* at 152-180, 188. The ID included the ALJ's recommended determination on remedy and bonding ("RD"). The RD recommended that, should the Commission find a violation, issuance of a limited exclusion order and a cease and desist order would be appropriate. ID/RD at 190-193. The RD also recommended imposing no bond for covered products imported during the period of Presidential review. *Id.* at 194-95.

On July 11, 2022, Apple filed a petition for review of the final ID and AliveCor filed a

[3] The ALJ issued a corrected final ID on July 26, 2022, correcting the table of contents.

combined petition and contingent petition for review.[4] On July 19, 2022, the private parties and OUII's investigative attorney filed responses to the petitions.[5]

On September 22, 2022, the Commission determined to review the final ID in part. 87 Fed. Reg. 58819-21 (Sept. 28, 2022). Specifically, the Commission determined to review the final ID's invalidity findings, including patent eligibility under 35 U.S.C. § 101 and obviousness under 35 U.S.C. § 103, and the economic prong of the domestic industry requirement for all three patents. *Id.* The Commission requested briefing on certain issues under review and on remedy, the public interest, and bonding. *Id.*

On October 6, 2022, the parties filed initial submissions in response to the Commission's request for briefing.[6] On October 14, 2022,[7] the parties filed reply submissions.[8] On October

[4] *See* Respondent Apple Inc's Petition for Review of the Initial Determination on Violation of Section 337 ("Apple Pet."); Complainant AliveCor, Inc.'s Combined Petition for Review and Contingent Petition for Review of the Initial Determination ("AliveCor Pet.").

[5] *See* Respondent Apple Inc.'s Response to the Complainant's Petition for Review of the Initial Determination ("Apple Rep."); Complainant AliveCor Inc.'s Response to Respondent Apple Inc.'s Petition for Review of the Initial Determination on Violation of Section 337 ("AliveCor Rep."); Combined Response of the Office of Unfair Import Investigations Response to the Private Parties' Petitions for Review of the Final Initial Determination on Violation ("OUII Rep.").

[6] *See* Respondent Apple Inc.'s Opening Brief in Response to the Commission's Request for Written Submissions on the Issues Under Review and on Remedy, the Public Interest, and Bonding ("Apple Sub."); Complainant AliveCor, Inc.'s Submission in Response to the Commission's September 22, 2022 Notice of a Commission Determination to Review in Part ("AliveCor Sub."); Brief of the Office of Unfair Import Investigations on the Issues Under Review and on Remedy, the Public Interest, and Bonding ("OUII Sub.").

[7] On October 12, 2022, the Chair granted the parties' request to extend the due date for their reply briefs by one day. *See* Commission Letter Granting Request for Extension of Time to File Replies to the Commission's Request for Written Submissions; *Certain Wearable Electronic Devices with ECG Functionality and Components Thereof*, Inv. 337-TA-1266 (Oct. 12, 2022).

[8] *See* Respondent Apple Inc.'s Reply Brief to AliveCor and OUII's Response to the Commission's Request for Written Submissions on the Issues Under Review and on Remedy, the

21, 2022, Apple moved for leave to file a sur-reply to AliveCor's reply submission.[9] On October 24, 2022, AliveCor filed an opposition.[10] OUII filed a response in opposition on November 2, 2022.[11] The Commission has determined to reject Apple's motion for leave to file a sur-reply to AliveCor's reply submission. The Commission finds that Apple has not shown AliveCor's reply submission contains errors that warrant a sur-reply.

On December 7, 2022, Apple filed an emergency motion, asking "the Commission to suspend any remedial orders or, in the alternative, extend the December 12, 2022 Target Date of its Final Determination and stay all proceedings prior to issuance of any Final Determination pending final resolution of any appeal of the PTAB's decisions."[12] Apple Emergency Motion at

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Public Interest, and Bonding ("Apple R.Sub."); Complainant AliveCor, Inc.'s Reply Submission in Response to the Commission's September 22, 2022 Notice of a Commission Determination to Review in Part ("AliveCor R.Sub."); Reply Brief of the Office of Unfair Import Investigations on the Issues Under Review and on Remedy, the Public Interest, and Bonding ("OUII R.Sub.").

[9] *See* Respondent Apple Inc.'s Motion for Leave to File Sur-Reply Brief to AliveCor's Reply to the Commission's Request for Written Submissions on the Issues Under Review and on Remedy, the Public Interest, and Bonding.

[10] *See* AliveCor's Opposition to Apple's Motion for Leave to File Sur-Reply to AliveCor's Reply to the Commission's Request for Written Submissions on the Issues Under Review and on Remedy, the Public Interest, and Bonding.

[11] *See* Response of the Unfair Import Investigations to Respondent Apple Inc.'s Motion for Leave to file Sur-Reply Brief to AliveCor's Reply to the Commission's Request for Written Submissions on the Issues Under Review and on Remedy, the Public Interest, and Bonding.

[12] *See* Respondent Apple Inc.'s Emergency Motion to Suspend any Remedy or Extend the Target Date and Stay Proceedings Pending Resolution of any Appeal of the Patent Office's Decision that United States Patent Nos. 10,638,941, 10,595,731, and 9,572,499 Are Unpatentable ("Apple Emergency Motion").

1. On December 9, 2022, AliveCor filed an opposition to Apple's motion.[13] On December 16, 2022, OUII filed a response to the motion.[14]

B. Overview of the Technology

The technology at issue generally relates to systems, devices, and methods for monitoring cardiac health and managing cardiac disease. ID at 3.

The '941 patent entitled, "Discordance Monitoring," issued on May 5, 2020. '941 patent (JX-0003). The patent describes systems, devices, and methods that can be used to "conveniently sense the presence of an intermittent arrhythmia in an individual." '941 patent, Abstract. The systems, devices, and methods can also "be configured to sense an electrocardiogram." *Id.*

The '731 patent entitled, "Methods and Systems for Arrhythmia Tracking and Scoring," issued on March 24, 2020. '731 patent (JX-0002). The patent describes "a dashboard centered around arrhythmia or atrial fibrillation." '731 patent, Abstract. "The dashboard includes a heart or cardiac health score that can be calculated in response to data from the user such as their ECG and other personal information and cardiac health influencing factors." *Id.* "The dashboard also provides to the user recommendations or goals, such as daily goals, for the user to meet and thereby improve their heart or cardiac health score." *Id.*

The '449 patent, also entitled, "Methods and Systems for Arrhythmia Tracking and Scoring," issued on February 21, 2017. '449 patent (JX-0001). The patent also describes "a

[13] *See* AliveCor's Opposition to Apple's Emergency Motion to Suspend any Remedy or Extend the Target Date and Stay Proceedings ("AliveCor Opposition").

[14] *See* Response of the Office of Unfair Import Investigations to Respondent Apple Inc.'s Emergency Motion to Suspend any Remedy or Extend the Target Date and Stay Proceedings Pending Resolution of any Appeal of the Patent Office's Decision that United State Patent Nos. 10,638,941, and 9,572,499 Are Unpatentable ("OUII Reply to Emergency Motion").

dashboard centered around arrhythmia or atrial fibrillation." '449 patent, Abstract. "The dashboard includes a heart or cardiac health score that can be calculated in response to data from the user such as their ECG and other personal information and cardiac health influencing factors." *Id.*

C. The Accused Products

The accused products consist of four generations of Apple smartwatches:

Apple Model(s)	Category
A1975, A1976, A1977, A1978	Series 4
A2092, A2093, A2094, A2095	Series 5
A2291, A2292, A2293, A2294	Series 6
A2473, A2474, A2475, A2477	Series 7

ID at 6. The parties explained that the "Apple Watch Series 6 is sufficiently representative from a hardware standpoint of all other Accused Products" and they describe the "salient features of the Accused Products via the Series 6 as 'a motion/activity sensor known as an accelerometer, a photoplethysmography ('PPG')[15] sensor, an electrocardiogram ('ECG') sensor, a display screen, a processor, and memory.'" ID at 6 (citing Hr'g Tr. (Jafari) at 303:19-24; JX-0221C (Waydo) at 207:10-14, 208:14-209:11; CX-0107). The ID further found that the "software running on these devices is also important, taking the form of Apple's operating system, WatchOS" and that "[a]s with hardware, the parties have agreed that version 7.6.2 of WatchOS is representative of all other versions that contain the diagnostic tools implicated by the Asserted Claims." *Id.*

[15] PPG is used to sense the amount of oxygen in the blood.

D. Domestic Industry Products

The domestic industry products include "wearable electronic devices, being developed, manufactured, and/or sold by AliveCor under the tradenames KardiaBand System, [[ ]]." ID at 4. "Each product includes, 'among other things, a smartwatch, activity sensor, PPG sensor, and ECG sensor.'" *Id.* at 4-5. "The KardiaBand System ('KBS') comprises the KardiaBand watch band, and an Apple Watch (Series 1, 2, 3) with Watch OS 5.0 or earlier running a program called KardiaApp." *Id.* at 5 (citing Hr'g Tr. (Jafari) at 385:16-386:15). Complainant relies on its KBS product for its domestic industry that exists and relies on its [[ ]] products for its domestic industry in the process of being established.

III. COMMISSION REVIEW OF THE ID

When the Commission reviews an initial determination, in whole or in part, it reviews the determination *de novo*. *Certain Soft-Edged Trampolines and Components Thereof*, Inv. No. 337-TA-908, Comm'n Op. at 4 (May 1, 2015). Upon review, the "Commission has 'all the powers which it would have in making the initial determination,' except where the issues are limited on notice or by rule." *Certain Flash Memory Circuits & Prods. Containing Same*, Inv. No. 337-TA-382, USITC Pub. No. 3046, Comm'n Op. at 9-10 (July 1997) (quoting *Certain Acid-Washed Denim Garments & Accessories*, Inv. No. 337-TA-324, Comm'n Op. at 5 (Nov. 1992)). With respect to the issues under review, "the Commission may affirm, reverse, modify, set aside or remand for further proceedings, in whole or in part, the initial determination of the administrative law judge." 19 C.F.R. § 210.45(c). The Commission also "may take no position on specific issues or portions of the initial determination," and "may make any finding or conclusions that in its judgment are proper based on the record in the proceeding." *Id.*; *see also Beloit Corp. v. Valmet Oy*, 742 F.2d 1421, 1423 (Fed. Cir. 1984).

IV. ANALYSIS

A. Economic Prong of the Domestic Industry Requirement

The Commission determined to review the economic prong of the domestic industry requirement for all three patents and asked the parties for briefing. 87 Fed. Reg. 58819-20 (Sept. 28, 2022).

On review, the Commission has determined to affirm the ID's findings that AliveCor failed to establish the economic prong of the domestic industry requirement as to a domestic industry in the process of being established, and an existing industry under subsections (A) and (B), but proved the existence of a domestic industry under subsection (C). With respect to the industry in the process of being established and an existing industry under subsection (A), the Commission affirms the ID for the reasons stated therein. Regarding subsections (B) and (C), the Commission affirms the ID as modified below.

1. Legal Standard

In patent-based proceedings under section 337, a complainant must establish that a domestic industry "relating to the articles protected by the patent . . . exists or is in the process of being established." 19 U.S.C. § 1337(a)(2). Under Commission precedent, this domestic industry requirement consists of an "economic prong" and a "technical prong." *See Alloc, Inc. v. Intl Trade Comm'n,* 342 F.3d 1361, 1375 (Fed. Cir. 2003). To satisfy the "technical prong," the complainant must establish that it practices at least one claim of each of the asserted patents. *Certain Point of Sale Terminals and Components Thereof*, Inv. No. 337-TA-524, Order No. 40 at 17-18 (Apr. 11, 2005). To satisfy the "economic prong," paragraph (3) of section 337(a) provides:

> For purposes of paragraph (2), an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned –

(A) significant investment in plant and equipment;

(B) significant employment of labor or capital; or

(C) substantial investment in its exploitation, including engineering, research and development, or licensing.

19 U.S.C. § 1337(a)(3). Expenditures in each of the above three categories under section 337(a)(3) must "pertain to the complainant's industry with respect to the articles protected by the asserted IP rights." *See, e.g.*, *Certain Television Sets, Television Receivers, Television Tuners, and Components Thereof*, Inv. No. 337-TA-910, Comm'n Op. at 68 (Oct. 30, 2015); *Certain Marine Sonar Imaging Devices, Including Downscan and Sidescan Devices, Prods. Containing the Same, and Components Thereof*, Inv. No. 337-TA-921, Comm'n Op. at 40 (Jan. 6, 2016).

Under subsection (C), a domestic industry will be found to exist if, "with respect to the articles protected by the patent," a complainant can show "substantial investment in *its exploitation*, including engineering, research and development, or licensing." 19 U.S.C. § 1337(a)(3)(C) (emphasis added). For this provision, the Federal Circuit has interpreted "its" to mean the patent (or other enumerated IP right in subsections 337(a)(1)(B)-(E)), so there must be a nexus between the domestic investments and the exploitation of the asserted patents, beyond showing that those investments relate to the protected domestic industry ("DI") articles. *InterDigital Communications, LLC v. Int'l Trade Comm'n*, 707 F.3d 1295, 1297-1301 (Fed. Cir. 2013).[16] To establish the nexus, the complainant must show the connection between its

[16] The ID states that "[u]nlike subsections (A) and (B), where a connection is made between an alleged investment and a patent-practicing product, a subsection (C) analysis requires a connection between the R&D investment and the asserted patents (*i.e.*, nexus)." ID at 170 (citation omitted). We clarify that while subsection (C) requires a nexus between the claimed investments and the asserted patents, the requirement that investments be "with respect to articles protected by the patent" applies with respect to subsections (A), (B), and (C). *See* 19 U.S.C. § 1337(a)(3); *see also InterDigital,* 707 F.3d at 1298 ("Thus, just as the 'plant or equipment'

investments and the patented aspect(s) of the invention that it is exploiting. *See Certain Integrated Circuit Chips and Products Containing the Same*, Inv. No. 337-TA-859, Comm'n Op. at 49-50 (Aug. 2014) ("As a matter of statutory construction, an investment in the article is not automatically an investment in the asserted patent."). It is not enough for a complainant to assert that it generally conducts research and development, or that its R&D relates to non-patented features incorporated into articles that also practice the patent at issue. *Id.*

Depending on the particular facts of a case, a complainant's domestic industry with respect to articles protected by the asserted IP rights may extend beyond the protected article, to include those additional parts or components that are necessary to use or exploit the patented invention. *See Motorola Mobility, LLC v. Int'l Trade Comm'n*, 737 F.3d 1345, 1351 (Fed. Cir. 2013) (explaining that "nothing in § 337 precludes a complainant from relying on investments or employment directed to significant components, specifically tailored for use in an article protected by the patent"). However, there may be investments that are too far removed from the articles protected by the asserted intellectual property rights to be considered part of the complainant's domestic industry. *See Certain Video Game Systems and Wireless Controllers and Components Thereof*, Inv. No. 337-TA-770, Comm'n Op. at 66 (Oct. 28, 2013) ("[W]e agree with the ALJ that the language of the patent is directed to the toy wand and not the toy wand plus the entire MagiQuest attraction."). Nevertheless, for subsection (C), the focus remains on whether the claimed investments are related to the exploitation of the patent and whether those investments in the exploitation of the patent are substantial.

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referred to in subparagraph (A) must exist with respect to articles protected by the patent, such as by producing protected goods, the research and development or licensing activities referred to in subparagraph (C) must also exist with respect to articles protected by the patent, such as by licensing protected products.").

Whether a complainant satisfies the economic prong is not analyzed according to a rigid mathematical formula. *Certain Male Prophylactic Devices*, Inv. No. 337-TA-546, Comm'n Op. at 39 (Aug. 1, 2007). The Commission decides the domestic industry requirement has been established in each investigation based on "an examination of the facts in each investigation, the article of commerce, and the realities of the marketplace." *Id.* A complainant does not need to show any "minimum monetary expenditure," and does not "need to define or quantify the industry itself in absolute mathematical terms." *Stringed Musical Instruments,* Inv. No. 337-TA-586, Comm'n Op. at 16-17 (May 16, 2008) ("A precise accounting [of the complainant's domestic investments] is not necessary, as most people do not document their daily affairs in contemplation of possible litigation."). The burden is on the complainant to show by a preponderance of the evidence that the domestic industry requirement is satisfied. *See Certain Multimedia Display and Navigation Devices and Systems, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-694, Comm'n Op. at 5 (July 22, 2011).

To satisfy the domestic industry requirement, section 337(a)(3) requires that a complainant's asserted investments must be "significant" or "substantial." The Federal Circuit has held that "qualitative factors alone are insufficient" to show that domestic industry investments are significant or substantial. *Lelo Inc. v. Int'l Trade Comm'n*, 786 F.3d 879, 885 (Fed. Cir. 2015). The statute "requires a quantitative analysis to determine whether there is a 'significant' [or 'substantial'] increase or attribution by virtue of the claimant's asserted commercial activity in the United States." *Id.* at 883. "[T]he terms 'significant' and 'substantial' refer to an increase in quantity, or to a benchmark in numbers." *Id.* at 885; *see also Certain Carburetors & Prods. Containing Such Carburetors*, Inv. No. 337-TA-1123, Comm'n Op. at 15-16 (Oct. 28, 2019). While significance may not be established on qualitative evidence alone,

"qualitative evidence may still be relied upon to support a finding that a complainant's investments are significant." *Carburetors*, Comm'n Op. at 24; *see also id.* at 23 ("There may be facts and circumstances where, based on an assessment of quantitative information, it remains unclear whether a complainant's investments are significant or not. In such cases, resorting to qualitative factors that may indicate significance could be relevant to the evaluation."). In this regard, the Commission considers the "nature and significance" of a complainant's activities with respect to the protected articles. *Certain Printing and Imaging Devices*, Inv. No. 337-TA-690, Comm'n Op. at 30 (Feb. 17, 2011). The Commission may consider, *inter alia*, whether the "activities were important to the articles protected by the asserted patents in the context of the company's operations, the marketplace, or the industry in question, or whether complainant's undertakings had a direct bearing on the practice of the patent" or "whether and to what extent [] domestic activities added value to the imported products." *Id*.

2. Economic Prong of the Domestic Industry Requirement Under Subsection (C)

a) Background

AliveCor is a U.S. company based in California that designs and develops wearable electronic devices to help diagnose heart conditions. *See* Compl. at ¶ 11; CDX-005C.13; Tr. (Albert) at 53:22-54:20; CDX-005C.29; Tr. (Albert) at 77:24-78:14. AliveCor developed the inventions claimed in the Asserted Patents in the United States and introduced the "technology to consumers through the KBS, a system that included an app and watchband accessory for the Apple Watch," clearing the KBS with the U.S. Food and Drug Administration ("FDA") for use in connection with the Apple Watch. ID at 4-5; Tr. (Albert) 83:8-85:19; 199:3-201:21; CDX-0005C.34-36. There is no dispute that the KBS domestic industry product was developed in the United States and the [[ ]] products are also being developed in the United States.

Although AliveCor ceased to manufacture and sell the KBS product in 2018, AliveCor continued to invest in the technology of the patents through the date of the complaint filing. Under Commission precedent, past expenditures in R&D can be counted towards establishing a domestic industry in a product that exists but has been discontinued, like the KBS, if there are continuing investments. *See, e.g.*, *Certain Marine Sonar Imaging Devices*, Inv. No. 337-TA-921, Comm'n Op., at 59 (Jan. 6, 2016) (crediting "labor and capital expenditures related to . . . software updates" used in a discontinued but practicing product), *affirmed*, *Hyosung TNS Inc. v. Int'l Trade Comm'n*, 926 F.3d 1353, 1361-2 (Fed. Cir. 2019) ("[P]ast expenditures may be considered to support a domestic industry claim so long as those investments pertain to the complainant's industry with respect to the articles protected by the asserted [intellectual property] rights and the complainant is continuing to make qualifying investments at the time the complaint is filed.").

b) AliveCor Established the Nexus Requirement for Both Past Investments and Continuing Investments

AliveCor has established both (1) that its past investments in R&D were directed to each of the asserted patents to develop the KBS and to use the technology of the patents to develop [[ ]]; and (2) that after AliveCor ceased manufacture and sales of the KBS in 2018, AliveCor continued to make on-going R&D domestic investments directed to exploiting the asserted patents and these continuing investments benefit current users of the KBS. Moreover, the evidence shows that, since 2018, AliveCor has continued to incur ongoing expenditures to address customers' concerns for the KardiaBand through its customer service contractor iQor which benefits current KBS users. *See* RX-0484C.48.

AliveCor proffered evidence of its internal costs as well as contractor costs to support its claim that DI was met under subsection (C). The ALJ did not credit the majority of AliveCor's

internal labor R&D expenditures because they were not sufficiently reliable to determine the quantitative amount that could be properly allocated to the domestic industry products. ID at 170-75. The ID found the evidence of payments to outside contractors to be reliable and sufficient to show AliveCor's investments in R&D of [[ ]] from 2017 through 2020. The Commission agrees with these findings.

The evidence of record establishes that these payments were directed to exploitation of the patents. *See, e.g.*, CPX-0048; CX-09236C; ID at 175-76; Tr. (Albert) at 176:22-177:3 ("We didn't just stop KardiaBand. [[

]]; AliveCor Rep. at 3-6. Accordingly, AliveCor's past R&D expenditures to exploit the patents in the KBS, together with continuing R&D investments in the [[ ]] that benefit KBS users support AliveCor's claim that it has established the requisite nexus exists for purposes of a domestic industry under subsection (C). Further, as noted AliveCor has made continuing investments in the KBS through its customer service contractor iQor.

Apple persists in its argument that the ID erred in finding that AliveCor established a nexus between the alleged R&D contractor expenditures and the Asserted Patents for purposes of subsection (C). Apple Pet. at 19; Apple Sub. at 24-26. We disagree. In finding the nexus

requirement for these contractor investments met, the ID stated, with respect to a physical exhibit recording these contractor expenditures, that "CPX-0048C [on its face] provides at least some description of the activity behind each cost that *suggests* a nexus to sensors, circuitry, and housing structure." ID at 175-76 (citing CX-09236C (presenting totals for "DI Contractor R&D Labor"). Under Commission precedent, the nexus requirement can be inferred under these facts. *See, e.g.*, *Certain Integrated Circuit Chips and Products Containing the Same*, Inv. No. 337-TA-859, Comm'n Op. at 42 (Aug. 22, 2014) ("[A] complainant's evidence of its investment in a protected article that practices the patent ordinarily also can support the inference that the investment was itself an exploitation of the patent.").

The record evidence shows that "the core part of the invention" claimed in the Asserted Patents is "technology that measures heart rate and heart rate parameters in the background," that "use[s] … AI [artificial intelligence] and machine learning algorithms to mine that data and" when it "identif[ies] irregularities that are suggestive of atrial fibrillation, provide[s] a trigger to the user to take an ECG" and allows "the user [to] take on-demand ECG on the wrist." Tr. (Jafari) at 292:17-293:2; AliveCor Rep. at 11. As the ID found, the evidence shows that the contractor expenditures are directed to the sensors, circuitry, and the housing structure of the AliveCor wristbands, *i.e.*, the KardiaBands. CPX-0048; CX-09236C; ID at 175-76. Further, as AliveCor explained, this "development work for the SmartRhythm algorithms, described above, is directed to the technology in the KBS that identif[ies] irregularities that are suggestive of atrial fibrillation, provide[s] a trigger to the user to take an ECG." AliveCor Rep. at 11 (citing Tr. (Somayajula) at 198:13-227:20). Moreover, the "development work for KardiaAI is directed to technology that allows [existing] KBS users to take an on-demand ECG." *Id.*; Tr. (Albert) at 64:1-67:8. That is, the record evidence shows that the development work undertaken by the

contractors pertains to the patented features of the domestic industry products for the benefit of current users of the KBS. As the Commission has held, '"[e]xploitation' is a generally broad term that encompasses activities such as efforts to improve, develop, or otherwise take advantage of the asserted patent." *Certain Integrated Circuit Chips and Products Containing the Same*, Inv. No. 337-TA-859, Comm'n Op., 2014 WL 12796437, at *21 (Aug. 22, 2014).

c) AliveCor's Investment in Exploiting the Patents is Substantial

Having found the relevant nexus between the investments and the Asserted Patents, the ALJ found that the investments, totaling [[ ]] for the technology of each of the three patents, were "substantial" under subsection (C).[17] ID at 180-83. We agree for the reasons stated in the ID, as supplemented below.

As stated above, we agree with the ID's finding that payment to outside contractors show R&D investments of [[ ]] from 2017 through 2020. Beyond these contractors' investments, the ID found with respect to continuing investments in exploiting the asserted patents that the "record certainly evidences a qualitative effort on the part of ALC to refine and improve the KBS features like SmartRhythm and KardiaAI—which have a clear nexus to the heart rate and ECG analysis limitations recited in the Asserted Claims of the 941, 731, and 499 patents." ID at 170-171. The quantitative evidence also shows that, since 2018, AliveCor has continued to incur ongoing expenditures to address customers' concerns for the KardiaBand through its customer service contractor iQor, which as discussed above, has a nexus to exploiting the asserted patents. The table below shows the labor costs related to iQor tickets for KardiaBand or AliveCor's Kardia app:

[17] We note that DI product for each of the three asserted patents is the KBS and thus there is no need to allocate the investments among the three patents. That is, the DI product for each patent standing alone is the KBS.

Year	KardiaBand Tickets	Hardware Unknown Tickets	Total Tickets With Sufficient Information to Code	Cost to AliveCor for KB + Software	Percentage of KB + Software Tickets
2018	[[				
2019					
2020					
Jan-Sept 2021 (Sept)					]]

RX-0484C.48.

Apple separately argues that the [[ ]] expenditures for R&D contractor expenses includes foreign expenditure. Apple Sub. at 27, Apple R.Sub. at 18. The record, however, does not support Apple's argument. As AliveCor explains, its Chief Financial Officer Clyde Hosein testified at his deposition that "he had reviewed the information underlying his declaration and thought it best to remove some expenses paid to one vendor, [[ ]], because it was 'not clear whether those costs were incurred in United States or all of it was incurred in the United States.'" AliveCor Sub. at 24 (citing JX-0229C (Hosein Depo.) at 90:18-92:11). Mr. Hosein submitted the declaration in question with AliveCor's complaint enumerating "expenses related to United States-based consultants and contractors preforming hardware engineering, testing, development, and support work for AliveCor's DI Products from 2016 through 2020." *Id.* (citing Compl. Ex. 20, Hosen Decl. ¶ 14 (EDIS No. 740374); CPX-048C at tabs 2017 QB & NS 2018-2020). AliveCor states that "[i]n accordance with Mr. Hosein's declaration and testimony, [its] economic expert, Dr. Akemann, removed all payments to [[ ]] from his calculations" and that "[w]ith those payments removed, Dr. Akemann determined that AliveCor incurred [[ ]] in qualifying investments to domestic R&D contractors." *Id.* at 25 (citing CX-0925C ("Excludes expenses with Vendor Name of [[ ]] . . . ")). Apple

points to the ID's statement that "ALC's record of R&D contractor payments do suggest a material amount of foreign payments towards the DI Products in 2016-2020 that have otherwise gone unaddressed in ALC's briefing (see CPX-0048C (Tabs [[

]]" and that "they only add up to [[

]]." ID at 182. Apple misapprehends the ID's statement. The ID was contrasting AliveCor's domestic contractor expenditure to its foreign contractor expenditure. The evidence shows that the ID did not find that the credited [[ ]] in domestic R&D contractor payments included the [[ ]] of payments to foreign contractors as Apple contends. *Id.* Indeed, there is no evidence to support Apple's assertion.

As mentioned above, the ID correctly found that the [[ ]] expenditures for R&D contractor expenses is substantial. As an initial matter, the evidence supports the ID's finding that AliveCor's "R&D labor expenses overall, including for the DI Products, are mostly domestic." ID at 181. The ID pointed to Dr. Akemann's opinion that "over the entire DI period [[ ]] of ALC's total headcount was domestic" and that "[a]fter comparing domestic and foreign R&D headcount, especially for the period 2016-19, it is likely that ALC's internal R&D labor expenses for KBS were overwhelmingly domestic, even without allocation." *Id.* (citing CX-0937C). In addition, the ID observed that of the total R&D contractor payments incurred in the development of the KBS, the foreign payments towards the KBS DI Products in 2016-2020 "only add up to [[ ]]" and that "[i]f this is the true extent of foreign R&D payments over this time and dedicated to the DI Products, then it only further supports the substantiality of the [[ ]] domestic spend." *Id.* at 181-82 (citing CX-0935C). In other words, a comparison of the domestic contractor expenses to the foreign contractor

expenses shows that the domestic expenditure is substantial. The Commission agrees with the ALJ's reasoning.

We note the ID's statement that the "overall analysis here is troubling, to be sure" because "[i]t is no secret that a domestic-to-foreign comparison is at least the preferred method of proving economic prong" and that "[t]he parties were even warned at the end of the evidentiary hearing that 'you need to compare foreign and domestic investments.'" *Id.* at 182 (citing *Carburetors*, Inv. No. 337-TA-1123, Comm'n Op at 17-19); Hr'g Tr. at 1312:17-18. The Commission, however, has made clear that a domestic-to-foreign comparison is not a requirement, nor is it "preferred" as a general matter to show significance. *See Carburetors*, Comm'n Op at 8-9, 17-19.[18] The appropriate context for evaluating significance may vary depending upon the facts of a particular investigation. For example, significance may be shown, *inter alia,* by demonstrating the value added by domestic activities, by comparing domestic investments to costs or revenues for DI products, or other contextual evidence of significance to the company's operations, the marketplace, or the industry in question. *See id.* Here, the Commission finds that the ID's reliance on the comparison of the domestic contractor expenses to the foreign contractor expenses and Dr. Akemann's "sufficiently detailed and pertinent headcount comparison showing it more likely than not that DI-related R&D labor expenses were substantially domestic" is sufficient to show that AliveCor's domestic expenditure in the exploitation of its patents is substantial under subsection (C) for a domestic industry relating to

[18] In the view of Commissioner Kearns, a proper contextual analysis for "significance" requires some comparison of domestic and foreign activities or investments where the domestic industry products benefit from both. This comparison can be through, for example, a comparison of domestic to foreign expenditures or a value-added analysis. *See Certain Electronic Candle Products and Components Thereof*, Inv No. 337-TA-1195, Comm'n Op. at 38 n.22 (Kearns footnote) (July 14, 2022).

the KBS products that "exists." *See* ID at 183. Moreover, AliveCor's continued activities after the KBS products ceased to be manufactured and sold are sufficient to show an industry that exists as of the date AliveCor filed its complaint.

3. Economic Prong of the Domestic Industry Requirement Under Subsection (B)

The Commission has determined to affirm the ID's finding that AliveCor failed to establish the economic prong of the domestic industry requirement under subsection (B) relating to the KBS products. In support of its assertion that its [[ ]] investments in R&D labor allocated to the KBS products were significant, AliveCor offered a comparison of these investments to its company-wide labor and capital expenditures, as well as a comparison of KBS sales revenue to its company-wide hardware and total sales revenues. ID at 178. Having found AliveCor's evidence of internal R&D labor expenditures to be unreliable, the ID considered instead AliveCor's domestic R&D contractor, customer support, and regulatory expenditures of [[ ]] to evaluate significance and compared that figure to AliveCor's proffered company-wide labor and capital expenditures.[19] The ID found that these investments by AliveCor totaling [[ ]] from 2016 to 2021 were "closer to [[ ]] of its total labor and capital investments from 2016 to 2020, instead of [AliveCor]'s calculated [[ ]]."[20] *Id.* at 178. Although the ID had misgivings about the relevance of comparing domestic industry investments to total company-wide investments to show significance, the ID, nonetheless, considered it and found that "[t]his is not a significant percentage on its own." *Id.* at 178-79. With respect to the comparison of

[19] The Commission agrees with the ID's findings relating to the unreliability of AliveCor's evidence of its internal labor allocations.

[20] It appears that AliveCor expected the ID to credit all of its allocated labor expenses, which would have resulted in a contextual expenditure of [[ ]] of its total labor and capital investments as opposed to the [[ ]] that the ALJ found based on those expenditures supported by reliable evidence.

KBS sales revenue to company-wide hardware and total sales revenues from 2018 to 2019, the ID observed that this proffered contextual analysis "is not material because it does not involve investments at all, and is for a limited range of years." *Id*. at 180.

We find that the contextual analysis relied on by AliveCor fails to support a finding that its domestic industry investments are quantitatively significant. Specifically, AliveCor failed to show how or why its comparison of its domestic labor expenses in the DI product to its overall company-wide labor and capital expenditure showed that its domestic investment was significant. The ID correctly reasoned that "[a] large company with many products may have a domestic industry based on one such product, even though it only accounts for a tiny percentage of the company's expenses; conversely, a small company with a single qualifying product may not have a domestic industry if the bulk of its investments are overseas" based upon the location of its investment. ID at 179. Because of this, while we do not preclude that a complainant may rely on a comparison of its domestic industry investments to company-wide investments in establishing significance given the facts and circumstances of a particular investigation,

AliveCor has failed to explain or substantiate why such a comparison in the context of this investigation nonetheless demonstrates the significance of its domestic industry investments.[21, 22]

Regarding AliveCor's second proffered basis for showing quantitative significance, we agree with the ID that this also falls short. The ID found this basis – a comparison of KBS sales from 2018 to 2019 to its hardware revenues and its total revenues – inapt as "the percentage of

[21] While Commissioner Schmidtlein agrees that AliveCor has failed to demonstrate that the investments as credited by the ID are significant, she does not join the majority's analysis on this point. This is because the majority is applying a recently established additional threshold requirement that complainants must "explain or substantiate" why certain contextual analysis is appropriate before the majority will consider whether that analysis shows the investments are significant. It is a subtle difference, but Commissioner Schmidtlein's decision in this case is based on the failure of AliveCor to demonstrate that its credited investments of approximately [[ ]] percent of company-wide labor and capital investments are significant. In contrast, the majority does not reach whether these investments are significant because AliveCor did not "explain or substantiate" why a comparison of the domestic industry investments to company-wide investments is the appropriate comparison. *See infra* note 22. The majority cites the recent case C*ertain Electronic Candle Products and Components Thereof*, Inv. No. 337-TA-1195, Comm'n Op. (Oct. 4, 2022) (Comm'r Schmidtlein dissenting) (Pub. Vers.) as precedent for the Commission requiring a complainant to explain or substantiate the contextual benchmark upon which it relies. There, under its analysis of complainants' investments in plant and equipment, the majority in that case rejected one of complainants' sub-arguments "that their investments as a percent of gross profits show that their investments are significant" because the complainants did not explain the relevance of that particular benchmark. *Id*. at 37- 38. Commissioner Schmidtlein dissented finding the domestic industry requirement to be satisfied. In considering the complainant's proffer of an alternative contextual analysis, she noted that she saw no reason to discount the comparison using gross profit. *See id., Dissenting Views of Commissioner Schmidtlein* at 18 n.7. Similarly, in this case, Commissioner Schmidtlein declines to join the majority in requiring the complainants to "explain or substantiate" why a certain contextual analysis is appropriate.

[22] In response to footnote 21, the Commission is not establishing a new requirement, or affirming a previously established one, for all domestic industry analyses but instead observes the concerns noted by the ALJ with the particular contextual analysis offered by Complainant here and that Complainant has not, in light of those concerns, explained or substantiated why its proposed contextual analysis establishes that its claimed investments are significant. *See, e.g.*, *Certain Electronic Candle Products and Components Thereof*, Inv. No. 337-TA-1195, Comm'n Op. at 38 (July 14, 2022) (declining to find complainants' proffered comparison of domestic industry investments to gross profits as a relevant benchmark to assess significance absent an explanation as to how or why that proffered metric is meaningful in relation to the protected articles).

ALC total revenue provided by KBS, is not material because it does not involve investment at all, and is for a limited range of years. *See* CIB at 160 (highlighting that in 2018-2019, KBS supplied "[[ ]] of AliveCor's hardware revenues and [[ ]] of AliveCor's total revenues.")." *Id.* at 180.

Given that these data are the only contextual framework that AliveCor relied on before the ALJ, it has failed to show a domestic industry exists under subsection (B). The headcount and regulatory comparisons that AliveCor now presents in its submission to the Commission were never presented to the ALJ and the Commission declines to consider them because they are waived. *Broadcom Corp. v. Int'l Trade Comm'n*, 542 F.3d 894, 901 (Fed. Cir. 2008).

As discussed above with respect to subsection (C), the Commission notes that certain statements in the ID pertaining to subsection (B) suggest that the Commission prefers foreign comparisons in determining domestic significance of an investment. *See* ID at 179-180.[23] The Commission once again makes clear that it does not require a domestic-to-foreign comparison, nor does it express a general preference for such a comparison to establish significance. *Carburetors*, Inv. No. 337-TA-1123, Comm'n Op at 8-9, 17-19. Thus, the fact that AliveCor did not offer one is not fatal to its efforts to support its claims of significance under subsection (B). However, as discussed above, AliveCor failed to offer a meaningful contextual analysis by which to evaluate the quantitative significance of its investments and thus failed to establish that a domestic industry exists by virtue of significant investments in labor or capital under subsection (B).

[23] Even though the ID contemplated a similar result if AliveCor's investments were compared to its foreign manufacturing costs, the ID did not require such an analysis nor reach its conclusion on that basis. ID at 178.

B. The ID's Patent Eligibility Findings Under 35 U.S.C § 101

The Commission determined to review the final ID's invalidity findings, including patent eligibility under 35 U.S.C. § 101. 87 Fed. Reg. 58819-20 (Sept. 28, 2022).

1. Legal Standard

Section 101 limits patent-eligible subject matter to "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101. The Supreme Court has held that the statute excludes laws of nature, natural phenomena, and abstract ideas from patentability. *Mayo Collaborative Services v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012). The statute renders these categories unpatentable because "they are the basic tools of scientific and technological work" and "monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it." *Mayo*, 132 S. Ct. at 1293 (quoting *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)).

Under Supreme Court precedent, "applications of abstract concepts 'to a new and useful end remain patent eligible." *Alice Corp. Pty. v. CLS Bank Intern.*, 573 U.S. 208, 217-18, 221 (2014). A tribunal, however, must determine whether the claims transform the abstract idea into patent-eligible subject matter. To make this determination, *Alice* prescribes a two-step inquiry: a court must first "determine whether the claims at issue are directed to" a "patent-ineligible concept[]"; if they are, the court must then "determine whether [any] additional elements 'transform the nature of the claim' into a patent-eligible application," requiring an "inventive concept" or "additional features" to "ensure that the patent does not seek simply to monopolize the abstract idea." *Id.* The Federal Circuit has explained that "[t]he 'directed to' inquiry applies a stage-one filter to claims, considered in light of the specification, based on whether 'their character as a whole is directed to excluded subject matter.'" *Enfish, LLC v. Microsoft Corp.*,

822 F.3d 1327, 1335 (Fed. Cir. 2016). To save a patent at the second step, the inventive concept or additional features must be evident in the claims themselves. *Synopsys, Inc. v. Mentor Graphics Corp.*, 839 F.3d 1138, 1151-52 (Fed. Cir. 2016).

2. Whether the ID Erred in Finding Claim 12 of the '941 Patent Patentable Under Alice

a) The ID

The ID found that "claim 12 of the '941[24] patent is not invalid under 35 U.S.C. § 101, although it is directed to an ineligible concept under *Alice* step one." ID at 66. The ID explained that claim 12 consists of a first portion reciting "the structure of a smartwatch (found to be limiting, above) loaded with a processor and particular sensors" and a second portion that "refers to instructions causing analysis of the sensors' data and indicating (by any means) at least one result to the user." *Id.* at 67. The ID stated that "[t]he first portion alone typically would be

[24] Claim 12 of the '941 patent recites:

A smartwatch, comprising:
a processor;
a first sensor configured to sense an activity level value of a user, wherein the first sensor is coupled to the processor;
a photoplethysmogram ("PPG") sensor configured to sense a heart rate parameter of the user when the activity level value is resting, wherein the PPG sensor is coupled to the processor;
an electrocardiogram ("ECG") sensor configured to sense electrical signals of a heart, wherein the ECG sensor comprises a first electrode and a second electrode, and wherein the ECG sensor is coupled to the processor; and
a non-transitory computer readable storage medium encoded with a computer program including instructions executable by the processor to cause the processor to:
determine if a discordance is present between the activity level value of the user and the heart rate parameter of the user;
based on the presence of the discordance, indicate to the user a possibility of an arrhythmia being present; and
receive electric signals of the user from the ECG sensor to confirm the presence of the arrhythmia.

'941 patent, col. 17, l. 53-col. 18, l. 19.

considered patent-eligible subject matter (as an apparatus), but the second portion alone typically would be questionable (as a set of algorithms)." *Id.* The ID defined the issue as "whether the claim, in view of the specification, is directed primarily to the apparatus or to the instructions" and found that "[t]he intrinsic evidence supports the latter." *Id.* For support, the ID observed that "[t]he majority of '941 patent claims focus on data analysis and returning results of that analysis to a user (941 patent at cls. 2-9, 13-21), while only a handful recite non-algorithmic features (*id.* at cls. 10, 11, 22, 23)." *Id.* The ID further observed that "[t]he specification similarly speaks at length to diagnostic techniques for arrhythmias, and the benefits of a discordance determination preceding an ECG measurement." *Id.* at 67-68 (citing '941 patent, Title, 1:66-2:3, 2:10-3:12, 12:55-65, 12:66-13:7, 13:67-14:8, 14:8, 14:36-42, Fig. 7). The ID surmised that "it is fair to say that claim 12 is directed to the abstract idea of analyzing a combination of heart rate and activity, and then measuring and analyzing ECG electric signals for medical diagnosis, as medical practitioners have routinely done for years" and thus is "directed to non-patent eligible subject matter." *Id.* at 68 (citing *Intellectual Ventures I LLC v. Symantec Corp.*, 838 F.3d 1307, 1314 (Fed. Cir. 2016) ("The Supreme Court has held that 'fundamental . . . practice[s] long prevalent' are abstract ideas.")).

The ID found that "[t]he structural elements within claim 12, however, are sufficient to transform the claim into patent eligible subject matter under *Alice* step two." *Id.* The ID explained that "[t]he claim's recitation of a smartwatch comprising 'a photoplethysmogram ('PPG') sensor configured to sense a heart rate parameter of the user when the activity level value is resting, wherein the PPG sensor is coupled to the processor,' is particularly specific and structural." *Id.* The ID added that "a PPG sensor on a smartwatch is specific and innovative." *Id.* at 69 (citing Hr'g Tr. (Albert) at 66:2-11; Hr'g Tr. (Jafari) at 513:12-15; Hr'g Tr. (Waydo) at

823:12-824:1). The ID reasoned that the "recitation of a PPG sensor within a smartwatch, while not the entire focus of the claim, does move it away from the ineligible concept of data collection/analysis and towards a specific electro-mechanical apparatus." *Id.* (citing *Alice*, 573 U.S. at 217-18 (asking whether the additional elements "transform the nature of the claim" into patent-eligible subject matter)).

The ID stated that "[t]he claim's 'electrocardiogram ('ECG') sensor configured to sense electrical signals of a heart, wherein the ECG sensor comprises a first electrode and a second electrode, and wherein the ECG sensor is coupled to the processor' on the smartwatch adds to this finding." *Id.* The ID pointed to record evidence showing that "ECG sensors collect data in a certain way and provide a very particular waveform." *Id.* at 69-70 (citing Hr'g Tr. (Albert) at 48:6-49:24; Hr'g Tr. (Jafari) at 291:4-13; Hr'g Tr. (Stultz) at 1058:16-1059:13, 0195:1-10; '941 patent at Fig. 1, 8:l- 9:23). The ID concluded that "[a]n ECG sensor, in combination with a smartwatch that also includes a PPG sensor, as well as an activity level sensor, amounts to significantly more than a patent on the ineligible concept of analyzing a heart rate and activity, and then measuring and analyzing ECG electric signals for medical diagnosis." *Id.* The ID acknowledged that "[t]aken individually, each separate component may be conventional," but that "combining all the various sensors on a smartwatch, for a specific function that is not traditional for smartwatches, is sufficiently 'unconventional' to satisfy Section 101 under *Alice* step two." *Id.* at 70.

The ID found unpersuasive Apple's main argument that "it is not enough to implement an abstract idea with 'well-understood,' 'routine,' or 'conventional' technology" and that the combined use of PPG sensor data and ECG sensor data for arrhythmia detection was "well-known and not inventive as of 2013." *Id.* at 70 (citing RIB at 57; RRB at 34-35). The test, the

ID stated, "is whether a smartwatch with integrated processor, activity sensor, PPG sensor, and ECG sensor (with at least two electrodes) adds something more than carrying out heart rate discordance determination, user indication of arrhythmia, and arrhythmia confirmation on generic hardware," which, as noted above, the ID found it does. *Id.* at 71.

b) Analysis

The Commission finds that the ID erred in concluding that claim 12 of the '941 patent is directed to an abstract idea under *Alice* step one.[25] As the ID observed, the claim recites "the structure of a smartwatch loaded with a processor and particular sensors." ID at 67. The second portion, referring to instructions, supports the technological advancement of using a smartwatch to detect possible heart defects. *Id.* Indeed, the ID found that the "recitation of a PPG sensor within a smartwatch, while not the entire focus of the claim, does move it away from the ineligible concept of data collection/analysis and towards a specific electro-mechanical apparatus." ID at 68. This finding reflects that the claimed invention passes muster under *Alice* step one. There is no requirement for the entire focus of the claim to be directed to non-abstract concepts. The step-one inquiry is always whether the character of the claims, considered in light of the specification, is directed to excluded subject matter. *Enfish*, 822 F.3d at 1335.

Put differently, the issue is whether claim 12 of the '941 patent is "directed to the abstract idea of analyzing a combination of heart rate and activity, and then measuring and analyzing ECG electric signals for medical diagnosis, as medical practitioners have routinely done for

[25] The ID found that "[t]here is no principled distinction between the claims of the '731 patent and those of the '941 patent under Section 101." ID at 114. The Commission notes that claims 1, 12, and 16 of the '731 patent are similar in substance to claims 12, 13, and 16 of the '941 patent, in that each of the claims are directed to a smart watch with a particular arrangement of sensors to detect the presence of an arrhythmia. Thus, the Commission's analysis applies equally to the asserted claims of the '731 patent.

years," as the ID found (ID at 68); or whether the claim is directed to technological improvements in cardiac monitoring technology, as AliveCor contends. AliveCor Pet. at 16-17; AliveCor Rep. at 41-46. In our judgment, the claim as a whole, considered in light of the specification, supports AliveCor's argument.

The specification of the '941 patent discloses that diagnosing intermittent arrhythmias using conventional methods was "difficult, because, for example, it is not practical to be prepared to apply one of the aforementioned diagnostic modalities at the exact time that an individual experiences an intermittent arrhythmia." '941 patent col. 1, ll. 49-53. The specification explains that by sensing heart rate parameters and activity level, the smartwatch can "determine the future onset of or the presence of an arrhythmia by identifying discordance between these two parameter values" and "[i]n response to the identification of the future onset of or presence of an arrhythmia an electrocardiogram may be caused to be sensed." *Id*. at col.1 ll.61-66, col.2 ll.1-3. That is, the patented invention solves a concrete problem by implementing a particular configuration of sensors and steps on a smartwatch. As AliveCor's expert, Dr. Efimov, testified, by monitoring the user's heart rate parameter in the background and indicating to the user when an arrhythmia may be present, the claimed device allows users to record an ECG outside clinical settings and "confirm" arrhythmias that a doctor would have otherwise missed. Tr. (Efimov) at 1229:24-1231:6. Contrary to the ID's findings, the claimed invention does not simply analyze a combination of heart rate and activity, and then measure and analyze ECG electric signals for medical diagnosis, as medical practitioners have routinely done for years. ID at 68. Rather, the claims recite a specific system that uses a first sensor to sense an activity level value of a user, and a photoplethysmogram ("PPG") sensor configured to sense a heart rate parameter of the user so as to alert the user of the possibility of an arrhythmia and to

enable the capture of an ECG. '941 patent col.1 ll.49-57, claim 12. This technological advancement enables the capture of ephemeral cardiac events in a way not possible using prior cardiac monitoring technology. Tr. (Efimov) at 1252:15-1254:18; CDX-002C.45; IA Rep. 22-23.

We agree with AliveCor that the asserted claims are akin to the claims the Federal Circuit found pass muster under *Alice* step one in C*ardioNet, LLC v. InfoBionic, Inc*, 955 F.3d 1358 (Fed. Cir. 2020). In *CardioNet*, the patent "describe[d] cardiac monitoring systems and techniques for detecting and distinguishing atrial fibrillation and atrial flutter from other various forms of cardiac arrhythmia."[26] *Id*. at 1362. In reversing the district court, the Federal Circuit stated that "the language of claim 1 indicates that it is directed to a device that detects beat-to-beat timing of cardiac activity, detects premature ventricular beats, and determines the relevance of the beat-to-beat timing to atrial fibrillation or atrial flutter, taking into account the variability in the beat-to-beat-timing caused by premature ventricular beats identified by the device's ventricular beat detector." *Id*. at 1368. The Court pointed to the specification's disclosure that the claimed device "more accurately detects the occurrence of atrial fibrillation and atrial flutter—as distinct from [ventricular tachycardia] and other arrhythmias—and allows for more

[26] As the Court stated in *CardioNet*, 955 F.3d at 1365, claim 1 recited:
A device, comprising:
a beat detector to identify a beat-to-beat timing of cardiac activity;
a ventricular beat detector to identify ventricular beats in the cardiac activity;
variability determination logic to determine a variability in the beat-to-beat timing of a collection of beats;
relevance determination logic to identify a relevance of the variability in the beat-to-beat timing to at least one of atrial fibrillation and atrial flutter;
and an event generator to generate an event when the variability in the beat-to-beat timing is identified as relevant to the at least one of atrial fibrillation and atrial flutter in light of the variability in the beat-to-beat timing caused by ventricular beats identified by the ventricular beat detector.

reliable and immediate treatment of these two medical conditions" and "achieves multiple technological improvements." *Id*. at 1368-69. Here too, the evidence shows that claimed device (smartwatch in claim 12) monitors the user's heart rate parameter in the background and indicates to the user when an arrhythmia may be present, allowing users to record an ECG outside clinical settings to "confirm" arrhythmias that a doctor would have otherwise missed. Tr. (Efimov) at 1229:24-1231:6. That is, the claim is directed to technological improvements in cardiac monitoring.

In any event, even if the claims are directed to an abstract idea under *Alice* step one as the ID found, the Commission agrees with the ID that the claims would be patentable under *Alice* step two. Under *Alice* step two, the asserted claims do not merely claim a "generic environment in which to carry out the abstract idea." ID at 70. Rather, the claimed configuration of sensors and other hardware components implemented in a smartwatch is inventive. *Id.* ("Taken individually, each separate component may be conventional, but combining all the various sensors on a smartwatch, for a specific function that is not traditional for smartwatches, is sufficiently 'unconventional' to satisfy Section 101 under *Alice* step two."). As the ID added, "[t]here may come a time when every smartwatch includes the various claimed sensors, and runs the needed algorithms to practice claim 12, but as of the date of the invention the 'ordered combination' of the claim's elements was sufficiently 'transform[ative].'" *Id*. (citing *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1369 (Fed. Cir. 2018) ("The mere fact that something was disclosed in a piece of prior art, for example, does not mean it was well-understood, routine, and conventional.")).

3. Whether Claims 16 and 17 of the '499 Patent Are Patentable Under Alice

a) The ID

The ID concluded that independent claim 11,[27] from which claims 16 and 17 depend, is directed to the abstract idea of "taking in heart rate data (of any kind), taking in activity level data (of any kind), calculating heart rate variability, comparing that variability with the activity (by any means), and then alerting the user to 'record an electrocardiogram using said mobile computing device.'"[28] ID at 143. In making that determination, the ID observed that the "bulk of the claim is directed to the data analysis algorithms taking place within the 'processor' and

[27] While independent claim 11 itself has not been asserted in this investigation, we analyze it because asserted claims 16 and 17 necessarily include the limitations of claim 11, from which they depend.

[28] The claims recite:

> 11. A system for determining the presence of an arrhythmia of a first user, comprising a heart rate sensor coupled to said first user;
>
> a mobile computing device comprising a processor, wherein said mobile computing device is coupled to said heart rate sensor, and wherein said mobile computing device is configured to sense an electrocardiogram of said first user; and
>
> a motion sensor
>
> a non-transitory computer readable medium encoded with a computer program including instructions executable by said processor to cause said processor to receive a heart rate of said first user from said heart rate sensor, sense an activity level of said first user from said motion sensor, determine a heart rate variability of said first user based on said heart rate of said first user, compare and activity level of said first user to said heart rate variability of said first user, and alert said first user to record an electrocardiogram using said mobile computing device.
>
> 16. The system of claim 11, wherein said mobile computing device comprises a Smartwatch.
>
> 17. The system of claim 11, wherein said computer program further causes said processor to determine a presence of said arrhythmia using a machine learning algorithm.

according to the 'instructions' saved in memory (*i.e.*, ineligible subject matter)" and that the "bit of apparatus recited (*i.e.*, potentially eligible subject matter) is devoid of specificity, such that it can only be considered generic computer hardware—'a heart rate sensor,' 'mobile computing device,' 'a processor,' 'a motion sensor,' and 'non-transitory computer readable medium.'" *Id.* The ID also pointed to the testimony of Dr. Stultz, who testified that "carrying out these steps is common in medical practice." *Id.* (citing Hr'g Tr. (Stultz) at 1058:13-1059:19, 1077:21-1078:15, 1085:15-22). The ID thus found that "claim 11 is directed to ineligible subject matter under *Alice* step one." *Id.*

The ID then considered claims 16 and 17 and found that they "fare similarly" under *Alice* step one. *Id.* at 144. The ID explained that claim 16 recites that the "mobile computing device" is a "smartwatch" and that "does not materially transform the claim as there is no other limitation that benefits or is affected by the computing device being in this form factor." *Id.* (*comparing* '499 patent at cl. 16 *with* '941 patent at cl. 22 ("wherein the PPG sensor is located on a back of the smartwatch")). Regarding claim 17, the ID noted that it requires the processor to further "determine a presence of said arrhythmia using a machine learning algorithm" but that "[t]his is literally just another algorithm and only deepens the connection between the claim and ineligible subject matter." *Id.*

Turning to *Alice* step two, the ID concluded that "claim 11's non-ineligible elements, either individually or as an ordered combination, do not transform the nature of the claim into something more than a patent on the abstract concept." *Id.* (citing *Alice*, 573 U.S. at 217-18). The ID explained that "there are sensors recited ('heart rate,' 'electrocardiogram,' 'motion'), but they are unrestricted as to structure, arrangement, or data output so long as they relate to 'heart rate,' electrical activity of the heart, or 'activity level,' respectively." *Id.* The ID stated that "an

ECG sensor is rather specific; but unlike claim 12 of the '941 patent, claim 11 of the '499 patent does not recite the number of leads to further specify the type of ECG sensor, nor does it expressly recite any use for the ECG data—it simply exists within the 'mobile computing device.'" *Id.* The ID added that "[i]n essence the claim covers the addition of generic sensors to an existing ECG machine, and for no particular purpose" and that "[a]lone or as an ordered combination, all this is equivalent to the basic idea of using such sensors." *Id.* The ID found that "[t]he remaining hardware limitations ('mobile computing device,' 'processor,' and 'computer readable medium') are equally generic, if not more so, and perform their generic functions (be configurable, contain and execute instructions)" and that "there is nothing recited that could be viewed as improving the operation of any of these computing elements (*e.g.*, faster, fewer errors, less power consumption, etc.)." *Id.*

With respect to claim 16, however, the ID found the recitation of a "smartwatch" was sufficient to pass muster under *Alice* step two. *Id.* The ID stated that "[u]ndoubtedly claim 16 is more abstract than the claims of the '941 and '731 patents, because no particular kind of heart rate sensor or motion sensor is required" but found that "incorporating even any kind of heart rate sensor into a smartwatch, especially when combined with an ECG sensor, lifts that smartwatch out of the realm of 'well-understood, routine, and conventional.'" *Id.* Regarding claim 17, however, the ID found it failed *Alice* step two because the recited "machine learning algorithm" is an unspecified "algorithmic step." *Id.* at 145.

a) Analysis

The Commission agrees with the ID that the claims are directed to the abstract idea of "taking in heart rate data (of any kind), taking in activity level data (of any kind), calculating heart rate variability, comparing that variability with the activity (by any means), and then

alerting the user to 'record an electrocardiogram using said mobile computing device.'" ID at 143. We also agree with the ID that claims 16 and 17 fare no better under *Alice* step one for the reasons provided in the ID. *Id.* at 144.

The Commission affirms the ID's finding as to claim 17. After finding that claim 11 recited an abstract idea, the ID correctly concluded that "claim 11's non-ineligible elements, either individually or as an ordered combination, do not transform the nature of the claim into something more than a patent on the abstract concept." *Id.* at 144. The ID reasoned that "there are sensors recited ('heart rate,' 'electrocardiogram,' 'motion'), but they are unrestricted as to structure, arrangement, or data output so long as they relate to 'heart rate,' electrical activity of the heart, or 'activity level,' respectively." *Id.* That is, the claims are broad enough to cover any generic and conventional sensor that can carry out those functions. Even when the claims recite a specific sensor, ECG sensor, as the ID observed, "unlike claim 12 of the '941 patent, claim 11 of the '499 patent does not recite the number of leads to further specify the type of ECG sensor, nor does it expressly recite any use for the ECG data—it simply exists within the 'mobile computing device.'" ID at 144.

Under *Alice* step two, the Commission looks for an "inventive concept" or "additional features" to ensure that the patent does not seek simply to "monopolize the abstract idea." *Alice*, 573 U.S. at 221. As the ID found, claim 17 in essence "covers the addition of generic sensors to an existing ECG machine, and for no particular purpose." ID at 144. We adopt the ID's finding that "[a]lone or as an ordered combination, all this is equivalent to the basic idea of using such sensors" in their well-known and conventional manner. *See id.* We further agree with the ID that the "hardware limitations ('mobile computing device,' 'processor,' and 'computer readable medium') are equally generic, if not more so, and perform their generic functions (be

configurable, contain and execute instructions)." *Id.* Indeed, "there is nothing recited that could be viewed as improving the operation of any of these computing elements (*e.g.*, faster, fewer errors, less power consumption, etc.)." *Id.*

As to claim 16, however, the Commission disagrees with the ID that simply reciting a "smartwatch" imbues the recited abstract idea with patentable subject matter. As the ID acknowledged, "[u]ndoubtedly claim 16 is more abstract than the claims of the 941 and 731 patents, because no particular kind of heart rate sensor or motion sensor is required." ID at 145. That is, unlike the asserted claims of the '941 and '731 patents that require specific sensors arranged in a specific configuration, claim 16 simply incorporates generic sensors used in their well-known and conventional manner in a "smartwatch." We disagree with the ID that "incorporating even any kind of heart rate sensor into a smartwatch, especially when combined with an ECG sensor, lifts that smartwatch out of the realm of 'well-understood, routine, and conventional.'" *Id.* The only difference between claims 16 and 17 is the environment in which the abstract idea is carried out. Under Federal Circuit precedent, this is insufficient to confer patentability on claim 16. *See Intellectual Ventures v. Capital One Bank*, 792 F.3d at 1366 ("An abstract idea does not become nonabstract by limiting the invention to a particular field of use or technological environment, such as the Internet."); *Affinity Labs*, 838 F.3d at 1259 ("[M]erely limiting the field of use of the abstract idea to a particular existing technological environment does not render the claims any less abstract."). Moreover, it would stifle innovation to find that at the relevant time a claim that describes generic sensors used in a conventional way is patentable when implemented in a smartwatch. As the Supreme Court has explained, "the underlying functional concern here is a *relative* one: how much future innovation is foreclosed relative to the contribution of the inventor." *Mayo Collaborative Servs. v. Prometheus Labs.,*

Inc., 566 U.S. 66, 88 (2012) (emphasis in original) (citation omitted). Accordingly, the Commission reverses the ID's finding as to claim 16 and finds it patent ineligible under section 101.

C. The ID's Findings with Respect to Obviousness Under 35 U.S.C § 103

The ID found that Apple failed to show that the asserted claims of the '941 patent are invalid for obviousness. ID at 60-98. For the '731 patent, the ID found that Apple failed to prove that asserted claims 3, 5, 9, 10, and 15 are invalid for obviousness, but proved that asserted claims 1, 8, 12, and 16 are invalid for obviousness. *Id.* at 113-127. The Commission determined to review the final ID's invalidity findings, including obviousness under 35 U.S.C. § 103, and asked for briefing. 87 Fed. Reg. 58819-20 (Sept. 28, 2022). On review, the Commission has determined to affirm the ID's invalidity findings with the modification below as to secondary considerations.

1. Legal Standard

"Obviousness is a question of law based on underlying questions of fact." *Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V.*, 528 F.3d 1365, 1379 (Fed. Cir. 2008). The underlying factual determinations include the so-called "Graham factors": "(1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) objective indicia of non-obviousness." *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966). The U.S. Supreme Court has held that the critical inquiry in determining the differences between the claimed invention and the prior art is whether there is a reason to combine the prior art references. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418-21 (2007). While specific teachings, suggestions, or motivations to combine prior art may provide helpful insights into the state of the art at the time of the alleged invention, "an obviousness analysis cannot be confined by a formalistic conception of the words teaching,

suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents." *Id.* at 420.

An obviousness determination should also include a consideration of "secondary considerations," that is, "commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." *Graham*, 338 U.S. at 17-18; *see Merck & Cie v. Gnosis S.P.A.*, 808 F.3d 829, 837 (Fed. Cir. 2015). "[I]n order to accord substantial weight to secondary considerations of nonobviousness, the evidence of secondary considerations must have a 'nexus' to the claims, *i.e.*, there must be 'a legally and factually sufficient connection' between the evidence and the patented invention." *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1332 (Fed. Cir. 2019) (internal citations omitted).

Under established Federal Circuit precedent, "a patentee is entitled to a rebuttable presumption of nexus between the asserted evidence of secondary considerations and a patent claim if the patentee shows that the asserted evidence is tied to a specific product and that the product '*is* the invention disclosed and claimed.'" *Teva Pharms. Int'l GmBH v. Eli Lilly & Co.*, 8 F.4th 1349, 1360 (Fed. Cir. 2021) (citing *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366 (Fed. Cir. 2019)). This presumption applies "when the patentee shows that the asserted objective evidence is tied to a specific product and that product 'embodies the claimed features, and is coextensive with them.'" *Id.* (internal citations omitted). "Conversely, '[w]hen the thing that is commercially successful is not coextensive with the patented invention—for example, if the patented invention is only a component of a commercially successful machine or process,' the patentee is not entitled to a presumption of nexus." *Id.* (internal citations omitted). The Court stated that it has "rejected attempts 'to reduce the coextensiveness requirement to an inquiry into

whether the patent claims broadly cover the product that is the subject of the evidence of secondary considerations.'" *Id.* at 1360-61. As the Court explained, rather, "the degree of correspondence between a product and a patent claim falls along a spectrum. At one end of the spectrum lies 'perfect or near perfect correspondence,' and at the other end lies 'no or very little correspondence.'" *Id.* at 1361 (internal citations omitted). "Although we do not require the patentee to prove perfect correspondence to meet the coextensiveness requirement, what we do require is that the patentee demonstrate that the product is essentially the claimed invention." *Id.* "Whether a product is coextensive with the patented invention, and therefore whether a presumption of nexus is appropriate in a given case, is a question of fact." *Id.*

2. Analysis

For the reasons stated herein, the Commission has determined to affirm the ID's findings that Apple failed to prove that claims 12, 13, 19, and 20-23 of the '941 patent are invalid for obviousness. The Commission has also determined to affirm the ID's findings that Apple failed to prove that claims 3, 5, 9, 10, and 15 of the '731 patent are invalid for obviousness for the reasons stated in the ID. The Commission, however, has determined to reverse the ID's findings that Apple proved that claims 1, 8, 12, and 16 of the '731 patent are invalid for obviousness as explained below. In sum, the Commission finds that none of the asserted claims has been shown to be invalid for obviousness.

a) Record Evidence of Industry Praise and Copying Is Sufficient to Overcome the Prima Facie Showing of Obviousness with Respect to Claims 12, 16, 20, 22, and 23 of the '941 Patent

The ID found that because KBS practices claims 12, 16, 20, 22, and 23 of the '941 patent, AliveCor was entitled to a presumption of nexus where the secondary consideration evidence pertains to KBS. ID at 93. The ID found that AliveCor's evidence and argument as to

commercial success, copying, and industry praise were sufficient to overcome Apple's *prima facie* showing of obviousness.

With respect to commercial success, the ID found that AliveCor's evidence of [[ ]] in funding it received did not have a clear connection to the KBS. ID at 95. AliveCor does not challenge this finding. The ID credited certain evidence "show[ing] that KBS 'was selling very successfully,' as ALC's chief financial officer testified." ID at 95 (citing RX-0384C (Hosein Deposition) at 77:24-78:11; CX-0934C; CX-0935C (showing that KBS revenues for calendar years 2017, 2018, and 2019 totaled over [[ ]]"). *Id.* But the ID found that "KBS' profitability is not clear, though, so the evidence of commercial success is not as persuasive as the evidence of industry praise."

Apple challenged the ID's nexus presumption as to commercial success based on the KBS sales revenues because that evidence pertained solely to the KardiaBand, which lacks the PPG and activity sensors required by the asserted claims. Apple Pet. at 86-87. AliveCor acknowledges that "the KardiaBand is but one element of the KBS" and can be used without SmartRhythm. AliveCor Rep. at 67. AliveCor explains that "because each product was sold by separate manufacturers, AliveCor could not produce evidence of the KBS's commercial success as a whole." *Id.* AliveCor, however, contends that "it is equally true that the KardiaBand could not be used without the Apple Watch" and that "Apple produced no evidence suggesting that consumers who purchased the KardiaBand did not use that accessory with the Apple Watch." *Id.* AliveCor points to its former chief technology officer, Mr. Somayajula, who testified that for "whoever was buying [the KardiaBand], it was obvious that it required the KardiaBand System, which comprised of the Apple Watch, for it to be functional" and that "[o]therwise that hardware would be of no use to the customer." *Id.* (citing JX-0226C (Somayajula Dep.) at 43:12-23).

AliveCor also argues that its commercial success evidence as to KardiaBand undervalues the commercial success of KBS as a whole because it does not account for Apple Watch sales that were made to take advantage of the KBS's features, *id.* at 68; however, AliveCor cites no proof as to revenues or profits associated with its theory of additional Apple Watch sales. *Id.* The Commission finds, based on this record, that AliveCor's evidence of commercial success regarding the '941 patent claims is weak and gives it little weight in determining whether the evidence of secondary consideration is sufficient to overcome the *prima facie* evidence of obviousness. Specifically, the Commission agrees with the ID that KBS' profitability is not clear and AliveCor's evidence of [[ ]] in funding it received did not have a clear connection to the KBS. ID at 95.

The Commission, however, finds that the evidence of "industry praise" and "copying" together, even without commercial success, is sufficient to overcome the *prima facie* showing of obviousness.[29] Apple argues that the ID's findings on "industry praise" and "copying" are in error and that even if they were not, the evidence is insufficient to overcome its prima facie obviousness showing. Apple Sub. at 4-7. The ID's findings as to copying and industry praise, however, are amply supported by the record evidence. ID at 93-96. Moreover, the cases that

[29] Chairman Johanson would not find that the secondary indicia of nonobviousness outweigh the *prima facie* case of obviousness. The ALJ found that "the prima facie case is strong." FID at 97. With respect to claims 12, 16, 20, 22, and 23 of the '941 patent, he found that "except for one element of independent claim 12, every element of every claim is found in AMON." FID at 97. With respect to that one missing limitation ("based on the presence of the discordance, indicate to the user a possibility of an arrhythmia being present") the ALJ finds that "[i]n essence, AMON discloses a genus (inform the user of the sensed condition in an appropriate form) of which the 'indicate' limitation is a species . . . . AMON itself implies multiple possibilities, but it surely would have been obvious to that skilled artisan to just program the device to display a plain language description of the detected discordance . . . in fact, it likely would have been the simplest implementation." FID at 76. Given the strength of these findings, Chairman Johanson would not find the evidence of obviousness outweighed by the cited evidence of nonobviousness.

Apple relies on predate the Court's *Graham* 1966 decision. *See* Apple Sub. at 4 (citing *Dow Chem. Co. v. Halliburton Oil Well Cementing Co.*, 324 U.S. 320, 330 (1945); *Jungersen v. Ostby & Barton Co.*, 335 U.S. 560, 567 (1949)). *Graham* and its progeny make clear "[t]hat evidence is 'secondary' in time does not mean that it is secondary in importance." *Truswal Sys. Corp. v. Hydro–Air Eng'g, Inc.*, 813 F.2d 1207, 1212 (Fed. Cir. 1987). The Federal Circuit has explained that the requirement that courts always consider secondary considerations "is in recognition of the fact that each of the *Graham* factors helps to inform the ultimate obviousness determination." *See WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1328 (Fed. Cir. 2016).

b) Secondary Considerations for Claims 1, 12, and 16 of the '731 Patent

The ID stated that the elements of claims 1, 12, and 16 of the '731 patent are disclosed in AMON and that "[b]ecause anticipation is 'the epitome of obviousness' [(*Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1373 (Fed. Cir. 2019)], claims 1, 12, and 16 are invalid, without regard to secondary considerations of non-obviousness." ID at 126.

In its petition for review, AliveCor asserted that the ID's finding is legal error. AliveCor Pet. at 27-29. Specifically, AliveCor argued that the Federal Circuit "has consistently pronounced that all evidence pertaining to the objective indicia of nonobviousness must be considered before reaching an obviousness conclusion." *Id.* at 28 (citing *Plantronics, Inc. v. Aliph, Inc.*, 724 F.3d 1343, 1355 (Fed. Cir. 2013); *Stratoflex, Inc. v. Aeroquip Cor.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983) ("[Evidence of secondary considerations] is to be considered as part of all the evidence, not just when the decisionmaker remains in doubt after reviewing the art.")).

The Federal Circuit has emphasized that "[t]he significance of this fourth *Graham* factor cannot be overlooked or be relegated to 'secondary status.'" *Plantronics*, 724 F.3d at 1355. The

mere fact that anticipation is the "epitome of obviousness" does not make anticipation and obviousness the same. These are two distinct legal doctrines with distinct bodies of law. While secondary considerations remain relevant in an obviousness inquiry, such considerations are absent from anticipation. Thus, the issue is whether the ID was considering obviousness or anticipation when analyzing Apple's invalidity case as to the '731 patent. As AliveCor points out, Apple did not assert anticipation as a defense at the hearing or in its pre- or post-hearing briefing. AliveCor Pet. at 29 (citing Respondent's Initial Post-HB at 95-104 (asserting only obviousness); Respondent's Reply Post-HB at 55-61 (same)). OUII stated that "to the extent that the ID found that each limitation of claims 1, 12, and 16 is found in AMON, those claims are anticipated and secondary considerations of obviousness do not apply," even though OUII did not assert anticipation before the ALJ. OUII Rep. at 42. But relying on a single reference to show obviousness, as here, does not convert the obviousness inquiry into an anticipation inquiry. Indeed, none of the parties made an anticipation argument.

Apple asserts that the "ID did not commit legal error when it determined that Apple's *prima facie* case of obviousness was so strong that it was equivalent to anticipation, and therefore secondary considerations need not be considered." Apple Rep. at 24. We disagree. Apple cites *Planet Bingo, LLC v. GameTech Int'l,* Inc., 472 F.3d 1338, 1346 (Fed. Cir. 2006), as holding that "if an accused infringer makes a non-frivolous argument that 'each and every limitation of a claim is found, expressly or inherently, in [a] single prior art reference,' the accused infringer generally is entitled to have anticipation decided by the finder of fact." *Planet Bingo,* however, is an anticipation case, and says nothing about obviousness. In any event, the Supreme Court's precedent, *Graham*, is clear that a tribunal must consider secondary

considerations of nonobviousness in determining whether an invention would have been obvious to a person of ordinary skill in the art at the time of the invention. *Graham,* 383 U.S. at 17.

We therefore agree with AliveCor that the ID erred in failing to consider the evidence of secondary considerations before concluding the relevant claims of the '731 patent are invalid as obvious. The Commission finds that the ID's secondary consideration findings as to the '941 patent applies to claims 1, 12, and 16 of the '731 patent as well.[30] The Commission thus finds that the secondary considerations of "industry praise" and "copying" are sufficient to overcome the *prima facie* showing of obviousness for claims 1, 12, and 16 of the '731 patent.[31]

V. REMEDY

Where a violation of section 337 has been found, the Commission must consider the issues of remedy, the public interest, and bonding. Section 337(d)(1) provides that:

> If the Commission determines, as a result of an investigation under this section, that there is a violation of this section, it shall direct that the articles concerned, imported by any person violating the provision of this section, be excluded from entry into the United States, unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry

19 U.S.C. § 1337(d)(1); *see also Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1358 (Fed. Cir. 2010) ("[T]he Commission is required to issue an exclusion order upon the finding of

[30] Chairman Johanson would not find that the secondary indicia of nonobviousness outweigh the *prima facie* case of obviousness as to claims 1, 12, and 16 of the '731 patent. The ALJ found that "claims 1, 12, and 16 are disclosed in AMON" in a manner that is tantamount to anticipation. FID at 126. Commissioner Johanson agrees that the Commission must consider evidence of nonobviousness as to these claims but would not find the strong showing of obviousness to be outweighed by the evidence of nonobviousness.

[31] We note that claims 1, 12, and 16 of the '731 patent are similar in substance to claims 12, 13, and 16 of the '941 patent, in that each of the claims are directed to a smart watch with a particular arrangement of sensors to detect the presence of an arrhythmia.

a Section 337 violation absent a finding that the effects of one of the statutorily-enumerated public interest factors counsel otherwise."). The Commission has "broad discretion in selecting the form, scope, and extent of the remedy." *Viscofan, S.A. v. U.S. Int'l Trade Comm'n*, 787 F.2d 544, 548 (Fed. Cir. 1986). The Commission may issue an exclusion order excluding the goods of the person(s) found in violation (*i.e.*, a limited exclusion order) or, if certain criteria are met, against all infringing goods regardless of the source (*i.e.*, a general exclusion order).

In conjunction with (or in lieu of) an exclusion order, the Commission may also issue orders directing persons found in violation of section 337 "to cease and desist from engaging in the unfair methods or acts involved." 19 U.S.C. § 1337(f). The Commission generally issues a cease and desist order ("CDO") when the evidence shows that the respondent maintains a "commercially significant" inventory of imported infringing products in the United States or has significant domestic operations that could undercut the remedy provided by an exclusion order.[32] *See, e.g.*, *Certain Elec. Skin Care Devices, Brushes & Chargers Therefor, & Kits Containing the Same*, Inv. No. 337-TA-959, Comm'n Op. at 26 (Feb. 13, 2017).

A. Limited Exclusion Order

As noted above, the ID included the ALJ's Recommended Determination ("RD") on remedy and bonding. ID/RD at 189-195. In the RD on remedy and bonding, the ALJ recommended that, in the event the Commission finds a violation of section 337, "there is no

[32] When the presence of infringing domestic inventory or domestic operations is asserted as the basis for a CDO under section 337(f)(1), Commissioner Schmidtlein does not adopt the view that the inventory or domestic operations need(s) to be "commercially significant" in order to issue the CDO. *See, e.g.*, *Certain Magnetic Tape Cartridges & Components Thereof*, Inv. No. 337-TA-1058, Comm'n Op. at 65 n.24 (Apr. 9, 2019); *Certain Table Saws Incorporating Active Injury Mitigation Tech. & Components Thereof*, Inv. No. 337-TA-965, Comm'n Op. at 6 n.2 (Feb. 1, 2017). In Commissioner Schmidtlein's view, the presence of some infringing domestic inventory or domestic operations, regardless of its commercial significance, provides a basis to issue a CDO.

dispute that a limited exclusion order ('LEO') should issue against Apple that covers all infringing products imported by or on behalf of Apple or its agents." ID/RD at 190. The ALJ recommended that the LEO include the Commission's standard certification as "it has been Commission practice for the past several years to include certification provisions in its exclusion orders to aid CBP [Customs and Border Protection]." *Id.* at 92.

AliveCor and OUII agree with the ID's recommendation. AliveCor Sub. at 35; OUII Sub. at 8-9. Apple argues that no remedial orders should issue because it would have an adverse effect on the public interest. Apple Sub. at 37-64. Apple also argues that should the Commission issue an LEO, it should "suspend enforcement thereof for at least two years to allow for sufficient production of adequate replacements to Apple Watch and, at a minimum, until final resolution of the Patent Office's Final Written Decisions on AliveCor's Asserted Patents" and "tailor its remedy to allow for support of Apple Watch users, clinical use, certain personal imports, governmental use, and standard certification." *Id.* at 67; Apple Pet. at 98 (citing Apple's Notice of Institution of Petitions for *Inter Partes* Review and noting that "[t]he PTAB's FWDs on each asserted claim is expected December 8, 2022"). We discuss these issues below.

The Commission has determined to issue a limited exclusion order covering the unlicensed importation of wearable electronic devices with ECG functionality and components thereof that infringe one or more of claims 12, 13, and 19-23 of the '941 patent; and claims 1, 3, 5, 8-10, 12, 15, and 16 of the '731 patent that are manufactured abroad by or on behalf of, or imported by or on behalf of, Respondent or any of its affiliated companies, parents, subsidiaries, or other related business entities, or their successors or assigns, are excluded from entry for consumption into the United States, entry for consumption from a foreign trade zone, or withdrawal from a warehouse for consumption, for the remaining terms of the patents, except

under license of the patent owner or as provided by law, and except for articles or components imported for use in servicing, repairing, or replacing covered articles that were imported prior to the effective date of this Order pursuant to existing service and warranty contracts.[33]

The Commission agrees that the LEO should include the standard certification provision under which, at the discretion of CBP and pursuant to the procedures it establishes, persons seeking to import articles that are potentially subject to the LEO may be required to certify that they are familiar with the terms of the LEO, that they have made appropriate inquiry, and thereupon state that, to the best of their knowledge and belief, the products being imported are not excluded from entry under the LEO. Certification is only acceptable for those articles that were previously determined not to infringe. *See Automated Teller Machines, ATM Modules, Components Thereof, & Prods. Containing the Same*, Inv. No. 337-TA-972, Comm'n Op. at 27 (June 12, 2017) ("The standard certification language does not apply to redesigns that have not been adjudicated as non-infringing."). As discussed below, the Commission finds that the public interest factors do not counsel against issuance of remedial orders, but warrant an exception for servicing, repairing, or replacing covered articles that were imported prior to the effective date of this Order pursuant to existing service and warranty contracts.

[33] Apple also requested an exemption for software updates and personal imports. Apple Sub. at 70-73. Commission exclusion orders, however, do not extend to electronic transmissions. *See ClearCorrect, Inc. v. Int'l. Trade Comm'n*, 810 F.3d 1283 (Fed. Cir. 2015). As to personal imports, the exclusion order here is directed to infringing articles "that are manufactured abroad by or on behalf of, or imported by or on behalf of, Respondent or any of its affiliated companies, parents, subsidiaries, or other related business entities, or their successors or assigns." LEO ¶ 1. Apple has not shown why an exemption for personal imports is warranted.

B. Cease and Desist Order

The ALJ noted that Apple stipulated that it "'will not dispute that it currently maintains a commercially significant inventory of the Accused Apple Products in the United States at the time hearing evidence is submitted in this Investigation.'" ID/RD at 192 (citing CX-0904C.3). The ALJ found that, "[p]er that stipulation, ALC reports 'a domestic inventory of [[ ]] that cumulatively value at over [[ ]]' and argues it is 'commercially significant' as well as an underestimation." *Id.* The ALJ stated that "[g]iven the stipulation referenced above, this inventory requirement is certainly met for Apple, and it is my recommendation that a cease and desist order ("CDO") issue against this respondent." *Id.* at 193 (citing CX-0904C.3).

AliveCor and OUII agree with the ALJ that a CDO is warranted in this investigation. AliveCor Sub. at 39-40; OUII Sub. at 9. Specifically, OUII notes that "Apple has stipulated that it has an inventory of at least [[ ]] of the Accused Products in the United States valued at over [[ ]]" and that "[t]his inventory is used to support Apple's commercial operations in the United States, and Apple does not dispute that it is commercially significant." OUII Sub. at 9 (citing CX-904C (Import Stip.)).

In light of the undisputed evidence of commercially significant domestic inventory, the Commission has determined to issue a CDO against Apple. [34] The CDO directs Apple to cease and desist from conducting any of the following activities in the United States: importing, selling, offering for sale, marketing, advertising, distributing, transferring (except for exportation), soliciting United States agents or distributors, and aiding or abetting other entities in the importation, sale for importation, sale after importation, transfer (except for exportation),

[34] In light of the undisputed evidence of domestic inventory, Commissioner Schmidtlein agrees with issuing a CDO as to Apple in this case. *See supra* note 32.

or distribution of wearable electronic devices with ECG functionality and components thereof that infringe one or more of claims 12, 13, and 19-23 of the '941 patent, and claims 1, 3, 5, 8-10, 12, 15, and 16 of the '731 patent.

C. The Public Interest

Prior to issuing remedial orders under section 337, the Commission must weigh the effect the orders would have on four public interest factors: (1) the public health and welfare; (2) competitive conditions in the United States economy; (3) the production of like or directly competitive articles in the United States; and (4) United States consumers. 19 U.S.C. §§ 1337(d), (f). In connection with the statutory public interest requirement and based upon statements on the public interest received from the parties and various third parties, the Commission asked for briefing in its Notice of Review. 87 Fed. Reg. 58819-20 (Sept. 28, 2022).

The private parties and numerous third parties filed public interest statements. Apple argues that the public interest favors suspension of any exclusion order in particular to avoid any adverse impact on public health and welfare for U.S. consumers and researchers that use the Apple Watch with ECG and IRN[35] for early identification of AFib and other health conditions. *See* Respondent Apple Inc's Public Interest Statement at 4; Apple Pet. at 99. According to Apple, there are insufficient substitutes for its accused Apple watches.

The following entities submitted public interest statements in support of Apple's position and presented essentially the same arguments as Apple:

- Statement of Third Parties Computer & Communications Industry Association and Netchoice in Response to the Commission's July 15, 2022, Notice of Request for Statements on the Public Interest (July 26, 2022)
- Dr. Marco Perez, Associate Professor in Cardiovascular Medicine, Stanford School of Medicine

[35] "IRN" stands for Irregular Rhythm Notification.

- Dr. Calkins, Professor of Cardiology, Johns Hopkins School of Medicine
- Dr. Richard Milani, Chief Clinical Transformation Officer, Ochsner Health System
- Mellanie True Hills CEO and Founder of StopAfib.org, an atrial fibrillation patient advocacy organization and patient-to-patient resource
- Members of Congress: Representatives Eric Swalwell, Zoe Lofgren, Donald Beyer, Anna Eshoo, Jimmy Panetta, Linda Sanchez, and J Luis Correa expressed concern that issuing an exclusion order against Apple's wearable devices would present a significant detriment to American consumers

The American Heart Association ("AHA") submitted a statement "not in support of any party," but their position is consistent with Apple. *See* Statement of Non-Party American Heart Association on the Public Interest of the Recommended Remedial Orders But Not in Support of Any Party (July 26, 2022). The AHA stated that the "recommended remedial orders would harm scientific research, healthcare consumers, and healthcare providers and in the United States. Accordingly, the AHA urges the Commission to tailor any remedial orders to allow researchers adequate time to complete ongoing research projects and transition to new research protocols with devices that are not subject to any exclusion order."

AliveCor asserts that its requests for an LEO and a CDO will benefit the public in that they "will promote intellectual property rights and continued innovation, and prevent a powerful company from holding health technology hostage simply because it is a large company that has successfully excluded competition." Complainant AliveCor, Inc.'s Statement on the Public Interest at 1-2. According to AliveCor, there is a "diverse field of suppliers" of alternative products that offer the health monitoring technologies of the accused Apple watches. *Id.*

The following entities submitted public interest statements in support of AliveCor's position and presented essentially the same arguments as AliveCor:

- Dr. Swerdlow, Professor of Medicine, Cedars Sinai Clinical Professor of Medicine, UCLA Cedars-Sinai Heart Institute

- Dr. Topol, Executive VP, Scripps Research and Director, Scripps Research Translational Institute

- Dr. Reynolds, Chief of Cardiovasular Section, the University of Oklahoma Health Sciences Center

- Cardiovascular Research Foundation of Southern California ("The answer could not be more transparent and clear that excluding infringing Apple Watches does not harm the public interest.")

- Medical Device Manufactures Association (The recommended relief is in the public interest given the need to protect the patent rights of medical device innovators from the threat of companies such as Apple who can afford to engage in "efficient infringement" as a business strategy.)

- Members of Congress: Representatives Henry "Hank" Johnson, Jr. and Lucy McBath expressed sentiment that the public interest is best served when the Commission takes action to protect intellectual property, enforce our nation's patent laws, and promote fair and robust competition

1. Apple Submission

a) Public Health and Welfare

Apple asserts that the recommended remedy "will seriously harm the public health and welfare" in three ways: (1) it will "reduce early detection of AFib, a prevalent and life-threatening disease that often goes undetected until a patient experiences serious or fatal complications, and may reduce detection of other cardiac conditions"; (2) it will "irreparably disrupt ongoing research into AFib, depriving the American public of potentially 'breakthrough' treatments for this disease and wasting millions of dollars in public and private investment already devoted to medical research using Apple Watch"; and (3) it will "deprive consumers of Apple Watch's numerous other invaluable health, wellness, and safety functions and disrupt ongoing research on these unaccused features." Apple Sub. at 40.

With respect to the first reason, Apple states that it "recognized the potential for Apple Watch to help detect AFib early, before a user experiences a stroke or other major medical

event" and that after years development, "followed by extensive clinical trials establishing the safety and efficacy of each of ECG app and IRN, Apple received *de novo* FDA authorizations for each separate feature in September 2018." *Id.* at 41 (citing Tr. (Waydo) at 738:6-9). Apple contends that its "ECG app and IRN each help facilitate 'diagnoses that otherwise would have either been diagnosed much later or missed altogether without an Apple Watch.'" *Id.* Apple explains that the "ECG app enables users to record an electrocardiogram on demand using two electrodes on Apple Watch" that "record the electrical activity of the user's heart for a 30-second period." *Id.* at 41-42. The ECG app on Apple Watch then "rapidly analyzes the heart's electrical signals to detect whether signs of AFib are present." *Id.* at 42. Apple points to the FDA's statement in approving its ECG app that "having this 'convenient and readily accessible means to record' an ECG on demand 'is especially valuable for users with recurrent, transient but infrequent symptoms, which can be difficult to catch with traditional cardiac monitors.'" *Id.* Apple further explains that upon activation, the IRN "operates in the background, periodically measuring and analyzing the user's pulse rate using PPG sensors located on the back of Apple Watch to identify irregular heart rhythms" and that "[i]f IRN identifies and confirms heart rhythms suggestive of AFib, IRN will notify the user and prompt them to 'talk to [their] doctor.'" *Id.* at 42 (citing ID at136 (quoting IRN notification)). Once again, Apple notes the FDA's statement that this feature "is an effective device for identifying abnormal pulse rates that may suggest the presence of [AFib]." *Id.* Apple "estimates that there are [[ ]] Apple Watch users in the United States who have activated IRN on their Apple Watch, and a similar number who have activated ECG app." *Id.* at 43.

Regarding the second reason, Apple asserts that remedial orders "will jeopardize ongoing and planned AFib research, depriving the public of critical advances in medical knowledge." *Id.*

at 47. According to Apple, there are numerous ongoing studies related to heart diseases using the Apple Watch. *Id.* As an example, Apple points to the "American Heart Association's collaboration with Northwestern University and researchers from Johns Hopkins University, Stanford University, and the University of California at San Francisco on the REACT-AF study, a seven-year, 5,400-patient research trial that will study the potential of Apple Watch to minimize the amount of time that a patient with AFib needs to take blood thinning medications." *Id.* (citing Kristin Samuelson, *Can Apple Watch reduce patients' reliance on blood thinners*, Northwestern University (Aug. 29, 2022), https://tinyurl.com/bddd9evk). Apple asserts that "[t]he NIH already awarded researchers $37 million to conduct the study" and that '"government support' for research is an important factor "in determining the importance of a public interest."[36] *Id.* (citing *Certain Microfluidic Devices*, Inv. No. 337-TA-1068, Comm'n Op. at 16 (Jan. 10, 2020)). Apple asserts that for ongoing studies using the accused Apple Watches, "the recommended remedial orders could jeopardize their scientific merit and cause waste of resources spent for the studies." *Id.* at 48.

As to the third reason, Apple contends that a remedial order "would deprive consumers of numerous other important life-saving features wholly unrelated to AliveCor's Asserted Patents [and not accused by AliveCor], and disrupt dozens of ongoing medical studies involving these features. *Id.* at 49. As examples Apple asserts that (1) "Apple Watch Series 4 and later offer fall detection, which connects wearers with emergency services after detecting a hard fall that has rendered the wearer immobile"; (2) "Apple Watch Series 6 and later include a blood oxygen monitoring feature that allows users to take on-demand measurements of their blood oxygen saturation—the amount of oxygen the red blood cells carry from the lungs to the rest of the

[36] "NIH" refers to National Institute of Health.

body—providing users with insight into their overall wellness; and (3) both Apple Watch Series 8 and Ultra "offer industry-leading crash detection technology," which "can automatically connect the wearer with emergency services, provide dispatchers with the location of the crash, and notify the wearer's emergency contacts." *Id.* at 50.

b) U.S. Consumers

Apple asserts that the recommended remedy will harm U.S. consumers directly by risking serious harm to consumers' health and welfare as discussed above. *Id.* at 52. Apple argues that remedial orders will also harm U.S. consumers "indirectly by disrupting crucial research and hampering the efficacy of the health care available to them." *Id.* Apple further argues that remedial orders will result in a lack of competition that will further harm U.S. consumers. *Id.*

c) Suitable Alternatives

Apple asserts that "there are not alternative smartwatches capable of counteracting the grave damage to public health and welfare and to consumers described above that would result from exclusion of the accused Apple Watches" and that "no new or upgraded product could redress that harm in a commercially reasonable time, because development, regulatory clearance, and production of such a product takes years." *Id.* at 53-54. According to Apple, "[t]he only suitable alternatives, for purposes of remedying the harm from exclusion, are wearable devices with both FDA-cleared ECG and IRN functions." *Id.* at 54. Apple argues that there are only "two options that meet those criteria currently available in the United States, but neither would ameliorate the harm to public health from an exclusion order." *Id.* Apple identifies "Fitbit, maker of the Charge 5 and Sense," as the only other company in the United States that "currently offers wearable products with HHRN and both an FDA-cleared ECG and IRN feature." *Id.* at 55. Apple, however, contends that "neither Charge 5 nor Sense could sufficiently compensate

for the wide-ranging harms to consumer and public health and welfare in the event of exclusion of Apple Watch from the U.S." *Id.* Apple adds that "[e]ven if Fitbit could ramp up manufacturing to fully meet consumer demand in the event of the sudden shortfall that would occur—which it cannot—the Sense and Charge 5 are markedly inferior to Apple Watch in their functionality, breadth of features, and ability to deliver life-saving cardiac and other benefits." *Id.* Apple further argues that "no other product could take the place of Apple Watch in the groundbreaking research" and that "Apple Watch's prevalence is the actual *subject* of some research, which looks to better understand and measure the public health benefits of a device with such widespread adoption." *Id.* at 57.

Apple observes that "[b]efore issuing an exclusion order, the Commission also considers the ability of AliveCor, its licensees, and third parties to satisfy demand for Apple Watch in the event the recommended remedy issues." *Id.* (citing 19 C.F.R. § 210.8(b)(3)). Apple states that "[n]o one, alone or in combination, can substantially replace the sudden supply shortfall that will arise if Apple Watch is excluded." *Id.* Apple explains that "[g]iven the complexities of engineering new electronic wearables, obtaining FDA clearance, and navigating the fragile and intricate procurement and manufacturing process, companies necessarily plan product launch and output years in advance" and that "[h]ere, where the massive shortfall would result from an external market shock, those companies would be caught flat-footed, unable to meet the enormous demand gap within a commercially reasonable time frame." *Id.* at 57-58.

d) Competitive Conditions in the United States

Apple contends that remedial orders "will also harm competitive conditions in the United States by harming third-parties reliant on the accused products and reducing market pressure on Apple Watch's competitors to cut costs and deliver innovative new products" and that "[t]hese

competitive harms will not be offset by any benefit to domestic 'production of like or directly competitive articles,' 19 U.S.C. § 1337(d)(1), because neither AliveCor nor any of Apple's primary competitors manufactures their competitive products in the United States." *Id.* at 61. Apple explains that "various U.S.-based components suppliers for Apple Watch 'have invested heavily in manufacturing to Apple specifications, … as Apple represents a large percentage of their business'" and that "[t]hese companies 'will likely experience negative impacts due to an exclusion order.'" *Id.* at 62. Apple adds that "numerous 'healthcare companies, hospitals, medical researchers and research institutions … have all made investments to work on projects … that rely on and sync with the Apple Watch.'" *Id.* Apple states that "removing a product as popular as Apple Watch, with as many sales as Apple Watch has, would 'weaken a primary force that underlies the current competitive environment'—vigorous competition between Apple and others." *Id.* at 63.

According to Apple, "[t]he substantial competitive harms caused by an exclusion order will not be offset by any benefit to 'the production of like or directly competitive articles in the United States'" because "the handheld ECG products that AliveCor does sell are not produced in the United States." *Id.* (citing 19 U.S.C. § 1337(d)(1), (f)(1)). Apple adds that to its knowledge, "Apple Watch's competitors, such as Samsung, Fitbit, and Garmin, do not produce their products in the United States either" and that it "is not aware of any company that manufactures full-featured smartwatches in the United States." *Id.* at 64.

e) Apple's Position

Against this backdrop, Apple asserts that the Commission should exercise its discretion and decline to issue an exclusion order. Apple Sub. at 65-67. Apple states that "[s]hould the Commission choose to issue a remedy despite the fact that doing so will place American lives at

risk, it should: (A) suspend enforcement thereof for at least two years to allow for sufficient production of adequate replacements to Apple Watch and, at a minimum, until final resolution of the Patent Office's Final Written Decisions on AliveCor's Asserted Patents" and "(B) tailor its remedy to allow for support of Apple Watch users, clinical use, certain personal imports, governmental use, and standard certification." *Id.* at 67.

Apple argues that "Fitbit, which is currently the only company with FDA-clearances for an ECG app and an IRN feature," "would have to increase its current production of ECG and IRN-enabled products 'many times over' to replace the excluded Apple Watches." *Id.* at 68. Apple states that "given the existing supply chain issues, chip and neon gas shortages, logistics obstacles, and other issues, there is no reasonable likelihood Fitbit could increase its production to meet that demand in less than two years." *Id.* Apple adds that "[f]or any other company that does not have a current smartwatch with both of the two FDA authorized features in development, releasing such a smartwatch in the United States would require developing a working prototype, receiving FDA authorization, and overcoming the substantial supply chain hurdles currently roiling the global economy." *Id.* Apple states that "just receiving the necessary FDA clearance for any replacement product will likely require at least two years—assuming the product qualifies for the most straightforward FDA clearance pathway, which is no guarantee." *Id.* (citing Ex. 2 (Lietzan Decl.) ¶¶ 24-25). Apple thus asserts that "[d]elaying enforcement by two years is therefore the minimum time necessary for suitable alternative products to become available for sale on a scale sufficient to replace excluded Apple Watches." *Id.*

Apple contends that "[r]egardless of whether the Commission chooses to suspend enforcement of any remedial order until alternatives are ready, it should suspend enforcement

until final resolution of the Patent Office's Final Written Decisions for each of the Asserted Patents." *Id.* at 69. Apple states that it "filed petitions for *inter partes* review alleging that all of the claims asserted in this Investigation are unpatentable and should be cancelled" and that a final decision is expected by December 8, 2022, "*before* the Commission's target date to issue its Final Decision." *Id.* (citing *Certain Unmanned Aerial Vehicles*, Inv. No. 337-TA-1133, Comm'n Op., 2020 WL 5407477, at *21 (Sept. 8, 2020) ("Suspension of [any] remedial orders pending resolution of the PTAB's Final Written Decision[s]" is fully "consistent with the Commission's past practice on this issue.").

Apple also argues that the Commission should "tailor its remedy to allow for support of Apple Watch users, clinical use, certain personal imports, governmental use, and standard certification." *Id.* at 67. Apple explains that "[[ ]] Americans have activated EGC and IRN on their Apple Watches" and that millions more own Apple Watches but have not yet activated these features. *Id.* at 70. Apple states that "[a]n exception permitting software maintenance releases and updates for all Apple Watches, including units with the Accused Features installed" because "[s]uch updates for Apple Watches are important '[t]o make sure that … Apple devices have the latest bug fixes and security enhancements.'" *Id.* (citing RX-644.1). Apple further argues that "[a]ny remedial order should permit Apple to honor all service and repair obligations—including obligations under applicable warranties and law, and other applicable service and repair obligations—by providing technical support, service, repair, and replacement for all permissibly obtained Apple Watches, including models with the Accused Features installed." *Id.* at 71. Apple explains that "[t]he Accused Products are subject to a manufacturer's warranty that requires Apple to repair or replace products for one or two years, depending on the model." *Id.* (citing CX-60C; CX-6; *Certain Liquid Crystal Display Modules*,

Inv. No. 337-TA-634, Comm'n Op., 2009 WL 4087135, at *2 (Nov. 24, 2009) (exempting infringing repair parts from remedial orders and allowing importation of service and replacement parts)).

Apple asserts that it "should also be permitted to continue the sale, replacement, or exchange of bands for the Apple Watches at issue" as well as "charging accessories like charging pucks and compatible adapters." *Id.* at 71-72. Apple asserts that "AliveCor's accusations have nothing to do with watch bands, and the bands are articles in commerce which users may choose to purchase or seek to have replaced." *Id.* Apple further contends that "[a]ny remedy should also include an exemption permitting continued sale of new AppleCare service and repair plans." *Id.* at 72.

Apple states that "[a]ny prohibition on 'marketing' or other customer facing communications in the Commission's Cease and Desist Order should expressly permit Apple to continue to provide and update informational and support materials for users of all Apple Watches on its website, including information specifically on ECG app, IRN, and HHRN." *Id.* at 72. Apple explains that "[i]n some instances, such as instructions for use, Apple is obligated by FDA to keep these materials accessible" and that "[i]n other instances, these materials help educate doctors and others about how to use Apple Watch to achieve better health results." *Id.*

Apple asserts that "[s]eparate from permitting support for existing end users, any remedy should also include an exception for products made, marketed, used, or sold solely for uses reasonably related to the development and submission of information under the FDCA." *Id.* at 73. Apple argues that "[a]n exclusion order should also include a personal importation exemption that would cover (i) American Apple Watch users who travel abroad with an accused Apple Watch and then return with that device; (ii) foreign visitors who enter and then depart the

United States with a personal Apple Watch; and (iii) U.S. travelers who buy an Apple Watch abroad, or have a watch replaced abroad under warranty." *Id.* According to Apple, "[t]hese exceptions are necessary to avoid harming unwitting consumers who are merely traveling with their Apple Watch products or choose to make a purchase decision abroad." *Id.*

2. AliveCor Submission

a) Public Health and Welfare

AliveCor contends that "the requested remedial orders do not raise any public health, safety, or welfare concerns" because there are numerous substitutes (discussed below) available that "will allow consumers to access wearable monitoring devices that can record ECGs and monitor cardiac events." AliveCor Sub. at 48. For support, AliveCor points to the public interest statements submitted by third parties. Specifically, AliveCor points to Dr. Topol's submission that '"[p]ublic health is far more served by encouraging and protecting those who innovate to make better medical technology' rather than by making an exception for large companies like Apple 'because that would be protecting those who use without authorization, simply because they are large.'" *Id.* AliveCor also points to Dr. Reynolds' statement in contemplation of Apple's intended argument that '"as a major seller of smartwatches in the U.S. [that] the public would somehow suffer if the Commission excluded its infringing Apple Watches' is actually 'a situation of Apple's own making'" in that "Apple created this situation by using its power and influence to 'exclude AliveCor and other competitors while Apple simultaneously introduced its infringing Apple Watches.'" *Id.*

In response to Apple's argument, AliveCor asserts that remedial orders will not apply to unaccused watches, including watches from Apple itself. AliveCor R.Sub. at 36. Specifically, AliveCor identifies the Apple Watch SE as a suitable substitute because it "has IRN, HHRN, Low Cardio Fitness Notifications, sleep stages, fall detection, crash detection, cycle tracking,

emergency SOS, noise monitoring, and backtrack." *Id.* Regarding Apple's assertion about the ECG, AliveCor states that "the majority of the testimonials that Apple attached to its brief—over 250 of them, *see* Apple Br., Ex. 8—do not appear to mention ECG functionality at all," and "[s]o there is no reason to think an exclusion order would affect the functionalities being touted." *Id.* AliveCor adds that "the nearly 30 million people who already own infringing devices would not be affected by any remedy in this case" and that "all of these Apple Watches—those unaccused, and those already in the stream of commerce—could be paired with relevant accessories, like AliveCor's KBS, to add functionalities." *Id.* at 36-37. AliveCor states that "[i]f Apple would stop its anticompetitive actions and restore access to the raw PPG data and APIs, AliveCor could make updated versions of KBS for the unaccused Apple Watches." *Id.* at 37.

b) Suitable Alternatives

AliveCor states that "numerous major electronic suppliers market reasonable substitutes for Apple's infringing functionalities." AliveCor Sub. at 44. According to AliveCor, "Apple itself sells and markets the Apple Watch SE series, which, although it provides IRN and HHRN, does not contain an ECG sensor and therefore has not been accused." *Id.* AliveCor adds that "[t]hose unaccused Apple Watches can, moreover, be combined with the KBS to provide ECG functionality" and that "[a]ll Apple needs to do is reverse its anticompetitive changes to watchOS that prevent SmartRhythm from working." *Id.* AliveCor also identifies certain third parties as offering reasonable substitutes. *Id.* Specifically, AliveCor argues that Samsung watches, including Galaxy Watch 5, Galaxy Watch 4, Galaxy Watch 3, and Galaxy Watch Active 2, "provide the capability of an on-demand 30-second ECG that can detect the presence of Afib" and that "[t]hese watches also provide continuous heartrate monitoring using an optical heart rate sensor (*i.e.*, PPG) that detects and keeps track of heart rate and heart rate changes in the

background." *Id.* AliveCor further argues that "Fitbit offers numerous products, cleared by the FDA, that provide AFib detection capabilities using an ECG app13 and a PPG-based background detection algorithm," including the Fitbit Sense, the Fitbit Versa, the Fitbit Versa Lite, the Fitbit Charge 4, and the Fitbit Inspire 2." *Id.* at 45. According to AliveCor, "[t]he substitute Fitbit devices are also capable of tracking elevated heart rates (similar to Apple's HHRN) as well as tracking heart rate variability ('HRV'), which is a measure of the time variances in between heartbeats that can indicate whether the heart is beating irregularly." *Id.* AliveCor also identifies other "wearable smartwatches on the market that have received FDA clearance and have heart-rate monitoring capabilities." *Id.* at 46. These include the "Oppowatch, which contains an optical heartrate sensor and monitors the user's heartrate" and the "Withings Scanwatch, which not only uses ECG and PPG for Afib detection, but specifically highlights those detection capabilities to consumers on its website." *Id.*

AliveCor emphasizes that "[t]he infringing Apple Watches that would be subject to the recommended exclusion order comprise only a subset of Apple's watch offerings; those products that include both **(1)** PPG-based arrhythmia detection features (*i.e.*, the Irregular Rhythm Notification feature ("IRN") and the High Heart Rate Notification ("HHRN") feature) and **(2)** the ECG App." *Id.* at 46. AliveCor states that "Apple offers numerous unaccused Apple Watch products that lack ECG hardware (and thus do not accommodate the ECG App), but which nevertheless offer both the IRN and HHRN features" and that "[t]hese unaccused models would not be subject to the recommended exclusion order." *Id.*

c) Competitive Conditions in the United States

AliveCor asserts that "the requested remedial orders will not, in fact, remove any competitor from the market." AliveCor R.Sub at 45. AliveCor contends that "Apple can

continue offering unaccused watches" and that "Samsung, Fitbit, and others can continue competing with Apple." *Id.* at 46. AliveCor contends that "it is Apple that is engaging in anticompetitive behavior." *Id.* AliveCor explains that "Apple's unfair acts of competition" "are substantial and ongoing: Apple met with, considered acquiring, stole technology from AliveCor and is continuing to infringe AliveCor's patents and exclude AliveCor's products." *Id.* (citing AliveCor Sub at 10-14; OUII Sub at 17 ("This effectively excluded AliveCor from the Apple Watch market," so "[i]t appears likely that the effect of the requested remedial orders would benefit competitive conditions by opening up markets.").

d) AliveCor Position

AliveCor states that the remedial orders should issue immediately and without carveouts. AliveCor R.Sub. at 48. AliveCor asserts that "[t]here is no need for any exception for software updates" as "[t]he investigation Apple itself cites confirms that Customs does 'not [ ] regulate electronic transmissions.'" *Id.* at 49 (citing *Certain Systems for Detecting and Removing Viruses or Worms*, Inv. No. 337-TA-510, Comm'n Op., 2005 WL 8153587, at *3 (Aug. 23, 2005)). Regarding an exception for service and repair, AliveCor asserts that "Apple's corporate designee confirmed under oath that, under its warranty, it can provide a refund in lieu of repairing a broken watch" and that "[i]n such circumstances, a service and repair exemption is not warranted." *Id.* (citing JX-220C (Rollins) at 162:21-163:3, 167:1-9; CX-0060C; CX-0061; *Certain Light-Emitting Diode Products, Fixtures, and Components Thereof*, 337-TA-1213, Comm'n Op. at 13 (Jan. 14, 2022). Finally, AliveCor argues that "Apple's request that any remedy be suspended for two years is based on a claim that 'there are no suitable alternatives to Apple Watch" but that "[t]he record shows otherwise." *Id.* (pointing to immediately available, FDA-cleared alternatives from Fitbit, Samsung, and even Apple itself).

With respect to suspending remedial orders until final resolution of the IPRs, AliveCor states that "[i]n every case Apple cites, the Commission has acted only **after** a FWD decision issues, and only with respect to patent claims actually deemed invalid" and thus "[a] suspension of the remedial orders should therefore not even be under consideration unless every patent claim on which a violation is found has been held invalid in a FWD." *Id.* at 50.

3. OUII Submission

a) Public Health and Welfare

OUII states that on balance, "the requested remedial orders will not adversely affect the public health and welfare" because "[s]imilar irregular rhythm notification and ECG features are available on a variety of other devices." OUII Sub. at 13. OUII asserts that "consumers may purchase existing alternative devices including the Samsung Galaxy 4 smartwatch, the Samsung Galaxy 3 smartwatch, and the FitBit Charge 5 smartwatch." *Id.* OUII explains that the "Samsung Galaxy Watch 4 allows users to monitor for abnormal or irregular heart rhythm and to take electrocardiograms ('ECG') in real time." *Id.* OUII adds that "ECG technology is likely to be introduced in various existing and future products" and that "Garmin has completed clinical trials for its smartwatch ECG technology and is expected to enable such functionality in certain devices (including the Garmin Venu smartwatches) once it has secured necessary FDA clearance." *Id.* OUII states that "various alternative devices are available on the market to monitor heart health, including AliveCor KardiaMobile Card personal ECG device, Oura Ring Gen 3 smart ring, and Prevention Circul+ smart ring with ECG and blood pressure monitoring capabilities." *Id.* at 14. According to OUII, "[g]iven the wide availability of alternatives, it does not appear to OUII that the public health and welfare would be adversely impacted by the requested remedial orders." *Id.*

OUII states that "[w]hile the Apple Watch has certainly been used in various on-going research projects, at this time it has not been shown that alternative products cannot be used in its place." *Id.* OUII contends that "remedial orders would not impact the function of the existing Apple Watch installed base, and would thus appear unlikely to affect on-going research projects in any meaningful way." OUII R.Sub. at 16. OUII observes that "the non-accused Apple Watch SE provides the IRN and HHRN features that work in the background to detect irregular heart rhythms" and that "it appears that all of the research projects identified in public interest comments and briefing could be performed by an Apple Watch SE alone, or in combination with an external ECG device such as AliveCor's KardiaMobile Card." *Id.*

b) Competitive Conditions in the United States Economy

OUII argues that "remedial orders will promote competitive conditions in the United States economy." OUII Sub. at 16. OUII explains that "[i]n 2013, Apple tried unsuccessfully to design a smartwatch with the accused functionality" and that "when AliveCor successfully introduced its technology to the Apple Watch platform, Apple took steps to copy that technology by seeking information from the FDA, by commissioning research on AliveCor's technology, and by requesting meetings and live demonstrations to obtain information from AliveCor." *Id.* at 16-17. According to OUII, "once Apple had successfully implemented the patented technology, Apple revised its watchOS API in a manner such that AliveCor's KardiaBand System was no longer functional," which "effectively excluded AliveCor from the Apple Watch market, leaving consumers with fewer and less effective options." *Id.* at 17 (citing Tr. (Albert) at 83:20-85:19). OUII states that thus "[i]t appears likely that the effect of the requested remedial orders would benefit competitive conditions by opening up markets, allowing wider access to superior

technology, and encouraging innovation." *Id.* OUII also notes the availability of alternatives. *Id.* at 16.

c) Production of Like or Directly Competitive Products in the United States

OUII states that it is not aware of any evidence of record regarding the impact of the requested remedial orders on the production of like or directly competitive articles in the United States. *Id.* at 17.

d) United States Consumers

OUII states that on balance, remedial orders will not adversely impact U.S. consumers, pointing to the availability of alternatives for support. *Id.* at 18-19.

e) OUII Position

OUII asserts that based on the evidence provided in Apple's initial written submission, "any remedial order should be tailored to allow support of existing Apple Watch users." OUII R.Sub at 20. OUII also agrees with Apple's request that any remedial orders be tailored to permit Apple "to provide (1) 'software maintenance releases and updates for all Apple Watches, including units with Accused Features installed' and (2) to honor its service and repair obligations." *Id.* at 21. According to OUII, "Apple has demonstrated that 'Consumers who purchased an Accused Product reasonably expected to get the *full* scope of the accompanying warranty or insurance contract.'" *Id.* (citing JX-220C (Rollins Dep. Tr.) at 79:1-9; 160:9-168:21). OUII proposes an exception to the remedial orders as follows: "except for service or repair of wearable electronic devices with ECG functionality that were imported prior to the Commission's determination becoming final within the meaning of 19 U.S.C. § 1337(j)(4)." *Id.* OUII states that the evidence of record does not support any additional tailoring of the requested remedial orders. *Id.*

4. Analysis

Under Federal Circuit precedent, "the Commission is required to issue an exclusion order upon the finding of a Section 337 violation absent a finding that the effects of one of the statutorily-enumerated public interest factors counsel otherwise." *Spansion*, 629 F.3d at 1358; 19 U.S.C. § 1337(d)(1) ("If the Commission determines, as a result of an investigation under this section, that there is a violation of this section, it shall direct that the articles concerned, imported by any person violating the provision of this section, be excluded from entry into the United States …"). The Commission finds that issuance of remedial orders in this investigation will not have such an adverse effect on the public interest factors that would warrant denying a remedy. Thus, the Commission declines Apple's invitation to exercise its discretion and deny a remedy.

a) Public Health and Welfare

The Commission agrees with AliveCor and OUII that remedial orders in this investigation would not raise significant public health or welfare concerns. *See* AliveCor Sub. at 48; OUII Sub. at 13.

Apple identifies three public health and welfare concerns that it contends would be affected by the remedial orders here: (1) the ability of current users to continue to enjoy the health, wellness, and safety features of the infringing Apple watch; (2) the disruption of ongoing research projects into Afib that utilize the infringing watches (no new studies were identified); and (3) curtailing consumer access to unaccused features of the infringing Apple watches and ongoing research projects pertaining to those unaccused features.

With respect to the first concern, the potential impact on existing owners of infringing Apple watches, the Commission finds, consistent with AliveCor's representation, that remedial relief against the infringing Apple watches would not affect current users of Apple's infringing watches as nothing in the relevant remedial orders would prevent them from being able to

continue using all of the features without interruption, which would include software updates and the like to maintain the functional status of the watches that are in the hands of U.S. consumers.[37] *See* AliveCor R.Sub. at 36 ("the nearly 30 million people who already own infringing devices would not be affected by any remedy in this case"). Moreover, the Commission has determined that the evidence of record supports an exemption for service, repair, and replacement of those infringing watches pursuant to Apple's warranty obligations described below. This exemption would enable consumers who possess infringing watches to continue to benefit from the health, wellness, safety and other features that they have accessed since those watches were purchased prior to the orders becoming final.

With respect to the second concern, the effect on ongoing research projects, the Apple infringing watches used in those ongoing projects would likewise be unaffected by the remedial orders. Apple contends that remedial orders will "irreparably disrupt ongoing research into AFib, depriving the American public of potentially 'breakthrough' treatments for this disease and wasting millions of dollars in public and private investment already devoted to medical research using Apple Watch." Apple Sub. at 40. According to Apple, there are numerous ongoing studies related to heart diseases using the Apple Watch. *Id.* Apple does not identify any new studies that would be impacted by the remedial orders here, but rather the issue pertains solely to studies already underway. Remedial orders will not take Apple Watches away from existing study participants, and Apple does not contend that these studies need additional Apple Watches for additional participants, much less quantify that need. Therefore, infringing Apple watches supplied to research subjects at the commencement of those projects would remain

[37] Apple requests an exemption from the orders to account for software maintenance and updates and technical support for current Apple watch owners. Apple Sub. at 70-71. No exemption is necessary as these are not covered by the remedial orders.

available to the persons participating in those studies given that current users can continue to utilize all of the features without interruption as noted above. Moreover, to the extent that study participants' watches malfunction or break, Apple can continue to provide service and repair under its warranty obligations under the Commission's exemption. The service and warranty exception will allow Apple to repair or replace malfunctioning watches for existing participants, and any new studies can utilize any of the numerous alternatives discussed below, including the Apple Watch SE paired with ECG functionality.

As to the third concern, the curtailment of consumer access to non-accused features of infringing watches and ongoing research into those unaccused features, persons who already possess these infringing watches whether for their own use or ongoing research, their continued access is unaffected as explained above. To the extent that Apple's concerns relate to potential new customers of infringing watches, Apple has failed to substantiate or detail its concerns.

With respect to persons who seek to purchase new watches after the orders become final, the parties dispute whether there are suitable substitutes available to address public health, safety, and welfare concerns that may arise due to exclusion of the infringing Apple watches. Apple contends that "suitable alternatives for purposes of remedying the harm from exclusion must (1) include ECG, IRN, and HHRN features; (2) be a wearable; and (3) be FDA-cleared." Apple Sub. at 54. AliveCor responds that "the majority of the testimonials that Apple attached to its brief—over 250 of them, *see* Apple Br., Ex. 8—do not appear to mention ECG functionality at all." AliveCor R.Sub. at 36. OUII states that due to a "wide availability of alternatives, it does not appear to OUII that the public health and welfare would be adversely impacted by the requested remedial orders." OUII Sub. at 14.

The Commission finds that suitable alternatives are available to meet the public health concerns raised by Apple's comments. As to Apple's first and second points regarding suitable alternatives, Apple explains that for substitutability with Apple's infringing watches, portability is key because a device offering IRN functionality without a readily available ECG app "would mean that wearers concerned about their heart health—either because of an IRN alert or because of how they are feeling—would need to go to the hospital or acquire an inconvenient and separate at-home ECG device to accurately detect AFib, by which time their fleeting symptoms may have passed." Apple Sub. at 44. Thus, in Apple's view, wearable devices that have an IRN function and a means by which the user can quickly take an ECG would provide a suitable alternative. In contrast to IRN, Apple explains that HHRN "cannot itself detect any heart conditions, [but] it provides valuable information to users that can encourage them to seek medical care, which can in turn lead to the identification of a range of cardiac conditions that might otherwise have gone undiagnosed. *Id.* AliveCor and OUII concur that a combination of portable devices can readily replace the infringing Apple watches. AliveCor Sub. at 44-47; OUII Sub. at 12-16. In view of these comments, the Commission finds that wearable devices that have IRN and HHRN functionality along with portable ECG devices represent a reasonable alternative to the Apple watches to be excluded under our remedial orders. As discussed in detail below, various portable devices are currently available on the market to provide these functionalities.

With regard to Apple's third point regarding substitutability, FDA clearance, Apple contends that FDA-clearance provides a "rigorous authorization process for software as a medical device (SaMD) [which] requires high-quality validated sensor inputs that have clinical-level accuracy." Apple Sub. at 54. Apple argues that "[no]n-cleared devices that purport to measure cardiac activity through PPG sensors have not been determined to accurately identify

potential AFib" and that decisions as to medications and treatments based on these data would be "ill-advised." *Id.* at 55 (citing StopAfib.org Sub. at 3). Apple's assertion, however, is based exclusively upon the conclusory statement that "non-FDA cleared devices are often inaccurate and may lead to ill-advised decisions about medications and treatment." StopAfib.org Sub. at 3. Aside from this general admonition, Apple provides no evidence showing that particular non-FDA cleared portable devices are, in fact, inaccurate or that doctors or patients have made medical decisions on medications and treatments for AFib based solely on data generated by non-FDA cleared software. Absent such factual basis, the Commission does not credit Apple's conclusory assertion that FDA-clearance is mandatory in order for alternative devices to serve as suitable substitutes for the infringing devices.

Even if suitable alternatives were restricted to the three-part definition that Apple advocates, Apple concedes that Fitbit's Charge 5 and Sense are alternatives currently available in the United States. Apple Sub. at 55-56. According to AliveCor, Fitbit offers "numerous products, cleared by the FDA, that provide AFib detection capabilities using an ECG app13 and a PPG-based background detection algorithm," including the Fitbit Sense, the Fitbit Versa, the Fitbit Versa Lite, the Fitbit Charge 4, and the Fitbit Inspire 2" that "are also capable of tracking elevated heart rates (similar to Apple's HHRN) as well as tracking heart rate variability ('HRV'), which is a measure of the time variances in between heartbeats that can indicate whether the heart is beating irregularly." AliveCor Sub. at 45. Apple, however, asserts that Fitbit cannot ramp up manufacturing to fully meet consumer demand in the event of the sudden shortfall that would occur. *Id.* at 55, 68. Specifically, Apple states that "given the existing supply chain issues, chip and neon gas shortages, logistics obstacles, and other issues, there is no reasonable likelihood Fitbit could increase its production to meet that demand in less than two years." *Id.* at

68 (citing Exh. 6 (Davies Decl.) ¶¶ 17, 22, 37, 53, 90)).[38] Again, Apple (including the cited paragraphs of the declaration), provides no evidence to substantiate its assertions that Fitbit presently lacks the manufacturing capability to produce new products that include FDA-cleared ECG, IRN, and HHRN features in a single wearable device to meet the narrow band of consumer demand for products so defined, and Apple's assumption that consumers would forego all other portable devices that provide some or all these features, which are widely available in the U.S. market as discussed below. In any event, as noted above, the Commission is suspending the remedial orders pending final resolution of the PTAB's final written decisions which will give adequate time for alternatives to be readily available.

Under the Commission's understanding of reasonable alternatives, the record evidence shows that, in addition to Fitbit, there are substitutes that offer a wide range of health, safety, and wellness features including some that "will allow consumers to access wearable monitoring devices that can record ECGs and monitor cardiac events." AliveCor R.Sub. at 36. As AliveCor notes, "Apple itself sells and markets the Apple Watch SE series, which, although it provides IRN and HHRN, does not contain an ECG sensor and therefore has not been accused." *Id.* at 44. The evidence shows that the Apple Watch SE series can be combined with ECG devices, such as the KBS, to serve as an adequate substitute. *See* AliveCor Sub. at 44.[39]

[38] Apple filed a motion for leave to file "further corrected Exhibits 5 and 6" on October 11, 2022, after omitting these exhibits from its October 6, 2022 opening submission, obtaining leave from the Commission to file these omitted exhibits, then served a first corrected version on October 7, 2022, followed by this second set of corrected exhibits filed and served on October 11, 2022. *See* Apple Mot. at 1-2 (Oct. 11, 2022). The Commission has determined to grant Apple's motion.

[39] We note that the KBS was previously pared with the Apple watch series 1-3 to provide ECG functionality in a single device. That situation ended around December of 2018 when Apple changed its software to no longer support the KBS. AliveCor Sub. at 41 (citing RX-0047C; Somayajula Tr. at 84:1-84:3, 199:18-200:20). Apple has not provided evidence that

AliveCor also identifies other third parties as offering reasonable substitutes that carry out the same functions, specifically Samsung watches including the Galaxy Watch 5, Galaxy Watch 4, Galaxy Watch 3, and Galaxy Watch Active 2. The Samsung watches provide "the capability of an on-demand 30-second [FDA cleared] ECG that can detect the presence of Afib" and also "provide continuous heartrate monitoring using an optical heart rate sensor (*i.e.*, PPG) that detects and keeps track of heart rate and heart rate changes in the background." *Id.* Apple does not disagree with AliveCor's statement, nor does it contend that Samsung's products are not competitive with its own smartwatches. Apple R.Sub. at 26. Rather, Apple responds that Samsung products are not "FDA-cleared to continuously monitor for irregular heart rhythms suggesting potential AFib," albeit Apple concedes that Samsung offers a feature comparable to HHRN. *Id.* As discussed above, Apple has failed to substantiate its contention that suitable substitutes must have FDA clearance. Apple also raises the same high level general supply constraints observations as it raises with respect to Fitbit relating to global supply of semiconductor chips in 2021. Apple Sub. at 61.

OUII also points out that "ECG technology is likely to be introduced in various existing and future products," noting that "Garmin has completed clinical trials for its smartwatch ECG technology and is expected to enable such functionality in certain devices (including the Garmin Venu smartwatches) once it has secured necessary FDA clearance." OUII Sub. at 13. Apple responds that it is unaware of the status of Garmin's FDA application, clinical trials, or IRN-type feature under development. Apple R.Sub. at 30.

changing its software to again allow compatibility with the KBS would require a substantial ramp up period, including in light of the suspension of enforcement of the orders.

OUII points to other alternative devices "available on the market to monitor heart health, including AliveCor KardiaMobile Card personal ECG device, Oura Ring Gen 3 smart ring, and Prevention Circul+ smart ring with ECG and blood pressure monitoring capabilities" and states that "[g]iven the wide availability of alternatives, it does not appear to OUII that the public health and welfare would be adversely impacted by the requested remedial orders." *Id.* at 13-14. The table below, submitted by AliveCor, identifies devices that are suitable alternatives:

TABLE 1: SELECTED SMARTWATCH FEATURES PROMOTED BY DEVICE MANUFACTURERS

	Apple		Competitors				
	Apple Watch (Series 8) [A]	Apple Watch (SE 2nd Gen) [B]	Samsung Galaxy (Watch 5) [C]	Fitbit (Sense2) [D]	Fossil (Gen 6) [E]	Garmin (Venu 2 Plus) [F]	Zepp (Amazfit GTS4) [G]
GPS	✓	✓	✓	✓	✓	✓	✓
Emergency SOS Capability	✓	✓	✓	x	x	✓	x
Water Resistant	✓	✓	✓	✓	✓	✓	✓
Speaker and Microphone	✓	✓	✓	✓	✓	✓	✓
24+ Hour Battery Life	✓	✓	✓	✓	✓	✓	✓
iOS Compatability	✓	✓	x	✓	✓	✓	✓
Cellular Connectivity	✓	✓	✓	✓	✓	✓	✓
Personalizable Design	✓	✓	✓	✓	✓	✓	✓
Health Functions							
ECG	✓	x	✓	✓	x	x	x
HHRN	✓	✓	✓	✓	-	✓	✓
IRN	✓	✓	-	✓	-	✓	✓
Low Cardio Fitness Notifications	✓	✓	-	✓	✓	✓	✓
Blood Oxygen	✓	x	✓	✓	✓	✓	✓
Fall Detection	✓	✓	✓	x	x	✓	✓
Crash Detection	✓	✓	✓	x	x	✓	✓
Wrist Temperature	✓	x	✓	✓	x	x	x
Sleep Monitoring	✓	✓	✓	✓	✓	✓	✓

AliveCor R.Sub. at 37.

Apple contends that AliveCor and third parties cannot meet demand within a commercially reasonable time if its infringing watches were to be excluded. Apple Sub. at 57 ("No one, alone or in combination, can substantially replace the sudden supply shortfall that will arise if Apple Watch is excluded."). Apple submitted the following IDC data for imports by U.S. retailers of Apple watches (with and without the infringing functionalities) as well as other smartwatch and fitness trackers for the period 2015 through 2021:[[

]] Apple Sub., Exh. 5 (Dippon Decl.) ¶ 11. The infringing Apple watches comprise [[ ]] of the total Apple shipments listed above in 2021, amounting to [[ ]] infringing Apple watches. *Id.* ¶ 25.

As relevant to Apple's public health and welfare arguments focused on U.S. consumers with Afib, Apple states that of the total number of infringing units sold in the United States, [[ ]] users have activated IRN and ECG on their infringing watches. Apple Sub. at 70. Afib affects up to 6 million people in the United States. Apple Sub., Exh. 5 (Dippon Decl.) ¶ 49. These data indicate that consumers, and particularly those affected by Afib, who need portable devices offering health and safety features discussed above have already purchased and activated IRN and ECG on their Apple watches, Fitbit, or other devices or if they are new purchasers, they would be able to obtain devices that meet their needs from third party suppliers.

Moreover, as noted above, nothing in the remedial orders prevents current users and researchers from continuing to use their Apple watches. We also find Apple's argument that remedial orders "would deprive consumers of numerous other important life-saving features," and "disrupt dozens of ongoing medical studies involving these features" unpersuasive and unsubstantiated. Apple Sub. at 49. Moreover, the available substitutes for the infringing watches can be used for new studies.

b) Competitive Conditions in the United States Economy

In our judgment, the evidence of record shows that the remedial orders would not have any adverse impact on competitive conditions in the United States economy. Apple's argument to the contrary depends entirely on its view that there are no suitable alternatives other than Fitbit. As discussed above, the record evidence shows an abundance of suppliers that offer competing products. With respect to market shares of these competitors, Apple offers the following data from IDC regarding U.S. smartwatch and fitness tracker shipment shares in 2021:[[

]] *See* Apple Sub., Exh. 5 (Dippon Decl.) ¶ 24. As shown in the table above, these suppliers of competitive products include Samsung, Garmin, Fitbit, Fossil, and Zepp, among others. Apple itself can remain a competitor in the U.S. market with products that do not infringe such as the Apple Watch SE.

Apple argues that remedial orders will "harm competitive conditions in the United States by harming third-parties reliant on the accused products and reducing market pressure on Apple

Watch's competitors to cut costs and deliver innovative new products." Apple Sub. at 62. This argument, however, is wholly unsubstantiated.

c) The Production of Like or Directly Competitive Articles in the United States

The record contains no evidence that remedial orders will adversely impact the production of like of directly competitive articles in the United States. We note that neither the infringing products nor the reasonable alternatives are manufactured in the United States.

d) United States Consumers

As to potential effects on consumers, Apple argues public health considerations relating to consumers that the Commission has discussed above. Apple Sub. at 52. Apple further argues that exclusion would likely result in higher prices and poorer quality alternatives diminishing consumer choice. *Id.* Apple's argument, however, is unsubstantiated. Indeed, Apple does not present evidence of a direct price comparison between and among the competing products to support its allegation. *See Certain Audio Players & Controllers*, Inv. No. 337-TA-1191, Comm'n Op. at 32 (Jan. 6, 2022).

The record evidence indicates that [[ ]] own infringing Apple Watches. As discussed above, current owners of the infringing Apple watches will be unaffected by the remedial orders here thus alleviating any concerns regarding current users of these products.

While these consumers will not be affected by any remedy in this case, they bought their watches reasonably expecting to get the *full* scope of the accompanying warranty and insurance contract. JX-220C (Rollins Dep. Tr.) at 79:1-9; 160:9-168:21. For this reason, as well as to allow individuals using the Apple Watch to participate in ongoing studies as discussed above, the

Commission has determined to tailor the remedial orders to allow Apple "to honor its service, repair, and replacement obligations." *See* OUII R.Sub. at 21.

AliveCor suggests that a refund would suffice. AliveCor R.Sub. at 48. However, AliveCor and OUII have not shown that a refund will be adequate to compensate consumers who are seeking to maintain their Apple Watches or to participate in ongoing health-related studies using the Apple Watch. Accordingly, based upon the reasonable expectations of those consumers who purchased infringing Apple Watches and in consideration of ongoing research projects involving infringing Apple Watches that may malfunction or break, the Commission's remedial orders include the following exemption: "except under license of the patent owner or as provided by law, and except for articles or components imported for use in servicing, repairing, or replacing covered articles that were imported prior to the effective date of this Order pursuant to existing service and warranty contracts."[40]

e) Summary

In sum, the public interest factors do not compel the Commission to decline to issue remedial orders in this investigation. The Commission, however, has determined to include an exemption to allow Apple to honor its service, repair, and replacement obligations. The orders

[40] Commissioner Stayin does not believe that a warranty or service exception is justified merely because consumers expect the full scope of their bargain, as this would justify such an exception in every case involving a product sold with a warranty or service agreement. Moreover, in his view, it was Apple's burden to show an exception is necessary, and not AliveCor's burden to show a refund was sufficient. *See Certain Audio Players & Controllers, Components Thereof, & Prods. Containing the Same*, Inv. No. 337-TA-1191, Comm'n Op. at 25 (Feb. 1, 2022) (finding respondent failed to show a warranty exception was appropriate, including because respondent could provide a refund in lieu of repair). Nonetheless, given the specific health-related functionality at issue in this case, Commissioner Stayin believes a warranty and service exception is appropriate so that existing consumers do not bear the burden of switching to a new device for monitoring purposes in the event an issue arises with their previously purchased device after the remedial orders go into effect.

also include an exemption for articles imported by or for U.S. Government use, as usual, and include the Commission's standard certification provision.

D. Bond

If the Commission enters an exclusion order and/or cease and desist order, a respondent may continue to import and sell its products during the 60-day period of Presidential review subject to posting a bond. 19 U.S.C. § 1337(j)(3). The amount of the bond is specified by the Commission and must be sufficient to protect a complainant from any injury. *Id.*; 19 C.F.R. §§ 210.50(a)(3), 210.42(a)(1)(ii). "The Commission typically sets the bond based on the price differential between the imported infringing product and the domestic industry article or based on a reasonable royalty. However, where the available pricing or royalty information is inadequate, the bond may be set at one hundred (100%) percent of the entered value of the infringing product." *Loom Kits*, Comm'n Op. at 18 (citations omitted). A complainant bears the burden of establishing its requested bond amount. *See, e.g.*, *Certain Liquid Crystal Display Devices*, Inv. No. 337-TA-631, Comm'n Op. at 28 (July 10, 2009). Should a complainant fail to meet its burden, the Commission may determine to impose no bond for products imported during the period of Presidential review period. *Id.*

The ALJ recommended that the Commission set no bond for entry of infringing products during the period of Presidential review. ID/RD at 194. The ALJ stated that "[i]t is entirely unclear what competitive harm ALC will face during this time as the KBS product has not been sold for some time (Hr'g Tr. (Albert) at 135:14-136:22) and [[ ]] are, at best, in development." *Id.* OUII and Apple agree with the ID's recommendation. OUII Sub. at 74; Apple Sub. at 21.

AliveCor asserts that "[t]he Commission should impose a bond of $13 per imported article." AliveCor Sub. at 40. According to AliveCor, "[t]he amount of bond to be posted during the sixty-day period for Presidential review must be at least sufficient to 'offset any

competitive advantages resulting from the unfair method of competition or unfair act enjoyed by persons benefitting from the importation.'" *Id.* (citing S. Rep. No. 1298, 93 Cong., 2d Sess. 198 (1974); 19 U.S.C. § 1337(e)(1), (j)(3); *see also Certain Semiconductor Chips with Minimized Chip Package Size and Products Containing Same*, Inv. No. 337-TA-432, RD at 7 (Oct. 1, 2001)). AliveCor argues that "Apple's continued patent infringement and unfair competition are harming AliveCor" and that "[t]hrough its unfair acts, Apple excluded AliveCor's KBS from the market." *Id.* AliveCor asserts that the record evidence contains [[

]]. *Id.* at 42 (citing Tr. (Akemann) 638:18-639:24; JX-007C; JX-008C; JX-010C; CX-0872C). AliveCor points to [[

]]." *Id.* (citing Tr. (Akemann) 638:18-639:24; JX-008C.4). Thus, AliveCor argues that the Commission should set the bond at $13 per imported article. *Id.*

The Commission finds that the record evidence supports a bond in this investigation. Apple argues that "AliveCor does not compete with the accused Apple Watches, and has failed to prove that it would be injured by the importation of the accused Apple Watches, or that Apple enjoys a competitive advantage resulting from its alleged infringement," and therefore the Commission should not impose a bond for importation of infringing products during the period of Presidential review. ID at 193. However, Apple is [[

]]. *See* AliveCor Sub. at 40. Thus, the Commission finds Apple's argument self-serving and unpersuasive.

Regarding the appropriate bond rate, AliveCor asserts that "a bond—$13 infringing import—is consistent with [[

]].'" AliveCor R.Sub. at 50. As OUII notes, however, the [[

]]. OUII Sub. at 22; *See* JX-008C.4; Tr. (Vander Veen) at 1048:25-1051:4. The ID also observed that "[w]ith Apple using its own software, the $13 rate is demonstrably too high," and concluded that because AliveCor "has not offered alternative proposals reflecting this reality, it has not met its burden." ID at 194-95. The record evidence, however, includes [[

]]." AliveCor R. Sub. at 50 (citing CX-0872C.16). Accordingly, the Commission has determined to set a bond in the amount of $2.00 per unit article for infringing products imported during the period of Presidential review.[41]

[41] Commissioners Schmidtlein and Stayin agree the record evidence supports a bond in this investigation, but they disagree with the Commission's determination to set that bond in the amount of $2.00 per unit article. While various licenses were cited by AliveCor in its briefing before both the ALJ and the Commission as evidence available for considering a reasonable royalty rate, AliveCor has consistently indicated that "[t]he most straight forward and applicable [[ ]] *See, e.g.*, AliveCor Sub. at 42. And as noted by the Commission, AliveCor also contends [[

]] *Id*. (citations omitted). In Commissioner Schmidtlein and Commissioner Stayin's view, rather than requiring absolute precision, the purpose of the bond determination under the statute and the Commission's Rules is to protect the complainant from harm. *See* 19 U.S.C. § 1337(j)(3) (". . . bond prescribed by the Secretary in an amount determined by the Commission to be sufficient to protect the complainant from any injury."); 19 C.F.R. §§ 210.50(a)(3) (". . . [d]etermine the amount of the bond to be posted by a respondent . . . taking into account the requirement of section 337(e) and (j)(3) that the amount of the bond be sufficient to protect the complainant from any injury."). Here, while the cited royalty rate may cover [[ ]], on this record they find the $13.00 [[ ]] sufficient to protect the complainant from any injury. *See, e.g.*, *Certain Audio Digital-to-Analog Converters and*

E. Suspension of Remedial Orders

As noted above, Apple, on December 7, 2022, filed an emergency motion, asking "the Commission to suspend any remedial orders or, in the alternative, extend the December 12, 2022 Target Date of its Final Determination and stay all proceedings prior to issuance of any Final Determination pending final resolution of any appeal of the PTAB's decisions." Apple Emergency Motion at 1. Apple contends that "suspension is consistent with the Commission's routine past practice" and that "[a] stay will simplify the issues and conserve agency and party resources—by avoiding issuance of a merits determination that is likely to be mooted by an affirmance of the PTAB's Final Written Decisions—without causing any harm to Complainant." *Id.* Apple states that "either a suspension or a stay accords due deference to the Patent Office's role as the lead agency in assessing patentability and honors Congress's intent that invalid patents should not be enforced." *Id.*

AliveCor filed an opposition to Apple's motion on December 9, 2022. AliveCor asserts that "[g]ranting the requested stay would be unprecedented" and that "[t]he Commission has never stayed an investigation that is in this posture pending the appeal of a FWD when the complainant opposes, and Apple cites no authority to the contrary." AliveCor Opposition at 1. According to AliveCor, "[a]t most, the Commission could exercise its discretion to suspend enforcement of any remedial orders" but that "Apple's argument for the Commission to do so is weaker than in any past investigation when the Commission has implemented a suspension." *Id.* at 9. AliveCor explains that "Apple did not file IPRs on those patents until June 2021, six months" after institution of the investigation and that due to "Apple's delay, the FWDs were

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Products Containing Same, Inv. No. 337-TA-499, Comm'n Op. at 28 (Mar. 3, 2005) (Public Version) ("adopt[ing] the ALJ's finding that a bond of 5 percent is adequate to protect the complainant from injury during the 60-day Presidential review period" where "[t]ypical royalty rates in the semiconductor industry range from 0.75 percent - 5 percent.").

expected to issue after the Commission's Final Determination," which was expected on September 28, 2022, before "the Commission extended the Target Date." *Id.*

On December 16, 2022, OUII filed a response. OUII "supports Apple's motion to the extent that it requests that any remedy that issued by the Commission be suspended pending appeal of the PTAB decisions." Otherwise, OUII "opposes Apple's motion." *See* OUII Reply to Emergency Motion at 4.

The Commission has found a violation and determined that issuance of an LEO and CDO is warranted. The Commission agrees with AliveCor and OUII that granting a stay would not be consistent with Commission practice nor has Apple established the requisite showing to justify a stay of the proceedings. *See Certain Magnetic Tape Cartridges and Tape Components Thereof*, Inv. No. 337-TA-1058, Comm'n Op. at 61 (Apr. 9, 2019); *Certain Semiconductor Chips with Minimized Chip Package Size and Products Containing Same*, Inv. No. 337-TA-605, Comm'n Op. at 3 (July 29, 2009).

However, the Commission has determined to exercise its discretion to suspend enforcement of those remedial orders pending final resolution of the PTAB's Final Written Decisions finding all the asserted claims to be unpatentable. *See Viscofan*, 787 F.2d at 548 (finding that the Commission has "broad discretion in selecting the form, scope, and extent of the remedy"). Suspension of the remedial orders pending resolution of the PTAB's Final Written Decisions is consistent with the Commission's past practice on this issue. *See, e.g.*, *Certain Unmanned Aerial Vehicles and Components Thereof* (*"Unmanned Aerial Vehicles"*), 337-TA-1133, Comm'n Op. at 35 (Sep. 8, 2020); *Certain Magnetic Tape Cartridges and Tape Components Thereof*, Inv. No. 337-TA-1058, Comm'n Op. at 62-63 (Apr. 9, 2019); *Certain Three-Dimensional Cinema Systems and Components Thereof*, Inv. No. 337-TA-939, Comm'n

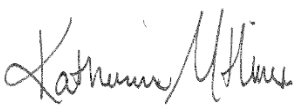
Op. at 60 (July 21, 2016). As the Commission explained at length under similar circumstances in *Unmanned Aerial Vehicles*, suspension of remedial orders is within the Commission's discretion over the form, scope, and extent of its remedy and may be appropriate where, as here, the PTAB issues final written decisions of unpatentability concerning certain claims before the Commission issues remedial orders based on those same claims. *Unmanned Aerial Vehicles*, Comm'n Op. at 35-38. The Commission has determined that it is appropriate under the facts in this investigation to suspend enforcement of the limited exclusion order and cease and desist order, including the bond provision, pending final resolution of the PTAB's Final Written Decisions finding the asserted claims of the '941, '731, and '499 patents unpatentable. AliveCor's contention that Apple delayed in filing its case at the Patent Office is not sufficient to overcome the other considerations warranting suspension of the remedial orders in this case.

VI. CONCLUSION

For the reasons detailed above, the Commission has determined to affirm the ID's finding of a violation of section 337. Regarding the issues under review, the Commission has determined to affirm the ID's economic prong of the domestic industry findings with the modifications described herein. Concerning invalidity, the Commission has determined to affirm the ID's patent eligibility findings under 35 U.S.C. § 101 as modified, but reverse as to one claim; and reverse the ID's decision not to consider objective indicia of non-obviousness for certain asserted claims. For remedy, the Commission has determined to: (1) issue a limited exclusion order prohibiting the unlicensed importation of wearable electronic devices with ECG functionality and components thereof that infringe one or more of claims 12, 13, and 19-23 of the '941 patent and claims 1, 3, 5, 8-10, 12, 15, and 16 of the '731 patent that are manufactured abroad by or on behalf of, or imported by or on behalf of, Respondent or any of its affiliated

companies, parents, subsidiaries, or other related business entities, or their successors or assigns, and stating that they are excluded from entry for consumption into the United States, entry for consumption from a foreign trade zone, or withdrawal from a warehouse for consumption, for the remaining terms of the patents, except under license of the patent owner or as provided by law, and except for articles or components imported for use in servicing, repairing, or replacing covered articles that were imported prior to the effective date of this Order pursuant to existing service and warranty contracts; (2) issue a cease and desist order directing that respondent Apple, cease and desist from conducting any of the following activities in the United States: importing, selling, offering for sale, marketing, advertising, distributing, transferring (except for exportation), soliciting United States agents or distributors, and aiding or abetting other entities in the importation, sale for importation, sale after importation, transfer (except for exportation), or distribution of wearable electronic devices with ECG functionality and components thereof that infringe one or more of claims 12, 13, and 19-23 of the ’941 patent; and claims 1, 3, 5, 8-10, 12, 15, and 16 of the ’731 patent; (3) find that the public interest factors do not preclude the issuance of the proposed remedial orders; and (4) set a bond in the amount of $2 per unit of article for infringing products imported during the period of Presidential review. The Commission, however, has determined to suspend enforcement of the orders, including the bond provision, pending final resolution of the PTAB’s Final Written Decisions finding the asserted claims of the ’941, ’731, and ’499 patents unpatentable.

By order of the Commission.



Katherine M. Hiner
Acting Secretary to the Commission

Issued: January 20, 2023

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN WEARABLE ELECTRONIC DEVICES WITH ECG FUNCTIONALITY AND COMPONENTS THEREOF**	**Investigation No. 337-TA-1266**

NOTICE OF THE COMMISSION'S FINAL DETERMINATION FINDING A VIOLATION OF SECTION 337; ISSUANCE AND SUSPENSION OF A LIMITED EXCLUSION ORDER AND A CEASE AND DESIST ORDER; TERMINATION OF THE INVESTIGATION

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission ("Commission") has determined that there is a violation of section 337 in the above-captioned investigation. The Commission has further determined to issue a limited exclusion order and a cease and desist order and to set a bond in the amount of $2 per unit of covered articles imported or sold during the period of Presidential review. The enforcement of these orders, including the bond provision, is suspended pending final resolution of the U.S. Patent and Trademark Office, Patent Trial and Appeal Board's ("PTAB") Final Written Decisions finding the asserted patent claims unpatentable.

FOR FURTHER INFORMATION CONTACT: Panyin A. Hughes, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-3042. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov*. For help accessing EDIS, please email *EDIS3Help@usitc.gov*. General information concerning the Commission may also be obtained by accessing its Internet server at *https://www.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal, telephone (202) 205-1810.

SUPPLEMENTARY INFORMATION: On May 26, 2021, the Commission instituted this investigation based on a complaint filed by AliveCor, Inc. of Mountain View, California ("AliveCor"). 86 FR 28382 (May 26, 2021). The complaint alleged violations of section 337 based on the importation into the United States, the sale for importation, or the sale within the United States after importation of certain wearable electronic devices with ECG functionality and components thereof by reason of infringement of one or more of claims 1-30 of U.S. Patent No. 10,595,731 ("the '731 patent"); claims 1-23 of U.S. Patent No. 10,638,941 ("the '941 patent"); and claims 1-4, 6-14, 16-20 of U.S. Patent No. 9,572,499 ("the '499 patent"). *Id.* The

Commission's notice of investigation named Apple Inc. of Cupertino, California ("Apple") as the sole respondent. The Office of Unfair Import Investigations ("OUII") is named as a party in this investigation. *Id.*

On February 23, 2022, the ALJ issued an initial determination granting AliveCor's motion to terminate the investigation as to (1) claims 1-4, 6-14, and 18-20 of the '499 patent; (2) claims 2, 4, 6, 7, 11, 13, 14, and 17-30 of the '731 patent; and (3) claims 1-11, 14, 15, 17, and 18 of the '941 patent based upon withdrawal of allegations from the complaint as to those claims. Order No. 16 (Feb. 23, 2022), *unreviewed by* Notice (Mar. 18, 2022).

On June 27, 2022, the ALJ issued the final initial determination ("ID") finding a violation of section 337 as to the '941 and '731 patents, and no violation of section 337 as to the '499 patent. The ID found that the parties do not contest personal jurisdiction and that the Commission has *in rem* jurisdiction over the accused products. ID at 18. The ID further found that the importation requirement under 19 U.S.C. 1337(a)(1)(B) is satisfied. *Id.* (citing CX-0904C (Apple stipulating that it imports the accused products into the United States)). Regarding the '941 patent, the ID found that AliveCor has proven infringement of the asserted claims, claims 12, 13, 19, and 20-23, and that Apple failed to show that any of the asserted claims are invalid. *Id.* at 30-45, 60-98. For the '731 patent, the ID found that AliveCor has proven infringement of the asserted claims, claims 1, 3, 5, 8-10, 12, 15, and 16, but that Apple has proven that claims 1, 8, 12, and 16 are invalid for obviousness. *Id.* at 105-108, 113-127. For the '499 patent, the ID found that AliveCor failed to prove infringement of the asserted claims, claims 16 and 17, and that claim 17 is invalid for lack of patentable subject matter under 35 U.S.C. 101. *Id.* at 129-138, 140-152. Finally, the ID found that AliveCor has proven the existence of a domestic industry that practices the asserted patents as required by 19 U.S.C. 1337(a)(2). *Id.* at 152-183. The ID included the ALJ's recommended determination on remedy and bonding ("RD"). The RD recommended that, should the Commission find a violation, issuance of a limited exclusion order and a cease and desist order would be appropriate. ID/RD at 190-193. The RD also recommended imposing no bond for covered products imported during the period of Presidential review. ID at 193-95.

On July 11, 2022, Apple filed a petition for review of the ID, and AliveCor filed a combined petition and contingent petition for review of the ID. On July 19, 2022, the private parties and OUII's investigative attorney filed responses to the petitions.

On September 22, 2022, the Commission determined to review the final ID in part. 87 Fed. Reg. 58819-21 (Sept. 28, 2022). Specifically, the Commission determined to review the final ID's invalidity findings, including patent eligibility under 35 U.S.C. 101 and obviousness under 35 U.S.C. 103, and the economic prong of the domestic industry requirement for all three patents. *Id.* The Commission requested briefing from the parties on certain issues under review. The Commission requested briefing from the parties, interested government agencies, and interested persons on remedy, the public interest, and bonding. *Id.*

On October 6, 2022, the parties filed initial submissions in response to the Commission's request for briefing. On October 14, 2022, the parties filed reply submissions. On October 21,

2022, Apple moved for leave to file a sur-reply to AliveCor's reply submission. On October 24, 2022, AliveCor filed an opposition. OUII filed a response in opposition on November 2, 2022.

The Commission has determined to deny Apple's motion for leave to file a sur-reply to AliveCor's reply submission.

On December 7, 2022, Apple filed an emergency motion, asking "the Commission to suspend any remedial orders or, in the alternative, extend the December 12, 2022 Target Date of its Final Determination and stay all proceedings prior to issuance of any Final Determination pending final resolution of any appeal of the PTAB's decisions" finding the asserted patent claims unpatentable. Apple Emergency Motion at 1. On December 9, 2022, AliveCor filed an opposition to Apple's motion. On December 16, 2022, OUII filed a response in support of Apple's motion, but only to the extent that any remedy the Commission issues be suspended pending appeal of the PTAB decisions. OUII Reply to Emergency Motion at 4.

Upon review of the parties' submissions, the ID, the RD, evidence of record, and public interest filings, the Commission has determined that Apple violated section 337 by reason of importation and sale of articles that infringe asserted claims 12, 13, and 19-23 of the '941 patent; and claims 1, 3, 5, 8-10, 12, 15, and 16 of the '731 patent. Regarding the issues under review, the Commission has determined to affirm the ID's economic prong of the domestic industry findings with the modifications described in the accompanying Commission opinion. Concerning invalidity, the Commission has determined to affirm the ID's patent eligibility findings under 35 U.S.C. 101 as to one claim with modifications explained in the Commission opinion and reverse as to another; and to correct the ID for not considering objective indicia of non-obviousness for certain asserted claims. For remedy, the Commission has determined to issue a limited exclusion order prohibiting further importation of infringing products and a cease and desist order against Apple. The Commission has determined that the public interest factors do not counsel against issuing remedial orders. The Commission has determined that a bond in the amount of $2 per unit of covered articles is required for covered products imported or sold during the period of Presidential review.

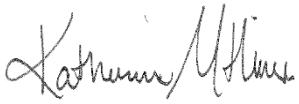
The enforcement of these orders, including the bond provision, is suspended pending final resolution of the PTAB's Final Written Decisions finding the asserted patent claims unpatentable. *See* 35 U.S.C. 318(b); *Apple, Inc. v. AliveCor, Inc.*, IPR2021-00971, Patent 10,595,731, Final Written Decision Determining All Challenged Claims Unpatentable (Dec. 6, 2022); *Apple, Inc. v. AliveCor, Inc.*, IPR2021-00972, Patent 10,638,941, Final Written Decision Determining All Challenged Claims Unpatentable (Dec. 6, 2022).

The Commission's vote on this determination took place on December 22, 2022.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of

Practice and Procedure (19 CFR 210).

By order of the Commission.



Katherine M. Hiner
Acting Secretary to the Commission

Issued: December 22, 2022

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of	
CERTAIN WEARABLE ELECTRONIC DEVICES WITH ECG FUNCTIONALITY AND COMPONENTS THEREOF	**Investigation No. 337-TA-1266**

NOTICE OF A COMMISSION DETERMINATION TO REVIEW IN PART A FINAL INITIAL DETERMINATION FINDING A VIOLATION OF SECTION 337; REQUEST FOR WRITTEN SUBMISSIONS ON THE ISSUES UNDER REVIEW AND ON REMEDY, THE PUBLIC INTEREST, AND BONDING; EXTENSION OF THE TARGET DATE

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission ("Commission") has determined to review in part a final initial determination ("ID") of the presiding administrative law judge ("ALJ"), finding a violation of section 337 as to two of the three asserted patents. The Commission requests written submissions from the parties on the issues under review and from the parties, interested government agencies, and other interested persons on the issues of remedy, the public interest, and bonding, under the schedule set forth below.

FOR FURTHER INFORMATION CONTACT: Panyin A. Hughes, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-3042. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov*. For help accessing EDIS, please email *EDIS3Help@usitc.gov*. General information concerning the Commission may also be obtained by accessing its Internet server at *https://www.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal, telephone (202) 205-1810.

SUPPLEMENTARY INFORMATION: On May 26, 2021, the Commission instituted this investigation based on a complaint filed by AliveCor, Inc. of Mountain View, California ("AliveCor"). 86 FR 28382 (May 26, 2021). The complaint alleged violations of section 337 based on the importation into the United States, the sale for importation, or the sale within the United States after importation of certain wearable electronic devices with ECG functionality and components thereof by reason of infringement of one or more of claims 1-30 of U.S. Patent No. 10,595,731 ("the '731 patent"); claims 1-23 of U.S. Patent No. 10,638,941 ("the '941 patent"); and claims 1-4, 6-14, 16-20 of U.S. Patent No. 9,572,499 ("the '499 patent"). *Id.* The

Commission's notice of investigation named Apple Inc. of Cupertino, California ("Apple") as the sole respondent. The Office of Unfair Import Investigations ("OUII") is named as a party in this investigation. *Id.*

On February 23, 2022, the ALJ issued an initial determination granting AliveCor's motion to terminate the investigation as to (1) claims 1-4, 6-14, and 18-20 of the '499 patent; (2) claims 2, 4, 6, 7, 11, 13, 14, and 17-30 of the '731 patent; and (3) claims 1-11, 14, 15, 17, and 18 of the '941 patent based upon withdrawal of allegations from the complaint as to those claims. Order No. 16 (Feb. 23, 2022), *unreviewed by* Notice (Mar. 18, 2022).

On June 27, 2022, the ALJ issued the final initial determination ("ID") finding a violation of section 337 as to the '941 and '731 patents, and no violation of section 337 as to the '499 patent.[1] The ID found that the parties do not contest personal jurisdiction, and that the Commission has *in rem* jurisdiction over the accused products. ID at 18. The ID further found that the importation requirement under 19 U.S.C. 1337(a)(1)(B) is satisfied. *Id.* (citing CX-0904C (Apple stipulating that it imports the accused products into the United States)). Regarding the '941 patent, the ID found that AliveCor has proven infringement of the asserted claims, claims 12, 13, 19, and 20-23, and that Apple failed to show that any of the asserted claims are invalid. *Id.* at 30-45, 60-98. For the '731 patent, the ID found that AliveCor has proven infringement of the asserted claims, claims 1, 3, 5, 8-10, 12, 15, and 16, but that Apple has proven that claims 1, 8, 12, and 16 are invalid for obviousness. *Id.* at 105-108, 113-127. For the '499 patent, the ID found that AliveCor failed to prove infringement of the asserted claims, claims 16 and 17, and that claim 17 is invalid for lack of patentable subject matter under 35 U.S.C. 101. *Id.* at 129-138, 140-152. Finally, the ID found that AliveCor has proven the existence of a domestic industry that practices the asserted patents as required by 19 U.S.C. 1337(a)(2). *Id.* at 152-183. The ID included the ALJ's recommended determination on remedy and bonding ("RD"). The RD recommended that, should the Commission find a violation, issuance of a limited exclusion order and cease and desist orders would be appropriate. ID/RD at 190-193. The RD also recommended imposing no bond for covered products imported during the period of Presidential review. ID at 193-95.

On July 11, 2022, Apple filed a petition for review of the ID, and AliveCor filed a combined petition and contingent petition for review of the ID. On July 19, 2022, the private parties and OUII's investigative attorney filed responses to the petitions.

Having reviewed the record of the investigation, including the final ID, the parties' submissions to the ALJ, the petitions for review, and the responses thereto, the Commission has determined to review the ID in part. Specifically, the Commission has determined to review the final ID's invalidity findings, including patent eligibility under 35 U.S.C. 101 and obviousness under 35 U.S.C. 103, and the economic prong of the domestic industry requirement.

In connection with its review, the Commission requests responses from the parties to the following questions. The parties are requested to brief their positions with reference to the applicable law and the existing evidentiary record.

[1] The ALJ issued a corrected final ID on July 26, 2022, correcting the table of contents.

(1) Discuss whether the record evidence of "industry praise" and "copying" is sufficient to establish the requisite objective indicia of non-obviousness. *See Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966).
(2) Please explain whether and how the Complainant's investments credited by the ID under subsection 337(a)(3)(B) are quantitatively and qualitatively significant.
(3) Please explain whether and how the Complainant's employment of labor in research and development in the exploitation of the patents under subsection 337(a)(3)(C) are quantitatively and qualitatively substantial. Please state whether the R&D contract labor amount credited by the ID under subsection 337(a)(3)(C) includes foreign contract labor and, if so, please quantify such included amounts.
(4) What is the factual and legal basis for crediting Complainant's investments in the KBP and PRD products toward satisfaction of the domestic industry requirement under subsection (C)?

The parties are invited to brief only these discrete questions. The parties are not to brief other issues on review, which are adequately presented in the parties' existing filings.

In connection with the final disposition of this investigation, the statute authorizes issuance of, *inter alia,* (1) an exclusion order that could result in the exclusion of the subject articles from entry into the United States; and/or (2) cease and desist orders that could result in the respondent being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360, USITC Pub. No. 2843, Comm'n Op. at 7-10 (Dec. 1994).

The statute requires the Commission to consider the effects of that remedy upon the public interest. The public interest factors the Commission will consider include the effect that an exclusion order and cease and desist orders would have on: (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation. In particular, the Commission requests that the parties, interested government agencies, and interested persons respond to the following:

(1) Please provide information and argument that responds to the statements on the public interest submitted on the public record by the parties and the various third parties.
(2) Please provide data and factual information that specifically addresses whether and to what extent each of the four public interest factors would be adversely impacted by the remedial orders recommended in the RD, including details regarding the extent to which alternatives to the infringing products would be available to replace the infringing products and address the public health and welfare concerns raised.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve, disapprove, or take no action on the Commission's determination. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

WRITTEN SUBMISSIONS: The parties to the investigation are requested to file written submissions on the questions identified in this notice. Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding and to provide factual information and data requested above with respect to the public interest, including responding to the submissions of the parties and third parties that are in the record of this investigation. Such submissions should address the recommended determination by the ALJ on remedy and bonding.

In its initial submission, Complainant is also requested to identify the remedy sought and Complainant and OUII are requested to submit proposed remedial orders for the Commission's consideration. Complainant is further requested to provide the HTSUS subheadings under which the accused products are imported, and to supply the identification information for all known importers of the products at issue in this investigation. The initial written submissions and proposed remedial orders must be filed no later than close of business on October 6, 2022. Reply submissions must be filed no later than the close of business on October 13, 2022. No further submissions on these issues will be permitted unless otherwise ordered by the Commission. Opening submissions are limited to 75 pages. Reply submissions are limited to 50 pages. No further submissions on any of these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (March 19, 2020). Submissions should refer to the investigation number (Inv. No. 337-TA-1266) in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf*). Persons with questions regarding filing should contact the Secretary, (202) 205-2000.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. Any non-party wishing to submit comments containing confidential information must serve those comments on the parties to the investigation pursuant to the applicable Administrative Protective Order. A redacted non-confidential version of the document must also be filed with the Commission and served on any parties to the investigation within two business days of any confidential filing. All information, including confidential business information and documents

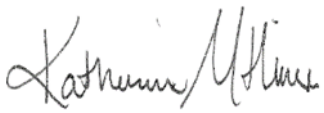
for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

The Commission has determined to extend the target date to December 12, 2022.

The Commission vote for this determination took place on September 22, 2022.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR Part 210).

By order of the Commission.



Katherine M. Hiner
Acting Secretary to the Commission

Issued: September 22, 2022

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of **CERTAIN WEARABLE ELECTRONIC DEVICES WITH ECG FUNCTIONALITY AND COMPONENTS THEREOF**	**Inv. No. 337-TA-1266**

[CORRECTED] INITIAL DETERMINATION ON VIOLATION OF SECTION 337 AND RECOMMENDED DETERMINATION ON REMEDY AND BOND

Administrative Law Judge Cameron Elliot

(June 27, 2022)

Pursuant to the Notice of Investigation and Rule 210.42(a) of the Rules of Practice and Procedure of the United States International Trade Commission, this is my Initial Determination in the matter of *Certain Wearable Electronic Devices with ECG Functionality and Components Thereof*, Investigation No. 337-TA-1266.

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TABLE OF ABBREVIATIONS

CDX	Complainant's Demonstrative Exhibit
CIB	Complainant's Revised Initial Post-Hearing Brief
CPB	Complainant's Pre-Hearing Brief
CPX	Complainant's Physical Exhibit
CRB	Complainant's Reply Post-Hearing Brief
CX	Complainant's Exhibit
Hr'g Tr.	Hearing Transcript
JX	Joint Exhibit
RDX	Respondents' Demonstrative Exhibit
RIB	Respondents' Initial Post-Hearing Brief
RPB	Respondents' Pre-Hearing Brief
RPX	Respondents' Physical Exhibit
RRB	Respondents' Reply Post-Hearing Brief
RX	Respondents' Exhibit
SDX	Staff's Demonstrative Exhibit
SIB	Staff's Initial Post-Hearing Brief
SPB	Staff's Pre-Hearing Brief
SRB	Staff's Reply Post-Hearing Brief
SX	Staff's Exhibit

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I. INTRODUCTION

A. Procedural Background

Complainant AliveCor, Inc. ("AliveCor," "ALC," or "Complainant") filed the complaint underlying this investigation on April 20, 2021. The complaint alleged respondent Apple Inc. ("Apple" or "Respondent") imports or sells in connection with an importation certain wearable electronic devices with electrocardiogram ("ECG") functionality that infringe one or more claims of U.S. Patent Nos. 10,595,731 ("the 731 patent"), 10,638,941 ("the 941 patent"), and 9,572,499 ("the 499 patent") (together, the "Asserted Patents").

By publication of a notice in the *Federal Register* on May 26, 2021, the U.S. International Trade Commission ordered that:

> Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of products identified in paragraph (2) by reason of infringement of one or more of claims 1-30 of the '731 patent; claims 1-23 of the '941 patent; claims 1-4, 6-14, 16-20 of the '499 patent, and whether an industry in the United States exists or is in the process of being established as required by subsection (a)(2) of section 337[.]

86 Fed. Reg. 28382 (May 26, 2021). In addition to Apple, the Commission named the Office of Unfair Import Investigations as a party (hereafter, "Commission Investigative Staff" or "Staff"). *Id.*

On June 10, 2021, I set a target date of October 26, 2022 for completion of this investigation via initial determination. Order No. 4. Also on June 10, 2021, I set a *Markman* hearing date of October 26-27, 2021 and the evidentiary hearing for March 28 through April 1, 2022. Order No. 5. On October 15, 2021, the *Markman* hearing was cancelled (Order No. 11), with the parties' disputes resolved on the papers on November 4, 2021 (Order No. 12).

With respect to the asserted claims, on February 22, 2022, ALC moved (1266-010) to terminate claims 1-4, 6-14, and 18-20 of the 499 patent; claims 2, 4, 6, 7, 11, 13, 14, and 17-30 of the 731 patent; and claims 1-11, 14, 15, 17, and 18 of the 941 patent, all by reason of withdrawal. This motion was granted via initial determination on February 23, 2022. Order No. 16. On March 18, 2022, the Commission determined not to review Order No. 16. EDIS Doc. ID 765832.

Finally, a virtual evidentiary hearing using the Commission's videoconference software took place on March 28 through April 1, 2022. At the pre-hearing conference, Apple's motion to amend its witness list as contained within its pre-hearing statement (1266-028) was denied. Hr'g Tr. at 15:19-21. Pursuant to the procedural schedule, the parties submitted initial and reply post-hearing briefs on April 15, 2022 and April 29, 2022, respectively. On April 27, 2022, ALC moved (1266-30) for leave to file a corrected version of its initial post-hearing brief, which was granted on April 28, 2022. Order No. 30. As of the date of this initial determination, no motions remain pending.

B. The Parties

Complainant ALC is a U.S. corporation organized in Delaware and with a principal place of business in Mountain View, CA. CIB at 4. ALC was founded in 2011 and develops computerized devices for mobile health monitoring. *Id.*

Respondent Apple is a U.S. corporation organized in California and with a principal place of business in Cupertino, CA. RIB at 2. "Apple designs, manufactures, and markets smartphones, personal computers, tablets, wearables and accessories—including the Apple Watch Series 1-7 and SE." *Id.* at 2-3.

C. The Asserted Patents and Claims

The 941 patent, entitled "Discordance Monitoring," issued on May 5, 2020 to David Albert, Omar Dawood, and Ravi Gopalakrishnan. JX-0003 (cited as "941 patent"). The 941 patent reports an assignment on its face to AliveCor, and claims priority to a provisional application filed on May 13, 2015.

The 731 patent, entitled "Methods and Systems for Arrhythmia Tracking and Scoring," issued on March 24, 2020 to Ravi Gopalakrishnan, Lev Korzinov, Fei Wang, Euan Thomson, Nupur Srivastava, Omar Dawood, Iman Abuzeid, and David Albert. JX-0002 (cited as "731 patent"). The 731 patent reports an assignment on its face to AliveCor, and claims priority to a provisional application filed on December 12, 2013.

The 499 patent, also entitled "Methods and Systems for Arrhythmia Tracking and Scoring," issued on February 21, 2017 to Ravi Gopalakrishnan, Lev Korzinov, Fei Wang, Euan Thomson, Nupur Srivastava, Omar Dawood, Iman Abuzeid, and David Albert. JX-0001 (cited as "499 patent"). The 499 patent reports an assignment on its face to AliveCor, and claims priority to a provisional application filed on June 19, 2014.

The three patents in suit relate to systems, devices, and methods for monitoring cardiac health and managing cardiac disease. *See* 941 patent at 1:26-33; 731 patent at 1:29-33. The specific cardiac condition addressed by all the asserted claims is arrhythmia, or abnormal heart rhythm. *See* 941 patent at 4:9-10; 499 patent at cl. 1 (preamble). The devices recited in the claims, including in the method claims, are either a smartwatch (for the 941 and 731 patents) or a mobile computing device (for the 499 patent). The smartwatch claims require an electrocardiogram (ECG) sensor and at least one other sensor. *See, e.g.*, 941 patent at cl. 1; 731 patent at cl. 25. For most asserted smartwatch claims one of the other sensors is a photoplethysmogram (PPG) sensor,

which detects heart rate optically. *See* 731 patent at 8:51-55. The mobile computing device claims require an ECG sensor, a heart rate sensor, and a motion sensor. *See, e.g.*, 499 patent at cls. 1, 11. Whether reciting a method or apparatus, the asserted independent claims generally involve monitoring heart rate (*e.g.*, "sensing a heart rate" (499 patent at cl. 1)), detecting or determining possible arrhythmia or irregularity in heart rate variability ("HRV") (*e.g.*, "detect, based on the PPG data, the presence of an arrythmia" (731 patent at cl. 1)), and either performing an ECG or alerting the user that an ECG is called for (*e.g.*, "receive electric signals of the user from the ECG sensor to confirm the presence of the arrythmia" (941 patent at cl. 12)).

The following patent claims are presently at issue in this investigation, as determined from ALC's briefing:

Asserted Patent	Infringement Claims	Domestic Industry Claims
10,638,941	12, 13, **18**, 19, 20, 21, 22, 23	12, 16, **18**, 20, 21, 22, 23
10,595,731	1, **2**, 3, **4**, 5, **7**, 8, 9, 10, 12, 15, 16	1, **2**, 3, 12, 15, 16
9,572,499	**11**, 16, 17	**11**, 16, 17

See generally CIB at 30, 43, 89, 95, 122, 134. The claim numbers identified in bold are not explicitly asserted for infringement or domestic industry, but are necessary intervening claims to those that are asserted.

D. Products at Issue

1. Domestic Industry Products

The domestic industry products in this investigation are "wearable electronic devices, being developed, manufactured, and/or sold by AliveCor under the tradenames KardiaBand System, [redacted], and [redacted]" (altogether, the "DI Products"). CIB at 15. Each product includes, "among other things, a smartwatch, activity sensor, PPG sensor, and

ECG sensor." *Id.* The KardiaBand System ("KBS") comprises the KardiaBand watch band, and an Apple Watch (Series 1, 2, 3) with Watch OS 5.0 or earlier running a program called KardiaApp. *Id.* (citing Hr'g Tr. (Jafari) at 385:16-386:15). There are two important features to KardiaApp—KardiaAI and SmartRhythm (versions 1 and 2). KardiaAI represents ALC's proprietary algorithms to classify ECG recordings. *Id.* at 16 (citing Hr'g Tr. (Somayajula) at 196:17-197:14; CX-0271C at 1, 3, 5; CPX-0021C).

2. Accused Products

The accused products consist of four generations of Apple smartwatches. CIB at 7. ALC references a joint stipulation filed earlier in the investigation which collects the particular model numbers. These are reproduced below:

Apple Model(s)	Category
A1975, A1976, A1977, A1978	Series 4
A2092, A2093, A2094, A2095	Series 5
A2291, A2292, A2293, A2294	Series 6
A2473, A2474, A2475, A2477	Series 7

EDIS Doc. ID 758097; CIB at 7; RIB at 10. Accordingly, the accused products in this investigation are those listed in the table above (hereafter "Accused Products"). ALC explains that the parties have further agreed, via that stipulation, that the Apple Watch Series 6 is sufficiently representative from a hardware standpoint of all other Accused Products. CIB at 8 (citing EDIS Doc. ID 758097); *see* RIB at 10 n.22. ALC describes the salient features of the Accused Products via the Series 6 as "a motion/activity sensor known as an accelerometer, a photoplethysmography ('PPG') sensor, an electrocardiogram ('ECG') sensor, a display screen, a processor, and memory." CIB at 8 (citing Hr'g Tr. (Jafari) at 303:19-24; JX-0221C (Waydo) at 207:10-14, 208:14-209:11; CX-0107).

The software running on these devices is also important, taking the form of Apple's operating system, WatchOS. CIB at 7; RIB at 10. As with hardware, the parties have agreed that version 7.6.2 of WatchOS is representative of all other versions that contain the diagnostic tools implicated by the Asserted Claims. CIB at 9; RIB at 10 n.22; EDIS Doc. ID 758097. These tools include Apple's: High Heart Rate Notification feature ("HHRN"), Irregular Rhythm Notification ("IRN"), and Electrocardiogram App/Feature version 2.0 ("ECG"). CIB at 7-8; RIB at 10-14. According to ALC:

> (a) The HHRN Feature monitors a user's heart rate in the background using the PPG sensor technology and alerts the user if their heart rate exceeds a threshold level (set to a default of 120 beats per minute ("bpm") by Apple) when the user has

> been sedentary for a period of at least 10 minutes. Tr. (Jafari) 306:19-307:15; JX-221C (Waydo) at 289:24-290:20.
>
> (b) The IRN Feature monitors a user's heart activity in the background using the PPG sensor—initiating measurement opportunities approximately every 2 hours when the user is sedentary—and determines whether the user's heart rate variability (*i.e.*, the instantaneous beat-to-beat variance in the user's heart rate) (hereafter "HRV") shows signs of an irregular rhythm suggestive of AFib. Tr. (Jafari) at 311:11-21; JX-218C (Framhein) at 97:22-98:23; CX-0048C.8-10, 87 (IRN Design Specification); CX-0619 (Using Apple Watch of Arrhythmia Detection); CX-0080 (IRN FDA Clearance)
>
> (c) The ECG App records a 30-second ECG from the user when the user wears the watch and initiates contact with the digital crown using the opposing hand, and the representative ECG 2.0 App will attempt to classify the user's ECG as (*inter alia*) normal sinus rhythm, AFib, AFib with high heart rate, or high heart rate. Tr. (Jafari) at 321:20-322:11; CX-51C.5, 8, 65 (ECG 2.0 Specification); CX-0619; CX-0640C (ECG 2.0 510(k) clearance).

CIB at 9. Apple adds that HHRN uses a feature called Background Heart Rate ("BGHR") "to monitor whether the user's heart rate is above or below the user-set threshold." RIB at 10 (citing Hr'g Tr. (Waydo) at 751:12-24). According to Apple, IRN also uses BGHR to collect heart rate data, [redacted], and ECG is unlike either HHRN or IRN in that it is not continuously running, but "requires the user to affirmatively open the ECG App." *See id.* at 11-13.

II. STANDARDS OF LAW

A. Standing

Commission Rule 210.12 states in relevant part "[f]or every intellectual property based complaint (regardless of the type of intellectual property involved), [the complaint must] include a showing that at least one complainant is the owner or exclusive licensee of the subject intellectual property." 19 C.F.R. § 210.12(a)(7). In determining whether this rule is met, the Commission looks to the standing requirement used by courts in patent infringement cases. *Certain Audio*

Processing Hardware, Software, and Products Containing the Same, Inv. No. 337-TA-1026, Comm'n Op. at 9 (April 18, 2018) (citations omitted).

B. Claim Construction

"The construction of claims is simply a way of elaborating the normally terse claim language in order to understand and explain, but not to change, the scope of the claims." *Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1347 (Fed. Cir. 2000). Although most of the disputed claim terms were construed in an earlier order, some of the issues presented below are only resolvable with additional claim construction.

Claim construction focuses on the intrinsic evidence, which consists of the claims themselves, the specification, and the prosecution history. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc); *see also Markman v. Westview Instr., Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc). As the Federal Circuit in *Phillips* explained, courts must analyze each of these components to determine the "ordinary and customary meaning of a claim term" as understood by a person of ordinary skill in art at the time of the invention. 415 F.3d at 1313. "Such intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language." *Bell Atl. Network Servs., Inc. v. Covad Commc'ns Grp., Inc.*, 262 F.3d 1258, 1267 (Fed. Cir. 2001).

"It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Phillips*, 415 F.3d at 1312 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). "Quite apart from the written description and the prosecution history, the claims themselves provide substantial guidance as to the meaning" of particular claim terms. *Id.* at 1314; *see Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) ("In

construing claims, the analytical focus must begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to 'particularly point [ ] out and distinctly claim [ ] the subject matter which the patentee regards as his invention."). The context in which a term is used in an asserted claim can be "highly instructive." *Phillips*, 415 F.3d at 1314. Additionally, other claims in the same patent, asserted or unasserted, may also provide guidance as to the meaning of a claim term. *Id.* "Courts do not rewrite claims; instead, we give effect to the terms chosen by the patentee." *K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1364 (Fed. Cir. 1999). "[T]he specification 'is always highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed term.'" *Phillips*, 415 F.3d at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). "[T]he specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Id.* at 1316.

In addition to the claims and the specification, the prosecution history should be examined, if in evidence. *Phillips*, 415 F.3d at 1317; *see Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 913 (Fed. Cir. 2004). The prosecution history can "often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Phillips*, 415 F.3d at 1317; *see Chimie v. PPG Indus. Inc.*, 402 F.3d 1371, 1384 (Fed. Cir. 2005) ("The purpose of consulting the prosecution history in construing a claim is to exclude any interpretation that was disclaimed during prosecution.").

When the intrinsic evidence does not establish the meaning of a claim, then extrinsic evidence (*i.e.*, all evidence external to the patent and the prosecution history, including

dictionaries, inventor testimony, expert testimony, and learned treatises) may be considered. *Phillips*, 415 F.3d at 1317. Extrinsic evidence is generally viewed as less reliable than the patent itself and its prosecution history in determining how to define claim terms. *Id.* "The court may receive extrinsic evidence to educate itself about the invention and the relevant technology, but the court may not use extrinsic evidence to arrive at a claim construction that is clearly at odds with the construction mandated by the intrinsic evidence." *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 977 (Fed. Cir. 1999).

The construction of a claim term is generally guided by its ordinary meaning. However, courts may deviate from the ordinary meaning when: (1) "the intrinsic evidence shows that the patentee distinguished that term from prior art on the basis of a particular embodiment, expressly disclaimed subject matter, or described a particular embodiment as important to the invention;" or (2) "the patentee acted as his own lexicographer and clearly set forth a definition of the disputed claim term in either the specification or prosecution history." *Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1329 (Fed. Cir. 2009); *see GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1309 (Fed. Cir. 2014) ("the specification and prosecution history only compel departure from the plain meaning in two instances: lexicography and disavowal."); *Omega Eng'g, Inc, v. Raytek Corp.*, 334 F.3d 1314, 1324 (Fed. Cir. 2003) ("[W]here the patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender."); *Rheox, Inc. v. Entact, Inc*., 276 F.3d 1319, 1325 (Fed. Cir. 2002) ("The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution."). Nevertheless, there is a "heavy presumption that a claim term carries its ordinary and customary meaning." *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir.

2002) (citations omitted). The standard for deviating from the plain and ordinary meaning is "exacting" and requires "a clear and unmistakable disclaimer." *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1366-67 (Fed. Cir. 2012); *see Epistar Corp. v. Int'l Trade Comm'n*, 566 F.3d 1321, 1334 (Fed. Cir. 2009) (requiring "expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope" to deviate from the ordinary meaning) (citation omitted).

C. Infringement

"An infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing." *Markman*, 52 F.3d at 976. A patentee may prove infringement either literally or under the doctrine of equivalents. Infringement of either sort must be proven by a preponderance of the evidence. *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988). A preponderance of the evidence standard "requires proving that infringement was more likely than not to have occurred." *Warner-Lambert Co. v. Teva Pharm. USA, Inc.*, 418 F.3d 1326, 1341 n.15 (Fed. Cir. 2005).

Literal infringement is a question of fact. *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1332 (Fed. Cir. 2008). "To establish literal infringement, every limitation set forth in a claim must be found in an accused product, exactly." *Microsoft Corp. v. GeoTag, Inc.*, 817 F.3d 1305, 1313 (Fed. Cir. 2016) (quoting *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir. 1995). If any claim limitation is absent, there is no literal infringement of that claim as a matter of law. *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000).

Doctrine of equivalents is also a form of infringement. One rubric for evaluating if a claimed feature is not literally, but nonetheless equivalent to, a claimed feature is known as the

function-way-result test. Under this test, the accused feature is equivalent to the claim limitation when "it performs substantially the same function in substantially the same way to obtain the same result." *Duncan Parking Techs., Inc. v. IPS Grp., Inc.*, 914 F.3d 1347, 1362 (Fed. Cir. 2019) (quoting *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950)). Another is known as the insubstantial differences test, where "[a]n element in the accused device is equivalent to a claim limitation if the only differences between the two are insubstantial." *Voda v. Gordia Corp.*, 536 F.3d 1311, 1326 (Fed. Cir. 2008) (citing *Honeywell Int'l Inc. v. Hamilton Sundstrand Corp.*, 370 F.3d 1131, 1139 (Fed. Cir. 2004)). The Supreme Court has further instructed, "the proper time for evaluating equivalency . . . is at the time of infringement, not at the time the patent was issued." *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 37 (1997).

D. Domestic Industry

In an investigation based on a claim of patent infringement, section 337 requires that an industry in the United States, relating to the articles protected by the patent, exist or be in the process of being established. 19 U.S.C. § 1337(a)(2). Under Commission precedent, the domestic industry requirement has been divided into (i) a "technical prong" (which requires articles covered by the asserted patent) and (ii) an "economic prong" (which requires certain levels of activity with respect to the protected articles or patent itself). *See Certain Video Game Systems and Controllers*, Inv. No. 337-TA-743, Comm'n Op. at 6-7 (April 14, 2011) ("*Video Game Systems*").

1. Technical Prong

The technical prong of the domestic industry requirement is satisfied when the complainant in a patent-based section 337 investigation establishes that it is practicing or exploiting the patents at issue. *See* 19 U.S.C. §§ 1337 (a)(2), (3); *Certain Microsphere Adhesives, Process for Making Same and Prods. Containing Same, Including Self-Stick Repositionable Notes*, Inv. No. 337-TA-366, Comm'n Op. at 8 (U.S.I.T.C. Jan. 16, 1996). "In order to satisfy the technical prong of the

domestic industry requirement, it is sufficient to show that the domestic industry practices any claim of that patent, not necessarily an asserted claim of that patent." *Certain Ammonium Octamolybdate Isomers*, Inv. No. 337-TA-477, Comm'n Op. at 55 (U.S.I.T.C. Aug. 28, 2003). Historically, the Commission permits the complainant's products, and those of its licensees, to be considered for technical prong purposes. *See Certain Magnetic Tape Cartridges and Components Thereof*, Inv. No. 337-TA-1058, Comm'n Op. at 28-29 (April 9, 2019).

The test for claim coverage for the purposes of the technical prong of the domestic industry requirement is the same as that for infringement. *See Certain Doxorubicin and Preparations Containing Same*, Inv. No. 337-TA-300, Initial Determination at 109 (U.S.I.T.C. May 21, 1990), *aff'd*, Views of the Commission at 22 (U.S.I.T.C. Oct. 31, 1990); *Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1375 (Fed. Cir. 2003). "First, the claims of the patent are construed. Second, the complainant's article or process is examined to determine whether it falls within the scope of the claims." *Certain Doxorubicin and Preparations Containing Same*, Inv. No. 337-TA-300, Initial Determination at 109. As with infringement, the technical prong of the domestic industry can be satisfied either literally or under the doctrine of equivalents. *Certain Dynamic Sequential Gradient Devices and Component Parts Thereof*, Inv. No. 337-TA-335, ID at 44, Pub. No. 2575 (U.S.I.T.C. May 15, 1992). In short, the patentee must establish by a preponderance of the evidence that the domestic product practices one or more claims of the patent.

2. Economic Prong

The "economic prong" of the domestic industry requirement is satisfied when there exists in the United States, in connection with products practicing at least one claim of the patent at issue: (A) significant investment in plant and equipment; (B) significant employment of labor or capital; or (C) substantial investment in its exploitation, including engineering, research and development, and licensing. 19 U.S.C. § 1337(a)(3). Establishment of the "economic prong" is not dependent

on any "minimum monetary expenditure" and there is no need for complainant "to define the industry itself in absolute mathematical terms." *Certain Stringed Musical Instruments and Components Thereof*, Inv. No. 337-TA-586, Comm'n Op. at 25-26 (May 16, 2008) ("*Stringed Instruments*").

However, a complainant must substantiate the significance of its activities with respect to the articles protected by the patent. *Certain Printing and Imaging Devices and Components Thereof*, Inv. No. 337-TA-690, Comm'n Op. at 30 (Feb. 17, 2011) ("*Imaging Devices*"). A complainant can show that its activities are significant by showing how those activities are important to the articles protected by the patent in the context of the company's operations, the marketplace, or the industry in question. *Id.* at 27-28. That significance, however, must be shown in a quantitative context. *Lelo Inc. v. Int'l Trade Comm'n*, 786 F.3d 879, 886 (Fed. Cir. 2015). The Federal Circuit noted that when the ITC first addressed this requirement, it found the word "'significant' denoted 'an assessment of the *relative* importance of the domestic activities.'" *Id.* at 883-4 (internal citation omitted) (emphasis added). In general, "[t]he purpose of the domestic industry requirement is to prevent the ITC from becoming a forum for resolving disputes brought by foreign complainants whose only connection with the United States is ownership of a U.S. patent." *Certain Battery-Powered Ride-On Toy Vehicles*, Inv. No. 337-TA-314, USITC Pub. No. 2420, Initial Determination at 21 (Aug. 1991); *see Certain Vacuum Insulated Flasks and Components Thereof*, Inv. No. 337-TA-1216, Notice at 3-4 (Oct. 21, 2021) ("Given the nature and extent of [complainant's] investments in plant and equipment as a whole, [complainant] is not a mere importer.").

Moreover, otherwise qualifying investments must not be aggregated across products that practice different patents, or practice no asserted patents at all. *Certain Electronic Stud Finders,*

Metal Detectors and Electrical Scanners, Inv. No. 337-TA-1221, Comm'n Op. at 48 (Mar. 14, 2022). Aggregating investments across domestic industry products that practice different asserted patents "fail[s] to provide the Commission with an adequate basis to evaluate the investments and the significance of those investments with respect to each asserted patent." *Id.*; *see id.* at 50-54 (collecting cases).

E. Invalidity

1. 35 U.S.C. § 101

Section 101 states:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

35 U.S.C. § 101. To determine patent eligibility under § 101, courts apply the two-step *Alice* test and first, "determine whether the claims at issue are directed to a patent-ineligible concept" and then if so, "examine the elements of the claim to determine whether it contains an 'inventive concept' sufficient to 'transform' the claimed abstract idea into a patent-eligible application." *Alice Corp. Pty. v. CLS Bank Intern.*, 573 U.S. 208, 217-18, 221 (2014). "The 'directed to' inquiry applies a stage-one filter to claims, considered in light of the specification, based on whether 'their character as a whole is directed to excluded subject matter.'" *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1335 (Fed. Cir. 2016) (citing *Internet Patents Corp. v. Active Network, Inc.*, 790 F.3d 1343, 1346 (Fed. Cir. 2015); *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1375 (Fed. Cir. 2016)). To save a patent at the second step, an inventive concept must be evident in the claims. *Synopsys, Inc. v. Mentor Graphics Corp.*, 839 F.3d 1138, 1151-52 (Fed. Cir. 2016).

2. 35 U.S.C. § 102

Pursuant to 35 U.S.C. § 102, a patent claim is invalid as anticipated if:

> (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or
>
> (2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

35 U.S.C. § 102 (post-AIA). "A patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention. Moreover, a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference." *Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003) (citations omitted); *see Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1354 (Fed. Cir. 2012). "A century-old axiom of patent law holds that a product 'which would literally infringe if later in time anticipates if earlier.'" *Upsher-Smith Labs., Inc. v. Pamlab, L.L.C.*, 412 F.3d 1319, 1322 (Fed. Cir. 2005) (citing *Schering Corp.*, 339 F.3d at 1322). Anticipation, and all other grounds of patent invalidity, must be proved by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 95, (2011).

3. 35 U.S.C. § 103

Section 103 of the Patent Act states:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

35 U.S.C. § 103(a) (post-AIA). "Obviousness is a question of law based on underlying questions of fact." *Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V.*, 528 F.3d 1365, 1379 (Fed. Cir. 2008). The underlying factual determinations include: "(1) the scope and content of the prior art,

(2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) objective indicia of non-obviousness." *Id.* (citing *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966)). These factual determinations are often referred to as the "*Graham* factors."

The critical inquiry in determining the differences between the claimed invention and the prior art is whether there is a reason to combine the prior art references. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418-21 (2007). In *KSR*, the Supreme Court rejected the Federal Circuit's rigid application of the teaching-suggestion-motivation test. While the Court stated that "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does," it described a more flexible analysis:

> Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue . . . . As our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.

Id. at 418. Since *KSR*, the Federal Circuit has announced that, where a patent challenger contends that a patent is invalid for obviousness based on a combination of prior art references, "the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the composition or device . . . and would have had a reasonable expectation of success in doing so." *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007); *see KSR*, 550 U.S. at 399 ("The proper question was whether a pedal designer of ordinary skill in the art, facing the wide range of needs created by developments in the field, would have seen an obvious benefit to upgrading Asano with

a sensor."). In addition to demonstrating that a reason exists to combine prior art references, the challenger must demonstrate that the combination of prior art references discloses all of the limitations of the claims. *Velander v. Garner*, 348 F.3d 1359, 1363 (Fed. Cir. 2003) (explaining that a requirement for a finding of obviousness is that "all the elements of an invention are found in a combination of prior art references").

An obviousness determination must also include a consideration of "secondary considerations," because "commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." *Graham*, 338 U.S. at 17-18. "For [such] objective evidence to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention." *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995); *see Merck & Cie v. Gnosis S.P.A.*, 808 F.3d 829, 837 (Fed. Cir. 2015). "Where the offered secondary consideration actually results from something other than what is both claimed and novel in the claim, there is no nexus to the merits of the claimed invention." *In re Huai-Hung Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011); *see Apple Inc. v. Samsung Elecs. Co., Ltd.*, 839 F.3d 1034, 1054-1056 (Fed. Cir. 2016).

III. IMPORTATION AND JURISDICTION

In its initial post-hearing brief, ALC explains that, "Apple stipulated that it imports accused products into the United States" such that the importation requirement of 19 U.S.C. § 1337 is satisfied. CIB at 20-21 (citing CX-0904C). Apple confirms in its brief that it "do[es] not dispute that the Commission has jurisdiction to adjudicate this Investigation." RIB at 15. The Staff similarly finds the importation requirement met, citing the stipulation entered into by Apple. SIB at 11 (citing CX-0904C).

Accordingly, the importation requirement under 19 U.S.C. § 1337(a)(1)(B) is satisfied, and the Commission has *in rem* jurisdiction over the Accused Products.

IV. U.S. PATENT NO. 10,638,941

A. Level of Ordinary Skill in the Art

A person having ordinary skill in the art of the 941 patent at the time of invention:

> would have had either (1) a bachelor of science degree in electrical engineering, mechanical engineering, biomedical engineering, computer science, or a related discipline, with at least two years of relevant work experience designing wearable devices and/or sensors for measuring physiological signals or parameters of mammals, or (2) a medical degree and at least five years of relevant work experience designing wearable devices and/or sensors for measuring physiological signals or parameters of mammals. Also, relevant experience could substitute for education and vice versa for both categories of skilled artisan

Order No. 12 at 8. The parties do not challenge this definition and it is applied throughout this initial determination.

B. Claims-at-Issue

Claims 12, 13, 16, and 19-23 of the 941 patent are at issue in this investigation, either through allegations of infringement or domestic industry technical prong. *See generally* CIB at 30, 43. They are reproduced below, along with intervening claim 18:

> 12. A smartwatch, comprising:
>
> a processor;
>
> a first sensor configured to sense an activity level value of a user, wherein the first sensor is coupled to the processor;
>
> a photoplethysmogram ("PPG") sensor configured to sense a heart rate parameter of the user when the activity level value is resting, wherein the PPG sensor is coupled to the processor;
>
> an electrocardiogram ("ECG") sensor configured to sense electrical signals of a heart, wherein the ECG sensor comprises a first electrode and a second electrode, and wherein the ECG sensor is coupled to the processor; and
>
> a non-transitory computer readable storage medium encoded with a computer program including instructions executable by the processor to cause the processor to:

> determine if a discordance is present between the activity level value of the user and the heart rate parameter of the user;
>
> based on the presence of the discordance, indicate to the user a possibility of an arrhythmia being present; and
>
> receive electric signals of the user from the ECG sensor to confirm the presence of the arrhythmia.
>
> 13. The smartwatch or wristlet according to claim 12, wherein the heart rate parameter comprises an indication of a heart rate variability, and wherein the arrhythmia is atrial fibrillation.
>
> . . . .
>
> 16. The smartwatch or wristlet according to claim 12, wherein indicating to the user further comprises: instructing the user to record an ECG using the ECG sensor.
>
> . . . .
>
> 18. The smartwatch according to claim 12, wherein the heart rate parameter is a PPG signal.
>
> 19. The smartwatch according to claim 18, wherein the heart rate parameter is a heartrate variability ("HRV") value, wherein the HRV value is derived from the PPG signal.
>
> 20. The smartwatch according to claim 18, wherein the heart rate parameter is a heartrate, wherein the heartrate is derived from the PPG signal.
>
> 21. The smartwatch according to claim 12, the processor further to: display an ECG rhythm strip from the electric signals.
>
> 22. The smartwatch according to claim 12, wherein the PPG sensor is located on a back of the smartwatch.
>
> 23. The smartwatch according to claim 12, wherein the first electrode is located on the smartwatch where the first electrode contacts a first side of the user's body while the user wears the smartwatch, and the second electrode is located on the smartwatch where the user must actively contact the second electrode with a second side of the user's body opposite from the first side.

941 patent at cls. 12, 13, 16, 18-23.

C. Claim Construction

As part of the *Markman* process, the following claim terms of the 941 patent were

construed, either as-agreed between the parties or determined by Order No. 12:

Claim Term	Construction
"arrhythmia"	"a cardiac condition in which the electrical activity of the heart is irregular or is faster or slower than normal"
"to confirm a presence of the arrhythmia" / "to confirm the presence of the arrhythmia"	Do not require a comparison of the ECG sensor results to the discordance determination
"when the activity level is resting" / "when the activity level value is resting"	Not indefinite
"discordance"	Plain and ordinary meaning
Order of method steps	the step of "when the activity level is resting, sensing a heat rate parameter of the user with a second sensor on the smartwatch" may be performed after or simultaneously with the step of "sensing an activity level of a user with a first sensor on a smartwatch worn by the user," and the step of "receiving electric signals of the user from an [ECG] on the smartwatch to confirm a presence of the arrhythmia" need not be performed last.

See Order No. 12 at 12, 26, 29, 30, 31. The parties explicitly identify two terms that need additional construction. These are discussed below.

1. "A smartwatch, comprising"

In its initial brief, ALC identifies the preamble of claim 12, "a smartwatch, comprising," as needing construction over whether it is limiting. CIB at 23-24. ALC argues it is, and points to dependent claims 22 and 23 which recite "smartwatch" in their claim bodies. *Id.* at 23. ALC argues this creates a need for an antecedent basis for "smartwatch." *Id.* (citing *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002)). Apple agrees with ALC that the preamble is limiting. RIB at 8; RRB at 3. And both ALC and Apple further refer to this investigation's *Markman* order that "if a preamble is limiting for a dependent claim it is also

limiting for the associated independent claim, because a dependent claim possesses all the elements of the claim from which it depends." Order No. 12 at 15; CIB at 24; RRB at 4.

Within a discussion of invalidity, the Staff takes the opposite position and argues the preamble is not limiting. SIB at 36. The Staff contends, "the preamble recites no necessary structure, and the preamble could be deleted without affecting the claimed invention." *Id.* (citing, *inter alia*, *Catalina*, 289 F.3d at 809).

ALC and Apple have the more persuasive position. Dependent claim 22's recitation of "wherein the PPG sensor is located on the back of the smartwatch," and the recitation of "the smartwatch" in claim 23, both require an antecedent basis as alleged, and under the rationale provided in the *Markman* order, the preamble of claim 12 is determined to be limiting.

2. "confirm the presence of arrhythmia"

ALC also identifies "confirm the presence of arrhythmia" as needing construction. CIB at 24. ALC contends it means to confirm the "condition" of arrhythmia, as opposed to confirming the particular episode of arrhythmia which may have been previously sensed by the PPG sensor. *See id.* at 24-25 (citing, *inter alia*, Hr'g Tr. (Jafari) at 342:21-343:11, 346:18-348:5, 455:16-456:17, 458:7-11, 461:1-15), 26 (citing, *inter alia*, 941 patent at 3:63-4:15, 1:43-57). ALC argues there is no intrinsic support for requiring the PPG data to overlap with the ECG, as Apple contends. *Id.* at 25-26. ALC further observes that Apple's experts, Dr. Picard and Dr. Stultz, appear to take contradicting positions on the topic. *Id.* at 25 (citing H'r Tr. (Picard) at 887:16-888:13, 890:10-891:1; Hr'g Tr. (Stultz) at 1154:21-1156:3), 27-28 (stating, "it is 'axiomatic that claims are construed the same way for both invalidity and infringement.'"); CRB at 13-14. ALC summarizes, "the '941 and '731 patents provide solutions where a PPG device may opportunistically measure heart parameters in the background, identify irregularities suggestive of arrhythmia, and provide a trigger to the user to take an ECG that can be analyzed on the device to confirm the presence of

the detected arrhythmia." CIB at 26 (citing 941 patent at Fig. 7, 4:65-15:16, 15:27-32, 15:35-43, 15:52-59). ALC also claims Apple's expert eventually admitted that flowcharts showing the sequential, not parallel, testing in the patent are embodiments of the claim. *See id.* at 27 (citing Hr'g Tr. (Picard) at 948:6-25, 952:21-953:3); *see* 941 patent at Fig. 7.

In its reply brief, ALC views Apple as relying entirely on Figure 1 of the 941 patent for its "simultaneous ECG/PPG" construction. CRB at 11. ALC notes, however, that the word "confirmed" does not appear anywhere in the discussion of Figure 1. *Id.* at 11-12 (citing Hr'g Tr. (Picard) at 977:5-979:4). Rather, as ALC argues above, "Figure 7 of the '941 patent (and accompanying disclosures) support numerous embodiments where an ECG is taken after a discordance determination that, itself, may indicate the presence of an arrhythmia . . . teaching that the arrhythmia '*should be confirmed* with the ECG.'" *Id.* at 12 (citing 941 patent at Fig. 7, 14:65-15:16, 15:27-32, 15:35-43, 15:52-59) (emphasis by ALC). ALC also disputes the idea that the "confirm" limitation represents testing or establishing what those in the art call a "ground truth." *See id.* at 12-13. ALC summarizes, "as a POSITA would readily understand, [] the user indeed has a detectable arrhythmia condition—the same condition which triggered the system to indicate the presence of such condition, first detected by the PPG sensor, to the user's attention." *Id.* at 13.

Apple presents its preferred meaning as "the ECG confirmation must be as to the particular arrhythmic event detected by the PPG sensor." RIB at 26 (citing Hr'g Tr. (Picard) at 886:6-887:15); RRB at 10. Practically, it explains, this "requires the ECG sensor to record and analyze data significantly overlapping in time with the data collected by the PPG sensor." RIB at 26-27 (citing Hr'g Tr. (Picard) at 887:16-22). Apple looks to Figure 1 of the 941 patent for support, which allegedly shows a PPG with an ECG trace "sensed from the same individual, over the same period of time" (*id.* at 27; RRB at 11) along with that portion of the specification which states "a

prediction of arrhythmia is more accurate when two or more physiologic parameters are concurrently sensed and analyzed with respect to one another" (*id.* at 11 (citing 941 patent at 10:21-23)). Despite ALC's suggestion to the contrary, Apple claims its experts are in agreement on this issue. *Id.* at 28 (citing Hr'g Tr. (Picard) at 890:8-891:1; Hr'g Tr. (Stultz) at 1121:23-1123, 1177:4-1178:9).

Apple also views ALC's and the Staff's construction as introducing intolerable ambiguity to the claim; specifically, ambiguity over how long the program can wait to take the ECG measurement and still "confirm" the earlier PPG diagnosis. RIB at 32-33; RRB at 14-16. Even if ALC's construction is adopted, Apple contends the claimed system must have "some algorithm that brings together the PPG-based discordance with the ECG measurement result to conduct the 'confirmation' analysis." *Id.* at 14.

The Staff agrees with ALC: "the '941 patent discloses preferred embodiments that take ECGs (steps 712A-D) *after* sensing heart rate and activity level values (step 700)." SIB at 18 (citing 941 patent at Fig. 7); SRB at 6 (citing 941 patent at 14:47-16:53). The Staff also cites the patent teaching that arrhythmias "may occur continuously or may occur intermittently" (SIB at 18 (citing 941 patent at 1:34-35)), and reasons, "[a]n arrhythmia can logically be confirmed at any time that it is still present" (*id.*).

ALC's and the Staff's interpretation of "confirm" is more persuasive, as there is scant intrinsic evidence to support Apple's simultaneous-measurement theory. Apple cites Figure 1 and 10:21-23 from the specification. Yet the patent is clear that Figure 1 (and associated discussion at 4:33-38) is essentially a background explanation of the cardiac monitoring arts. It shows concurrent ECG and heart rate tracings to demonstrate how heart rate variability (HRV) can serve as an indicator of atrial fibrillation. *See* 941 patent at 4:33-46 (explaining how ECG shows an

AFib episode, and during that episode, heart rate rapidly increased). This, accordingly, is used to justify the patent's teaching of continuously monitoring HRV to report or predict cardiac events. *See, e.g.*, *id.* at 4:44-46 ("HRV changes are therefore associated with atrial fibrillation, wherein increased HRV is found during periods of intermittent atrial fibrillation."); 5:11-14 ("For example, a user wearing a smartwatch having a heart rate sensor is alerted by the smartwatch to record an ECG when the HRV of the user increases."), 15:22-27 ("If, as shown in step 704, an increased heart rate is sensed together with an increased heart rate variability, and a normal or resting activity level is sensed. The increased heart rate and HRV are in discordance with the normal or resting activity level, and a presence of a discordance is determined by the device or system processor."). The figure does not, and is not intended to, reflect any embodiment of the invention.

Lines 10:21-23 from the specification fare no better. The excerpt states, "[a] prediction of arrhythmia is more accurate when two or more physiologic parameters are concurrently sensed and analyzed with respect to one another." 941 patent at 10:21-23. Not only does this sentence not mention ECG as one of those parameters "concurrently sensed," but the discussion in which it appears relates to predicting the *onset* of arrhythmia (*i.e.*, before it happens).

> In some embodiments, the devices described herein are configured to predict an onset of an arrhythmia in an individual. The onset of an arrhythmia is, for example, predicted due to a sudden and significant shift in the value of a sensed physiologic parameter such as heart rate. A prediction of arrhythmia is more accurate when two or more physiologic parameters are concurrently sensed and analyzed with respect to one another. For example, sensing of heart rate changes with respect to a sensed activity level provides contextual information for the sensed heart rate.

See id. at 10:16-25. There is no fair reading of claim 12, however, which covers predicting the onset of arrhythmia. By its plain language, the recited invention is reactive to arrhythmias—not predictive of them:

> a non-transitory computer readable storage medium encoded with a computer program including instructions executable by the processor to cause the processor to:

> determine if a discordance is present between the activity level value of the user and the heart rate parameter of the user;
>
> based on the presence of the discordance, indicate to the user a possibility of an arrhythmia *being present*; and
>
> receive electric signals of the user from the ECG sensor to confirm *the presence* of the arrhythmia.

Id. at cl. 12 (emphasis added).

ALC's and the Staff's construction, on the other hand, enjoys plentiful support. The patent repeatedly describes a process where ECG is initiated or sensed in response to (*i.e.*, later in time than) other physiological measured parameters:

> For example, discordance between two sensed values may indicate the future onset of or the presence of an arrhythmia. In response to the identification of the future onset of or presence of an arrhythmia an electrocardiogram may be caused to be sensed.

941 patent at 1:67-2:3;

> Described herein is a method for cardiac monitoring . . . and indicating to said individual with said wearable device to record an electrocardiogram when said discordance is determined to be present.

id. at 2:10-21;

> determine if a discordance is present between said activity level value of said individual and said heart rate value of said individual; and indicate that said electrocardiogram be recorded when said discordance is determined to be present.

id. at 2:52-56;

> Many arrhythmias occur intermittently and relatively infrequently. Thus, in order to monitor and capture an intermittent arrhythmia, continuous monitoring is typically required. ECGs can be measured continuously in the ambulatory patient using holter monitoring, but this type of monitoring is cumbersome for the patient and is thus not widely used. A device or system configured to take an intermittent ECG is much more convenient for users. Such devices or systems comprise a mobile computing device that includes one or more electrodes that sense an ECG when contacted by a skin surface of the patient. Such devices are light and portable and don't necessarily require the user to be in continuous physical contact with one or more electrodes as they would with a holter type monitor. Intermittent

> arrhythmias can be recorded with these devices and systems *when a user is given an indication that an intermittent arrhythmia is occurring*.

id. at 4:14-30 (emphasis added);

> The one or more continuously sensed parameters of the user of such a technology as, for example, shown in FIG. 4, are then used to indicate to the user to use a device or system to sense an ECG. For example, a user wearing a smartwatch having a heart rate sensor is alerted by the smartwatch to record an ECG when the HRV of the user increases.

id. at 5:8-14;

> An accelerated heart rate of an individual sensed by the device in addition to, for example, a low blood pressure of the individual concurrently sensed by the device, triggers the processor of the device to indicate to the individual to engage with the electrodes of the device in order to sense an electrocardiogram.

id. at 9:32-37;

> In some embodiments, an electrocardiogram of an individual may be sensed in response to one or more sensed parameters. For example, an electrocardiogram may be caused to be sensed in response to a heart rate value.

id. at 11:18-21;

> The identified discordance may indicate the presence of an arrhythmia. As such, an ECG is caused to be sensed in a step 712A.

id. at 14:65-67;

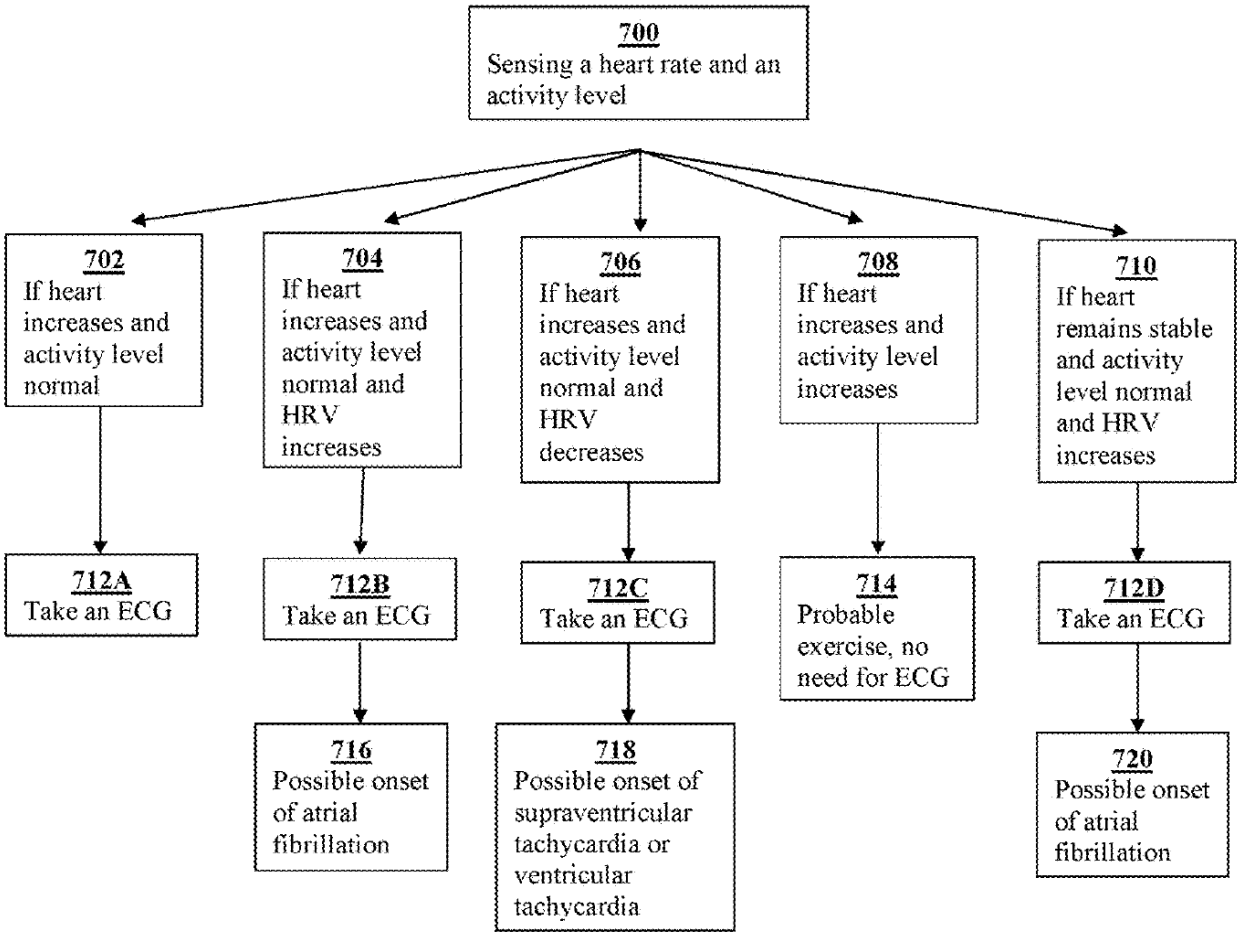
> Once the discordance is determined, an ECG is caused to be sensed in a step 712B as, for example, described herein with respect to step 712A. As shown, in step 716, this particular discordance may be indicative of the presence of atrial fibrillation and it should be confirmed with the ECG 712B.

id. at 15:27-32.

> The ECG sensing device may be the device or part of the system used to sense the heart rate and activity level or may be a separate device. For example, a user wearing a smartwatch with heart rate and activity level monitoring receives an audible and/or visual indication from the smartwatch to sense an ECG when a discordance is present between a sensed heart rate value and a sensed activity level value.

id. at 15:4-11.

The flowchart of Figure 7 is perhaps the most illustrative. Unlike Figure 1, it reflects possible embodiments of the invention, and teaches the recording of an ECG after the sensing of heart rate and activity level:



Id. at Fig. 7.

One other specification passage, in particular, uses the term "confirm" and concerns the training of the machine learning algorithm which evaluates for discordances. *See* 941 patent at 13:52-14:42. In this training, sensed electrocardiogram data may be "compared back" to other parameter values. Even then, however, the patent explains that the electrocardiogram data is taken at a later point in time:

> For example, in some embodiments, sensed electrocardiogram data may be compared back to parameter values such as, for example, sensed heart rates and activity levels that triggered the sensing of said electrocardiograms. When, for example, sensed electrocardiograms confirm the presence of an arrhythmia, the presence of which was indicated by, for example, a discordance between other parameter values, the machine algorithm causes the device or system described herein to learn from that data. Similarly, when, for example, sensed electrocardiograms do not confirm the presence of an arrhythmia, the presence of which was indicated by, for example, a discordance between other parameter values, the machine algorithm causes the device or system described herein to learn from that data as well. That is, in some embodiments, the machine learning algorithm correlates the sensed electrocardiogram with the discordance between parameter values that caused it (*i.e.* the electrocardiogram) to be sensed.

Id. at 13:63-14:14; *see* Order No. 12 at 26. Altogether, the above passages and figure are more than enough support for reading "confirm the presence of the arrhythmia" to encompass later-in-time ECG measurements.

Admittedly, one passage describes an embodiment where an ECG may be taken simultaneously with another measured parameter, such as heart rate:

> In some embodiments, one or more continuous sensors may sense one or more parameters that cause the initiation of intermittent cardiac monitoring by one or more sensors. . . In some embodiments, an intermittently sensed electrocardiogram is caused to be sensed in response to a continuously measured heart rate of an individual. . . . In some embodiments, an intermittently sensed electrocardiogram is caused to be sensed in response to both a continuously measured heart rate and a continuously measured activity level. In some embodiments, an intermittently sensed electrocardiogram is caused to be sensed in response to a continuously sensed heart rate, a continuously sensed activity level, and a continuously sensed heart rate variability.

941 patent at 11:22-42. The recitation here of an "intermittent" ECG (*i.e.*, sometimes) and a "continuous" sensed heart rate (*i.e.*, always) would logically result in occasional overlap between ECG and heart rate measurements. But there is otherwise no suggestion that this is part of a "confirm[ation]" process for arrhythmias. Thus, this passage, weighed against the other passages listed above, is not enough to limit claim 12 to Apple's interpretation. The proper path is to give the limitation its full plain and ordinary meaning which, covers simultaneous or sequential data

readings. *Epistar*, 566 F.3d at 1334 (holding there is "a heavy presumption that claim terms carry their full ordinary and customary meaning, unless it can show the patentee expressly relinquished claim scope."); *Eon Corp. IP Holdings v. Silver Spring Networks*, 815 F.3d 1314, 1320 (Fed. Cir. 2016) (holding claims must be interpreted in full view of the specification) (citations omitted).

Accordingly, "confirm the presence of the arrhythmia" does not mean ECG data must be recorded at the same time as PPG data.

D. Infringement

ALC contends, "Apple directly infringes claims 12, 13, 19, 20, 21, 22, and 23 of the '941 patent." CIB at 30. Of these, claim 12 is independent and the rest depend from it. For the reasons discussed below, ALC has shown infringement of claims 12, 13, 19, 20, 21, 22, and 23.

1. Claim 12

For reference, claim 12 of the 941 patent requires:

12. [12(a)] A smartwatch, comprising:

[12(b)] a processor;

[12(c)] a first sensor configured to sense an activity level value of a user, wherein the first sensor is coupled to the processor;

[12(d)] a photoplethysmogram ("PPG") sensor configured to sense a heart rate parameter of the user when the activity level value is resting, wherein the PPG sensor is coupled to the processor;

[12€] an electrocardiogram ("ECG") sensor configured to sense electrical signals of a heart, wherein the ECG sensor comprises a first electrode and a second electrode, and wherein the ECG sensor is coupled to the processor; and

[12(f)] a non-transitory computer readable storage medium encoded with a computer program including instructions executable by the processor to cause the processor to:

[12(f)(i)] determine if a discordance is present between the activity level value of the user and the heart rate parameter of the user;

[12(f)(ii)] based on the presence of the discordance, indicate to the user a possibility of an arrhythmia being present; and

> [12(f)(iii)] receive electric signals of the user from the ECG sensor to confirm the presence of the arrhythmia.

941 patent at cl. 12 (annotated).

As it concerns the Accused Products, only a few limitations are in dispute. ALC explains its view that, "Apple only contests infringement with respect to claim element 12(f)(i) (specifically for the IRN feature) and claim element 12(f)(iii) as to all accused features." CIB at 30 (citing Hr'g Tr. (Jafari) at 327:25-328:19). ALC thus reasons that any other disputes from Apple have been waived pursuant to Ground Rules 9.2 and 13.1. *Id.* And while ALC acknowledges that Apple did present an additional dispute for limitation 12(f)(ii) in its pre-hearing brief with respect to the HHRN feature, it notes that Apple presented no evidence or expert testimony at the hearing on the issue. *Id.* at 38 n.10. ALC argues Apple has thus waived the issue. *Id.*

The Staff contends that claim 12 is infringed. *See* SIB at 14. Apple does not concede the point, and it only addresses the elements of limitation 12(f) in its post-hearing briefs, but it does argue specifically that element 12(f)(ii) is not met. *See* RRB at 4-20.

ALC's position on limitation 12(f)(ii) is not persuasive. It is undisputed that Apple presented the argument in its pre-hearing brief. Thus, no violation of the ground rules occurred, the contention is not waived, and the limitation is discussed below. As to the remaining, undisputed, limitations of claim 12, they are found to be present in the Accused Products in light of the evidence and testimony provided by Dr. Jafari. CIB at 30-32 (citing Hr'g Tr. (Jafari) at 328:22-330:19, 340:16-22). In particular, the representative Apple Watch 6 is a smartwatch having an accelerometer, PPG sensor, ECG sensor, and memory, all coupled to a processor. *See* CDX-0003C.16.

a. [12(f)(i)] "determine if a discordance is present between the activity level value of the user and the heart rate parameter of the user"

As for "determine if a discordance is present between the activity level value of the user and the heart rate parameter of the user," ALC represents that there is no dispute it is met by Apple's HHRN feature—only IRN is contested. CIB at 32.

For HHRN, ALC argues it meets the limitation by running the [redacted], which finds discordances "when the user is confidently determined to be in a resting state (as determined by [redacted] . . .) for a period of 10 minutes, but where his heart rate is above the high heart rate threshold (default is 120 bpm)." CIB at 33 (citing Hr'g Tr. (Jafari) at 309:13-210:19). Neither Apple nor the Staff contests this point, and the limitation is practiced by HHRN. *See* RIB at 17-21 (discussing only IRN); RRB at 4-9 (same); SIB at 14-16 (same).

For IRN, ALC argues it also meets the limitation through a combination of the [redacted], and [redacted] CIB at 33. More specifically, it argues, "the [redacted] for the IRN feature [redacted]" *Id.* at 34 (citing JX-0281C (Framhein) at 97:22-98:23; JX-0221C (Waydo) at 242:2-16) (emphasis in original). Thus, according to ALC, the "future/continued resting condition is used on an ongoing basis to determine a discordance as the heart parameter continues to be collected by the green LEDs of the PPG sensor" (*id.* (citing Hr'g Tr. (Jafari) at 314:12-315:7, 334:24-335:25)) and "the user of the IRN feature '[redacted],

[redacted]" (*id.* (citing Hr'g Tr. (Jafari) at 336:15-21, 337:2-14, 438:7-13; CX-0080.2; CX-0048C.87). Importantly, ALC reasons:

> By [redacted], which according to the '941 patent's disclosure could represent a situation where no discordance is present at all (*e.g.*, where the user is exercising, JX-003 at Figure 7, 15:44-48; Tr. (Jafari) at 518:3-16), then any heart parameter measured by the IRN feature would necessarily embody a discordance because [redacted] *Id.*

Id. at 35.

ALC views Apple's "gatekeeping" arguments as inconsistent with the intrinsic evidence of the 941 patent with its invalidity positions. *See id.* at 36-37; CRB at 4, 9 (citing Hr'g Tr. (Stultz) at 1091:1-14). As to the former, ALC argues "there is no requirement . . . that detection of the presence of an arrhythmia by the claimed system requires that the activity level value be a direct input [to the discordance algorithm]. All that the claim requires is that a discordance is determined between the activity level value and the heart rate parameter." CRB at 5. And to the extent Apple argues activity level and heart rate parameter must be measured concurrently, ALC responds there is no such requirement, but even if there is, it is satisfied by IRN's [redacted] (*i.e.*, activity level is "brought together" with heart rate data). *See id.* at 6-7, 8-9 (citing RX-0835C.3); *see also* CIB at 36 (citing RX-0835C.3).

The Staff also finds the limitation met for both HHRN and IRN. The Staff argues that "[t]he IRN feature and HHRN feature . . . work in the same general manner – as discussed below, they both determine the possibility of an arrhythmia based on heart rate parameters that are inconsistent (or discordant) with a user being at rest. . . . This is exactly what the '941 patent describes." SIB at 15 (citing, *inter alia*, 941 patent at Fig. 7); *see* SRB at 3-4.

In opposition, Apple contends, "IRN does not make a discordance calculation at all." RIB at 15. Apple explains its "gatekeeping" noninfringement theory as follows:

> The IRN algorithm [redacted] As Apple's technical expert, Dr. Picard, testified and as confirmed by Apple's engineers, documents, and source code, and even by AliveCor's expert (Dr. Jafari), the [redacted], *e.g.*, RPX-4C (APLALIVE SC 0000089-93) ([redacted]); RX-179C.87; Tr. (Picard) at 848:3-885:19; Tr. (Waydo) at 762:22-763:4; Tr. (Jafari) at 437:16-438:17.

Id. at 16. Apple summarizes, "Dr. Waydo, Apple's Director of Health Algorithms, testified unequivocally [redacted]." *Id.* at 18 (citing Hr'g Tr. (Waydo) at 762:19-24); *see id.* at 19 (explaining [redacted]"); *see generally id.* at 19-21.

In its reply brief, Apple disputes that the limitation is satisfied "simply when a discordance exists—*e.g.*, when activity level is normal and the heart rate parameter increases. . . . [because this] ignores the '941 patent's requirement that there be computer instructions comparing both variables to '*determine* if a discordance is present.'" RRB at 5 (emphasis in original), 6 ("IRN *never* brings together activity level and heart rate data to determine a discordance") (emphasis in original). Apple reasons that because "the [IRN] process code analyzes [redacted]," it is necessarily true that the [redacted] *See id.* at 5-7. It

matters not, according to Apple, that these functions serve only IRN—the bottom line is they "[redacted] *Id.* at 8. As for its expert's, Dr. Stultz's, testimony on existing "at rest" clinical procedures for diagnosing arrhythmia (*id.* at 8 (citing Hr'g Tr. (Stultz) at 1091:1-14)), Apple claims IRN "operates entirely differently" because [redacted] A hypothetical doctor, on the other hand, "is mentally comparing the patent's activity level to the heart rate to determine if there is a discordance that might indicate a possible arrhythmia." *Id.*

The limitation is met. The accuracy of the algorithm shown in RX-0835C is not in dispute:

[redacted]

RX-0835C.3. Apple's technical witness, Dr. Waydo, testified that the process evaluates captured PPG data for "[redacted]." Hr'g Tr. (Waydo) at 758:7-15. It is beyond dispute that the "irregular rhythm" is only "irregular" because of the [redacted] *Id.* at 754:1-7, 763:2-4. In this way, the product is [redacted], or "discordance," of low activity but high heartrate (or high HRV). RIB at 19 ([redacted]

[redacted]). This meets the claim limitation. Even Apple's expert, Dr. Picard, opines that what is required is simply "a heart parameter and an activity are brought together, and there's a clear determination of a discordance." Hr'g Tr. (Picard) at 876:12-877:15.

Whether or not this process takes place entirely within IRN, or involves IRN plus another algorithm, is immaterial. Apple's internal nomenclature does not control whether an accused product includes executable instructions to "determine if a discordance is present between the activity level value of the user and the heart rate parameter of the user." *See, e.g.*, *Ferring Pharms. Inc. v. Par Pharm., Inc.*, 267 F.Supp.3d 501, 507-9 (D. Del. 2017) (refusing to credit defendant's ANDA characterization of a "spray-coating" process as "wet granulation" to avoid a "spray-coating" claim limitation); Oliver W. Holmes, *Law in Science and Science in Law*, in Collected Legal Papers, 12 Harv. L. Rev. 443, 460 (1899) ("We must think things not words, or at least we must constantly translate our words into the facts for which they stand, if we are to keep to the real and the true.").

And ALC is correct that Apple's invalidity case contradicts its non-infringement position. Apple seeks to differentiate its products from typical medical practice because the former "[redacted]" RRB at 8. Yet Dr. Stultz persuasively testified that the typical medical practice is also to "ensure the patient is at rest before an exam is done":

> Receiving heart rate data, we obtain vital signs when the patient comes into the room. Sensing activity level, we ensure the patient is at rest before an exam is done. While the patient is at rest, we look at -- we do this assessment, as I've already mentioned, of the rate and the qualitative assessment of heart rate variability. And then we assess these findings in the setting of the patient being at rest.

Hr'g Tr. (Stultz) at 1079:14-20.

Accordingly, the limitation is met in the Accused Products, through both the HHRN and IRN features.

b. [12(f)(ii)] "based on the presence of the discordance, indicate to the user a possibility of an arrhythmia being present"

For "based on the presence of the discordance, indicate to the user a possibility of an arrhythmia being present," ALC contends it is met by both the HHRN and IRN features. CIB at 37. For IRN, ALC argues it "is configured to surface an indication of alert to the user (after satisfying the requirements of the algorithm) that specifies that an irregular rhythm has been detected suggestive of AFib." *Id.* Apple does not dispute this, and the evidence supports it. *See* RIB at 23; CX-0611.1; CX-0048C.39, 71-72. For HHRN, ALC contends it "similarly indicates the possibility of an arrhythmia to the user, which may include an abnormal tachycardia . . . or an underlying arrhythmia like AFib manifesting as a discordant high heart rate." *Id.* at 37-38 (citing CX-0624.2; Hr'g Tr. (Jafari) at 339:5-340:9, 240:10-22, 241:18-242:10).

In its reply brief, for HHRN specifically, ALC considers it "undisputed that the HHRN feature of the Accused Products detects a tachycardia, which is a cardiac condition where the heart is beating faster than normally." CRB at 10. ALC also argues that the [redacted] makes it "more likely to determine an abnormal or unexpected tachycardia" as opposed to high heart rates due to exercise. *Id.* ALC highlights the claim's recitation of "possibility" in "indicate to the user a possibility of an arrhythmia being present" and argues it is met simply because some of the detected high heart rates "indisputably are arrhythmia." *Id.* at 11 (citing Hr'g Tr. (Jafari) at 339:5-340:9). Overall, ALC views it as irrelevant the actual message generated by Apple's HHRN does not include the words "tachycardia" or "arrhythmia." *Id.*

Apple disputes the limitation is met. For background, Apple suggests that tachycardia is simply an elevated heart rate, due to any number of causes, and therefore not necessarily indicative of arrhythmia. *See generally* RIB at 22-24; RRB at 9-10. Thus, Apple contends the "simple statement of fact" coming out of HHRN, that "the user is experiencing an elevated hear rate while

the user appears to be inactive during a ten-minute period," cannot meet the limitation. Apple contrasts this with the more detailed message coming out of the IRN and ECG apps. RIB at 23 (citing Hr'g Tr. (Jafari) at 442:19-443:6), 24 (citing Hr'g Tr. (Waydo) at 753:2-4; RX-0046C.0001). Apple notes that the heartrate threshold which HHRN measures against is set by the user, and as a consequence, "Apple deliberately chose not to provide the user a message about any possible arrythmia." *Id.* at 24. Apple summarizes:

> Thus, the HHRN's factual notification (*i.e.*, that the user's heart rate is above a threshold while the user seemed to be inactive for ten minutes), and the interpretation of this statement is dependent on the user and their own unique medical history or circumstances. In other words, not all high heart rates detected by HHRN are indicative of an underlying arrhythmia—many are not. Under these circumstances, the statement provided by HHRN does not "indicat[e] to the user, using the smartwatch, a possibility of an arrhythmia" as required by claim 12.

Id. at 24. Apple also offers a rebuttal to a doctrine of equivalence infringement theory (RIB at 25-26), but no such theory is present in ALC's briefing for this limitation (CIB at 37-38), so it need not be discussed.

In rebuttal, Apple addresses the Staff's reliance on an Apple website support page for HHRN which includes "a link to the American Heart Association (AHA) website." RRB at 10. Apple argues that AHA webpage "simply lists the multiple reasons why a user's heart rate may be high, many of which are not cardiac conditions" and otherwise are not displayed on the watch. *Id.* (citing Hr'g Tr. (Stultz) at 1070:24-1072:10; Hr'g Tr. (Jafari) at 439:18-440:23, 524:10-525:7). Thus, according to Apple, "they are not evidence that the accused system has instructions" as claimed. *Id.* (citing RPX-0004C at -118).

The Staff agrees with ALC, and views Apple's argument as inconsistent with the ordered construction for "arrhythmia." SIB at 17; SRB at 4-5. The Staff points specifically to the patent's statement that tachycardia is a type of arrhythmia and Apple's apparent concession that any heart rate above 100 bpm in a healthy adult is tachycardia. SIB at 17 (citing RPB at 45); SRB at 5 (citing

same). The Staff also finds Apple's support website, with links to AHA content, as further supporting infringement. SIB at 17 (citing Hr'g Tr. (Waydo) at 855:12-24); SRB at 5.

The limitation is met in the Accused Products. The parties' agreed construction for "arrhythmia" is very broad—"a cardiac condition in which the electrical activity of the heart is irregular or is faster or slower than normal." And the topic of the claimed notification is similarly broad—"the possibility of an arrhythmia." Put together, the limitation simply requires a notification of the possibility of faster or slower than normal heart rate or irregularity of any type.

With this in mind, the HHRN notification reads, "[y]our heart rate rose above 120 BPM while you seemed to be inactive for 10 minutes starting at 9:58 AM":

RX-0046C.1. The words "rose above" along with a quantitative heart rate value equates to a notification of a high heart rate. And when combined with the statement of inactivity (which anyone would understand to be associated with a low heart rate), this becomes a notification of an abnormal high heart rate (*i.e.*, arrhythmia) or, at least, the possibility of one.

Accordingly, the limitation is met through both IRN and HHRN in the Accused Products.

c. [12(f)(iii)] "receive electric signals of the user from the ECG sensor to confirm the presence of the arrhythmia"

For "receive electric signals of the user from the ECG sensor to confirm the presence of the arrhythmia," ALC remarks that it is undisputed the Accused Products include an ECG app such that "the only remaining dispute is whether the accused ECG App is capable of confirming the presence of arrhythmia." CIB at 38. Under the proper construction, in which the PPG and ECG need not be captured simultaneously, ALC argues it is so capable. *Id.*

ALC first explains why ECG "was and remains a superior measurement technique for arrhythmias such as AFib." *See generally id.* at 39-40 (discussing P wave detection); CRB at 15-16. ALC then argues why Apple's ECG feature is "highly accurate in the detection of AFib" (CIB at 40-41) and points to evidence showing [redacted] (*see id.* at 41; CRB at 17-18 (citing CX-0054C; CX-0370C)). ALC also refers to an Apple support webpage which teaches customers they can "take an ECG at any time" including "when they receive an irregular rhythm notification." CIB at 41 (citing CX-0073). ALC argues this messaging, in particular, "is intended to convey to its users that there is obvious clinical value in a user taking an ECG after receiving an IRN alert regarding irregular heart rhythms, and that value is because ECG is uniquely capable among the two technologies of confirming the underlying AFib." *Id.* at 42; *see* CRB at 18.

In rebuttal, ALC warrants, "to confirm the presence of the arrhythmia" means to confirm the presence of the condition, not an event. CRB at 15 (citing Hr'g Tr. (Jafari) at 343:3-11). ALC disputes there is any requirement for PPG sensor output to act as an input to an ECG sensor algorithm because "[t]he '941 patent specification says nothing about data or data output from the PPG sensor serving as 'input' into the ECG-based confirmation analysis." CRB at 14-15. ALC similarly disputes a need for a link between the two programs, and states that in the Accused

Products "the normal and ordinary operation of the ECG App inherently provides arrhythmia confirmation capability when the App is operated in the customary manner following the prior receipt of a PPG-based indication regarding the 'possibility' of an arrhythmia from either HHRN or IRN." *Id.* at 15. ALC also contends that leaving open the time between PPG and ECG data collection does not create indefiniteness problems. *See* CRB at 16-17.

Apple's opposition to this limitation is first rooted in a construction that requires simultaneous or overlapping PPG and ECG data capture. *See* RIB at 26-29 ("PPG and ECG sensors running at the same time"); RRB at 16-17 ("when ECG App is activated, the PPG sensors are deactivated"). As determined above, the limitation is not so limited.

Beyond this, Apple contends "there are no inputs from IRN to the ECG App such that there could be confirmation of the detected arrhythmia." RIB at 30 (citing Hr'g Tr. (Jafari) at 464:13-15, 462:10-14). Put another way, "there is no separate algorithm that combines the data or analysis from the IRN feature with the ECG App algorithms." *Id.* (citing Hr'g Tr. (Jafari) at 462:22-463:7, 463:11-24). Apple states it is the same situation for HHRN and ECG—they are not connected in any way. *Id.* (citing Hr'g Tr. (Jafari) at 463:25-464:4; Hr'g Tr. (Picard) at 892:19-24); *see id.* at 31-32 ("the ECG App was intentionally designed to not be used in conjunction with other medical devices, medicines, or other medical technologies, including [HHRN]. . . . The same is true of IRN, including use with ECG App."); RRB at 17, 19.

Apple then argues that ALC has, critically, made no showing of any "instructions" that accomplish the supposed confirmation—an alleged break with the claim language (RIB at 35 (citing Hr'g Tr. (Jafari) at 462:10-463:7))—and discounts the relevance of Apple's internal emails and data gathering (*id.* at 36-39 (citing, *inter alia*, CX-0054C; CX-0370C; CX-0073; RX-0183C; CX-0022C; CX-0051C)). Even if relevant, Apple alleges that they show "[t]he concept of linking

IRN app and ECG App, such as with a message or button alerting a user to take an ECG following an IRN, *was never implemented*." *Id.* at 37 (emphasis in original) (citing, *inter alia*, JX-0235C (Brittain) at 244:6-248:1; RX-0181C.11; Hr'g Tr. (Waydo) at 859:18-860:18); RRB at 17, 19. As for its support website, Apple notes, "Dr. Jafari admitted that there are no computer instructions on the Apple Watch that launch the website, or that direct the user to the website, or that provide any of the information on the website." RIB at 38 (citing Hr'g Tr. (Jafari) at 475:11-16, 476:18-477:3); RRB at 20. And as for FDA submissions, Apple contends "AliveCor simply cites to the appearance of the word 'confirm,' and hopes the Court will read no further. However, missing in these documents are any descriptions, instructions, or functions describing how Apple Watch confirms *the* arrhythmia first detected by the PPG sensor, as required by the '941 patent." RIB at 39 (emphasis in original). Rather, according to Apple, "AliveCor is forced to rely on the user—and not the system—to mentally confirm the arrhythmia." RRB at 18-19 (citing Hr'g Tr. (Jafari) at 377:2-8, 448:11-17).

The Staff finds the limitation met in the Accused Products on the ground that "confirm" does not mean simultaneous capture of PPG and ECG data. *See* SIB at 18-19 (discussing why Apple's construction is incorrect); SRB at 6-7. The Staff does not address whether there must otherwise be a link or connection between PPG and ECG analyses.

The limitation is met in the Accused Products. The present dispute is essentially the parties' second over the meaning of "confirm." Inasmuch as claim construction is implicated in this dispute, the intrinsic evidence does not support a requirement that PPG data or analytical outcome be involved in the "confirm[ation]" of an arrhythmia.

To begin, "confirm" is used infrequently in the specification. As reproduced above (and a second time below), it appears in the one context of training machine learning algorithms, where ECG data is "compared back" to sensed heart rates and activity levels:

> For example, in some embodiments, sensed electrocardiogram data may be compared back to parameter values such as, for example, sensed heart rates and activity levels that triggered the sensing of said electrocardiograms. When, for example, sensed electrocardiograms *confirm* the presence of an arrhythmia, the presence of which was indicated by, for example, a discordance between other parameter values, the machine algorithm causes the device or system described herein to learn from that data. Similarly, when, for example, sensed electrocardiograms *do not confirm* the presence of an arrhythmia, the presence of which was indicated by, for example, a discordance between other parameter values, the machine algorithm causes the device or system described herein to learn from that data as well.

941 patent at 13:63-14:10 (emphasis added). While this is a kind of link between PPG and ECG, it is clear that the comparing-back step only occurs after the arrhythmia has been confirmed or not confirmed by ECG data. In other words, the ECG "confirms" arrhythmia on its own, and the discordance algorithm is then cross-checked and trained. This is consistent with the only other usages of "confirm," where after a discordance is found, the conditions of "atrial fibrillation" or "supraventricular tachycardia" "should be confirmed with the ECG" without mention of earlier PPG events. 941 patent at 15:27-59, Fig. 7. Perhaps tellingly, Apple's briefing is devoid of examples in which "the output of the PPG sensor [is used as] an input to the ECG confirmation analysis"—either from the patent specification or real world. *See* RIB at 27-39; RRB at 10-14; Order No. 12 at 26 ("the disclosed embodiments associated with Figure 7 (a decision tree describing various combinations of measurements and their associated diagnoses) say nothing about such a comparison.").

Thus, what is required for this element, as relevant here, is simply a smartwatch with a "non-transitory computer readable storage medium" loaded with instructions "executable by the processor to cause the processor" to receive ECG signals, analyze those signals, and conclude (*i.e.*,

confirm) that "the arrhythmia" is present from those signals. This is the same process, as Respondents put it, as "what medical practitioners have been doing for decades." RIB at 32 (citing Hr'g Tr. (Stultz) at 1090:8-25); *see* Hr'g Tr. (Stultz) at 1079:3-23; Hr'g Tr. (Albert) at 48:2-49:5, 52:20-53:21, 212:7-21; Hr'g Tr. (Efimov) at 1307:15-1308:3. The claim does not require the processor to actually confirm the presence of the arrhythmia every time an ECG is measured, so long as the processor is programmed to so confirm the presence of the arrhythmia.

Apple's concern over the amount of time which may elapse between the PPG and ECG data collection (RIB at 33-35; RRB at 15-16) is not persuasive, and also beside the point. Infringement may be momentary or occasional (*Omega Patents, LLC v. CalAmp Corp.*, 920 F.3d 1337, 1344 (Fed. Cir. 2019) (upholding jury verdict of infringement when evidence showed occasional direct infringement "at least under some circumstances")) and it is far more likely than not that at least one user of each Accused Product has, at least one time, taken an ECG just moments after receiving either an HHRN or IRN notification. Dr. Waydo confirmed as much. Hr'g Tr. (Waydo) at 851:23-852:2 ("Q. [redacted]."). The evidence further shows the ECG program classifies the result (*i.e.*, "confirm the arrhythmia") and returns that classification to the user. CX-0050C.5 ("The ECG Apple Watch App analyzes ECG signals and determines the presence of atrial fibrillation (AFib) or sinus rhythm on a classifiable waveform in adults aged 22 and over."); CX-0022.5 (FDA 510(k) clearance). And again, the claim requires that the smartwatch be programmed to receive ECG signals "to confirm the presence of the arrhythmia," not that it actually do so in every instance.

Accordingly, the limitation is met in the Accused Products.

2. Other claims

Apple does not contest dependent claims 13 and 19-23 in the Accused Products apart from their dependency on independent claim 12. RIB at 39; RRB at 20. Neither does the Staff. SIB at 20-22. These claims are also met by the Accused Products based on the evidence and testimony cited by ALC. CIB at 42-43. In particular, Dr. Jafari testified that all elements of each claim are met, except for intervening claim 18. *See* Hr'g Tr. (Jafari) at 328:4-19. And for claim 18, Dr. Jafari testified that its dependent claims are met, so it, too, is necessarily met. *See id.*

E. Domestic Industry – Technical Prong

ALC contends, "KBS, [redacted] each practice claims 12, 16, 20, 21, 22, and 23 of the '941 patent literally and at least under the doctrine of equivalents." CIB at 43. Of these, claim 12 is independent and the rest depend therefrom. For the reasons discussed below, ALC has shown practice of claims 12, 16, 20, 21, 22, and 23 by the KBS DI Product. ALC has also shown practice of these claims is "in the process of being established" via the [redacted] products.

1. Claim 12

Claim 12 of the 941 patent is presented above in connection with infringement. Apple's initial post-hearing brief discusses limitations 12(f)(ii) and 12(f)(iii) for the KBS and [redacted] DI Products, and does not expressly dispute any other limitation for those products, although it does dispute whether the [redacted] is properly an "article" for DI purposes. RIB at 42-48.

For the [redacted], Apple's position is more expansive:

> The [redacted] does not practice the '941 patent because: (1) it is not a smartwatch (as AliveCor admits); (2) does not have a first sensor configured to sense an activity level of a user; (3) does not have a functioning PPG sensor; (4) cannot determine a discordance; (5) does not have instructions to indicate to the user a possibility of an arrhythmia based on a discordance calculation; and (6) does not receive electric signals of the user from an ECG to confirm the presence of the arrhythmia. Thus, the [redacted] does not practice all the limitations required of claim 12, either literally or under the doctrine of equivalents.

RIB at 53. This position perhaps stems from Apple's overall contention that [redacted]

A threshold issue, then, is whether the [redacted] DI Products qualify as "articles" for DI purposes. The Commission is adamant that domestic industry is to be assessed at the filing of the complaint absent "very specific circumstances, *i.e.*, 'when a significant and unusual development has occurred after the complaint has been filed.'" *Certain Thermoplastic-Encapsulated Electric Motors, Components Thereof, and Products and Vehicles Containing Same II*, Inv. No. 337-TA-1073, Comm'n Op. at 7 (Aug. 12, 2019) ("*Thermoplastic Motors*") (citing *Certain Collapsible Sockets for Mobile Electronic Devices and Components Thereof*, Inv. No. 337-TA-1056, Comm'n Op. at 15 n.10 (July 9, 2018)). In its reply brief, ALC appears to suggest that such an unusual development has occurred to justify a post-complaint analysis for a domestic industry that "exists." CRB at 82 n.20. But this one-off footnote, on its own, is not sufficient to deviate from the well-accepted standard.

Moreover, the law is clear that an actual article protected by the patent must exist to show that a domestic industry "exists":

> Both Federal Circuit law and Commission precedent require the existence of actual "articles protected by the patent" in order to find that a domestic industry exists. In *Microsoft Corp. v. International Trade Commission*, the Federal Circuit held:
>
> > Section 337, though not requiring that an article protected by the patent be produced in the United States, unmistakably requires that the domestic company's substantial

> investments relate to actual "articles protected by the patent." 19 U.S.C. § 1337(a)(2), (3). A company seeking section 337 protection must therefore provide evidence that its substantial domestic investment—*e.g.*, in research and development—relates to *an actual article that practices the patent*, regardless of whether or not that article is manufactured domestically or abroad. *InterDigital Commc'ns v. Int'l Trade Comm'n*, 707 F.3d 1295, 1299, 1304 (Fed. Cir. 2013).

731 F.3d 1354, 1361-62 (Fed. Cir. 2013) (emphasis added). In view of both *Microsoft* and *InterDigital* (cited in the block quotation above), the Commission has held that "a complainant alleging the existence of a domestic industry under 19 U.S.C. § 1337(a)(3)(C) must show the existence of articles." *Certain Computers and Computer Peripheral Devices, and Components Thereof, and Products Containing Same* ("*Certain Computers and Computer Peripheral Devices*"), Inv. No. 337-TA-841, Comm'n Op. at 40 (Jan. 9, 2014). Thus, to demonstrate that a domestic industry exists, the "existence of articles" requires a physical embodiment of the patented invention. We have clarified that this articles requirement is not "limited to commercial goods." *Certain Non-Volatile Memory Devices and Products Containing the Same*, Inv. No. 337-TA-1046, Comm'n Op. [at] 41 (Oct. 26, 2018) (public version).

Thermoplastic Motors, Inv. No. 337-TA-1073, Comm'n Op. at 9; *see id.* at 10 ("Without the existence of an article protected by the patent, *i.e.*, a physical embodiment of the patented invention, the Commission finds that IV cannot establish that a domestic industry 'exists' relating to the articles protected by the patent.").

It is essentially undisputed that the [redacted] at the time of the complaint. *See* Hr'g Tr. (Jafari) at 490:13-16, 491:21-492:4; Hr'g Tr. (Akemann) at 702:25-703:4; Hr'g Tr. (Somayajula) at 252:23-253:5 [redacted] *see generally* CIB at 18-20 (discussing what [redacted] "will" do), 55 (failing to dispute that [redacted] CRB at 19 (using present tense with [redacted] is developed to a point where it has been tested to show it practices the Asserted Patents"), 28 (failing to refute Apple's factual assertion that "[redacted] 82 n. 19 (failing to rebut that [redacted] at complaint filing, but arguing that is irrelevant

given its current status); SIB at 22-26; SRB at 8 (viewing dispute as whether there were "fully functional prototypes" at time of the complaint), 11 (same). [redacted] Accordingly, [redacted] cannot be deemed to practice claim 12 of the 941 patent (or any claim of any Asserted Patent) so as to support a domestic industry that "exists" under the statute. Whether practice of this and other claims by the [redacted] is "in the process of being established," however, is a separate matter and is addressed below.

Whether the [redacted] DI Product existed at the filing of the complaint to support a domestic industry that "exists" is more complicated. As discussed above, [redacted] have been introduced in this investigation, [redacted]. Testimony from ALC witness Mr. Somayajula indicates that [redacted] before the April 20, 2021 filing of the complaint. *See* Hr'g Tr. (Somayajula) at 243:11-245:25; RX-0488C (Somayajula Decl.) at ¶ 9. That same witness and ALC's expert, Dr. Jafari, both testified that [redacted]

to the filing of the complaint. Hr'g Tr. (Jafari) at 482:3-14, 486:21-25 [redacted] Hr'g Tr. (Somayajula) at 244:15-18.

Apple contends, however, that ALC's domestic industry theory relies on [redacted] RIB at 128 ("The [redacted] that AliveCor relies upon for domestic industry is the [redacted] This would be important for determining whether or not the [redacted] can support a domestic industry that "exists"—[redacted] But ALC's initial brief makes no mention of the [redacted] *See generally* CIB. And what discussion there is only further clouds the issue. ALC refers to core features the [redacted] "includes" but also "will have" or "will be able to" do. *Id.* at 18. Obviously, features that a product "will have" is not terribly supportive of a claim that a product already practices the patent. This is contrasted with its discussion of technical prong, specifically, where ALC describes a [redacted] that "practices" the 941 patent claims. *See id.* at 50-54. This implies the product has all necessary features.

ALC's reply brief seems to acknowledge different [redacted] CRB at 25. The discussion then shifts to an evaluation of an industry in the process of being established (*i.e.* not one that "exists"), and refutes the idea that any DI article must be commercialized or FDA-approved. *See id.* at 25-27. What the section does not do is make clear that [redacted] at the time of the complaint, is alleged to practice all limitations of claim 12 of the 941 patent. *See id.* at 25-27. Even ALC's economic prong arguments fail to present this basic contention, and instead emphasize ongoing and future development work on the product. *See* CRB at 82 (arguing an economic prong "at the time of the complaint" standard is satisfied "regardless [redacted] 82 n.19 (arguing that because the articles were produced during the investigation, "Apple's various arguments about when

prototypes first existed and which prototypes are currently be[ing] worked on are irrelevant"), 83 (arguing investments in [redacted] which is what existed at the time the complaint was filed). In fact, in an explicit discussion of economic prong "in the process of being established," ALC emphasizes that it is not necessary that completed [redacted] "exist":

> If AliveCor does not have an existing domestic industry, an industry related to the [redacted] is in the process of being established. AliveCor Post-HB at 164-69. Here, Apple's arguments about [redacted] bear even less weight. The Commission has never squarely held that an article needs exist to establish that an industry is in the process of being established. *See Certain Thermoplastic-Encapsulated Electric Motors*, Inv. No. 337-TA-1073, Comm'n Op., at 11 & n.14 (Aug. 12, 2019). And the Commission has found the domestic industry requirement satisfied based on an article that the ALJ characterized as "at most a precursor of what may someday be a prototype or an actual article." *Non-Volatile Memory Devices*, Comm'n Op., 2018 WL 6012622, at *20, *25-27.

Id. at 90-91.

Other record evidence additionally shows it unlikely ALC alleges [redacted] that practices the claims of the 941 patent. As one example, ALC's technology officer, Mr. Somayajula, mentioned only [redacted] at the hearing. Hr'g Tr. (Somayajula) at 213:17-214:9, 216:14-217:2. Even then, he testified that [redacted] *Id.* at 217:13-15, 219:6-11, 222:4-8; *see* Hr'g Tr. (Albert) at 158:21-24 [redacted] *but see* RX-0488C (Somayajula Decl.) at ¶ 9 ("AliveCor's ECG technology and [redacted]

In another example, Mr. Somayajula testified that [redacted] Hr'g Tr. (Somayajula) at 244:9-14. He mentioned the [redacted]

[redacted] *Id.* at 245:7-11. As part of her inspection of the [redacted], Apple's expert, Dr. Picard, also testified the [redacted]

[redacted]

Hr'g Tr. (Picard) at 911:2-10. Nowhere in ALC's briefing do they contest Dr. Picard's and Mr. Somayajula's testimony that [redacted] by the time of the complaint.

Accordingly, to the extent it is argued, ALC has not shown the [redacted] product(s) available at the time of the complaint practiced any claim of the 941 patent. Whether practice of these claims by the [redacted] is "in the process of being established," however, is a separate matter and is addressed below.

Turning back to the limitations of claim 12, those undisputed limitations are found to be present in the KBS DI Product in light of the evidence and testimony cited by ALC. CIB at 45-46. In particular, Dr. Jafari testified that each element of claim 12 is practiced by the KBS. *See* Hr'g Tr. (Jafari) at 393:11-395:25.

a. [12(f)(ii)] "based on the presence of the discordance, indicate to the user a possibility of an arrhythmia being present"

ALC contends the KBS DI Product "contains instructions executable by the processor to cause the processor to—based on the presence of the discordance—indicate to the user a possibility of an arrhythmia being present." CIB at 46 (citing Hr'g Tr. (Jafari) at 396:12-397:23; JX-0096C at 748, 751, Fig. 2). This is met by the SmartRhythm algorithm, according to ALC:

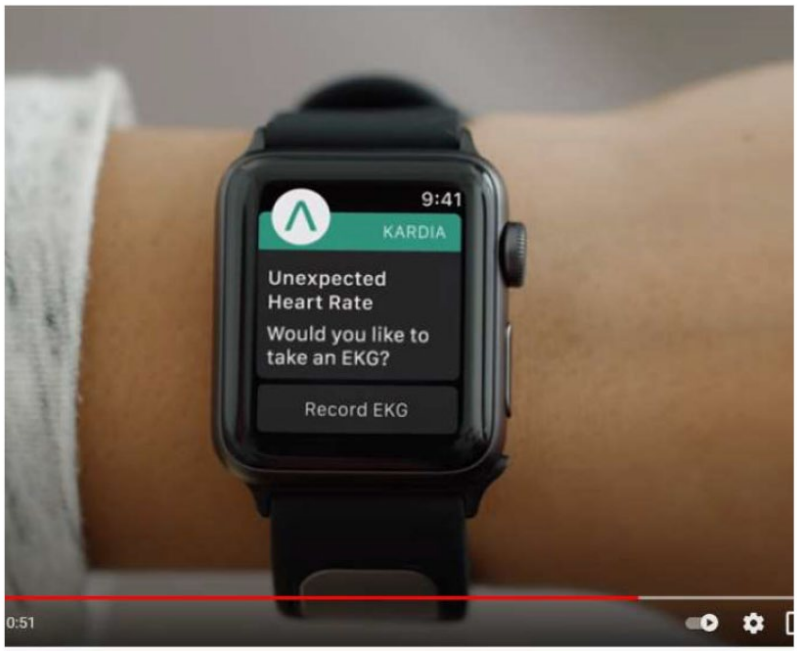
[redacted]

Id. at 47. ALC continues: [redacted], the system notifies the user by displaying the message: 'Unexpected heart Rate. Would you like to take an ECG?" *Id.* (citing CX-0132C; Hr'g Tr. (Jafari) at 396:14-398:9); CRB at 21. ALC alleges the limitation is also met under the doctrine of equivalents, using the function-way-result test. *See id.* (citing Hr'g Tr. (Jafari) at 393:11-395:11).

Apple contests the limitation. It explains the product's operation as:

[redacted]: "Unexpected Heart Rate[.] Would you like to take an EKG?" RPX-16C (How to record a clean EKG with KardiaBand.mp4). [redacted]

RIB at 41. Apple provides the following image showing this message:



Id. (citing RPX-0016C). Apple contends, "[t]his alert did not indicate to the user the possibility of an arrhythmia. Rather, it merely alerted the user that the system had identified an 'unexpected heart rate' that may be caused by many different factors, including normal factors that are not 'cardiac conditions.'" *Id.* at 42 (citing Hr'g Tr. (Stultz) at 1071:7-20; RX-0128C.12); RRB at 21.

The Staff finds the limitation met. The Staff reasons, "[i]f the system were able to determine with certainty that the detected discordance was or was not an arrhythmia, then there [would] be no reason to confirm that determination with an ECG . . . the message displayed by the KBS when a discordance is detected *is* a notification of the possibility of an arrhythmia." SIB at 24 (emphasis in original); SRB at 9.

The limitation is met in the KBS product. The parties' agreed construction for "arrhythmia" is very broad—"a cardiac condition in which the electrical activity of the heart is irregular or is faster or slower than normal." And the topic of the claimed notification is similarly broad—"the possibility of an arrhythmia." Put together, the limitation simply requires a notification of the possibility of a faster, slower, or in any way irregular heart rate. The word

"unexpected" in "Unexpected Heart Rate[.] Would you like to take an EKG?" (RPX-0016C) fairly communicates a heart rate that is unexpectedly faster or slower than normal.

Accordingly, the KBS DI Product practices this limitation.

b. [12(f)(iii)] "receive electric signals of the user from the ECG sensor to confirm the presence of the arrhythmia"

ALC contends the KBS "has instructions stored in memory that, when executed by the processing device, cause the processing device to confirm the presence of the arrhythmia based on the ECG data." CIB at 48. More specifically, it explains, "'[a]fter an ECG recording is complete, the ECG is analyzed to determine [redacted] ALC concludes, "[w]hen the ECG is classified as Normal or shows the presence of Atrial Fibrillation, the KardiaBand System has confirmed the presence of the arrhythmia." *Id.* (citing CPX-0021; CX-0110). ALC adds the limitation is practiced under the doctrine of equivalents as well, with the function-way-result test. *See id.* at 48-49.

Apple contests the limitation, again on claim construction grounds, that is, the limitation requires overlapping ECG and PPG data capture, and some means for the discordance determination to be "brought together" with ECG data. *See* RIB at 43. The Staff contends that the limitation is met. *See* SIB at 24-25.

The limitation is met. As discussed above in connection with claim construction, there is no requirement for overlapping PPG and ECG data capture. Nor is there a requirement that the discordance determination be "brought together" with the ECG data for "confirm[ation]." The record evidence shows it is more likely than not that at least one user of the KBS has, at least one time, taken an ECG just moments after receiving either a SmartRhythm notification. *See, e.g.*, CPX-0021C at 00:34-45; Hr'g Tr. (Albert) at 64:11-25 (detailing clinical studies); JX-0009C.17

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[redacted], 27. The evidence further shows the ECG program classifies the result (*i.e.*, "confirm the arrhythmia") and returns that classification to the user. CPX-0021C at 00:29 (displaying "Possible AF"); JX-0011C at ("After an ECG recording is complete, the ECG is analyzed to determine if it is at least 30 seconds long, if it is Normal, Unclassified, if Atrial Fibrillation is present, or if it is too noisy to interpret. . . Presence of Atrial Fibrillation (AF) in you ECG results may present only potential findings. If you are experiencing any symptoms or have concerns, contact your physician."). Thus, the KBS DI Product has a processor programmed to "receive electrical signals . . . to confirm the presence of the arrhythmia."

Accordingly, the KBS DI Product practices this limitation, and therefore practices all the limitations of claim 12.

2. Other Claims

Apple does not contest practice of claims 16, 20, 21, 22, and 23 by the DI Products apart from their dependency on independent claim 12. *See* RIB at 40-53. Neither does the Staff. SIB at 25. As ALC has shown practice of independent claim 12, discussed above, the dependent claims are found to be met in the KBS based on the undisputed evidence and testimony provided by ALC, particularly the testimony of Dr. Jafari. CIB at 50; *see* Hr'g Tr. (Jafari) at 393:11-401:12. As noted, the [redacted] and [redacted] have not been shown to practice any claim at the time of the filing of the complaint.

3. Whether technical prong is "in the process of being established"

As to whether practice of the 941 patent by the [redacted] and [redacted] products is "in the process of being established," the record supports finding in the affirmative.

Technical prong domestic industry is a nearly identical analysis to infringement. *Alloc*, 342 F.3d at 1375. In the more common domestic industry "exists" cases, the analysis involves a

comparison between claim language and an existing product. It follows that in "in the process of being established" cases, the analysis should remain as a comparison between claim language and a *future* product. The Commission has explicitly not foreclosed this approach to establishing technical prong domestic industry (*Thermoplastic Motors*, Inv. No. 337-TA-1073, Comm'n Op. at 11) even though it acknowledges possible problems with "domestic industry analysis as a moving target" (*id.* at 8-9 n.11). Nevertheless, the Commission has confirmed the complaint filing date standard applies to "in the process of being established" cases as well as "exists" cases, ruling out post-complaint evidence even when the complainant's future likelihood of success is challenged by a respondent. *See Certain Pouch-Type Battery Cells, Battery Modules, and Battery Packs, Components Thereof, and Products Containing the Same*, Inv. No. 337-TA-1179, Notice at 2 (Jan. 14, 2021); *see also Thermoplastic Motors*, Inv. No. 337-TA-1073, Comm'n Op. at 13 ("The testimony of IV's domestic industry expert, Ms. Kobe, shows that all of those activities occurred after IV filed the complaint in September 2017. . . . As discussed above, however, the Commission finds that the appropriate date here for determining whether a domestic industry was in the process of being established is September 5, 2017").

ALC makes only cursory references to "significant and unusual developments" that might shift the analysis away from the complaint filing date. *See* CRB at 82 n.20. Thus, later constructed [redacted] and [redacted] prototypes, or any other post-complaint developments, are not available for consideration as to whether the practice of the 941 patent is "in the process of being established."

Nevertheless, it is still more likely than not that, at the time of the complaint, ALC was taking the necessary and tangible steps to practice claims 12, 16, 20, 21, 22, and 23 of the 941 patent via the [redacted] and [redacted] products. Dr. Jafari testified that the [redacted] and [redacted] as planned will practice each element of claims 12, 16, 20, 21, 22, and 23, and his opinion is supported by

descriptions of the planned products. *See* Hr'g Tr. (Jafari) at 393:11-399:13; JX-0025C; JX-0095C; JX-0096C; CX-0251C; CX-0252C. For the [redacted] Apple only expressly disputes elements 12(f)(ii) and 12(f)(iii), the "indicate" and "confirm" elements, but it is undisputed that the [redacted] will display a notification when a high heart rate is detected and that an ECG is then available using the [redacted], so the [redacted] will be programmed to confirm the arrythmia the same way the KBS was. *See* RIB at 47-48; *see also* JX-0025C (showing ECG sensors on the [redacted]). For the [redacted] Apple disputes virtually every element of claim 12. *See* RIB at 53. But the [redacted] will be implemented on a smartwatch (*see* CX-0252C.5), it will monitor activity level with an accelerometer (*see* JX-0096C.1), it will have PPG and ECG sensors (*see* CX-0252C.5), it will identify a discordance and notify the user to take an ECG (*see id*. at *7), and will "alert" the user when a discordant heart rate is determined (JX-0096C.5). So the technical documentation shows that the [redacted] and [redacted] will actually practice the asserted claims, if produced.

Moreover, there is a significant likelihood that the [redacted] and [redacted] will actually work. As determined above, ALC's previous product, KBS, has been shown to practice all of these claims. ALC's expert, Dr. Jafari, supplies persuasive testimony on the transferability of the SmartRhythm (PPG analysis) and KardiaApp (ECG collection and analysis) features—primary software features behind the KBS' practice of the claims—to other portable heart monitors in development. *See* Hr'g Tr. (Jafari) at 389:1-7, 389:21-25, 390:6-15, 392:3-393:10. ALC's technical witnesses testified to the same effect. Hr'g Tr. (Somayajula) at 198:13-19, 202:11-21, 203:19-205:8, 210:19-212:2; 217:13-15, 218:22-219:20, 221:2-222:8; Hr'g Tr. (Raghavan) at 565:4-22, 596:7-599:22 (discussing predicate devices). And the prior art in this investigation, discussed below, shows that wrist-worn computerized devices containing both PPG and ECG sensors were achievable well

before the invention of the 941 patent. *See* RX-0419. So the hardware and software features of 12, 16, 20, 21, 22, and 23 are plainly achievable.

Apple offers two points of opposition here. The first is that the [redacted] and [redacted] are unlikely to become viable commercialized products. [redacted] But practice of an asserted patent claim for technical prong purposes does not depend on commercialization status. Prototypes are acceptable and do not depend, for instance, on FDA approval. *Non-Volatile Memory*, Inv. No. 337-TA-1046, Comm'n Op. at 41.

The second, particular to [redacted], is that "AliveCor's contention that SmartRhythm can simply be repurposed from KBS to [redacted] ignores the significant technical challenges in applying old source code to new hardware." RIB at 52; RRB at 27. Apple emphasizes, "AliveCor must develop and test its hardware and software, run clinical studies, and re-develop its hardware and software to have SmartRhythm functional on AliveCor's new devices." RIB at 52 (citing Hr'g Tr. (Picard) at 918:21-924:13; JX-0096C at 4; Hr'g Tr. (Somayajula) at 255:2-16). Apple then refers to the intensive efforts involved with clinical studies and FDA submissions "to demonstrate

sensitivity and specificity." *Id.* at 52-53 (citing Hr'g Tr. (Picard) at 922:8-923:24). Apple concludes, "it may take years of further development." *Id.* at 53.

Apple's points are well-taken, as discussed below in connection with economic prong, but they do little to show that ALC is not taking the necessary and practical steps to practice a claim, or not likely to succeed at it. For instance, in contrast to the [redacted] product, there is no assertion that ALC has abandoned the [redacted]. [redacted] And although the journey towards an FDA-cleared consumer medical device is long, the record indisputably shows it is familiar to ALC. *See generally* Hr'g Tr. (Albert) at 59:21-83:7; Hr'g Tr. (Raghavan) at 558:13-602:9. Moreover, to meet the technical prong, the sensors and algorithms need to work, but they do not need to work well.

Relatedly, and in rebuttal, Apple seems to challenge not just the feasibility but the intent of ALC to "repurpose" SmartRhythm for [redacted] and [redacted]. RRB at 27 (arguing the only evidence comprises "uncorroborated and conclusory testimony"). But the testimony from Dr. Albert, Mr. Somayajula, and Mr. Raghavan on this point was corroborated by internal planning documents. JX-0096C; JX-0090C; CX-0252C.5 [redacted] will "leverage AliveCor algorithms"), 16 [redacted] CX-0250C.6, 11; JX-0008C [redacted] JX-0095C (press release mentioning "AliveCor's ECG recording and AI technology" for [redacted]

Accordingly, ALC has shown it is more likely than not that practice of claims 12, 16, 20, 21, 22, and 23 by the [redacted] and [redacted] is "in the process of being established."

F. Validity and Other Affirmative Defenses

Apple identifies the following invalidity and unenforceability theories for the 941 patent:

Claims	Theory
12, 13, 16, 19, 20, 21, 22, 23	Invalid for lack of patent-eligible subject matter under 35 U.S.C. § 101
12, 13, 16, 19, 20, 21, 22, 23	Rendered obvious under 35 U.S.C. § 103 by AMON (RX-0419), alone or in combination with Kotzin (RX-0401) and Almen (RX-0400)
All claims	Unenforceable against Apple under experimental use exception

See generally RIB at 54-86.

As for prior art, Apple argues that an article entitled *AMON: A Wearable Multiparameter Medical Monitoring and Alert System* (RX-0419) ("AMON") published in December 2004, and is therefore prior art to the 941 patent under § 102(a). RIB at 60-61. Neither ALC nor the Staff disputes this prior art status for AMON. *See generally* CIB at 69-87; CRB at 35-49; SIB at 29.

Apple argues U.S. Patent No. 7,460,899 (RX-0400) ("Almen") is a published patent with a filing date of February 25, 2005 and an issue date of December 2, 2008, and is therefore prior art to the 941 patent under § 102(a). RIB at 61. Neither ALC nor the Staff disputes this prior art status for Almen. *See generally* CIB at 69-87; CRB at 35-49; SIB at 29.

Apple also argues international patent application WO 2004/012033 ("Kotzin") has a filing date of July 8, 2003 and a publication date of February 5, 2004, and is therefore prior art to the 941 patent under § 102(a). RIB at 61. Neither ALC nor the Staff disputes this prior art status for Kotzin. *See generally* CIB at 69-87; CRB at 35-49; SIB at 29.

Accordingly, each of AMON, Almen, and Kotzin are determined to qualify as prior art to the 941 patent at least under 35 U.S.C. § 102(a).

1. Ineligible Subject Matter

Apple contends claims 12, 13, 16, and 19-23 of the 941 patent are invalid under 35 U.S.C. § 101 for failure to claim patentable subject matter. To this end, Apple applies the two-step analysis from *Alice*.

Under *Alice* step one, regarding that which the claim is directed to (*Alice*, 573 U.S. at 217), Apple argues "[c]laim 12 is directed to nothing more than the abstract idea of recording patient data, analyzing the data to identify a possible cardiac irregularity, and then confirming that irregularity." RIB at 54 (citing *Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1353 (Fed. Cir. 2016)). Apple refers to the testimony of its expert, Dr. Stultz, to explain that the claim represents the routine steps medical doctors have manually preformed for some time:

> Dr. Stultz—who is the *only medical doctor* in this case, and is the *only expert who has ever diagnosed patients with arrhythmias*—testified that in a routine cardiac exam, a patient comes into the office for assessment, has their pulse measured (*e.g.* by PPG, manual palpation, auscultatory exam), and then an assessment of regular rate and rhythm is done mentally by the physician, *i.e.* considering HRV while the patient is confirmed to be at rest. Tr. (Stultz) at 1076:12-1077:15; *id.* at 1079:11-23; *id.* at 1084:14-17; *id.* at 1090:17-1091:14; RDX-3.21; RDX-3.23; RDX-3.33-3.34. If an irregular arrhythmia is detected, an ECG is ordered and analyzed, usually within minutes, to arrive at a diagnosis. Tr. (Stultz) at 1076:12-1077:15. Dr. Stultz testified in detail that this is the same process he used when he "began [his] training as a physician/scientist over 30 years ago." *Id.* at 1077:16-20.

Id. at 54-55 (emphasis in original); *see* RRB at 29. Apple views ALC's expert, Dr. Efimov, and founder, Dr. Albert, as conceding this point. RIB at 55 (citing Hr'g Tr. (Efimov) at 1295:4-1296:21; Hr'g Tr. (Albert) at 17:1-18:5, 38:4-42:3); RRB at 29-30, 33. Apple also disputes that claim 12 represents any improvement to the monitoring devices themselves (RIB at 55-56) and argues that it is instead similar to those claims found ineligible in *CardioNet, LLC v. InfoBionic, Inc.*, 816 F. App'x 471, 472 (Fed. Cir. 2020) ("*CardioNet II*") (*id.* at 56-57). In short, Apple

contends, "[c]laim 12 is thus directed at nothing more than automating long-standing clinical practices, which the Federal Circuit has repeatedly found invalid." *Id.* at 56-57 (citations omitted).

If found to be directed to an ineligible idea, Apple argues the remaining claim elements do not significantly add to the invention apart from conventional, routine, or well-understood technology. RIB at 57 (citing *Alice*, 573 U.S. at 221-26; *SAP Am., Inc. v. InvestPic, LLC*, 898 F.3d 1161, 1163 (Fed. Cir. 2018)). It contends the combination of PPG and motion sensors, and the subsequent use of an ECG, were well-known and not inventive as of 2013. *Id.* (citing Hr'g Tr. (Stultz) at 1091:6-1092:8; Hr'g Tr. (Efimov) at 1295:21-1296:18). Apple also reasons that because ALC's expert "admitted that only a doctor can diagnose atrial fibrillation—[] the '941 patent's device is not an advancement in ambulatory identification and diagnosis of arrhythmias at all." *Id.* at 57-58 (citing Hr'g Tr. (Efimov) at 1294:5-12, 1295:4-6), 58 (citing Hr'g Tr. (Efimov) at 1298:11-19, 1295:21-23, 1296:16-17), 59. Apple warrants, "'it is not enough' to point to conventional activities and mental processes 'and say 'do it on a computer.'" *Id.* (citing *Apple, Inc. v. Ameranth, Inc.*, 842 F.3d 1229, 1243 (Fed. Cir. 2016); *see id.* ("[T]here is nothing specific about the claimed smartwatch that makes it anything but an off-the shelf computer."); RRB at 34. As for dependent claims 13, 16, and 19-23, Apple argues they are directed to the same abstract idea as claim 12, represent common medical practice, recite only generic components, and are generally not inventive. *See* RIB at 59-60; RRB at 33, 36.

In response to ALC, Apple contends claim 12 is nothing like those at issue in *CardioNet, LLC v. InfoBionic, Inc.*, 955 F.3d 1358 (Fed. Cir. 2020) ("*CardioNet I*") or *Exergen Corp. v. Kaz USA, Inc.*, 725 Fed. App'x 959, 964 (Fed. Cir. 2018). RRB at 29-30, 32, 34. Apple rejects ALC's position that claim 12 is directed to a "'particular combination of sensors and algorithmic instructions'" because, in part, the "'algorithms' merely apply generic functional language that

doctors have long used as part of [the] diagnostic process." *Id.* at 30-31 (citing CIB at 59), 35-36 ("neither the Asserted Claims nor the specification say anything substantive about signal processing, development of the sensors, or perfection of algorithms that make the claims patent eligible").

Similarly rejected is ALC and the Staff's position that claim 12 "'more accurately detected arrhythmias in ambulatory patients than conventional devices could.'" *Id.* at 31. Apple explains "[t]here is nothing in claim 12 (or the '941 patent's specification) that limits the device to use in only ambulatory patients" and "patients could already record ECGs in an outpatient setting (via ECG patches and Holter monitors), as well as continuously monitor heart rate and activity level via the Apple Watch." *Id.* (citing 941 patent at 4:59-62); *see id.* at 31-32 (discussing Holter monitor deficiencies).

ALC contends the claims are directed to patentable subject matter, and even if not, they recite inventive concepts sufficient to render them patentable under 35 U.S.C. § 101. As to *Alice* step one, ALC argues claim 12 "is directed to a particular combination of sensors and algorithmic instructions" and its limitations show it can more accurately detect paroxysmal or asymptomatic arrhythmias than traditional medical practice. CIB at 59-60 (citing Hr'g Tr. (Efimov) at 1221:3-1236:1; Hr'g Tr. (Stultz) at 1096:22-1097:18). ALC compares claim 12 to the claim at issue in *CardioNet I*, mentioned above, where the improvements "over existing diagnostic methods" showed direction towards a non-abstract idea. *Id.* at 60-61; CRB at 30. ALC adds:

> Indeed, claim 12 is even more clearly directed to an improvement in cardiac monitoring technology than the claims asserted in *CardioNet I* because it adds further specific components and algorithmic instructions to more accurately detect arrhythmias. Whereas the device in *CardioNet I* merely generated "an event" when it detected AFib or atrial flutter, it did not perform any additional steps to "confirm" the presence of those conditions, as does the device of claim 12. *See* JX-003.19, cl. 12. And rather than claiming a "beat detector" and a "ventricular beat detector,"

> without specifying which type of sensor should be used, claim 12 requires a processor, a PPG sensor, an ECG sensor, and a motion sensor. *Id.*

CIB at 62.

ALC also disputes that the claim is simply "automating known techniques that doctors routinely used to diagnose arrhythmias such as atrial fibrillation." CIB at 63. The difference, it says, is that traditionally a doctor would have used a 12-lead ECG and even then "could not detect the asymptomatic episodes." *Id.* (citing Hr'g Tr. (Efimov) at 1235:6-1236:1, 1229:24-1230:20). In fact, ALC takes it one step further and reasons, "[b]ecause the claimed device is intended to detect arrhythmias when a doctor is *not* present, Dr. Stultz's testimony about steps doctors performed in clinical settings is irrelevant." *Id.* (emphasis in original); CRB at 33.

As for the dependent claims, ALC contends they "disclose additional limitations that place the claimed inventions even further outside the realm of abstract ideas." CIB at 63. In particular, ALC highlights HRV assessments (claims 13 and 19) which it asserts were previously done qualitatively and thus there is no evidence that "doctors routinely used wearable devices or algorithms running on them to determine HRV from PPG data." *Id.* at 64 (citing Hr'g Tr. (Stultz) at 1077:25-1078:11, 1085:11-22; *McRO Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299, 1314 (Fed. Cir. 2016)).

As for *Alice* step two, ALC points to the "discordance" determination as "innovative" because "it can filter out abnormal PPG readings that are caused by normal activities such as exercise." CIB at 65 (citing Hr'g Tr. (Efimov) at 1240:6-1241:12). This feature, according to ALC, makes the claim similar to that in *Exergen*. *See id.* at 65-66. ALC repeats, "[t]he claimed device is inventive because it can detect arrhythmias when a doctor is *not* present." *Id.* at 66 (emphasis in original). Even then, ALC suggests doctors "did not routinely use PPG sensors" for arrhythmia diagnosis such that "even if PPG sensors were known in the art, they were not used for

the specific purpose of detecting arrhythmias." *Id.* (citing Hr'g Tr. (Efimov) at 1236:2-16; *Exergen*, 725 F. App'x at 964-66); CRB at 31-33. ALC draws a sharp distinction between typical clinical practice and claim 12:

> Moreover, Dr. Stultz testified that doctors would qualitatively assess a patient's heart rate while the patient was at rest, which is a different concept than comparing the user's activity level from a motion sensor with a heart rate parameter from a PPG sensor to determine if there is a discordance between the two. Tr. (Stultz) at 1077:25-1078:11; 1085:11-22. Dr. Stultz opined that doctors "assess these findings in the setting of the patient being at rest," but he never testified that doctors compared heart rate parameters with an activity level achieved during normal exercise. Tr. (Stultz) at 1079:11-23.

CRB at 33.

Turning to hardware, ALC contends "the claimed device is not merely a generic computer. It is a unique combination of a processor, a PPG sensor, an ECG sensor, and a motion sensor that is capable of detecting and confirming the presence of arrhythmias . . ." CIB at 66-67 (citing, *inter alia*, Hr'g Tr. (Efimov) at 1238:4-14); CRB at 34. And for the dependent claims ALC argues they "provide further inventive concepts" and refers to the benefits these claims provide. *See id.* at 68-69; CRB at 35.

In response to Apple, ALC suggests the 941 patent is nothing like the invalid claims in *CardioNet II*. CRB at 31. Specifically, ALC argues "[c]laim 12 is different because it recites a specific implementation of an improvement over conventional cardiac monitoring devices." *Id.* ALC adds, "[t]his process of identifying a discordance, indicating to the user that an arrhythmia is present, and confirming the arrhythmia with ECG data is a specific implementation of a technological improvement to cardiac monitoring devices." *Id.* ALC contrasts this with *CardioNet II*'s claims which recited "'conventional processes.'" *Id.* (citing 816 Fed. App'x at 475).

The Staff agrees with ALC on each issue. The Staff describes *Alice* step one as "'asking what the patent asserts to be the focus of the claimed advance over the prior art.'" SIB at 27 (citing *TecSec, Inc. v. Adobe Inc.*, 978 F.3d 1278, 1292 (Fed. Cir. 2020); SRB at 13. To this question, Staff answers:

> The claims recite specific technical improvements that overcome deficiencies of conventional cardiac monitoring systems by sensing a user's activity level and a heart rate parameter to determine when to alert a user of the possibility of an arrhythmia being present, while also enabling the user to record an ECG to confirm the presence of the arrhythmia.

SIB at 27. The Staff views claim 12 as a specific "'means or method that improves cardiac monitoring technology.'" SIB at 28 (citing *CardioNet I*, 955 F.3d at 1368).

As for step two, the Staff contends:

> The evidence shows that the combination of limitations of the asserted claims supply an inventive concept that is sufficient to transform the nature of the claim to patent-eligible subject matter. *See* Tr. (Efimov) at 1252:15-1254:18; CDX-002C.45. Specifically, those claims recite a specific system that uses a first sensor to sense an activity level value of a user, and a photoplethysmogram ("PPG") sensor configured to sense a heart rate parameter of the user so as to alert the user of the possibility of an arrhythmia and to enable the capture of an ECG. *See* JX-003 ('941 patent) at cl. 12, col. 1:49-57. This technical advance enables the capture of ephemeral cardiac events in a way not possible using prior cardiac monitoring technology. *See* JX-003 ('499 patent) at col. 1:49-57; *see also* Tr. (Efimov) at 1252:15-1254:18; CDX-002C.45.

Id. at 28-29.

Claim 12 is not invalid under 35 U.S.C. § 101, although it is directed to an ineligible concept under *Alice* step one. For background, claim 12 recites:

> 12. [12(a)] A smartwatch, comprising:
>
> [12(b)] a processor;
>
> [12(c)] a first sensor configured to sense an activity level value of a user, wherein the first sensor is coupled to the processor;

> [12(d)] a photoplethysmogram ("PPG") sensor configured to sense a heart rate parameter of the user when the activity level value is resting, wherein the PPG sensor is coupled to the processor;
>
> [12(e)] an electrocardiogram ("ECG") sensor configured to sense electrical signals of a heart, wherein the ECG sensor comprises a first electrode and a second electrode, and wherein the ECG sensor is coupled to the processor; and
>
> [12(f)] a non-transitory computer readable storage medium encoded with a computer program including instructions executable by the processor to cause the processor to:
>
> [12(f)(i)] determine if a discordance is present between the activity level value of the user and the heart rate parameter of the user;
>
> [12(f)(ii)] based on the presence of the discordance, indicate to the user a possibility of an arrhythmia being present; and
>
> [12(f)(iii)] receive electric signals of the user from the ECG sensor to confirm the presence of the arrhythmia.

941 patent at cl. 12 (annotated). There are essentially two portions to this claim. The first recites the structure of a smartwatch (found to be limiting, above) loaded with a processor and particular sensors (limitations 12(a)-12(e)). The second portion refers to instructions causing analysis of the sensors' data and indicating (by any means) at least one result to the user (limitations 12(f)-12(f)(iii)). The first portion alone typically would be considered patent-eligible subject matter (as an apparatus), but the second portion alone typically would be questionable (as a set of algorithms). *See Yu v. Apple Inc.*, 1 F.4th 1040, 1043 (Fed. Cir. 2021) (in a claim for a digital camera, comparing limitations on lenses, sensors, and circuitry against limitations on image data enhancement).

The issue is then whether the claim, in view of the specification, is directed primarily to the apparatus or to the instructions. *Alice*, 573 U.S. at 217; *Yu*, 1 F.4th at 1043-45. The intrinsic evidence supports the latter. The majority of 941 patent claims focus on data analysis and returning results of that analysis to a user (941 patent at cls. 2-9, 13-21), while only a handful recite non-algorithmic features (*id.* at cls. 10, 11, 22, 23). The specification similarly speaks at length to

diagnostic techniques for arrhythmias, and the benefits of a discordance determination preceding an ECG measurement. *Id.* at Title, 1:66-2:3, 2:10-3:12, 12:55-65, 12:66-13:7, 13:67-14:18, 14:36-42, Fig. 7. On the other hand, the concept of a smartwatch embedded with all three of an activity sensor, a heart rate sensor, and an ECG sensor is discussed sparingly and in generalities (*see id.* at 2:42-3:12, 4:14-32; *see generally id.* at 5:33-9:37) and, importantly, is not presented as the main contribution to the art (*see id.* at 4:59-5:16 (discussing Apple Watch as an existing device)).

Accordingly, it is fair to say that claim 12 is directed to the abstract idea of analyzing a combination of heart rate and activity, and then measuring and analyzing ECG electric signals for medical diagnosis, as medical practitioners have routinely done for years. "The Supreme Court has held that 'fundamental . . . practice[s] long prevalent' are abstract ideas . . .. The Supreme Court and we have held that a wide variety of well-known and other activities constitute abstract ideas." *Intellectual Ventures I LLC v. Symantec Corp.*, 838 F.3d 1307, 1314 (Fed. Cir. 2016) (citing *Alice*, 134 S.Ct. at 2356). Claim 12 is thus directed to non-patent eligible subject matter.

The structural elements within claim 12, however, are sufficient to transform the claim into patent eligible subject matter under *Alice* step two. The claim's recitation of a smartwatch comprising "a photoplethysmogram ("PPG") sensor configured to sense a heart rate parameter of the user when the activity level value is resting, wherein the PPG sensor is coupled to the processor," is particularly specific and structural. As the 941 patent notes, "numerous sensors are known for measuring heart rate":

> Electronic devices suitable for use with the system 601 include mobile electronic devices such as smartphones, smartwatches, tablets, and laptops. The electronic device 601 comprises one or more sensors configured to sense a physiologic parameter. Numerous sensors are known for measuring heart rate. Non-limiting examples of suitable sensors include light based sensors such as, for example, infrared sensor/emitter, ultrasound sensors, and tactile sensors. Sensors for measuring rhythm include electrodes for measuring electrocardiograms (ECG) and light based sensors for measuring photoplethysmograms.

941 patent at 5:41-51.

The claim could have left it at "a sensor" for collecting heart rate, similar to what it did for "[a] sensor configured to sense an activity level." But a PPG sensor on a smartwatch is specific and innovative. ALC's founder, Dr. Albert, described it as "us[ing] a green wavelength. What they do is they shine light into the skin, and that light is modulated by the blood flow in the skin. Then they look at the reflected light, again, that's been modulated by the blood flow, and they get that pulse waveform you see." Hr'g Tr. (Albert) at 66:2-11. Dr. Jafari described it as "light going through the tissue and you get the reflection of it back through the photodiode." Hr'g Tr. (Jafari) at 513:12-15. Apple's engineering witness, Dr. Waydo, also testified to particular technical considerations that influence PPG data collection. Hr'g Tr. (Waydo) at 823:12-824:1 (describing PPG sensor's sensitivity to ambient light). And the 941 patent describes PPG as "provid[ing] cardiac cycle information and may, for example, be analyzed by a processor of a device described herein to determine a presence of a premature ventricular contraction." 941 patent at 9:54-57. Thus, recitation of a PPG sensor within a smartwatch, while not the entire focus of the claim, does move it away from the ineligible concept of data collection/analysis and towards a specific electro-mechanical apparatus. *Alice*, 573 U.S. at 217-18 (asking whether the additional elements "transform the nature of the claim" into patent-eligible subject matter).

The claim's "electrocardiogram ('ECG') sensor configured to sense electrical signals of a heart, wherein the ECG sensor comprises a first electrode and a second electrode, and wherein the ECG sensor is coupled to the processor" on the smartwatch adds to this finding. The claim did not recite any means for collection of any sort of "electrical signals of a heart," but rather an ECG, and one which includes first and second electrodes. The record shows that ECG sensors collect data in a certain way and provide a very particular waveform. *See, e.g.*, Hr'g Tr. (Albert) at 48:6-49:24;

Hr'g Tr. (Jafari) at 291:4-13; Hr'g Tr. (Stultz) at 1058:16-1059:13, 0195:1-10; 941 patent at Fig. 1, 8:1-9:23.

An ECG sensor, in combination with a smartwatch that also includes a PPG sensor, as well as an activity level sensor, amounts to significantly more than a patent on the ineligible concept of analyzing a heart rate and activity, and then measuring and analyzing ECG electric signals for medical diagnosis. *Alice*, 573 U.S. at 217-18. Taken individually, each separate component may be conventional, but combining all the various sensors on a smartwatch, for a specific function that is not traditional for smartwatches, is sufficiently "unconventional" to satisfy Section 101 under *Alice* step two. *BSG Tech LLC v. BuySeasons, Inc.*, 899 F.3d 1281, 1291 (Fed. Cir. 2018). There may come a time when every smartwatch includes the various claimed sensors, and runs the needed algorithms to practice claim 12, but as of the date of the invention the "ordered combination" of the claim's elements was sufficiently "transform[ative]." *Id*. at 1289; *see Berkheimer v. HP Inc.*, 881 F.3d 1360, 1369 (Fed. Cir. 2018) ("The mere fact that something was disclosed in a piece of prior art, for example, does not mean it was well-understood, routine, and conventional.").

Apple's argument to the contrary is not clear and convincing. *i4i*, 564 U.S. at 95. Apple principally argues "it is not enough to implement an abstract idea with 'well-understood,' 'routine,' or 'conventional' technology" and the combined use of PPG sensor data and ECG sensor data for arrhythmia detection was "well-known and not inventive as of 2013." RIB at 57 (citing, *inter alia*, *Alice*, 573 U.S. at 221-226); RRB at 34-35 (looking for "innovative advancement" and comparing to prior art). But the test is not whether what stands apart from the ineligible subject matter is inventive in the sense of being novel or non-obvious. *Synopsys, Inc. v. Mentor Graphics Corp.*, 839 F.3d 1138, 1151 (Fed. Cir. 2016) (distinguishing § 101 inventive concept from § 102 novelty

and § 103 obviousness). The test is whether a smartwatch with integrated processor, activity sensor, PPG sensor, and ECG sensor (with at least two electrodes) adds something more than carrying out heart rate discordance determination, user indication of arrhythmia, and arrhythmia confirmation on generic hardware. *Alice*, 573 U.S. at 225-226; *see* RRB (arguing claim 12 "exemplifies a fundamentally abstract idea implemented on generic computer hardware using generic functional language"). And the answer is that it does, as discussed above.

Even if claim 12 was clearly and convincingly shown to be invalid under 35 U.S.C. § 101, Apple has not met its burden for the dependent claims that add further specificity to the smartwatch structure. Claim 22 recites "wherein the PPG sensor is located on a back of the smartwatch" and claim 23 recites:

> [W]herein the first electrode is located on the smartwatch where the first electrode contacts a first side of the user's body while the user wears the smartwatch, and the second electrode is located on the smartwatch where the user must actively contact the second electrode with a second side of the user's body opposite from the first side.

941 patent at cls. 22, 23. Again, Apple offers little here beyond an assertion that such features would have been obvious, stating, "Dr. Stultz testified that these are effectively the only places that PPG and ECG sensors could be placed on a user's wrist to work effectively—there is nothing inventive about doing so." RIB at 60; *see* RRB at 36. Obviousness is not the test for an inventive concept, however.

Accordingly, none of the asserted claims of the 941 patent have been shown to be invalid for lack of patentable subject matter.

2. AMON in Combination with Almen and/or Kotzin

Apple contends AMON "alone or in combination with two others for minor limitations—renders obvious all of the '941 patent's Asserted Claims in this Investigation, including claims 12-13, 16, and 19-23." RIB at 60. Apple posits that four limitations within claim 12 are in dispute

under this theory (*id.* at 61) although ALC's briefs discuss only three (CIB at 74-77; CRB at 40-42). In addition, ALC presents disputes for claims 13 and 21. CIB at 77-80; CRB at 42-45.

There is a preliminary matter concerning claim 13. In its opening brief, Apple reasons that "[a]lthough AliveCor contests that heart rate variability is disclosed in AMON, it does not contest limitation 11[f] of the '499 patent . . . in its Pre-Hearing Brief. Therefore, AliveCor has waived its argument that AMON does not disclose heart rate variability across all three Asserted Patents." RIB at 72 n.32. This is not persuasive. A generalized discussion of claim 13 was contained in ALC's pre-hearing brief. CRB at 42 n.12; *see* CPB at 84 (citing other pre-hearing brief sections that attack combination of references). Thus, ALC's position on claim 13 was not waived.

a. Claim 12

As noted, three limitations are in dispute for claim 12. As to the remaining, undisputed, limitations, they are found to be disclosed in AMON as alleged. RIB at 67-69 (citing Hr'g Tr. (Stultz) at 1117:9-1118:7). In particular, AMON teaches a "wrist-worn device" that tells time, containing "processing devices," an "acceleration sensor . . . capable of detecting the level of user activity," an ECG with one electrode inside the device cuff and a second electrode on top, and flash and random access memory. RX-0419 at 1-2, 4, 6-7. Although AMON does not appear to use the term "PPG," it describes such a sensor located on "the top of the wrist," as well as its use for measuring pulse rate. *See id*. at 3-5.

i. [12(f)(i)] "determine if a discordance is present between the activity level value of the user and the heart rate parameter of the user"

Apple contends AMON discloses "determine if a discordance is present between the activity level value of the user and the heart rate parameter of the user." RIB at 69-70. In particular, Apple argues:

> As Dr. Stultz testified, AMON discloses "identifying high-risk zones given observations of patient data . . . [which] include[s] the pulse rate, and it tries to determine a high-risk zone based on settings." Tr. (Stultz) at 1118:8-1119:25. As Dr. Stultz explained, "[t]he key point here is that the settings are determined by the activity level" as set forth in Table I. *Id.* Effectively, AMON detects the level of user activity (walking, running, or resting) and correlates it to vital signs, where "the high risk areas . . . signify when the parameters are inconsistent with activity level." *Id.*

Id. As compared to the Accused Products, Apple avers AMON discloses this limitation "much more than the accused Apple Watch given that it has a specific table correlating activity to pulse rate." *Id.* at 70 (citing Hr'g Tr. (Stultz) at 1118:8-1119:25). Apple rejects the pre-set nature of the values as irrelevant because "[t]he critical point is that AMON detects user activity and correlates it with vital signs, where pulse limits are set according to the activity level." RRB at 39 (citing Hr'g Tr. (Stultz) at 1119:3-20; Hr'g Tr. (Efimov) at 1282:9-17).

The limitation is disclosed in AMON as alleged. AMON discloses two sets of risk thresholds for a patient's measured pulse, one for nonaerobic user activity and one for aerobic. RX-0419 at 6, Table I. AMON also discloses an acceleration sensor for determining which activity state a user is in. *Id.* at 3 ("AMON monitors pulse . . . and activity via acceleration continuously."), 5 ("Acceleration sensors provide information on the activities of the wearer.") 6 ("The selection of the active state is performed by user command or automatically by the wrist device when activity is detected."), Fig. 6. Thus, AMON teaches an evaluation for inordinately high or low pulse rates given one of two activity levels; *i.e.*, "a discordance is present between the activity level value of the user and the heart rate parameter of the user." And that heart rate can be provided by an optical, or "PPG," sensor. *Id.* at 6, 7 (explaining that an optical sensor runs and measures pulse for 30 seconds every 2 minutes, while other sensors are turned off most of the time). Thus, the limitation is met.

ALC argues that "the AMON device does not directly compare that activity level with the user's measured vital signs (including any heart rate parameter)." CIB at 75 (citing Hr'g Tr. (Efimov) at 1282:4-7); *see* CRB at 40. But the claims do not require a "comparison," they require "determin[ation]" of a "discordance," and that is clearly what AMON does.

Accordingly, the limitation is disclosed in AMON.

ii. [12(f)(ii)] "based on the presence of the discordance, indicate to the user a possibility of an arrhythmia being present"

Apple contends "based on the presence of the discordance, indicate to the user a possibility of an arrhythmia being present" is disclosed in AMON, "expressly or inherently"; and if not, it would have been obvious to modify AMON to arrive at this limitation of claim 12. RIB at 70-71. For support, Apple explains, "[t]he clinical algorithm disclosed in AMON also notes that if the pulse is outside the normal range, the user is asked to take an ECG measurement." *Id.* at 70 (citing RX-0419 at 6). Apple continues, "it would have been obvious to a POSITA with their knowledge as of May 2015 to modify the disclosure in AMON to meet this limitation (to the extent it's not expressly or inherently disclosed)." *Id.* (citing Hr'g Tr. (Stultz) at 1120:1-12)). Apple views ALC as admitting that AMON "'informs the user that one of the pre-set parameters may be outside of a normal range'" (RRB at 39 (citing CIB at 75)) and that "a heart rate outside of the normal range based on activity is inherently indicative of possible arrhythmia under AliveCor's and Dr. Jafari's application of the claims for infringement" (*id.* (citing Hr'g Tr. (Stultz) at 1120:1-12)). Apple emphasizes there is no need for the word "arrhythmia" to be displayed explicitly. *Id.*

The limitation is not disclosed, either expressly or inherently. AMON teaches, "[t]he initial analysis starts with a comparison of the pulse and oxygen saturation with predefined patient-specific values." RX-0419 at 3. AMON continues, "[b]ased on the results of this analysis, three different scenarios are possible," with one of those scenarios being, "Parameter out of range: A

remeasurement is performed. If the outcome is the same as before, the user is informed and additional measurements are required." *Id.* Another scenario is that more than one parameter is out of range, but "[i]n all cases, the patient is informed as to their own status and that of the device." *Id.* AMON also teaches that one of its "unique" features is "Online Analysis and Emergency Detection" which includes "an analysis of all measurements online, *presenting them in appropriate form* to both wearer and remote [telemedicine center, or TMC]." *Id.* at 2 (emphasis added).

The clear import of these statements is that when pulse is measured and found to be out of range (*i.e.*, too fast or too slow, the agreed construction of "arrhythmia"), the "user is informed" of that fact. But AMON does not specify exactly how this is done. ALC cites to the testimony of Dr. Efimov: "the alerts are only understood in the sense that the device can send a signal automatically to a hospital or a 9-1-1 call but not to the user." Hr'g Tr. (Efimov) at 1283:5-18; *see* CIB at 75. But this is not a reasonable reading of AMON, which states that the "patient is informed" in "all cases," including "[i]n the event of a failure to initiate communication with the [telemedicine center]." RX-0419 at 3. That is, direct communication to the user, as well as communication to a health professional at the telemedicine center, are both clearly contemplated by AMON. No particular method of "inform[ing]" is specified, however.

Nor does AMON expressly disclose the content of the information. But again, it discloses direct conveyance of information, including when a doctor at the telemedicine center cannot be reached, so it is not limited to a "human being mak[ing] medical judgments," and then expressing a diagnosis, "based on data transmitted" from the device. CIB at 75. Instead, the information is described as presented "in appropriate form" to the wearer. RX-0419 at 2. "Appropriate form" encompasses a range of possible messages, including messages that do not specifically "indicate" a "possibility of an arrhythmia," such as a directive to simply contact a cardiologist.

So this limitation is not expressly disclosed in AMON. It is also not inherently disclosed, because it is not "necessarily present." *Schering Corp.*, 339 F.3d at 1377. It is, however, an obvious manner of carrying out what AMON teaches. In essence, AMON discloses a genus (inform the user of the sensed condition in an appropriate form) of which the "indicate" limitation is a species (indicate to the user the possibility of an arrythmia). Any skilled artisan presented with AMON would need to fill in certain gaps to construct the device disclosed, including what method to use to inform the user that heart rate is discordant and exactly what information to convey. As noted, AMON itself implies multiple possibilities, but it surely would have been obvious to that skilled artisan to just program the device to display a plain language description of the detected discordance (in this case high heart rate) on AMON's screen—in fact, it likely would have been the simplest implementation. *See* RX-0419 at 6 ("[o]n each step, a result is displayed"). The testimony of Dr. Stultz, to the effect that it would have been obvious in 2015 to modify AMON to indicate an arrhythmia, is entirely consistent with this. *See* Hr'g Tr. (Stultz) at 1120:13-1121:1. If anything, Dr. Stultz's opinion understates the obviousness of this element, because AMON would not need to be "modified," just specified such that the relevant information would actually be conveyed in a particular, appropriate form. As noted, to a POSITA the most straightforward way of doing that would have been to display "high heart rate" or the like on AMON's screen. And that satisfies the claim element.

ALC agrees that "[t]o the extent the AMON device provides any 'indication,' it informs the user that one of the pre-set parameters may be outside of a normal range," but otherwise disputes this finding. CIB at 75. As explained, however, it would have been obvious to a POSITA to be precise about the out-of-range parameter, and to display that fact on AMON's screen. ALC also argues that AMON's algorithms are for signal processing, not for condition-specific detection.

Id. This, however, ignores AMON's explicit teaching of a risk threshold lookup table (including faster and slower heart rate ranges) and the parties' agreed construction of "arrhythmia" (faster or slower heart rate than normal). *See* RX-0419 at 6.

The Staff also argues the limitation is not taught. SIB at 33-34. But the Staff's contention that the limitation is not "suggest[ed]" by AMON is conclusory. *Id*. at 33 (stating only "AMON does not disclose or suggest alerting the user of a possibility of an arrhythmia."); SRB at 15 (same).

Accordingly, it would have been obvious to implement AMON in a manner that satisfies this limitation.

iii. [12(f)(iii)] "receive electric signals of the user from the ECG sensor to confirm the presence of the arrhythmia"

For "receive electric signals of the user from the ECG sensor to confirm the presence of the arrhythmia," Apple contends, "the 5-step algorithm in AMON describes taking an ECG in step 4 as a confirmatory measurement." RIB at 71 (citing RX-0419 at 6). Apple acknowledges that AMON does not mention arrhythmia by name, and does not dispute that diagnosis of a condition is "done by a clinician, even in AMON," but nonetheless relies on its expert to explain "arrhythmia is certainly a condition a POSITA would have looked for in high-risk cardiac patients, even though it is not expressly stated." *Id.* at 72 (citing Hr'g Tr. (Stultz) at 1120:1-1121:1); RRB at 40. Apple does not view AMON's reporting of its own ECG working poorly as preventing obviousness because AMON also discloses "'[i]mprovements [to] hardware and algorithm-wise are foreseen and should improve the measurements significantly.'" RIB at 72 (citing RX-0419 at 10). Apple further argues "a POSITA would have been motivated to confirm the arrhythmia with ECG data because Kotzin discloses sensing a different characteristic via a different biosensor (such as ECG) to indicate whether the condition is indeed present." *Id.* (citing Hr'g Tr. (Stultz) at 1121:11-22; RX-0401 at 18:10-24); RRB at 40.

The limitation is expressly disclosed in AMON. As determined above, there need be no link between the programming for evaluating discordances and receiving ECG signals for arrhythmia confirmation. And AMON discloses that ECG signals are both received and evaluated against a lookup table for confirmation of an abnormal, out of range, heart rate and QRS duration:

TABLE I
L1 AND H1 REPRESENT DEVIANT ZONE, L2 AND H2 RISK ZONE, AND L3 AND H3 HIGH-RISK ZONE

vital sign	L3	L2	L1	Normal	H1	H2	H3
Systolic (mmHg)	50-59	60-79	80-99	100-130	131-160	161-200	201-300
Diastolic (mmHg)	40-44	45-49	50-59	60-85	86-90	91-110	111-140
SpO2 (%)	65-79	80-91	92-94	95-100			1001
Pulse (per minute)	40-44	45-49	50-59	60-100	101-120	121-180	181-250
QRS duration (s)	0.01-0.03			0.04-0.12			0.121-0.35

See RX-0419 at 4, Table I; RX-0419 at 6 (discussing "Fourth Step"). As disclosed, and shown above, AMON "detect[s] and measure[s] a number of medical parameters from the ECG waveform, in particular, QRS complex width," and even employs a sort of machine learning algorithm to improve its detection:

> For QRS detection, a threshold set is computed during an initial learning stage (lasting 8 s): the upper threshold is calculated from 0.4 times the average maximum on the integrated signal; from this, a lower threshold is calculated by another factor of 0.4. During the detection process, the current integrated moving window value is compared with the upper threshold. If this threshold is exceeded, an R wave onset is assumed; QRS is confirmed by scanning backward (up to 100 ms) for a dip below the lower threshold. These threshold values are continually adjusted with each new QRS so as to compensate for variations in ECG baseline.

Id. at 4. Whether this is an accurate or medically reliable determination of an arrhythmia from a given ECG reading is immaterial; it is an evaluation and confirmation of a faster or slower than normal heart rate—*i.e.*, the parties' agreed construction for the condition. Order No. 12 at 12-13. Kotzin's relevant disclosures are redundant with AMON and need not be discussed. *Compare* RX-0401 at 6:14, 18:21-24 (discussing use of second sensor after particular result with first, including EKG) *with* RX-0419 at 6 (same).

In addition, the fifth step of the medical algorithm begins, "[p]attern recognition of the medical data for clinical diagnosis," and ends with "[o]n each step, a result is displayed and, if appropriate, sent to the TMC for further processing." RX-0419 at 6. Thus, AMON does not simply teach reporting back ECG data, but suggests applying pattern recognition to it with the result of that process displayed. If the result is an arrhythmia, then the device has "confirm[ed] the presence of the arrhythmia" as required. And as claim 12's "confirmation of the arrhythmia" is not limited to any particular process or algorithm, it is convincingly disclosed by AMON.

ALC's argument to the contrary is not persuasive. ALC contends, "AMON never discloses a 'confirmation' step performed on the device" and its five step process "never discloses any analysis performed by the device that could 'confirm' whether an arrhythmia is present." CIB at 76; CRB at 41. But in a plain and ordinary sense, comparing measured ECG values to a lookup table and concluding "high risk" is an analysis "to confirm" the presence of arrhythmia. Similarly, ALC claims, "[a]t best, AMON and Kotzin disclose recording an ECG after a different sensor detects an abnormality." CRB at 41. Again, and setting Kotzin aside, AMON's use of a lookup table *after* ECG signal recording proves this statement false.

ALC also argues AMON is a non-enabling reference, to the extent it is part of an obviousness analysis. CIB at 74. ALC explains, "'if an obviousness case is based on a non-self-enabled reference, and no other prior art reference or evidence would have enabled a skilled artisan to make the claimed invention, then the invention cannot be said to have been obvious.'" CRB at 36 (citing *Raytheon Techs. Corp. v. Gen. Elec. Co.*, 993 F.3d 1374, 1377 (Fed. Cir. 2021)). ALC refers specifically to the ECG functionality disclosed in AMON:

> Here, AMON itself states that the ECG sensor and algorithms could not reliably calculate heart rate or QRS wave lengths. RX-419.10. AMON's ECG algorithm did not even attempt to identify P-waves, which Dr. Stultz testified are important for

> detecting arrhythmias. Tr. (Stultz) at 1159:13-15. Accordingly, AMON is simply not capable of detecting arrhythmias using ECG sensing, as required by the claims.

Id. ALC views Apple's experts, Dr. Picard and Dr. Stultz, as agreeing that the types of sensor design and signal processing changes needed for AMON's ECG are long-term projects, indicating its status as non-enabling. *Id.* at 37 (citing Hr'g Tr. (Picard) at 919:3-920:4; Hr'g Tr. (Stultz) at 1153:8-25).

ALC's position is not persuasive for at least two reasons. First, it depends entirely on AMON's disclosure about its own ECG efficacy. ALC's expert offers none of his own opinions on the matter. *See generally* Hr'g Tr. (Efimov) at 1181:1-1310:10; *Raytheon*, 993 F.3d at 1382 (emphasizing independent expert testimony in enablement). And when AMON's disclosure is taken as a whole, the overall thrust is that reliable heart rate and QRS wavelength will be achieved in due course, that is, without undue experimentation:

> B. Conclusion
>
> 1) Measurement Results
>
> . . . .
>
> ECG provides poor or no results. Calculation of reliable heart rate and length of the QRS wave was not made possible. Noise was a problem for all measurements. Improvements hardware and algorithm-wise are foreseen and should improve the measurements significantly.
>
> The results are close to what we expected but the device needs some improvements. What can be stated is that the use of several sensors in the same device is possible.
>
> . . . .
>
> VI. Conclusion
>
> We have developed a wearable medical monitoring and alert system aimed at people at risk from heart and respiratory disease. The system combines multiparameter measurement of vital signs, online analysis and emergency detection, activity analysis, and cellular link to a TMC in an unobtrusive wrist-worn device. A prototype of both the wrist device and the medical center software has been implemented. Medical trials were performed on 33 patients. While first prototypes had problems with achieving the required medical accuracy on all the

> measurement, the tests have provided a clear indication of the feasibility of the concepts and validity of the solutions adapted by the project.

RX-0419.10; *see* RIB at 63-64.

It is only natural that if AMON's statements on its ECG reliability are to be believed, then so must its statements on the foreseeability of achieving improved reliability. And if it is true that there was difficulty in designing wearable deices with reliable ECG measurement, even at the time of the 941 patent (*see* Hr'g Tr. (Efimov) at 1259:16-24), the 941 patent offers essentially no information on how to achieve this (*see* 941 patent at Figs. 4, 5, 5:32-7:62 (discussing hardware in generalities and only at a high level)). In other words, the 941 patent effectively assumes such devices are ordinary:

> FIG. 4 shows available technologies 400 for continuously sensing a heart rate or an activity level. Shown are smartwatches made available by manufactures such as, for example, Apple. A wearer of one of the shown smartwatch technologies 400 may conveniently and continuously wear one or more sensors that are either coupled to or integrated with the watch throughout the day, thus, effectively continuously monitoring one or more parameter values via the one or more sensors that are either coupled to or integrated with the smartwatch. Thus, one of the smartwatch technologies 400 are an example of a type of device in the form of a wearable that conveniently provides continuous monitoring of one or more parameters of a user. Non-limiting examples of wearable devices that may have one or more sensors either coupled to them or integrated with them include watches (e.g. smartwatches), eyeglasses, wristbands, necklaces, and clothing.

Id. at 4:59-5:8.

Second, the actual claim limitation at issue for AMON's enablement is "receive electric signals of the user from the ECG sensor to confirm the presence of the arrhythmia." There is no required degree of performance (*e.g.*, reliability) for the "confirmation." All that is required is reception of ECG sensor signals and an evaluation of a faster or slower than normal heartbeat. On this point, Dr. Stultz offered unrebutted testimony that AMON's disclosure was "workable" as demonstrated by AMON's Figure 4 showing an ECG signal which "one could calculate heart rates

from." Hr'g Tr. (Stultz) at 1176:13-20. Therefore, AMON's own disclosure, in combination with the only expert testimony on the issue, supports an enabling disclosure.

Accordingly, the balance of the evidence shows AMON's disclosure is enabling for "receive electric signals of the user from the ECG sensor to confirm the presence of the arrhythmia." And the limitation is disclosed in AMON as alleged.

b. Claims 16, 18, 20, 22, and 23

Apple contends that dependent claims 16, 20, 22, and 23, and intervening claim 18, are either disclosed in AMON or constitute an obvious modification of it. *See* RIB at 74-76. ALC does not contest Apple's theory on these claims apart from their dependency from claim 12. CIB at 79-81; CRB at 43-45. Neither does the Staff. SIB at 29-39. As Apple has shown the obviousness of claim 12 these claims are also obvious based on AMON's teaching and on the testimony provided by Apple's expert, Dr. Stultz. RIB at 74-76 (citing Hr'g Tr. (Stultz) at 1126:23-1130:9). Specifically, the features added by these dependent claims are expressly disclosed in AMON, so no further obviousness analysis is needed: instructing the user to record an ECG as in claim 16 (RX-0419 at 3 ("additional measurements are required" and are "initiate[d]" by the device, including ECG)); the heart rate parameter is a heart rate derived from a PPG signal as in claims 18 and 20 (*id*. at 3-4 ("pulse" is compared with preset parameters, and is measured using an optical device matching the description of a PPG)); the PPG sensor is located on the back of the smartwatch as in claim 22 (*id*. at 3 (the optical sensor is placed "on the top of the wrist")); and the ECG electrode configuration of claim 23 (*id*. at 4 (describing "Left arm" and "right arm" electrodes)).

c. Claims 13 and 19

The most hotly contested obviousness issue, for all three Asserted Patents, is heart rate variability. AMON does not expressly disclose measurement of that parameter, so Apple's

obviousness case for claims encompassing HRV relies on multiple references. *See* Hr'g Tr. (Efimov) at 1284:16-1285:1. The 941 patent has two asserted claims covering it: claim 13 recites, "[t]he smartwatch or wristlet according to claim 12, wherein the heart rate parameter comprises an indication of a heart rate variability, and wherein the arrhythmia is atrial fibrillation"; and claim 19 recites, "[t]he smartwatch according to claim 18, wherein the heart rate parameter is a heartrate variability ("HRV") value, wherein the HRV value is derived from the PPG signal." 941 patent at cls. 13, 19.

Apple contends "Dr. Stultz testified that AMON specifically discloses the measurement of R-R distances, which is the equivalent of the instantaneous heart rate. Calculating HRV would have been a 'knee-jerk reaction' to a POSITA from R-R distances." RIB at 72-73 (citing Hr'g Tr. (Stultz) at 1123:17-1124:3). And while these distances were discussed in the context of ECG signals, Apple argues it would have been obvious to a person of ordinary skill to calculate "heart rate data via an optical sensor, also disclosed by AMON." *Id.* at 73 (citing Hr'g Tr. (Stultz) at 1124:7-14); RRB at 41. Overall, according to Apple, "Dr. Stultz testified that most of the published work regarding calculating HRV from PPG data using the R-R interval 'happened a little after 2004 . . . but certainly by 2013 and 2015 this was well-known.'" RIB at 73 (citing Hr'g Tr. (Stultz) at 1125:8-15). To the extent these points are contested, Apple then refers to prior art reference Almen to disclose a "'wrist worn heart rate variability monitor' and 'a heart rate variability test.'" *Id.* (citing RX-0400 at Abstract, 1:18-24, 10:28-35; Hr'g Tr. (Stultz) at 1126:6-16).

In light of the first three *Graham* factors, Apple has demonstrated a prima facie case that claim 13 would have been obvious over AMON in light of Almen. As discussed above, although there is no dispute AMON discloses a PPG sensor that detects heart rate, it fails to disclose

detecting or calculating heart rate variability. It also fails to "specifically mention[]" atrial fibrillation. Hr'g Tr. (Stultz) at 1158:22-1159:2. Almen, however, is focused on heart rate variability measurements, within the context of a smartwatch. *See* RX-0400 at Abstract. Almen also teaches the definition of heart rate variability and why it is valuable to measure:

> BACKGROUND OF THE PRESENT INVENTION
>
> Heart rate variability refers to the variability of the time interval between heartbeats and may be mathematically defined as the one-sigma standard deviation of the heart rate about the mean heart rate value. A heart rate variability test is a reflection of a person's current health status. By taking heart rate variability tests over time, an individual is able to gauge improvement or deterioration in their health status. Such improvements or deterioration of health may result from a number of sources including, *e.g.*, changes in lifestyle such as smoking cessation, starting an exercise program, surgery recovery, stressor additions or removals, diet changes. Thus, in this context, the HRV test may be used as a medical motivator. The HRV test may also be used as an early indicator diagnostic tool. For example, the HRV test has been demonstrated to have prognostic associations with future coronary disease and events.
>
> . . . .
>
> In addition, utilization of heart rate, heart rate variability, sleep stage patterns and pattern identification may be used to determine if the user is at risk of suffering from a wide variety of maladies or conditions relating in general to cardiovascular diseases or conditions and sleep breathing disorders or conditions. It would be highly desirable to have a device and method to identify certain maladies, conditions or related events (1) before they occur, (2) during the occurrence of the malady, event or condition, and/or (3) after the malady, event and/or condition has occurred to allow the user and/or health care professional to examine the data, identify the particular malady, event and/or condition, and take appropriate action to correct the problem.
>
> The present invention addresses these concerns.

RX-0400 at 1:18-2:7. The 941 patent makes no claim to the discovery of the utility of monitoring heart rate variability, and it would appear from both the 941 patent's and Almen's definitions that the metric can be derived from the typical heart rate data logged by AMON. *See* 941 patent at 3:63-4:3 ("Heart rate may vary between . . . bradycardia . . . , normal resting heart rate . . . , and tachycardia . . .. Variance of heart rate over a period of time may be referred to as Heart Rate

Variability (HRV)."); RX-0400 at 1:18-21 ("Heart rate variability refers to the variability of the time interval between heartbeats and may be mathematically defined as the one-sigma standard deviation of the heart rate about the mean heart rate value"). Dr. Stultz agreed. Hr'g Tr. (Stultz) at 1058:13-1059:19, 1077:21-1078:15 (clinicians look for "irregularly irregular" heart rate), 1085:19-22 ("using heart rate variability from pulse rate sensing to determine the presence of an arrhythmia is something qualitatively that clinicians do and have done.").

Thus, the required modification to AMON to sense HRV would have been nothing more than calculation of "the standard deviation of heart beat intervals." RX-0400 at 1:44. As shown in the heart rate chart from the 941 patent, the data needed to perform this calculation is seemingly readily available from processing "heart rate **202**" measurements:

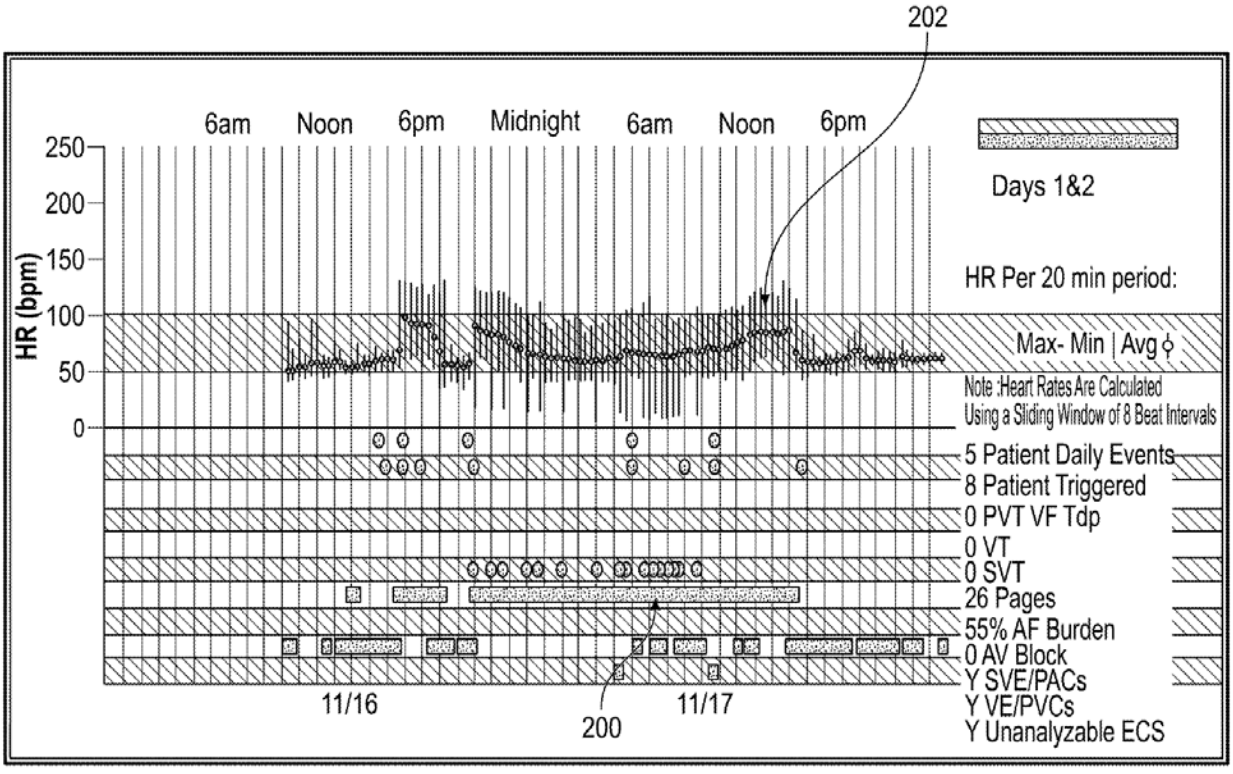


FIG. 2

941 patent at 4:47-53, Fig. 2.

Ironically, the Staff makes a convincing case of this (*see, e.g.*, SIB at 34-35 (providing hypothetical average heart rate and heart rate variability example)) as does ALC's expert, Dr. Efimov (Hr'g Tr. (Efimov) at 1308:4-1309:7 (explaining mathematical operations to obtain HRV). Calculating HRV is certainly within the level of ordinary skill defined above (*e.g.*, heart rate first derivative). And both AMON and Almen disclose the use of an optical sensor within a wrist-worn device to capture heart rate, making these references analogous art. *See* RX-0400 at 6:3-4 ("an infra-red sensor may be used to obtain or measure the heart rate").

In contrast to claim 12, however, where Apple's prima facie case for obviousness is based on a single reference, multiple references require both a reasonable expectation of success, which is discussed above, and a motivation to combine. *See Certain Infotainment Systems, Components Thereof, and Automobiles Containing the Same*, Inv. No. 337-TA-1119, Comm'n Op. at 36 (May 28, 2020) (public version) (citing *Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1373-76 (Fed. Cir. 2019)). Apple's substantive argument for such a motivation is terse: "Dr. Stultz explained that a POSITA would have been motivated to use HRV derived from heart rate data because Almen expressly teaches a 'wrist worn heart variability monitor' and '[a] heart rate variability test is a reflection of a person's current health status,'" and Almen expressly discloses that AFib is an arrhythmia. RIB at 73 (citing Hr'g Tr. (Stultz) 1126:6-16). To be sure, Dr. Stultz testified that because of their similarities, combining AMON and Almen "would have been natural to any person of ordinary skill in the art at the time." Hr'g Tr. (Stultz) at 1131:10-17. But Dr. Efimov testified that Almen lacked a teaching for modifying AMON. *See* Hr'g Tr. (Efimov) at 1285:8-21.

Nonetheless, Almen discloses that heart rate variability data "may be capable of detecting and/or assisting in diagnosing various heart maladies and/or conditions. Exemplary conditions

that may be detected or diagnosed comprise *inter alia*, cardiovascular disease such as . . . Arrhythmias [and] Atrial Fibrillation." RX-0400 at 7:26-33. And Dr. Stultz testified that a person of ordinary skill would understand that a rapid increase in heart rate (*i.e.*, high variability) is consistent with atrial fibrillation. Hr'g Tr. (Stultz) at 1125:16-1126:16. Thus, to the extent "indicate to the user a possibility of an arrhythmia being present" is an obvious design specification in implementing AMON (discussed above), it would have further been obvious to indicate atrial fibrillation as the type of that arrhythmia, and to detect it by determining HRV, because Almen explicitly says so. And once the processor is made to evaluate PPG data for the possibility of atrial fibrillation, it would have been natural for the processor to evaluate ECG data for the same purpose (*i.e.*, "receive electric signals of the user from the ECG sensor to confirm the presence of the [atrial fibrillation]."). Almen therefore provides an explicit "reason" to modify AMON to detect atrial fibrillation by determining heart rate variability. *KSR*, 550 U.S. at 418.

Thus, the first three *Graham* factors support obviousness. *Graham*, 383 U.S. at 17-18 (holding factual determinations include: "(1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art . . ."). In opposition, ALC argues that ECG detection of AFib requires identification of P-waves, and this is so difficult that even the AMON authors explicitly left it out of their device:

> The [AMON] algorithm does not, however, even attempt to identify P-waves. The AMON authors acknowledged, and Dr. Stultz agreed, that the PR interval was "left out for this work due to the nontriviality of P wave detection." CX-0664.4; Tr. (Stultz) at 1159:7-1160:1. This is significant because, as Dr. Stultz testified, the presence or absence of P-waves is an important indicator of whether the user has AFib. Tr. (Stultz) at 1159:13-15.

CIB at 78; *see* CRB at 36. But Dr. Stultz testified only that "the presence or absence of a P wave can be informative in diagnosing arrhythmias" (Hr'g Tr. (Stultz) at 1159:13-15), Almen teaches that heart rate variability can be measured by analyzing heart rate without consideration of P-

waves, and ALC offers no other evidence to support the alleged criticality (*see* CIB at 78 (citing only Dr. Stultz); CRB at 36 (same)). Thus, the record shows that derivation of heart rate variability from more typical heart rate data was a routine and appreciated determination by those of ordinary skill in the art. *See, e.g.*, 941 patent at Figs. 1, 2, 4:33-53 (discussing artifacts in ECG data showing atrial fibrillation).

ALC also contends, "Dr. Stultz fails to explain why a POSITA would have been motivated to refine the SpO_2 algorithm in AMON to do so, particularly given that the AMON device only uses the SpO_2 sensor to detect heart rate and blood oxygenation." CIB at 78; *see* SIB at 35. But as explained, refining AMON's algorithm would have been straightforward—simply calculate the first derivative of the heart rate (*i.e.*, rate of change of heart rate)—and Almen discloses use of an optical sensor (like the SpO_2 sensor in AMON) to measure heart rate and thereafter process it for determining heart rate variability. *See* RX-0400 at 6:3-6, 13:33-40. And Almen refutes ALC's assertion that prior to the 941 patent, it was not known to use PPG sensors for arrhythmia detection. *See id*. at 7:26-53; CRB at 39 (citing Hr'g Tr. (Efimov) at 1236:2-1237:7). This is all in addition to Dr. Stultz making a similar point:

> Q. We've also heard a fair amount about atrial fibrillation. Is there a common way doctors refer to atrial fibrillation with respect to the rate and rhythm of the heart measured during a physical exam?
>
> A. Yes, there is.
>
> Q. And how is that referred to by doctors?
>
> A. So on the physical exam we are taught to make qualitative assessments of the heart rhythm. This is learned in medical school. And I think this also echoes what Dr. Albert said earlier this week. Irregularly irregular is a description of the heart rhythm, and it's very irregular and it is very suggestive of atrial fibrillation.
>
> . . . .

> And on osculatory exam we are taught to assess the heart rate and the heart rhythm. So we report whether the rate is normal or whether it is elevated, tachycardic or bradycardic, and we also report on the regularity of the rhythm.
>
> So in medical school you learn a normal exam is regular, rate, and rhythm. Exams can be described as tachycardic and irregular, or it can be irregularly irregular where the latter clause is suggestive of atrial fibrillation.
>
> If an irregularity is suspected, an ECG is obtained. And this is done -- this is what I learned and what I did as an internal medicine resident. And then, of course, the ECG is analyzed to determine a diagnosis.
>
> . . . .
>
> This is what I learned – this is when I began my training as a physician/scientist approximately 30 years ago.

Hr'g Tr. 1073:9-21 (emphasis added).

ALC also seems to make the argument that AMON is non-analogous art to both Almen *and* the 941 patent itself. CIB at 70-71. ALC argues AMON is meant for patients that have already been diagnosed with heart disease while the 941 patent is meant for "users to detect arrhythmias without the aid of a medical professional." *Id.* at 70 (citing RX-0419 at 1; Hr'g Tr. (Efimov) at 1229:24-1230:20; 1231:7-1232:5; 1235:6-1236:1). This is far from persuasive. Each of AMON, Almen, and the 941 patent involve wrist-worn heart rate monitoring devices—*i.e.*, analogous art. Even then, ALC's supposed dichotomy is no such thing. ALC presents AMON as directed to "people currently confined to the hospital or their homes" (*id.* (citing RX-0419.1), but AMON is envisioned to allow users to escape those places—"[t]he idea is that by using an unobtrusive wrist-worn device, monitoring can be performed without interfering with the patients' everyday activities and without restricting their mobility" (RX-0419 at 1; *see* RX-0419 at 5 (detailing pulse limits set to activity levels of walking, running, or resting)).

ALC additionally suggests that AMON's admission that its ECG sensors as-constructed yielded poor or no results equates to a teaching-away of "wrist-worn device[s] used to capture

signals from multiple sensors." CIB at 71-72. This is not a true teaching away, though, because it does not teach away from the combination of AMON with sensing HRV data to detect and confirm atrial fibrillation. AMON's honesty over its system's drawbacks should not be confused with its overall positive outlook on the technology and the concept of wrist-worn medial monitoring. *See* RX-0419 at 9-10 (detailing sensor testing and patient feedback). The final conclusion stands out:

> We have developed a wearable medical monitoring and alert system aimed at people at risk from heart and respiratory disease. The system combines multiparameter measurement of vital signs, online analysis and emergency detection, activity analysis, and cellular link to a TMC in an unobtrusive wrist-worn device. A prototype of both the wrist device and the medical center software has been implemented. Medical trials were performed on 33 patients. While first prototypes had problems with achieving the required medical accuracy on all the measurement, the tests have provided a clear indication of the feasibility of the concepts and validity of the solutions adapted by the project.

RX-0419 at 10; *see id.* at 2 ("for the envisioned target group and application, such 'all-in-one design' is essential [because] the system must be worn on a daily basis and be put on without assistance."). This is a far cry from a "suggest[ion] that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." *Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1354 (Fed. Cir. 2012) (internal citation omitted); CIB at 72. And again, to the extent there are practical difficulties in a wrist-worn device conducting ECG and other data measurement (CIB at 73-74 (citing RX-0560.2)), the 941 patent offers no solutions of its own (*see* 941 patent at Figs. 4, 5, 5:32-7:62 (discussing hardware in generalities and at a high level)) and claims no particular manner of ECG sensor construction (*see id.* at cls. 1-23). So the 941 patent cannot be said to have solved the "multi-sensor on a wrist-worn platform" problem, if it is alleged to exist.

Accordingly, Apple has made out a prima facie case that the limitations of claim 13 would have been obvious over AMON in view of Almen.

Claim 19 is similar to claim 13, reciting, "[t]he smartwatch according to claim 18, wherein the heart rate parameter is a heartrate variability ("HRV") value, wherein the HRV value is derived from the PPG signal." 941 patent at cls. 19. Because claim 13 already requires the heart rate parameter to be "sense[d]" by the PPG sensor, the combination of AMON and Almen satisfies claim 19 for the same reasons as claim 13. 941 patent at cl. 12. ALC and Apple generally discuss the two together. *See* RIB at 74-75; CIB at 79. And the Staff does not mention claim 19 at all. SIB at 29-39; SRB at 15-17.

Accordingly, Apple has made out a prima facie case that the limitations of claim 19 would have been obvious over AMON in view of Almen.

d. Claim 21

Claim 21 recites, "[t]he smartwatch according to claim 12, the processor further to: display an ECG rhythm strip from the electric signals." 941 patent at cl. 12. Apple argues first, as a matter of claim construction, that claim 21 does not require that "the display of the ECG rhythm strip must be on the device itself." RIB at 75; RRB at 42. Nevertheless, Apple continues, "AMON discloses a display on which the ECG rhythm is displayed." RIB at 75 (citing RX-0419.6, Fig. 4). Apple reasons, "Dr. Efimov conceded that as early as 2013, any standard ECG taken would produce a digital cardiac rhythm strip, thus AMON as part of taking a user's ECG, was doing the same." *Id.* (citing Hr'g Tr. (Efimov) at 1296:22-1297:1); RRB at 42-43.

In rebuttal, however, Apple changes tack and states only that "AMON discloses both an ECG rhythm strip in Figure 4, as well as a display" before complaining of a lack of evidence "to say that the rhythm strip of Figure 4 was *not* 'displayed' on the AMON device." RRB at 42 (emphasis added). Apple then notes the disclosure of AMON that "'the distances RR, QRS, and QT are stored for every discovered QRS wave . . . for an overall result—as displayed to the user.'" *Id.* (citing RX-0419 at 4).

The limitation is not disclosed in AMON, nor does Apple demonstrate that it would have been obvious. As with claim 12, Apple's obviousness case is based on a single reference, AMON, and AMON does not teach or show an ECG rhythm strip on the display of the wrist-worn device. Indeed, AMON fails to teach or suggest the processor of the wrist-worn device driving *any* display to show an ECG rhythm strip (internal or external to the smartwatch). AMON's Figure 4, reproduced below, is as ALC describes it, a rhythm strip created for publication to demonstrate the efficacy of the single lead ECG sensor ("QT interval and QRS duration can be detected"):

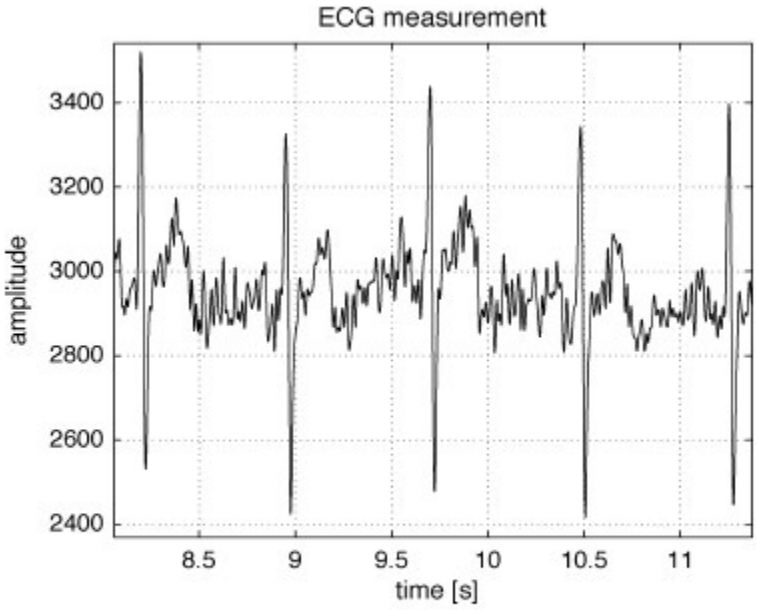


Fig. 4. AMON one lead ECG sample measurement: A digital bandpass filter [0.015 40]Hz has been applied to reduce noise. Heart rate, QT interval and QRS duration can be detected.

RX-0419 at Fig. 4. There is no disclosure in AMON that the rhythm strip illustrated was ever on a device driven by AMON's processor. Apple's assertion that there is a "lack of evidence . . . that the rhythm strip of Figure 4 was not 'displayed' on the AMON device" is incorrect. RRB at 42. What AMON does teach as being displayed to a user are average RR, QRS, and QT distance values: "[t]he distances RR, QRS, and QT are stored for every discovered QRS wave. For an overall result—as displayed to the user—averages are taken over all the valid QRS. Heart rate is

calculated directly from RR." RX-0419 at 4; *see id.* at 6 (discussing a fourth algorithm step calculating pulse rate, and "[o]n each step, a result is displayed"). Average distance values, however, need not be communicated with an ECG rhythm strip.

In addition to non-disclosure in AMON, Apple has not presented any reason why a POSITA would modify AMON's processor to drive a display (internal or external) to show an ECG rhythm strip. As it stands, AMON uses ECG data simply to determine heart rate and QRS durations. RX-0419 at 4, 6 (disclosing five step algorithm and threshold lookup table). These calculations do not require a visual presentation of an ECG rhythm strip, and neither Apple nor Dr. Stultz identifies a benefit for the processor to drive a display with that particular graphic. *See* RIB at 75; RRB at 42-43; Hr'g Tr. (Stultz) at 1129:7-14. It is not otherwise clear on its own why a layperson (as the user of the processor) would ever need to *see* their ECG rhythm strip as opposed to its post-analysis results—other than that it is attractive imagery.

Accordingly, the limitation of claim 21 is not disclosed in AMON, and has not been shown to have been obvious in view of AMON combined with the knowledge of a skilled artisan.

e. Secondary Considerations of Non-Obviousness

ALC points to secondary considerations including: industry praise, commercial success, copying, long-fled but unmet need, and failure of others. CIB at 81-87. ALC presents evidence that would support the non-obviousness of a single device which uses PPG and ECG data to monitor health (*e.g.*, the KBS and Accused Products). This, however, is not the issue at hand as AMON already discloses this PPG/ECG sensor combination. And Apple has not made out a prima facie case of obviousness of claim 21, so secondary considerations need not be analyzed for that claim.

ALC has shown that KBS practices claims 12, 16, 20, 22, and 23, and it is therefore entitled to a presumption of nexus where the secondary consideration pertains to KBS. *See Immunex Corp.*

v. Sandoz, Inc., 964 F.3d 1049, 1067 (Fed. Cir. 2020). But KBS does not practice claims 13 or 19, which involve HRV, so there is no presumption of a nexus. *See Apple Inc. v. Samsung Elecs. Co., Ltd.*, 839 F.3d 1034, 1053-4 (Fed. Cir. 2016) (summarizing evidence of praise directed at slide-to-unlock feature in contravention of argument that praise was merely generic). And ALC's arguments are not presented in the context of any particular claim or claim limitation. *See* CIB at 74-81 (claims 12-23 analysis), 81-87 (secondary considerations analysis); CRB at 40-45 (claims 12-23 analysis), 45-49 (secondary considerations analysis); *see also* SIB at 29-36, 36-39; SRB at 15-16, 16-17. This makes the secondary consideration analysis more difficult. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-9 (Fed. Cir. 1983).

Nonetheless, ALC offers persuasive evidence of industry praise for, and the commercial success of, the KBS, and (by presumption) the claims it practices. The industry praise is notably favorable (*see* RX-0564; CX-0470; CX-0471) and includes a positive technical analysis published in the Journal of the American College of Cardiology (*see* CX-0472), a peer-reviewed journal which Dr. Efimov views as the "topmost, high, impactful journal" in cardiology (Hr'g Tr. (Efimov) at 1198:21-1199:10). Admittedly, the cited exhibits do not offer unqualified praise and generally focus on the ECG function rather than the PPG function, as Apple explains. *See* RIB at 84-85. But each exhibit praises the "KardiaBand" as implemented on the Apple Watch, that is, the KBS, and the mere fact that a peer-reviewed medical journal published a laudatory article on the product is impressive, even if the article's specific focus was on only one of its functions. Taken as a whole, this is strong evidence of industry praise, and the presumption of nexus has not been rebutted. The Staff generally agrees. *See* SIB at 38.

There is also evidence of commercial success. ALC principally relies on funding it received, as opposed to revenues or profits derived from KBS, and on the fact that the Apple Watch

was commercially successful. *See* CIB at 82-83. But as Apple and the Staff point out, there is no clear nexus between the funding and KBS, especially because KBS was never ALC's biggest selling product, and the Apple Watch's commercial success is likely attributable to any number of factors unrelated to KBS. *See* CX-0469 (citing KardiaMobile but not KBS); CX-0935C (showing KardiaMobile as ALC's biggest revenue producer); SIB at 39; RIB at 81-83. Other evidence, however, shows that KBS "was selling very successfully," as ALC's chief financial officer testified. RX-0384C (Hosein Deposition) at 77:24-78:11. Specifically, KBS revenues for calendar years 2017, 2018, and 2019 totaled over [redacted]. *See* CX-0934C; CX-0935C. KBS' profitability is not clear, though, so the evidence of commercial success is not as persuasive as the evidence of industry praise.

ALC further argues that failure by others and a long-felt need weigh against obviousness. *See* CIB at 86-87. There is evidence of such considerations as they relate to detection of atrial fibrillation, but there is no clear nexus to the KBS, because the KBS does not practice claim 13. *See id*. (citing CX-0443; CX-0444; CX-0445; CX-0453; CX-0454). So to the extent the KBS is capable of detecting and confirming AFib, it is not clear that the long-felt need and failure by others relates to the claimed invention, as opposed to some other feature of the KBS, and the nexus presumption does not apply. These secondary considerations therefore do not weigh in favor of obviousness. The Staff agrees. *See* SIB at 39.

Lastly, ALC argues that Apple "copied AliveCor's technology." CIB at 83-86. The Staff concurs. *See* SIB at 37-38. Evidence ALC cites in favor of copying includes the fact that Apple had access to ALC's technology (necessarily so to some extent, because it was eventually incorporated into the Apple Watch), had multiple meetings with ALC personnel about KBS prior to KBS receiving FDA approval, and obtained KBS-related FDA submissions via Freedom of

Information Act requests. *See generally* CIB at 83-86. Apple is correct that taken individually such evidence is not especially probative. *See* RIB at 77-80.

But "multiple internal [Apple] presentations" and similar evidence do provide probative evidence of copying. *Apple*, 839 at 1054. [redacted]. JX-0219C (Klaassen Deposition) at 45:14-48:14. In March 2016 an Apple presentation characterized the [redacted]" as a "[redacted]" for its own ECG "[redacted]." CX-0375C.22. In an internal April 2016 email, [redacted]. CX-0911C. In an email chain in April 2017 Apple personnel discussed [redacted] which was Apple's internal name for what became part of the Accused Products. CX-0909C. In September 2017, shortly before KBS received FDA clearance, an Apple presentation described its method of mitigating problems with the Apple Watch as "[redacted]" (although the problems and solutions seemingly do not pertain to the claim limitations), and [redacted] CX-0370C.7, .14. And in Apple's own FDA submissions, it described [redacted] CX-0393C.27, .53; *see also* CX-0439C.11.

Taken as a whole, such evidence is not exactly a smoking gun, but it does point circumstantially to copying by Apple. So like industry praise and commercial success, copying weighs against a finding of obviousness.

f. Summary

In summary, there are three categories of claims: claims 12, 16, 20, 22, and 23, as to which Apple has shown a prima facie case of obviousness over a single reference and which are embodied by the KBS DI product; claims 13 and 19, as to which Apple has shown a prima facie case of obviousness over two references and which are not embodied by any DI product; and claim 21, as to which Apple has not shown a prima facie case of obviousness. For the first category, although the prima facie case is strong—except for one element of independent claim 12, every element of every claim is found in AMON—the secondary considerations are also strong. The nature and volume of industry praise is unusual, particularly the praise published in a respected medical journal, and although the evidence of copying is not especially impressive, some degree of commercial success is evident from the KBS sales data and the testimony of ALC's chief financial officer. On balance, the secondary considerations are sufficient to rebut the prima facie case, and have not been "dispelled" by Apple. *Certain Electronic Device, Including Streaming Players, Televisions, Set Top Boxes, Remote Controllers, and Components Thereof*, Inv. No. 337-TA-1200, Comm'n Op. at 29 (Dec. 3, 2021) (public version).

For claims 13 and 19, the claim from which they depend would not have been obvious, so they would not have been obvious, either, notwithstanding the lack of nexus to secondary considerations. *See Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1365 (Fed. Cir. 2008) ("But if claim 1 is not obvious [based on secondary considerations] then claims 6–8 also cannot be obvious because they all depend from a nonobvious claim."); *In re Fritch,* 972 F.2d 1260, 1266 (Fed.Cir.1992) ("[D]ependent claims are nonobvious if the independent claims from which they depend are nonobvious."). And the lack of prima facie obviousness for claim 21 necessarily renders it non-obvious.

Therefore, Apple has shown no claim of the 941 patent to have been obvious.

3. Unenforceability as to Experimental Use

Apple presents a third defense pursuant to the experimental use exception of 35 U.S.C. § 271(e)(1). RIB at 86. Apple contends "the use of any Apple Watch products, including the IRN and/or ECG App, that were or part of research in one or more clinical trials related to the possible identification of AFib 'reasonably relates' to obtaining FDA regulatory classification or clearance, and is exempt under § 271(e)(1)." *Id.*; RRB at 72.

Apple's understanding of the law may be correct, but it is irrelevant. Apple offers no suggestion that, should a violation be found in this investigation, it would be based on exempt experimental uses of the Accused Products. *See* RIB at 86; RRB at 72 ("to the extent AliveCor attempts to rely on any subsequent studies or clinical trials"). Indeed, "AliveCor does not accuse Apple of any acts that fall under the experimental use exception." CIB at 49. Staff helpfully adds:

> As discussed in the Staff's initial post-hearing brief, the products at issue have already received FDA clearance, and are now being manufactured, imported, and sold as commercial products. *See* CX-904C (Import Stipulation) at ¶¶ 3-6; Resp. Br. at 10. Clearly, the mass production and commercialization of the accused products is not necessary to obtain regulatory approval and thus does not qualify for the experimental use exception of § 271(e)(1). *See Eli Lilly and Company v. Medtronic, Inc.*, 496 U.S. 661, 671 (1990). Apple's defense should thus be rejected.

SIB at 17.

Accordingly, experimental use has not been shown to preclude any finding of infringement in this investigation.

V. U.S. PATENT NO. 10,595,731

A. Level of Ordinary Skill in the Art

A person having ordinary skill in the art of the 731 patent at the time of invention:

> would have had either (1) a bachelor of science degree in electrical engineering, mechanical engineering, biomedical engineering, computer science, or a related discipline, with at least two years of relevant work experience designing wearable devices and/or sensors for measuring physiological signals or parameters of mammals, or (2) a medical degree and at least five years of relevant work

> experience designing wearable devices and/or sensors for measuring physiological signals or parameters of mammals. Also, relevant experience could substitute for education and vice versa for both categories of skilled artisan

Order No. 12 at 8. The parties do not challenge this definition and it is applied throughout this initial determination.

B. Claims-at-Issue

Claims 1-5, 7-10, 12, 15, and 16 of the 731 patent are at issue in this investigation, either through allegations of infringement or domestic industry technical prong, with claims 2, 4, and 7 intervening and unasserted. *See generally* CIB at 89, 95. They are reproduced below:

> 1. A smart watch to detect the presence of an arrhythmia of a user, comprising:
>
> a processing device;
>
> a photoplethysmography ("PPG") sensor operatively coupled to the processing device;
>
> an ECG sensor, comprising two or more ECG electrodes, the ECG sensor operatively coupled to the processing device;
>
> a display operatively coupled to the processing device; and
>
> a memory, operatively coupled to the processing device, the memory having instructions stored thereon that, when executed by the processing device, cause the processing device to:
>
> receive PPG data from the PPG sensor;
>
> detect, based on the PPG data, the presence of an arrhythmia;
>
> receive ECG data from the ECG sensor; and
>
> confirm the presence of the arrhythmia based on the ECG data.
>
> 2. The smart watch of claim 1, further comprising a motion sensor operatively coupled to the processing device, wherein to detect the presence of the arrhythmia, the processing device is configured to:
>
> receive motion sensor data from the motion sensor; and
>
> determine, from motion sensor data, that the user is at rest.

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.

4. The smart watch of claim 2, wherein to detect the presence of the arrhythmia, the processing device is configured to:

determine heartrate variability ("HRV") data from the PPG data; and

detect, based on the HRV data, the presence of the arrhythmia.

5. The smart watch of claim 4, wherein to detect the presence of the arrhythmia, the processing device is configured to input the HRV data into a machine learning algorithm trained to detect arrhythmias.

. . . .

7. The smart watch of claim 1, wherein the processing device is further configured to:

extract one or more features from the PPG data; and

detect, based on the one or more features, the presence of the arrhythmia.

8. The smart watch of claim 7, wherein the one or more features correspond to an HRV signal analyzed in a time domain.

9. The smart watch of claim 7, wherein the one or more features comprise a nonlinear transform of R-R ratio or R-R ratio statistics with an adaptive weighting factor.

10. The smart watch of claim 7, wherein the one or more features are features of an HRV signal analyzed geometrically.

. . . .

12. The smart watch of claim 1, wherein the processing device is further configured to generate a notification of the detected arrhythmia.

. . . .

15. The smart watch of claim 1, the processing device further configured to display an ECG rhythm strip from the ECG data.

16. The smart watch of claim 1, the processing device further to receive the ECG data from the ECG sensor in response to receiving an indication of a user action.

731 patent at cls. 1-5, 7-10, 12, 15, 16.

C. Claim Construction

As part of the *Markman* process, the following claim terms of the 731 patent were construed, either as-agreed between the parties or determined by Order No. 12:

Claim Term	Construction
"arrhythmia"	"a cardiac condition in which the electrical activity of the heart is irregular or is faster or slower than normal"
"confirm the presence of the arrhythmia based on the ECG data" / "confirming the presence of the arrhythmia based on the ECG data"	Plain and ordinary meaning; no requirement to compare the ECG data to the PPG data
Order of method steps	the step of "receiving PPG data from a PPG sensor of the smartwatch" must be performed before the step of "detecting by a processing device, based on the PPG data, the presence of an arrhythmia," and the step of "receiving ECG data from an ECG sensor of the smartwatch" must be performed before the step of "confirming the presence of the arrhythmia based on the ECG data," but there is otherwise no restriction on the order of the steps.

See Order No. 12 at 12, 22, 24. The parties identify two terms that need additional construction. These are discussed below.

1. "A smart watch to detect the presence of an arrhythmia of a user"

As with the 941 patent, the parties dispute the limiting status of the preamble of claim 1 of the 731 patent. ALC contends it is not limiting. CIB at 88. The Staff concurs. SIB at 59 ("the preamble recites no necessary structure"). Apple, on the other hand, asserts that the dependent claims' recitations of "the smart watch of claim 7," for instance, to require antecedent basis for "smart watch" in earlier claims. *See* RIB at 9; RRB at 3. Apple also argues that without the preamble the claim is left without the "essence or fundamental characteristic of the claimed invention, *i.e.*, that all these sensors are incorporated into a smartwatch or wrist-worn device." RIB at 9 (citing *Vizio, Inc. v. Int'l Trade Comm'n*, 605 F.3d 1330, 1340 (Fed. Cir. 2010)); RRB at

4.

ALC and the Staff have the more persuasive position. Claim 1 recites a complete structure, with the preamble simply repeating the requirement that the PPG sensor "detect . . . the presence of an arrhythmia." No limitation within the body of claim 1 refers or depends on the structure or attributes that "smart watch" in the preamble confers. This is in stark contrast to claims 12, 22, and 23 of the 941 patent, discussed above, where sensors were required to be in particular locations within the physical smartwatch structure. 941 patent at cls. 22, 23. Thus, antecedent basis was needed for "the smartwatch" appearing in the body of those claims, and it could come only from the preamble of claim 12. *Cochlear Bone Anchored Solutions AB v. Oticon Medical AB*, 958 F.3d 1348, 1355 (Fed. Cir. 2020); *Eaton Corp. v. Rockwell Intern. Corp.*, 323 F.3d 1332, 1339 (Fed. Cir. 2003) ("When limitations in the body of the claim rely upon and derive antecedent basis from the preamble, then the preamble may act as a necessary component of the claimed invention."). The term "the smart watch" appearing in the dependent claims of the 731 patent is simply an introductory phrase to make a connection back to independent claim 1 (*i.e.*, not a claim body limitation), and could just as easily be replaced with the term "the apparatus" throughout the claims with no loss of structure or meaning.

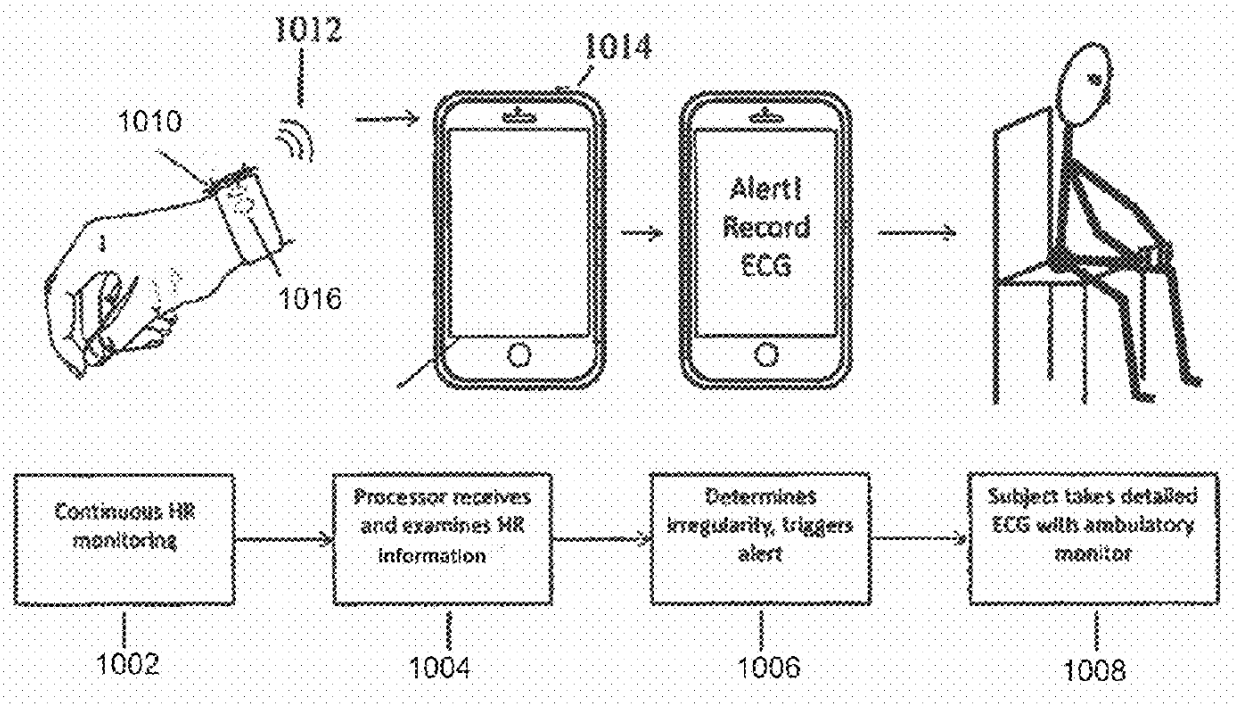
Accordingly, the preamble of claim 1 of the 731 patent is not limiting.

2. "confirm the presence of the arrhythmia"

ALC identifies the limitation "confirm the presence of the arrhythmia" as in claim 1 of the 731 patent as needing construction. CIB at 88. ALC "incorporates by reference its arguments regarding claim construction for this term from [941 patent discussion] as if the same were fully set forth herein." *Id.* ALC further notes that the 731 patent specification, albeit different from the 941 patent's, continues to include no embodiments with "simultaneous ECG and PPG recordings." CRB at 50. Rather, "[the] embodiments contemplate ECG being captured at a later time than the

PPG data that identified the possible arrhythmia, and that the indication to the user of the possible arrhythmia would 'trigger' the user to take a confirmatory ECG." *Id.* (citing Hr'g Tr. (Jafari) at 365:10-366:12). Thus, "confirm the presence of the arrhythmia" includes no requirement that "ECG and PPG be captured at simultaneous or substantially overlapping periods of time" according to ALC. *Id.* at 51. The Staff concurs. SIB at 47; SRB at 18-19. Apple does not provide an independent discussion of this construction issue, but similarly to ALC, "incorporates by reference the testimony, evidence, and analysis from [941 patent discussion]." RIB at 88; *see* RRB at 55.

"[C]onfirm the presence of the arrhythmia" in the 731 patent does not require simultaneous measurement of ECG and PPG data. The full claim language in which it appears does require that PPG or ECG data be "receive[d]," but otherwise places no restriction on when or how. *See* 731 patent at cl. 1 ("receive PPG data . . . detect . . . the presence of an arrhythmia . . . receive ECG data . . . confirm the presence of the arrhythmia."). With that said, the specification does teach ECG and PPG measurement "over substantially the same time scale or length," which is then used in "feature ranking" and "detection of atrial fibrillation." *Id.* at 19:65-20:1, 20:18-20, Fig. 6; *see also id.* at 22:3-19. But it also discloses "a person of ordinary skill in the art will recognize many variations based on the teaching described herein. The steps may be completed in a different order" (*id.* at 20:31-37; *see also* 22:50). Importantly, the 731 patent also discloses the two-step measurement technique featured prominently in the 941 patent—*i.e.*, the taking of ECG data pursuant to user prompt following another sensor's detection of a cardiac event:



Id. at Fig. 10; *see id.* at 23:3-34. The patent explains that the ECG serves to provide "a more detailed view of the heart" towards "disease diagnosis." *Id.* at 23:5-19. Clearly, in this embodiment the PPG and ECG data are both "receive[d]," but not simultaneously. This is consistent with the specification's sole use of the word "confirm"—"[f]or example, the ECG data can be classified as normal, low risk, moderate risk, high risk, and/or abnormal. The normal and abnormal designation may require health care professional evaluation, diagnosis, and/or *confirmation*." 731 patent at 15:56:60 (emphasis added).

Thus, the intrinsic evidence supports a broad reading of "confirm the presence of the arrhythmia" allowing for simultaneous and non-simultaneous reception of PPG and ECG data; there is no need to consider extrinsic evidence. *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1382 (Fed. Cir. 2008) ("A court may look to extrinsic evidence so long as the extrinsic evidence does not contradict the meaning otherwise apparent from the intrinsic record."). Accordingly, "confirm the presence of the arrhythmia" does not mean ECG sensor signals must

be recorded at the same time as PPG signals.

D. Infringement

ALC contends, "Apple directly infringes claims 1, 3, 5, 8, 9, 10, 12, 15, and 16 of the '731 patent." CIB at 89. Of these, claim 1 is independent and the rest depend therefrom. For the reasons discussed below, ALC has shown infringement of claims 1, 3, 5, 8, 9, 10, 12, 15, and 16.

1. Claim 1

For reference, claim 1 of the 731 patent requires:

1. [1a] A smart watch to detect the presence of an arrhythmia of a user, comprising:

[1b] a processing device;

[1c] a photoplethysmography ("PPG") sensor operatively coupled to the processing device;

[1d] an ECG sensor, comprising two or more ECG electrodes, the ECG sensor operatively coupled to the processing device;

[1e] a display operatively coupled to the processing device; and

[1f] 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:

[1f(i)] receive PPG data from the PPG sensor;

[1f(ii)] detect, based on the PPG data, the presence of an arrhythmia;

[1f(iii)] receive ECG data from the ECG sensor; and

[1f(iv)] confirm the presence of the arrhythmia based on the ECG data.

731 patent at cl. 1 (annotated).

The infringement disputes surrounding claim 1 of the 731 patent are similar to those for claim 12 of the 941 patent. ALC perceives Apple as only contesting "infringement with respect to claim element 1(f)(iv). Apple does not contest infringement as to the remaining elements of independent claim 1." CIB at 89. Again, ALC reasons that any other disputes from Apple have

been waived pursuant to Ground Rules 9.2 and 13.1. *Id.* And while ALC acknowledges that Apple did present an additional dispute for limitation 1f(ii) in its pre-hearing brief with respect to the HHRN feature, it argues that Apple's failure to present evidence or expert testimony at the hearing creates waiver of the issue. *Id.* at 91 n.10.

ALC's position on limitation 1f(ii) is not persuasive. It is undisputed that the argument was contained in Apple's pre-hearing brief. Thus, no violation of the ground rules occurred, the contention is not waived, and the limitation is discussed below. As to the remaining, undisputed, limitations of claim 1, they are found to be present in the Accused Products in light of the evidence and testimony provided by Dr. Jafari. CIB at 90-91 (citing Hr'g Tr. (Jafari) at 328:22-330:19, 361:5-364:5). In particular, the representative Apple Watch 6 has a PPG sensor, ECG sensor, display, and memory, all coupled to a processing device, and it is undisputed that the PPG sensor and ECG sensor send their data to the processing device. *See* CDX-0003C.16; RIB at 10-13.

a. [1f(ii)] "detect, based on the PPG data, the presence of an arrhythmia"

For this limitation, ALC contends, "the Accused Products contain instructions executable by the processor to cause the processor to detect the presence of an arrhythmia based on the PPG data." CIB at 91 (citing Hr'g Tr. (Jafari) at 362:22-364:5). In rebuttal, ALC remarks that Apple has only incorporated by reference its arguments for limitation 1(f)(ii) of the 941 patent and its own corresponding arguments should be viewed as referenced as well. *See* CRB at 49.

As noted, Apple does incorporate by reference its arguments from the 941 patent into this limitation. *See* RIB at 87; RRB at 53-54. To be clear, Apple repeats its position that "not all high heart rates, much less all high heart rates detected by HHRN, are indicative of an underlying arrhythmia, *i.e.*, they are not all caused by a 'cardiac condition.'" *Id.* at 54 (citing Hr'g Tr. (Waydo) at 753:2-4; 754:20-755:7; Hr'g Tr. (Stultz) at 1070:7-1072:20).

The Staff first remarks that the limitation is not disputed for Apple's IRN feature, only HHRN, similar to claim 12 of the 941 patent. SIB at 45. As with that patent, the Staff finds HHRN meets the limitation, stating, "[d]etecting a high heart rate while a user is at rest *is* detecting the presence of an arrhythmia." *Id.* (citing Hr'g Tr. (Jafari) at 363:6-364:5) (emphasis in original). More specifically, the Staff explains, "HHRN determines when a user's heart rate is unexpectedly high when the user is at rest." *Id.* at 45-46. According to the Staff, an unexpected high heart rate is properly considered arrhythmia under the ordered construction. *Id.* at 46 (citing Order No. 12 at 12).

The limitation is met in the Accused Products. There is no dispute that Apple's IRN feature meets the limitation, and the only difference between IRN and HHRN—as far as this limitation is concerned—is the algorithm applied to observed heart rate. When the user is at rest, IRN applies a more complicated algorithm to detect episodes of irregular rhythm (RIB at 11-12; RX-0004C.1) while HHRN simply compares heart rate to a pre-set threshold over a 10-minute period of time (RIB at 10). Apple's argument that not every 10-minute interval of an above-threshold heart rate is indicative of an arrhythmia or cardiac condition (*e.g.*, caffeine or anxiety) is irrelevant because when the condition exists the device contains the instructions in memory to detect it. *Omega Patents*, 920 F.3d at 1344.

Accordingly, the limitation is met in the Accused Products.

b. [1f(iv)] "confirm the presence of the arrhythmia based on the ECG data"

For this limitation, ALC "incorporates by reference the entirety of its argument and evidence presented in connection with the '941 patent limitation 12(f)(iii)." CIB at 92; CRB at 50-51. Apple makes similar incorporation by reference (RIB at 88; RRB at 55), and the Staff repeats its own points on the topic (SIB at 46-47; SRB at 20-21).

There is effectively no difference between this limitation and that discussed in connection with claim 12 of the 941 patent. Accordingly, and for the reasons presented above, the limitation is met in the Accused Products.

2. Other Claims

In its brief, ALC represents, "nor does Apple contest infringement as to asserted dependent claims 3, 5, 8, 9, 10, 12, 15, and 16 (except because they incorporate contested elements of independent claim 1 by virtue of their dependency)." CIB at 89. Apple does in fact not contest claims 3, 5, 8, 9, 10, 12, 15, and 16 apart from their dependency on independent claim 1. RIB at 88. Neither does the Staff. SIB at 48-51. As ALC has shown infringement of independent claim 1, discussed above, these claims are also found to be met in the Accused Products based on the undisputed evidence and testimony provided by ALC and Dr. Jafari. CIB at 92-95. In particular, Dr. Jafari testified that all elements of each claim are met, except for intervening claims 2, 4, and 7, the additional elements of which are met because their dependent claims are infringed. *See* Hr'g Tr. (Jafari) at 300:6-301:19, 318:5-319:11.

E. Domestic Industry – Technical Prong

ALC contends, "KBS, [redacted], and [redacted] products each practice claims 1, 3, 12, 15, and 16 of the '731 patent both literally and under the doctrine of equivalents." CIB at 95. Of these, claim 1 is independent and the rest depend therefrom. For the reasons discussed below, ALC has shown practice of claims 1, 3, 12, 15, and 16 by the KBS.

As a reminder, it is essentially undisputed that the [redacted] at the time of the complaint. Accordingly, it cannot support a domestic industry that "exists." *Thermoplastic Motors*, Inv. No. 337-TA-1073, Comm'n Op. at 10. And, as with the 941 patent, ALC has not adequately alleged that [redacted] Thus it too cannot be

considered to support a domestic industry that "exists." Whether practice of the claims by the [redacted] is "in the process of being established," however, is a separate matter addressed below.

1. Claim 1

Claim 1 of the 731 patent is presented above in connection with infringement. ALC identifies limitations 1(f)(ii) and 1(f)(iv) as in dispute. CIB at 95-108. Apple's initial post-hearing brief confirms that it disputes these limitations for the KBS product (RIB at 89, 90) and they are discussed below. For the remaining, undisputed limitations, they are found to be present in KBS in light of the evidence and testimony provided by Dr. Jafari. CIB at 95-96, 98. In particular, Dr. Jafari testified that each element of claim 1 is practiced by the KBS. *See* Hr'g Tr. (Jafari) at 400:16-406:13.

a. [1f(ii)] "detect, based on the PPG data, the presence of an arrhythmia"

ALC contends, "[t]he evidence shows that KBS contains instructions executable by the processor to cause the processor to detect the presence of an arrhythmia based on the PPG data." CIB at 96 (citing, *inter alia*, Hr'g Tr. (Jafari) at 400:16-406:13; CX-0266C). ALC refers to the parties' dispute over the similar limitation in claim 12 of the 941 patent (*id.* at 97; CRB at 51) and explains, "KBS uses SmartRhythm running on an Apple Watch SiP to output a 'record ECG' notification to the user (*i.e.*, indicated to the user a possibility of an arrhythmia) based on the PPG data from the PPG sensor" (CIB at 97 (citing Hr'g Tr. (Jafari) at 401:16-22, 404:5-405:9)). In response to Apple, ALC argues, "[i]f the system were able to determine with certainty that the detected discordance was or was not an arrhythmia, then there would be no reason to confirm that determination with an ECG" and "Apple's argument also relies on a misapplication of the law, which requires capability of accused devices to infringe device claims." *Id.* (citing, *inter alia*, Hr'g

Tr. (Jafari) at 404:14-405:9; CX-0266C at 910-911; *Finjan*, 626 F.3d at 1197). ALC also contends the limitation is met under the doctrine of equivalents, using the function-way-result test. *Id.* at 97-98 (citing Hr'g Tr. (Jafari) at 401:16-404:4).

As with infringement, Apple incorporates its argument from the 941 patent. RIB at 88. Apple specifies, however, "KBS's notification does not 'detect the presence of an arrhythmia,' as required by claim 1(f)(ii), but rather alerts the user that the system has identified an 'unexpected heart rate' that may be caused by many factors, including factors that are not 'cardiac conditions,' such as medication or infection." *Id.* at 89 (citing Hr'g Tr. (Stoltz) at 1070:7-23); RRB at 56. Apple adds its view that simultaneously recorded PPG and ECG data are required as well. *See* RIB at 89.

The Staff, too, largely addresses this limitation with argument taken from claim 12 of the 941 patent. SIB at 51. The Staff repeats its reasoning that "[i]f the system were able to determine with certainty that the detected discordance was or was not an arrhythmia, then there [would] be no reason to confirm that determination with an ECG" and "[t]he message displayed by the KBS when a discordance is detected *is* a notification of the possibility of an arrhythmia." *Id.* at 51-52 (emphasis in original); SRB at 19-20.

The limitation is practiced by KBS. The output of SmartRhythm is "Unexpected Heart Rate[.] Would you like to take an EKG?" RPX-0016C. As determined in connection with the 941 patent, the word "unexpected" in this context communicates a heart rate that is unexpectedly faster or slower than normal, which is a defining feature of a heart rate. This meets the agreed construction for arrhythmia. And it is largely irrelevant that not every 10-minute interval of an above-threshold heart rate is indicative of an arrhythmia or cardiac condition (*e.g.*, medication or

infection), because when the condition exists the device contains the instructions in memory to detect it. *Omega Patents*, 920 F.3d at 1344.

Accordingly, the limitation is practiced by the KBS DI Product.

b. [1f(iv)] "confirm the presence of the arrhythmia based on the ECG data"

ALC contends "confirm the presence of the arrhythmia based on the ECG data" is met in the Accused Products. It specifically states, "[a]fter an ECG recording is complete, the ECG is analyzed to determine if it is at least 30 seconds long, if it is Normal, Unclassified, if Atrial Fibrillation is present, or if it is too noisy to interpret. . . When the ECG is classified as Normal or shows the presence of Atrial Fibrillation, the KardiaBand System has confirmed the presence of the arrhythmia." CIB at 98 (citing JX-0011; CX-0266C). ALC adds that the limitation is also met under the doctrine of equivalents, using the function-way-result test. *Id.* at 99 (citing Hr'g Tr. (Jafari) at 401:16-22, 405:10-406:13); CRB at 52.

Apple opposes this on familiar grounds; namely, that simultaneous PPG and ECG data capture is required and the "results from the PPG sensor [must be] an input [] to [sic] the ECG algorithm for analysis." RIB at 89; RRB at 56. And the Staff finds the limitation met by the KBS on the same grounds as in the 941 patent, that "the [DI Products] confirm the presence of the arrhythmia by taking an analyzing an ECG to determine if the arrhythmia is present." SIB at 52; *see* SRB at 20-21.

There is effectively no difference between this limitation and that discussed in connection with claim 12 of the 941 patent. Accordingly, and for the reasons presented above, the limitation is practiced by the KBS DI Product.

2. Other Claims

Apple does not contest practice of claims 3, 12, 15, and 16 by the KBS apart from their dependency on independent claim 1. *See* RIB at 90-91. Neither does the Staff. SIB at 53. As ALC has shown practice of independent claim 1, discussed above, these claims are also practiced by the KBS DI Product based on the evidence, and particularly on the testimony of Dr. Jafari, with intervening claim 2 practiced based on Dr. Jafari's demonstratives. CIB at 99-100 (citing Hr'g Tr. (Jafari) at 401:13-406:13); *see* CDX-0003C.108. As noted, the [redacted] have not been shown to practice any claim at the time of the filing of the complaint.

3. Whether technical prong is "in the process of being established"

As to whether practice of the 731 patent by the [redacted] products is "in the process of being established," the record supports finding in the affirmative. Like with the 941 patent, the evidence shows that at the time of the complaint, ALC was taking necessary and tangible steps to practice claims 1, 3, 12, 15, and 16 of the 731 patent via the [redacted] products with a significant likelihood of success. *E.g.*, JX-025C; JX-096C; CX-0252C. As determined above, ALC's previous product, KBS, has been shown to practice all of these claims. ALC's expert, Dr. Jafari, has given persuasive testimony on the transferability of the SmartRhythm (PPG analysis) and KardiaApp (ECG collection and analysis) features—primary software features behind the KBS's practice of the claims—to other portable heart monitors in development. *See* Hr'g Tr. (Jafari) at 389:1-7, 389:21-25, 390:6-15, 392:3-393:10. ALC's technical witnesses testified to the same effect. Hr'g Tr. (Somayajula) at 198:13-19, 202:11-21, 203:19-205:8, 210:19-212:2; 217:13-15, 218:22-219:20, 221:2-222:8; Hr'g Tr. (Raghavan) at 565:4-22, 596:7-599:22 (discussing predicate devices). And the prior art in this investigation, discussed below, shows that wrist-worn computerized devices containing both PPG and ECG sensors were achievable well before the invention of the 941 patent. *See* RX-0419. There is little else in claims 1, 3, 12, 15, and 16 outside

of these hardware and software features. Apple offers no argument beyond that discussed in connection with the 941 patent, or the KBS product above. *See* RIB at 90-91; RRB at 56-58.

Accordingly, ALC has shown it is more likely than not that practice of claims 1, 3, 12, 15, and 16 by the [redacted] is "in the process of being established."

F. Validity and Other Affirmative Defenses

Apple identifies the following invalidity and unenforceability theories for the 731 patent:

Claims	Theory
1, 2, 3, 4, 5, 7, 8, 9, 10, 12, 15, 16	Invalid for lack of patent-eligible subject matter under 35 U.S.C. § 101
1, 2, 3, 4, 5, 7, 8, 9, 10, 12, 15, 16	Rendered obvious under 35 U.S.C. § 103 by AMON (RX-0419), alone or in combination with Kotzin (RX-0401) and Almen (RX-0400)
All claims	Unenforceable against Apple under experimental use exception

See generally RIB at 91-104.

As for prior art, AMON published in December 2004, Almen has a filing date of February 25, 2005 and an issue date of December 2, 2008, and Kotzin has a filing date of July 8, 2003 and a publication date of February 5, 2004. All three references are therefore prior art to the 731 patent under § 102(a).

1. Ineligible Subject Matter

As with the 941 patent, Apple contends "[c]laims 1, 3, 5, 8, 10, 12, 15, and 16 of the '731 patent are directed to the abstract ideas and mental processes which cannot constitute patent eligible subject matter." RIB at 91; RRB at 60 (incorporating argument from the 941 patent). As for claim 1, and *Alice* step one, Apple argues it "recites the bare bones, abstract idea of receiving data, detecting an irregularity in the data, receiving additional data, and confirming the

irregularity." RIB at 91. In Apple's view, the claim "recites nothing more than what medical doctors have routinely done for decades to diagnose arrhythmias." *Id.*; *see* RRB at 58-59.

As for *Alice* step two, Apple views the recited "smartwatch," "processing device," "a display," and "memory" as "all generic components that are part of a smartwatch, which itself is akin to a 'generic computer' in this context." RIB at 92. Apple adds "a PPG sensor and an ECG sensor with two or more electrodes—are conventional components known to doctors well before the '731 application existed . . . and used for arrhythmia detection before 2013." *Id.* at 93. Apple reasons, "[t]hus, independent claim 1 is directed to patent ineligible subject matter and provides no inventive concept at all." *Id.*

Apple takes a similar position on the abstract nature and/or conventional status for each of the features recited in dependent claims 3, 5, 8, 10, 12, 15, and 16. *See* RIB at 93-95; RRB at 59-61.

Apple has not met its clear and convincing burden here. There is no principled distinction between the claims of the 731 patent and those of the 941 patent under Section 101. So claim 1 is directed to ineligible subject matter through the executable instruction limitations (*i.e.*, "receive . . "detect . . . receive . . . and confirm . . . ."), but at *Alice* step two its recitations of "a photoplethysmography ("PPG") sensor," "an ECG sensor, comprising two or more ECG electrodes," and "a display," as an ordered combination all in a single apparatus, represent hardware that is non-generic and make the overall claim more than a patent on the abstract idea itself, as discussed in connection with the 941 patent. *Alice*, 573 U.S. at 225-26. That these features may otherwise be an obvious combination is irrelevant to the Section 101 inquiry, and the additional limitations of the dependent claims only reinforce the conclusion that Section 101 is satisfied.

Accordingly, none of the asserted claims of the 731 patent have been shown to be invalid for lack of patentable subject matter.

2. AMON in Combination with Almen and/or Kotzin

As with the 941 patent, Apple contends AMON "alone or in combination with Almen and/or Kotzin for minor limitations—renders obvious all of the '731 patent's Asserted Claims, including claims 1, 3, 5, 8-10, 12, [and] 15-16." RIB at 95. Apple argues again that ALC has waived the argument that AMON does not disclose heart rate variability across all three patents because of its failure to be discussed in the context of the 499 patent. RIB at 100 n.35. As before, ALC did contest claim 4, where heart rate variability first appears, in its pre-hearing brief. CPB at 134-135. Thus, no violation of the ground rules occurred, the contention is not waived, and the claim is discussed below.

a. Claim 1

Apple contends, "AMON alone or in combination with Almen and/or Kotzin discloses or at least renders obvious claim 1." RIB at 96. ALC contests only limitations 1(f)(ii) and 1(f)(iv) (CIB at 114-117; CRB at 56 (using alternate identifiers)) and Staff only discusses the latter (SIB at 58; SRB at 26). These are addressed below. As to the remaining, undisputed, limitations of claim 1, they are disclosed, as Dr. Stultz explains. RIB at 96-98 (citing Hr'g Tr. (Stultz) at 1132:21-1132:20). Specifically, AMON teaches a "wrist-worn device" that tells time, containing "processing devices," a display, an ECG with one electrode inside the device cuff and a second electrode on top, flash and random access memory, and "evaluation software." RX-0419 at 1-2, 4, 6-7, Fig. 1. Again, although AMON does not appear to use the term "PPG," it describes such a sensor located on "the top of the wrist," as well as its use for measuring pulse rate. *See id*. at 3, 5.

iv. [1(f)(ii)] "detect, based on the PPG data, the presence of an arrhythmia"

Apple argues "detect, based on the PPG data, the presence of an arrhythmia" is disclosed in AMON. RIB at 98 (citing Hr'g Tr. (Stultz) at 1115:5-21, 1134:8-21). Specifically, Apple states "an elevated heart rate detected by PPG data without a corresponding activity level increase is inherently indicative of a possible arrhythmia under AliveCor's and Dr. Jafari's application of the claims for infringement. . . . There is no basis to claim that AMON's comparison of activity level to heart rate data is not inherently indicative of 'detecting' an arrhythmia." RRB at 61-62.

In response to ALC's argument that there need be a separation between PPG detection and ECG confirmation, Apple states, "the clinical algorithm specifically contemplates at Steps 3 and 4, that when previous steps indicate a risk or high risk zone, a 'new measurement set is required,' which could include an ECG measurement." RIB at 98 (citing RX-0419 at 6). Apple adds, "any POSITA would have known that the use of such sensors for high-risk cardiac patients would necessarily include arrhythmia detection." *Id.* (citing Hr'g Tr. (Stultz) at 1120:1-1121:1).

The limitation is expressly disclosed in AMON. As discussed in connection with the 941 patent, heart rate can be provided by an optical, or PPG, sensor. RX-0419 at 6, 7. And AMON's optical sensor runs and measures pulse for 30 seconds every two minutes, whereas temperature, blood pressure, and ECG measurement (*i.e.*, not the optical sensor) are turned off most of the time. *See id.* at 7. According to the five step algorithm, as Apple alleges, that pulse value is compared to a lookup table to determine if it is out of range. *Id.* at 6. This satisfies the ordered construction for an arrhythmia, which is simply "a cardiac condition in which the electrical activity of the heart is irregular or is faster or slower than normal." Order No. 12.

Despite this evidence, ALC claims AMON "makes no mention of . . . any particular condition the system is designed to detect." CIB at 114-115. This is untenable in light of AMON's

use of threshold lookup tables for pulse (bpm) and the broad construction of "arrhythmia." RX-0419 at Table I. ALC also views Dr. Stultz as admitting that AMON does not "perform[] any detection of any medical condition on its own." *Id.* at 115 (citing Hr'g Tr. (Stultz) at 1161:6-9); CRB at 56. While the quotation is accurate—"Q. Okay. The AMON paper also doesn't disclose a wrist monitoring device that performs any detection of any medical condition on its own, right? A. I agree with that statement."—it does not overcome the clear disclosure in AMON that an optical sensor measures pulse and evaluates if it is faster or slower than expected via a lookup table.

Accordingly, the limitation is disclosed in AMON.

v. [1(f)(iv)] "confirm the presence of the arrhythmia based on the ECG data"

For "confirm the presence of the arrhythmia based on the ECG data," Apple largely refers to its discussion of the same limitation in claim 12 of the 941 patent. RIB at 99.; RRB at 62. ALC does not explicitly incorporate its previous discussion, but restates the same points. CIB at 115-117. The Staff offers no new rationales either. SIB at 58; SRB at 26.

Accordingly, for the reasons discussed in connection with claim 12 of the 941 patent, this limitation is disclosed in AMON.

b. Claims 2, 7, and 16

With respect to intervening claims 2 and 7 and claim 16, Apple contends that AMON discloses the limitations of each. RIB at 99-101, 104. In support of claims 2 and 16, Apple refers to its discussions of claims 12 and 16 of the 941 patent (*see id.* at 99, 104), and for claim 7, Apple relies on the testimony of Dr. Stultz and AMON's detection of out-of-range parameters (*see id.* at 101). ALC does not address or contest Apple's theory for claims 2 and 7, and disputes claim 16

only on the ground that it depends from claim 1. *See* CIB at 114-122; CRB at 55-61. The Staff does not challenge claims 2, 7, or 16. SIB at 59-60.

Apple has shown that all the elements of claim 1 are disclosed in AMON, and the elements added by claims 2, 7, and 16 are also disclosed based on the evidence and by the testimony provided by Dr. Stultz. RIB at 99-101, 104 (citing Hr'g Tr. (Stultz) at 1135:2-1136:1, 1139:9-25, 1142:10-19). In particular, AMON discloses a motion sensor coupled to a processing device, where the processing device receives motion sensor data to determine that the user is at rest, as in claim 2 (RX-0419 at 5, Fig. 7 ("acceleration sensor" transmitting data to the processing devices for determining a "resting" activity level)), detects arrhythmia by extraction of pulse rate from PPG data, as in claim 7 (*id*. at 3 (describing measurement of pulse rate by "comparing the changes of each wavelength during one pulsation")), and receives ECG data from the ECG sensor in response to receiving an indication of a user action, as in claim 16 (*id*. at 4 ("the patient must touch the [right arm electrode]" for the ECG to be measured)).

c. Claim 3

Claim 3 recites, "[t]he 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." 731 patent at cl. 3. Apple argues the limitation is disclosed through, as Dr. Stultz characterized them, threshold "learning stages," while also emphasizing that the claim allows for any kind of learning algorithm, simple or otherwise. RIB at 99 (citing Hr'g Tr. (Stultz) at 1136:8-1137:22; RX-0419 at 3-4); RRB at 62-63. Apple cites no other reference in support of its obviousness case. *See* RIB at 99.

The limitation is not disclosed in AMON. The "simple" learning algorithm referenced by Apple corresponds to the ECG sensor and its ability to recognize QRS widths, RR distances, and QT intervals. RX-0419 at 4. Not only is this not the PPG sensor, but it is not an algorithm for

detecting arrhythmias. It is an algorithm for determining characteristics of the wave (because ECG rhythm strips are complicated), with those characteristics then needing subsequent analysis to detect the cardiac condition (*e.g.*, compared to a lookup table (RX-0419 at Table I)). In other words, there is a difference between determining what the signals are and determining whether the signals are a problem. This example in AMON is directed to the former. Claim 3 is directed to the latter.

For AMON's light sensor (*i.e.*, the "PPG data" of claim 3) all that is disclosed is that "[t]he pulse oximeter probe and signal processing algorithms have been developed and manufactured exclusively for the AMON project by SPO Medical Equipment Ltd., Israel based on a specification by MDirect." RX-0419 at 4. Again, not only is machine learning not disclosed for those custom-made algorithms, but even if present they would not be for the purpose of detecting arrhythmia. That is, again, left to AMON's lookup table (RX-0419 at Table I) which is loaded with two sets of pre-set values (a.k.a. risk thresholds):

TABLE I
L1 AND H1 REPRESENT DEVIANT ZONE, L2 AND H2 RISK ZONE, AND L3 AND H3 HIGH-RISK ZONE

vital sign	L3	L2	L1	Normal	H1	H2	H3
Systolic (mmHg)	50-59	60-79	80-99	100-130	131-160	161-200	201-300
Diastolic (mmHg)	40-44	45-49	50-59	60-85	86-90	91-110	111-140
SpO2 (%)	65-79	80-91	92-94	95-100			1001
Pulse (per minute)	40-44	45-49	50-59	60-100	101-120	121-180	181-250
QRS duration (s)	0.01-0.03			0.04-0.12			0.121-0.35

> [M]easurement results are assigned to one of five zones—normal, deviant (abnormal values), risk, high risk, and error.
>
> . . . .
>
> The wrist device has two customizable sets of parameters, which are set by the health-care provider when handing the device over to the patient. The parameter values can be changed by the user's physician, the care provider, or in real time by the medical operator in the TMC via the cellular link.

> The two sets represent a nonaerobic state and an aerobic state corresponding to the level of user activity. The parameters are set according to age, gender, fitness, and medical history. The selection of the active set is performed by user command or automatically by the wrist device when activity is detected.

RX-0419 at 6. There is no disclosure here of automated adjustment to the parameter sets (*i.e.*, thresholds), which is the underpinning of any machine learning algorithm. Thus, the limitation is not disclosed, and Apple does not argue it would have otherwise been obvious, in view of any other reference or the knowledge of a skilled artisan. *See* RIB at 99.

Accordingly, claim 3 is not disclosed by AMON, nor would it have been an obvious modification of it.

d. Claims 4 and 5

Intervening claim 4 recites, "[t]he smart watch of claim 2, wherein to detect the presence of the arrhythmia, the processing device is configured to: determine heartrate variability ('HRV') data from the PPG data; and detect, based on the HRV data, the presence of the arrhythmia." 731 patent at cl. 4. For this claim, Apple argues it is disclosed in AMON for the same reasons explained in connection with claim 13 of the 941 patent. RIB at 100. Claim 5 recites, "[t]he smart watch of claim 4, wherein to detect the presence of the arrhythmia, the processing device is configured to input the HRV data into a machine learning algorithm trained to detect arrhythmias." 731 patent at cl. 5. Apple contends the limitation is disclosed by AMON (RIB at 100 ("As Dr. Stultz testified, AMON discloses claim 5.")), and refers back to its perceived disclosure of a machine learning algorithm in "whether the detected vital signs (*e.g.*, the PPG data from the SpO_2 sensor) are irregular by using data about activity level, age, gender, fitness, and medical history to set high risk and normal thresholds." RIB at 100 (citing RX-0419 at 3, 6).

As determined above, the concept of determining heart rate variability data, although not disclosed in AMON, would have been obvious in view of Almen and its motivation to combine.

But also as determined above, AMON does not disclose adjusting its own risk thresholds or any other machine learning algorithm. Adjusting risk thresholds is instead done "by the health-care provider when handing the device over to the patient. The parameter values can be changed by the user's physician, the care provider, or in real time by the medical operator in the TMC via the cellular link." RX-0419 at 6.

Apple continues, "AMON also discloses a machine learning algorithm for detecting the R-R distances . . . for use in determining if vital signs are irregular." RIB at 100. To be sure, AMON discloses continuous threshold adjustment (*i.e.*, machine learning) for identification of the QRS wave. It states, "[d]uring the detection process, the current integrated moving window is compared with the upper threshold. If this threshold is exceeded, an R wave onset is assumed. . . These threshold values are continually adjusted with each new QRS so as to compensate for variations in ECG baseline." RX-0419 at 4. But once determined, that QRS width is, again, compared to a simple lookup table of pre-set values. *Id.* at Table I ("QRS duration (s)"). So the actual detection of arrhythmia by "inputting" or otherwise processing HRV data does not involve machine learning, and the limitation is not disclosed. Dr. Stultz's opinion that AMON discloses a machine learning algorithm is therefore beside the point. *See* Hr'g Tr. (Stultz) at 1136:8-1137:22. And although Apple contends that "AMON discloses *or renders obvious* all the additional limitations of claim 5 of the '731 patent" (RIB at 100), it offers no discussion of obviousness in either of its briefs (*see id.*; RRB at 62-63).

Accordingly, claim 5 has not been shown to be disclosed or rendered obvious.

e. Claim 8

Claim 8 recites, "[t]he smart watch of claim 7, wherein the one or more features correspond to an HRV signal analyzed in a time domain." 731 patent at cl. 8. Here, Apple contends, "Dr. Stultz testified that the additional limitation of claim 8, an 'HRV signal analyzed in a time domain,'

was simply a well-known method of analyzing heart rate variability in 2013." RIB at 101 (citing Hr'g Tr. (Stultz) at 1140:1-25; 731 patent at 8:64-9:2); RRB at 63 (citing Hr'g Tr. (Stultz) at 1139:3-1141:7). Apple also suggests that analysis of heart rate variability is disclosed in AMON (incorrectly, as determined above), and that it would have been obvious through Almen's teaching: "'analysis of 24-hour HRV typically shows a nocturnal increase in the standard deviation of heartbeat intervals.'" RIB at 102 (citing RX-0400 at 12:66-13:10; Hr'g Tr. (Stultz) at 1141:1-7).

Apple has presented a prima facie case that claim 8 would have been obvious. Claim 1 and intervening claim 7 are fully disclosed by AMON, the heart rate variability element added by claim 8 would have been obvious in view of Almen, as discussed above in connection with claim 13 of the 941 patent, and Dr. Efimov seems to admit that Almen discloses analyzing heart rate variability with respect to time. Hr'g Tr. (Efimov) at 1275:9-24 ("What [Almen] states, essentially, is that measurements are done during sleep as shown on the right is heart rate, as you see in the beginning the heart rate is high in the awake state, and then goes down when you sleep. And then during sleep apnea, you have those large oscillations of heart rate . . .. So essentially, this device measures different time intervals.").

In opposition, ALC repeats its argument that AMON, Almen, and the 941 patent (impliedly, the 731 patent as well) are non-analogous. CIB at 120. As determined above, this is not persuasive; they are all wrist-worn heart-monitoring devices. ALC also claims that whatever modifications to AMON's device and its SpO_2 sensor would be necessary, they constitute "more complicated analysis" and would not be done on the wrist-worn device but at AMON's remote TMC. CRB at 58-59. This is not persuasive, either. Once AMON is modified to calculate heart rate variability from the SpO_2 sensor's pulse rate (as taught by Almen and discussed in connection with claim 13 of the 941 patent), a comparison to thresholds would likely occur on the device

itself—essentially another line in AMON's Table I. And Dr. Stultz offers unrebutted testimony that an HRV signal analyzed in the time domain was a routine and ordinary option. Hr'g Tr. (Stultz) at 1140:1-9; *see* Hr'g Tr. (Efimov) at 1274:17-1275:24.

Accordingly, Apple has made out a prima facie case that claim 8 would have been obvious over AMON in view of Almen.

f. Claim 9

Claim 9 recites, "[t]he smart watch of claim 7, wherein the one or more features comprise a nonlinear transform of R-R ratio or R-R ratio statistics with an adaptive weighting factor." 731 patent at cl. 9. Apple states, "Dr. Stultz also testified that the additional limitation of claim 9, a 'non-linear transform of RR ratio or R-R ratio statistics with an adaptive weighting factor,' was simply a well-known method of analyzing heart rate variability in 2013." RIB at 102 (citing Hr'g Tr. (Stultz) at 1140:1-25; RX-0551 at 2-3).

Apple argues that "AMON, alone or in combination with Almen," renders claim 9 obvious. RIB at 102. Claim 7, from which claim 9 depends, is not limited to heart rate variability, and AMON does not disclose measuring that parameter. So AMON alone does not disclose this element. And although Almen discloses measurement of HRV, it does not disclose doing so using a non-linear transform with an adaptive weighting factor. Even accepting Dr. Stultz's opinion that the claimed technique was well-known, the one reference Apple cites as disclosing the transform discusses it as applying to ECG data, not PPG data, as the claim requires. *See* RIB at 102 (citing RX-0551. 3 (describing measurement using "electrocardiography")). And although that reference arguably provides a motivation to combine, that motivation applies to ECG data, not PPG data. *See* RX-0551.0007 (characterizing the technique as "computationally less difficult" and "a good and reliable surrogate" for the technique to which it is compared). In essence, Apple's case for

the obviousness of claim 9 relies on three references, with no identified disclosure of the added element applied to PPG data.

Accordingly, claim 9 has not been shown to be disclosed or rendered obvious.

g. Claim 10

Claim 10 recites, "[t]he smart watch of claim 7, wherein the one or more features are features of an HRV signal analyzed geometrically." 731 patent at cl. 10. Apple states, "Dr. Stultz further testified that the additional limitation of claim 10, 'features of an HRV signal analyzed geometrically,' was simply a well-known method of analyzing heart rate variability in 2013." RIB at 102-103 (citing Hr'g Tr. (Stultz) at 1140:1-25; RX-0563 at 1-3, 5). Apple adds that Table IV within AMON "discloses a sample density distribution of pulse rates . . . which could easily be HRV as disclosed in Almen. . .. For example, a density distribution of 64% of the heart rates calculated from the SpO_2 sensor were distributed within 5 beats/min, 83% were within 10 beats/min, and 89% were within 15 beats/min." *Id.* at 103 (citing RX-0419 at Table IV; RX-0400 at 1:21-24, 7:26-35, 2:52-58, 8:43-61).

Claim 10 has not been shown to have been obvious. Claim 7, from which claim 10 depends, is not limited to heart rate variability, and AMON does not disclose measuring that parameter. Almen does, with a motivation to combine with AMON, as noted, and Apple cites a third reference disclosing Poincaré plots for HRV detection. *See* RIB at 103 (citing RX-0563). As with claim 9, however, the disclosed Poincaré plots are generated from ECG data. *See* RX-0563.1. Moreover, Apple's contention that Table IV in AMON "discloses a sample density distribution of pulse rates" is irrelevant, because the data is not analyzed geometrically, it is simply a summary of pulse measurements. RIB at 103; RX-0419 at Table IV. Like with claim 9, Apple's case for the obviousness of claim 10 relies on three references, with no identified disclosure of the added element applied to PPG data.

Accordingly, claim 10 has not been shown to be disclosed or rendered obvious.

h. Claim 12

Claim 12 recites, "[t]he smart watch of claim 1, wherein the processing device is further configured to generate a notification of the detected arrhythmia." 731 patent at cl. 12. Apple contends, as in claim 12 of the 941 patent, that AMON discloses a message or notification to users when their measured levels are out of range:

> Dr. Stultz testified that AMON discloses that if a vital parameter like pulse is irregular (outside the normal range), then a notification is generated. Tr. (Stultz) at 1141:8-20. Specifically, AMON's clinical algorithm also notes that in steps 1 and 3 that if the pulse is irregular, then a notification is generated to take more measurements. RX-419.3, 6, 10, Abstract (AMON). And "it specifically states in all cases that the patient is informed as to their own status and that of the device." Tr. (Stultz) at 1141:8-20. Dr. Efimov provided no testimony that this claim was not met by AMON at the hearing.

RIB at 103. According to Apple, Dr. Stultz considers the limitation inherent in AMON's disclosures, even without the word "arrhythmia." RRB at 63 (citing Hr'g Tr. (Stultz) at 1120-1-2).

Largely for the same reasons presented above in connection with claim 12 of the 941 patent, claim 12 of the 731 patent would have been obvious as a way of actually implementing the device disclosed in AMON. The optical (PPG) sensor operates every two minutes (RX-0419 at 7) to measure pulse (*id*. at 3), and the measurements are compared to a range of values to "determine if and what new measurement set," including ECG, "is required" (*id*. at 6). At "each step, a result is displayed," although AMON provides no guidance on the specific content of the displayed "result." *Id*. at 6. It surely would have been an obvious method of implementation to display the result of the pulse measurement, which (if in a "risk or high-risk zone") qualifies as a notification of a detected arrhythmia.

ALC argues "AMON does not discuss arrhythmias at all." CIB at 121. But as explained above, an abnormal heart parameter, identified by use of AMON's risk threshold lookup table, meets the parties' agreed construction of the term. ALC also argues that a POSITA would not have considered modifying the device to detect arrhythmias because the ECG signal was too poor. *See id*. But the arrhythmia is "detected" (as opposed to "confirmed") by the PPG sensor combined with a look-up table, not by the ECG sensor. *See* RX-0419 at 6. The Staff states the limitation is not met but offers no explanation. SIB at 59.

Accordingly, claim 12 is disclosed in AMON.

i. Claim 15

Claim 15 recites, "[t]he smart watch of claim 1, the processing device further configured to display an ECG rhythm strip from the ECG data." 731 patent at cl. 15. For this claim, Apple largely refers to its discussion of claim 21 in the 941 patent. *See* RIB at 104; RRB at 64. ALC follows suit. *See* CIB at 121; CRB at 61. The Staff avers that the limitation is absent, without elaboration. *See* SIB at 59-60.

For the same reasons presented above in connection with claim 21 of the 941 patent, claim 15 of the 731 patent is neither disclosed in AMON nor an obvious modification to it.

j. Summary

To summarize, asserted claims 1, 12, and 16 are disclosed in AMON, Apple has shown a prima facie case of obviousness of claim 8 over AMON in view of Almen, and Apple has not shown either disclosure or a prima facie case of obviousness of claims 3, 5, 9, 10, and 15. Because anticipation is "the epitome of obviousness" (*Realtime Data*, 912 F.3d at 1373), claims 1, 12, and 16 are invalid, without regard to secondary considerations of non-obviousness. And because claims 3, 5, 9, 10, and 15 have not been shown to be prima facie obvious, they are not invalid, also without regard to secondary considerations. As to claim 8, it is not embodied in any DI Product,

so ALC is not entitled to a presumption of nexus between the claim and secondary considerations, and it otherwise makes only a cursory effort to prove such a nexus. *See* CIB at 122. Therefore, no secondary considerations weigh against that claim's obviousness, and it depends from claims 1 and 7, which are invalid for obviousness.

Accordingly, claims 1, 8, 12, and 16 have been shown to have been obvious in view of AMON alone or AMON in combination with Almen.

3. Unenforceability as to Experimental Use

As with the 941 patent, ALC's infringement theory does not implicate any Apple experimental activity. *See* RIB at 104. Accordingly, experimental use has not been shown to preclude any finding of infringement in this investigation.

VI. U.S. PATENT NO. 9,572,499

A. Level of Ordinary Skill in the Art

A person having ordinary skill in the art of the 499 patent at the time of invention:

> would have had either (1) a bachelor of science degree in electrical engineering, mechanical engineering, biomedical engineering, computer science, or a related discipline, with at least two years of relevant work experience designing wearable devices and/or sensors for measuring physiological signals or parameters of mammals, or (2) a medical degree and at least five years of relevant work experience designing wearable devices and/or sensors for measuring physiological signals or parameters of mammals. Also, relevant experience could substitute for education and vice versa for both categories of skilled artisan

Order No. 12 at 8. The parties do not challenge this definition, and it is applied throughout this initial determination.

B. Claims-at-Issue

Claims 16 and 17 of the 499 patent are at issue in this investigation, either through allegations of infringement or domestic industry technical prong, as well as claim 11, from which claims 16 and 17 depend. *See generally* CIB at 122, 134. These claims are reproduced below:

> 11. A system for determining the presence of an arrhythmia of a first user, comprising
>
> a heart rate sensor coupled to said first user;
>
> a mobile computing device comprising a processor, wherein said mobile computing device is coupled to said heart rate sensor, and wherein said mobile computing device is configured to sense an electrocardiogram of said first user; and
>
> a motion sensor
>
> a non-transitory computer readable medium encoded with a computer program including instructions executable by said processor to cause said processor to receive a heart rate of said first user from said heart rate sensor, sense an activity level of said first user from said motion sensor, determine a heart rate variability of said first user based on said heart rate of said first user, compare [said] activity level of said first user to said heart rate variability of said first user, and alert said first user to record an electrocardiogram using said mobile computing device.
>
> . . . .
>
> 16. The system of claim 11, wherein said mobile computing device comprises a smartwatch.
>
> . . . .
>
> 17. The system of claim 11, wherein said computer program further causes said processor to determine a presence of said arrhythmia using a machine learning algorithm.

499 patent at cls. 11, 16, 17; *see* JX-0001 at Certificate of Correction.

C. Claim Construction

As part of the *Markman* process, the following claim terms of the 499 patent were construed, either as-agreed between the parties or determined by Order No. 12:

Claim Term	Construction
"arrhythmia"	"a cardiac condition in which the electrical activity of the heart is irregular or is faster or slower than normal"
Preambles of claim 1, 11	limiting
"alerting said first user to sense an electrocardiogram" / "alert"	Plain and ordinary meaning; "alert" is not limited to a message

"heart rate sensor"	Plain and ordinary meaning; heart rate sensors that sense heart rate both directly and indirectly
Order of method steps	the step of "sensing an activity level of said first user with a motion sensor" need not be performed after the step of "determining, using said mobile device, a heart rate variability of said first user based on said heart rate of said first user."

See Order No. 12 at 12, 15, 17, 18, 20. Although there is at least one claim construction dispute within the parties' discussions of infringement and domestic industry (*see, e.g.*, CIB at 127) the issue is already addressed above.

D. Infringement

ALC contends, "Apple directly infringes claims 16 and 17 of the '499 Patent." CIB at 122. Again, claim 11 is independent and claims 16 and 17 depend from it, so if claim 11 is not infringed, neither are claims 16 or 17. For the reasons discussed below, ALC has not shown infringement of claims 16 or 17.

1. Claim 11

For reference, claim 11 of the 499 patent requires:

> 11. [11(a)] A system for determining the presence of an arrhythmia of a first user, comprising
>
> [11(b)] a heart rate sensor coupled to said first user;
>
> [11(c)] a mobile computing device comprising a processor, wherein said mobile computing device is coupled to said heart rate sensor, and wherein said mobile computing device is configured to sense an electrocardiogram of said first user; and
>
> [11(d)] a motion sensor
>
> [11(e)] a non-transitory computer readable medium encoded with a computer program including instructions executable by said processor to cause said processor to
>
> [11(e)(i)] receive a heart rate of said first user from said heart rate sensor,

> [11(e)(ii)] sense an activity level of said first user from said motion sensor,
>
> [11(e)(iii)] determine a heart rate variability of said first user based on said heart rate of said first user,
>
> [11(e)(iv)] compare said activity level of said first user to said heart rate variability of said first user,
>
> [11(e)(v)] and alert said first user to record an electrocardiogram using said mobile computing device.

499 patent at cl. 11 (annotated); *see* JX-0001.40 (certificate of correction).

Only a few limitations are disputed in the Accused Products. ALC understands that, "Apple only contests infringement with respect to claim elements 11(e)(iv) and 11(e)(v) from the independent claim." CIB at 123. So ALC reasons that any other disputes from Apple have been waived pursuant to Ground Rules 9.2 and 13.1. *Id.* ALC's representations are consistent with the disputes identified in Apple's post-hearing brief. RIB at 105-112. The Staff, similarly, addresses no limitations in claim 11 other than 11(e)(iv) and 11(e)(v). SIB at 63-65. For those remaining limitations which are not in dispute, the Accused Products have been shown to meet them as alleged. *See* CIB at 123-125. In particular, Dr. Jafari testified that all elements of each claim are met. *See* Hr'g Tr. (Jafari) at 371:4-372:21.

a. [11e(iv)] "compare [said] activity level of said first user to said heart rate variability of said first user"

For this limitation, ALC incorporates its arguments from claim 12 of the 941 patent. CIB at 125, 127. ALC further explains, "the IRN feature analyzes HRV in determining whether or not there are irregular rhythms suggestive of AFib" by [redacted] " *Id.* at 126 (citing Hr'g Tr. (Jafari) at 374:11-24). ALC concludes that the IRN feature satisfies the limitation "because a processor literally [redacted]

[redacted]." *Id.* at 127 (citing Hr'g Tr. (Jafari) at 374:21-24).

ALC views Apple's non-infringement argument as identical to that offered against claim 12 of the 941 patent. *See* CIB at 126-127; CRB at 62. Accordingly, ALC counters, "[t]here is no requirement in the claim that motion sensor data be sensed at the same time as HRV is determined from the PPG data, nor is there any requirement in the claim that motion sensor data inform the basis for a determination regarding the detection of an arrhythmia (such as by way of input into the IRN classification algorithm)." CIB at 127. ALC adds, "[b]y contrast, the '499 patent's specification provides that the aim of 'comparing measured heart rate changes with measured activity changes' is to 'minimize[] false alarms'. JX-001 at 25:22-25. Nothing more is required, and Dr. Picard's insistence to the contrary is unsupported by the '499 patent." *Id.*

Apple argues, "[redacted]." RIB at 105-106. Apple then incorporates its discussion of claim 12 of the 941 patent to explain why this results in non-infringement. *Id.* at 106; *see* RRB at 65. Apple adds, "Apple's source code substantiates that [redacted]" and "[a]s Dr. Picard confirmed, there are '[redacted].'" RRB at 65 (citing JX-0237C at 253:1-256:23; Hr'g Tr. (Picard) at 881:7-11).

The Staff finds the limitation met. Staff refers to the 499 patent's teaching that the activity level and heart rate variability comparison is simply used to minimize false alarms (SIB at 63-64 (citing 499 patent at 25:17-25)) and finds the products "[redacted]

CONFIDENTIAL MATERIAL OMITTED

[redacted]

[redacted]" (*id.* at 64 (citing Hr'g Tr. (Jafari) at 372:22-374:24)).

The limitation is met in the Accused Products. Apple readily acknowledges that IRN will only monitor heart rate, compute HRV, and employ its AFib screening algorithms when the [redacted]." *See* RIB at 12. [redacted]. Hr'g Tr. (Waydo) at 762:25-763:4 [redacted]). Thus, at least some of the time, the motion sensor is associating measured heart rate and HRV values with a particular period of low activity. This association is exactly as the 499 patent describes the "compar[ing]" process, in an excerpt cited by both ALC and Apple:

> An advisory condition for recording an ECG may occur due to, for example, large continuing fluctuations in heart rate. An advisory condition for recording an ECG can also occur when a measured heart rate increases rapidly without a corresponding increase in activity monitored by, for example, an accelerometer. By comparing measured heart rate changes with measured activity changes, the presently disclosed software or "app" minimizes false alarms . . ..

499 patent at 25:17-25; *see* CIB at 126 (citing 499 patent at 25:17-25); RIB at 105 (citing 499 patent at 25:19-25).

It is true that the comparison is simplistic. [redacted]. *See* CX-0048C.87, .93 ([redacted]). But even such a binary comparison qualifies as a comparison. Apple's contention that "there are 'no instructions that bring together the heart rate or heart rate variability parameter and the motion'" (RRB at 65 (citing Hr'g Tr. (Picard) at 881:7-11) is plainly contradicted by Apple's graphical summary of IRN's "instructions," which show motion and heart rate variability considered together:

RX-0835C.3; *see* CX-0048C.93 ( ).

Accordingly, the limitation is met in the Accused Products.

b. [11e(v)] "alert said first user to record an electrocardiogram using said mobile computing device"

With respect to the claimed "alert," ALC contends it is met literally or under the doctrine of equivalents, "because Apple's IRN feature serves the aim of alerting the user to take a subsequent ECG after being notified regarding the detection of the known serious arrhythmia AFib." CIB at 128. ALC references the claim construction order stating, "'the claims are directed to determining whether or not an ECG is appropriate, and then "alerting" the user to that fact.'" (*id.* (citing Order No. 12 at 15-16; 499 patent at 25:17-25)), and then reasons "[t]he accused IRN feature readily satisfies limitation 11(e)(v) because the IRN's indication provided to a user concerning the background detection of AFib constitutes an advisory condition that triggers an appropriate/opportune moment to capture an ECG to confirm the AFib" (*id.* (citng Hr'g Tr. (Jafari)

at 375:6-13). ALC emphasizes that the context of the message returned by IRN is important and that context is demonstrated by:

> (1) externally-facing evidence that Apple provides or endorses concerning the nature of the IRN alert and that users take an ECG upon receiving such alert, and (2) internally-facing evidence that Apple has [redacted]

Id. at 128-129; *see id.* at 129-130 (citing, *inter alia*, CX-0048C; CX-0051C; CX-0073; CX-0623; CX-0626), 130-133 (citing, *inter alia*, CX-0067C; CX-0914C; CX-0026C; CX-0080; CX-0081C; CX-0914C; CX-0054C; CX-0913C); CRB at 66 (internal documents allegedly show the [redacted]

To the extent the limitation is not present literally in the Accused Products, ALC argues infringement under doctrine of equivalents, using the function-way-result approach. CIB at 133. ALC states:

> That is, the IRN alert provides substantially the same function (*e.g.*, to provide a triggering message that something is wrong" and "better observations" are needed via the ECG, Tr. (Jafari) at 376:8-12)) in substantially the same way (*e.g.*, the generation of a "trigger" message to prompt the user to take immediate action, Tr. (Jafari) at 376:17-21)), to achieve substantially the same result (*e.g.*, the user takes the ECG in response to the trigger to "confirm" "verify" or "augment our knowledge of the condition," Tr. (Jafari) at 376:22-377:1)).

Id.

In rebuttal to Apple and the Staff, ALC argues that the prior *Markman* order made clear "alert" was "'not limited to a message,'" and "the claims 'are directed to determining whether or not an ECG is appropriate, and then 'alerting' the user to that fact.'" CRB at 63 (citing Order No. 12). ALC finds it immaterial that the message's actual instruction is "'talk to [his or her] doctor'" because "the significant/unexpected 'pop-up' to the user on the watch's face constitutes the 'advisory condition' that indicates that a user should take an ECG, as described in the '499 patent

specification." *Id.* (citing 499 patent at 25:17-25; JX-0221C (Waydo) at 286:3-14); *id.* at 65 (referring to "advisory condition"). ALC continues:

> However, telling a user to talk to [his or her] doctor is not mutually exclusive from taking an ECG upon receipt of an IRN alert, nor has Apple identified any evidence that the IRN alert message (or anything else for that matter) discourages or dissuades a user from taking an ECG upon receipt of an IRN alert. Indeed, the evidence overwhelmingly demonstrates that Apple itself directly encourages users to take an ECG following receipt of an IRN alert.

Id. at 64. Overall, ALC posits, "[t]here is no question that the IRN alert itself alerts the user that 'an ECG is appropriate,' which the ALJ's claim construction order provides is what the '499 patent claims are directed to" and "Apple's instructions regarding the 'triggering' nature of the IRN alert message have been not only received but well understood by Apple's user base." *Id.* at 64-65 (citing CX-0692.16; CX-0623; CX-0626).

Apple opposes. Apple views the limitation as requiring, under a plain and ordinary meaning, two distinct features: "that the system provides a 'trigger message' or somehow prompts the user—*e.g.*, by displaying a 'Take ECG' message—to record an ECG by the Apple Watch"; and "an alert to the user to record an ECG each time there is a comparison of activity level to heart rate variability, and regardless of whether the comparison identifies an 'irregularity.'" RIB at 106-107 (citing Hr'g Tr. (Picard) at 904:1-17; JX-0223C (Albert) at 42:6-43:20, 44:7-21, 45:1-8).

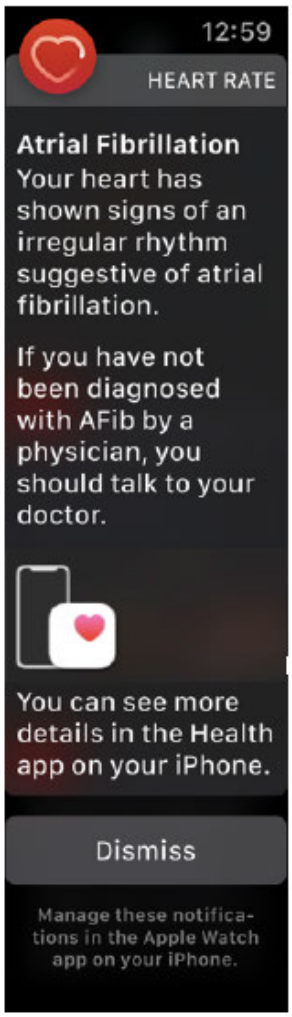
As to the first requirement, Apple cautions that its support website, press releases, and specifications are not instructions on the Apple Watch itself. SIB at 107, 109 (citing, *inter alia*, Hr'g Tr. (Jafari) at 476:18-477:3); *see id.* at 110-111 (arguing [redacted], 112 (tracked usage statistics have nothing to do with operation of the Apps); RRB at 66-67. And, if considered, it argues its Instructions for Use (IFU) "fail to instruct users to take an ECG right after receiving an IRN," and none of its "onboarding materials, press releases, or support web pages" claim that potential arrhythmias are confirmable by the ECG app. RIB at 109-110 (citing

RX-0051C). According to Apple's technical witness, its confidence in the accuracy of its IRN notification is so high that if it triggers, "we would really like their next step to be to discuss that with their physician" [redacted] *See* RIB at 111 (citing Hr'g Tr. (Waydo) at 859:18-860:18). As for the specific support page relied on by ALC, Apple highlights its express text that a user can take an ECG "at any time, including randomly during the day, when they feel unwell or symptomatic, or when their doctor recommends it" (*id.* at 110 (citing Hr'g Tr. (Waydo) at 846:1-15)). Apple also reminds that within the actual message displayed, "[y]our heart has shown signs of an irregular rhythm suggestive of atrial fibrillation . . . if you have not been diagnosed with AFib by a physician, you should talk to your doctor," there is no mention of ECG at all. *See id.* at 108 (citing Hr'g Tr. (Picard) at 9[0]5:2-16); RRB at 67.

Regarding the second requirement, Apple simply contends it is not met because there is no comparison whatsoever between activity level and HRV, as described in the previous limitation. RIB at 108. And regarding doctrine of equivalents, Apple argues there is a substantial difference between "take an ECG" and "talk to your doctor" messaging. *Id.* at 112; RRB at 67.

The Staff also finds the limitation not met. Staff argues there is no literal infringement, based simply on the text of the IRN alert message, which refers to talking with a doctor as opposed to taking an ECG. SIB at 64 (citing, *inter alia*, RX-0179C.72); SRB at 28. As for doctrine of equivalents, Staff agrees that alerting a user to talk with a doctor is "very different than alerting the user to capture an ECG" and "likely to achieve a substantially different result than alerting the user to take an ECG." SIB at 65.

The limitation is not met literally in the Accused Products. ALC does not cite the actual language of the message displayed to the user after an arrhythmia has been detected by IRN. *See* CIB at 127-129. That message, in its entirety, is below:



RX-0179C.0072. This is not an alert for the user to take an ECG; it is an alert for the user to see their doctor. No further testing of any kind is suggested, and ALC's "externally facing" and "internally facing" evidence is irrelevant in light of this plain language. ALC's expert, Dr. Jafari, acknowledged that this message would send a user to the doctor, and that the desire to take an ECG would need to come from the user asking themselves what else could be done and consulting additional resources:

> The second part of the message says, consult with a doctor. I'm sitting here testifying, or it might be at nighttime. I will consult with a doctor, I will try to find my cardiologist. Tomorrow I have to make a few phone calls, make an appointment, go see a doctor. I will do that. But is there anything else I can do.
>
> I might try to look up, you know, IRN notification, and it takes me to the Apple website and it says take an ECG. What do I have to lose by taking an ECG. I will take an ECG. And that, effectively, connects also to the example that I provided earlier with the alarm system and how we are going to react to it.

Hr'g Tr. (Jafari) at 380:2-13. Lastly, contrary to ALC's suggestion, Order No. 12's determination that an "alert" is not limited to a message is not implicated here. *See* CRB at 62-63 (alleging this determination is "a crucial framework under which the claims should be interpreted"). ALC identifies nothing other than the message itself that might qualify as such an "alert." *See id*.

As for doctrine of equivalents, ALC's position is not persuasive, either. IRN's message to see your doctor is certainly provided in the same way as a message to take an ECG; that is, text displayed on the watch's screen. And the function could be viewed the same as well; that is, the function of both alerts is to urge the user to take additional action. Yet the results are very different. The intended result of "alert said first user to record an electrocardiogram using said mobile computing device" is for an ECG to be taken using the mobile device's sensors. The intended result of "you should talk to you doctor" is a doctor's office visit where any number of procedures could occur. Thus, infringement under the doctrine of equivalents has not been shown.

Accordingly, the limitation has not been shown in the Accused Products.

2. Other Claims

Apple does not contest dependent claims 16 and 17 in the Accused Products apart from their dependency on independent claim 11. RIB at 112. Neither does the Staff. SIB at 66. While ALC has not shown infringement of independent claim 11, discussed above, the limitations of claims 16 and 17 are determined to be met in the Accused Products based on the undisputed evidence and testimony provided by ALC. CIB at 123, 133-134. In particular, the Accused

Products are smartwatches (claim 16) that employ a machine learning algorithm to determine the presence of arrhythmia (claim 17). *See* Hr'g Tr. (Jafari) at 312:18-314:11, 320:13-321:19.

E. Domestic Industry – Technical Prong

ALC contends, "AliveCor's KBS, [redacted] products each practice claims 16 and 17 of the '499 patent literally and under the doctrine of equivalents." CIB at 134. Technical prong for the 499 patent differs from the 941 and 731 patents in that Apple does not dispute practice of any of claims 11, 16, and 17 by the KBS product. *See* CIB at 134 (citing Hr'g Tr. (Jafari) at 406:14-409:25); RIB at 112-113; RRB at 67-68. Neither does the Staff. SIB at 66-68. Thus, in light of the undisputed testimony and evidence provided by Dr. Jafari (Hr'g Tr. (Jafari) at 406:14-409:25), the KBS is determined to practice asserted claims 16 and 17.

For [redacted], again, the [redacted] did not exist in any hardware-sense at the time of the complaint. Accordingly, it cannot support a domestic industry that "exists." *Thermoplastic Motors*, Inv. No. 337-TA-1073, Comm'n Op. at 10. And, as with the 941 and 731 patents, ALC has not adequately alleged that [redacted] practices any claim of the 499 patent. *See* CIB at 134-137. Thus it too cannot be considered to support a domestic industry that "exists."

Nevertheless, the practice of the 499 patent by the [redacted] products is "in the process of being established," for the same reasons as with the 941 and 731 patents. The evidence shows that at the time of the complaint, ALC was taking the necessary and tangible steps to practice claims 11, 16, and 17 via the [redacted] products with a significant likelihood of success. ALC's previous product, KBS, indisputably practices all of these claims. ALC's expert, Dr. Jafari, has given persuasive testimony on the transferability of the SmartRhythm (PPG analysis) and KardiaApp (ECG collection and analysis) features—primary software features behind this

practice—to other portable heart monitors. *See* Hr'g Tr. (Jafari) at 389:1-7, 389:21-25, 390:6-15, 392:3-393:10. ALC's technical witnesses testified to the same effect. Hr'g Tr. (Somayajula) at 198:13-19, 202:11-21, 203:19-205:8, 210:19-212:2; 217:13-15, 218:22-219:20, 221:2-222:8; Hr'g Tr. (Raghavan) at 565:4-22, 596:7-599:22 (discussing predicate devices). And the prior art in this investigation, discussed below, shows that wrist-worn computerized devices that contain both PPG and ECG sensors were achievable well before the invention of the 941 patent. *See* RX-0419. There is little else in claims 11, 16, and 17 outside of these hardware and software features. Apple offers no argument beyond that discussed in connection with the 941 patent, or the KBS product above. *See* RIB at 90-91; RRB at 56-58.

Accordingly, ALC has shown it is more likely than not that practice of asserted claims 16 and 17 by the [redacted] is "in the process of being established."

F. Validity and Other Affirmative Defenses

Apple identifies the following invalidity and unenforceability theories for the 499 patent:

Claims	Theory
11, 16, 17	Invalid for lack of patent-eligible subject matter under 35 U.S.C. § 101
11, 16, 17	Rendered obvious under 35 U.S.C. § 103 by AMON (RX-0419), alone or in combination with Kotzin (RX-0401) and Almen (RX-0400)
All claims	Unenforceable against Apple under experimental use exception

See generally RIB at 113-120.

As for prior art, Apple argues that because the 499 patent has the same priority date as the 731 patent, discussed above, each of AMON, Almen, and Kotzin qualify as prior art to the 499 patent under § 102(a) for the same reasons. Neither ALC nor the Staff disputes this (*see generally*

CIB at 144-146; CRB at 70-72; SIB at 71) so AMON, Almen, and Kotzin are prior art to the 499 patent at least under 35 U.S.C. § 102(a).

1. Ineligible Subject Matter

As with the 941 and 731 patents, Apple contends "[c]laims 16 and 17—which depend from non-asserted claim 11—are all directed at patent ineligible subject matter." RIB at 113. As for *Alice* step one, Apple argues independent claim 11 is "directed fundamentally at the abstract idea of sensing heart rate and activity data, processing the data, comparing the data, and then alerting a user to take more data." *Id.* at 114. Apple claims the steps are "fundamentally the steps clinicians have done historically as part of a routine cardiac exam, and merely automating such a basic human activity is insufficient to convey patentability under § 101." *Id.* Apple argues claims 16 and 17 are directed similarly. *Id.*

As for *Alice* step two, Apple views the recited hardware "a hear rate sensor, a processor, a motion sensor, a non-transistory computer readable medium, an ECG sensor, and a [] mobile computing device" as generic. RIB at 114. Apple adds, "the '499's inventors did not invent or in any way advance these generic hardware components." *Id.* Apple contends the "smartwatch" of claim 16 is effectively a generic computing device and "conventional as of 2013." *Id.* For claim 17, reciting, "determine a presence of said arrhythmia using a machine learning algorithm," Apple argues "a machine learning algorithm without specifics is nothing more than generic, functional language" and "[c]laim 17 recites nothing about how the algorithm is trained." *Id.* at 115.

ALC, on the other hand, contends the claims are subject matter eligible as "[c]laims 16 and 17 both require a specific combination of heart rate, motion, and ECG sensors." CIB at 142; CRB at 68 ("Apple ignores the specific configuration of sensors and computer-readable instructions executed on the device recited by the claims."). ALC, in a discussion of *Alice* step one, emphasizes the invention's advantages in early stage disease detection (CIB at 142) and notes the patent's

statement "that 'by comparing measured heart rate changes with measured activity changes, the presently disclosed software or 'app' minimizes false alarms.'" *Id.* (citing 499 patent at 25:22-25). Otherwise, ALC views the claims as similar enough to those in the 941 and 731 patents so as to incorporate its previous *Alice* step one discussions by reference. *Id.* at 143.

Continuing under *Alice* step two, ALC argues "the claimed devices of claims 16 and 17 are inventive because they perform functions that doctors or other medical professionals could not do before [so that by] comparing HRV to activity level, the claimed devices can more accurately alert users to take an ECG." CIB at 143; CRB at 68-69 (arguing doctors do not "alert" the user to take ECG, they would order it themselves). Additionally, according to ALC, the claims include inventive concepts because "they can alert the user to record an ECG when an arrhythmia is detected and thus enable users to capture this information even without a doctor present." CIB at 143; CRB at 69 (arguing the invention "allows users to record ECGs in the periods of greatest diagnostic value."). ALC again views the claims as similar enough to those in the 941 and 731 patents so as to incorporate those *Alice* step two discussions by reference. CIB at 144.

The Staff agrees with ALC on both steps of the *Alice* test, and repeats its commentary from the other patent discussions. SIB at 68-71; SRB at 30-33.

Unlike the claims of the 941 and 731 patents, claim 11 of the 499 patent is invalid for lack of patentable subject matter. For background, claim 11 recites:

> 11. [11(a)] A system for determining the presence of an arrhythmia of a first user, comprising
>
> [11(b)] a heart rate sensor coupled to said first user;
>
> [11(c)] a mobile computing device comprising a processor, wherein said mobile computing device is coupled to said heart rate sensor, and wherein said mobile computing device is configured to sense an electrocardiogram of said first user; and
>
> [11(d)] a motion sensor

> [11(e)] a non-transitory computer readable medium encoded with a computer program including instructions executable by said processor to cause said processor to
>
> [11(e)(i)] receive a heart rate of said first user from said heart rate sensor,
>
> [11(e)(ii)] sense an activity level of said first user from said motion sensor,
>
> [11(e)(iii)] determine a heart rate variability of said first user based on said heart rate of said first user,
>
> [11(e)(iv)] compare and [sic] activity level of said first user to said heart rate variability of said first user,
>
> [11(e)(v)] and alert said first user to record an electrocardiogram using said mobile computing device.

499 patent at cl. 11 (annotated). The bulk of the claim is directed to the data analysis algorithms taking place within the "processor" and according to the "instructions" saved in memory (*i.e.*, ineligible subject matter). The bit of apparatus recited (*i.e.*, potentially eligible subject matter) is devoid of specificity, such that it can only be considered generic computer hardware—"a heart rate sensor," "mobile computing device," "a processor," "a motion sensor," and "non-transitory computer readable medium." The fact that the preamble describes this as a "system" demonstrates that no particular form factor is envisioned or required. Thus, the claim is clearly directed to the idea of taking in heart rate data (of any kind), taking in activity level data (of any kind), calculating heart rate variability, comparing that variability with the activity (by any means), and then alerting the user to "record an electrocardiogram using said mobile computing device."

Dr. Stultz persuasively testified that carrying out these steps is common in medical practice. Hr'g Tr. (Stultz) at 1058:13-1059:19, 1077:21-1078:15, 1085:15-22. They are also ineligible mental processes. Accordingly, claim 11 is directed to ineligible subject matter under *Alice* step one. *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66, 71, (2012); *Intellectual*

Ventures I, 838 F.3d at 1314 ("The Supreme Court has held that 'fundamental . . . practices long prevalent' are abstract ideas.") (citing *Alice*, 134 S.Ct. at 2356).

Claims 16 and 17 fare similarly. Claim 16 specifies that the "mobile computing device" is a "smartwatch." But this does not materially transform the claim as there is no other limitation that benefits or is affected by the computing device being in this form factor. *Compare* 499 patent at cl. 16 *with* 941 patent at cl. 22 ("wherein the PPG sensor is located on a back of the smartwatch"). Claim 17 requires the processor to further "determine a presence of said arrhythmia using a machine learning algorithm." 499 patent at cl. 17. This is literally just another algorithm and only deepens the connection between the claim and ineligible subject matter.

Turning to *Alice* step two, claim 11's non-ineligible elements, either individually or as an ordered combination, do not transform the nature of the claim into something more than a patent on the abstract concept. *See Alice*, 573 U.S. at 217-18. As noted, there are sensors recited ("heart rate," "electrocardiogram," "motion"), but they are unrestricted as to structure, arrangement, or data output so long as they relate to "heart rate," electrical activity of the heart, or "activity level," respectively. 499 patent at cl. 11. Admittedly, an ECG sensor is rather specific; but unlike claim 12 of the 941 patent, claim 11 of the 499 patent does not recite the number of leads to further specify the type of ECG sensor, nor does it expressly recite any use for the ECG data—it simply exists within the "mobile computing device." 499 patent at cl. 11. In essence the claim covers the addition of generic sensors to an existing ECG machine, and for no particular purpose.

Alone or as an ordered combination, all this is equivalent to the basic idea of using such sensors. The remaining hardware limitations ("mobile computing device," "processor," and "computer readable medium") are equally generic, if not more so, and perform their generic functions (be configurable, contain and execute instructions). Moreover, there is nothing recited

that could be viewed as improving the operation of any of these computing elements (*e.g.*, faster, fewer errors, less power consumption, etc.). *See, e.g.*, *Enfish*, 822 F.3d at 1336 ("In this case, however, the plain focus of the claims is on an improvement to computer functionality itself, not on economic or other tasks for which a computer is used in its ordinary capacity."). Nor does the addition of a machine learning algorithm, as in claim 17, remove that claim from the category of "well-understood, routine, and conventional." *Berkheimer*, 881 F.3d at 1369.

ALC's arguments to the contrary are unpersuasive. The feature of claim 11 heralded to result in "improved cardiac monitoring technology" is an "algorithmic step," as is the (unspecified) "machine learning algorithm" of claim 17. CIB at 142 (discussing comparison of HRV to activity level). And the concept of alerting a user to take an ECG (by any means) may result in improved early detection of cardiac conditions (*id.* at 142-143), but it is still an algorithm contained in memory and executed by a processor (499 patent at cl. 11). On that point, processors do not "alert" a user themselves; additional, unrecited hardware is necessary (*e.g.*, speaker, LED, vibrating motor, display, etc.). ALC also contends, "the claimed devices of claims 16 and 17 are inventive because they perform functions that doctors or other medical professionals could not do before." CIB at 143; *see* SIB at 70-71. What has been done before, or not, is a novelty or non-obviousness argument, however, distinct from § 101. *Synopsys*, 839 F.3d at 1151.

Accordingly, claim 17 of the 499 patent has been shown to be invalid for lack of patentable subject matter. The same cannot be said of claim 16, however, for the same reason as discussed above for the 941 and 731 patents: it requires a "smartwatch" as at least part of the mobile computing device. Undoubtedly claim 16 is more abstract than the claims of the 941 and 731 patents, because no particular kind of heart rate sensor or motion sensor is required. But incorporating even any kind of heart rate sensor into a smartwatch, especially when combined with

an ECG sensor, lifts that smartwatch out of the realm of "well-understood, routine, and conventional." *Berkheimer*, 881 F.3d at 1369. Overall, the system of claim 16 is sufficiently unconventional that it qualifies as inventive at step two of *Alice*. Claim 16 therefore is not invalid for lack of patentable subject matter.

2. AMON in Combination with Almen and/or Kotzin

Apple states, "[j]ust like the '941 and '731 patents, AMON—alone or in combination with Almen and Kotzin for minor limitations—renders obvious all of the '499 patent's Asserted Claims in this Investigation, including claims 11, 16 and 17." RIB at 115-116.

a. Claim 11

For independent and intervening claim 11, Apple identifies several limitations it views as disputed, but are otherwise disclosed or obvious in light of AMON. *See generally* RIB at 116-120. In its briefing, ALC identifies limitations 11(e)(iii), 11(e)(iv), and 11(e)(v) as in dispute (CIB at 144-145; CRB at 70-71); and while Staff opposes limitations 11(e)(iii) and 11(e)(iv) it does so on essentially identical grounds to ALC (SIB at 72-75; SRB at 33-35). These are discussed below. As to the remaining, undisputed, limitations of claim 11, they are found to be obvious as alleged by Apple in light of the evidence and testimony provided by Dr. Stultz. RIB at 116-119 (citing Hr'g Tr. (Stultz) at 1142:20-1143:6).

i. [11(e)(iv)] "compare said activity level of said first user to said heart rate variability of said first user"

As noted above, AMON does not disclose element 11(e)(iii), "determine a heart rate variability of said first user based on said heart rate of said first user," but the combination of AMON and Almen renders that element obvious, so the following discussion pertains to that combination. As to "compare said activity level of said first user to said heart rate variability of said first user," Apple contends it also would have been obvious. *See* RIB at 119 (citing Hr'g Tr.

(Stultz) at 1119:3-25, 1142:20-1143:3). In reply, Apple asserts that the device in Almen monitors HRV even while a user is at rest. *Id.* (citing RX-0400 at Abstract; Hr'g Tr. (Stultz) at 1118:8-1126:16, 1142:20-1144:21).

The limitation would have been obvious over AMON in light of Almen. As determined above in connection with the 941 and 731 patents, AMON discloses the concept of comparing heart rate data (*i.e.*, pulse) against one of two pre-set thresholds depending on the user's activity level (aerobic or anaerobic). RX-0419 at 6, Table I. As further determined above, a person of ordinary skill would have had reason to calculate heart rate variability as a parameter to aid in evaluating arrhythmia, given the teachings of Almen. *See* RX-0400 at 1:61-66, 2:12-20, 7:26-53; *see also* Hr'g Tr. (Stultz) at 1058:13-1059:19, 1077:21-1078:15, 1085:15-22. It is logical to conclude that the device of AMON, once modified, would evaluate heart rate variability in the same manner as its other characteristics—*i.e.*, compare it to one of two pre-set thresholds depending on the user's activity level. After all, detecting when activity is "strenuous" (*i.e.*, aerobic) is the whole point of AMON's acceleration sensor:

> D. Acceleration Sensor
>
> Acceleration sensors provide information on the activities of the wearer. Three uses of this information are made: First, the pulse limits are set according to the activity level—*e.g.*, walking, running, or resting.
>
> . . . .
>
> 1) Activity Detection: The AMON system requires only very simple activity analysis compared to other wearable activity detection applications, *e.g.*, [24]. What we are interested in is the level of physical activity without being able to distinguish specific actions. The main problem that our analysis has to deal with is the fact that intensive arm motion by itself is by no means an indication of strenuous physical activity. Thus, for example eating, drinking, or just talking and gesticulating involves arm motions that are not particularly strenuous. Our analysis is based on the fact that strenuous activity is mostly associated with (fast) walking or running. This in turn has a characteristic periodic acceleration signature with the frequency indicating the walking speed (*see* Fig. 6). This periodic signature can be

> detected even if the arms do not follow the walking motion directly through swinging and are engaged in some other activity.

RX-0419 at 5.

ALC's points in opposition are not persuasive. Beyond those made (and rejected) in connection with claim 13 of the 941 patent, ALC argues "because Almen is targeted toward analysis during sleep cycles of the wearer, it would not be necessary for Almen to even consider the user's motion or activity level, let alone compare it to HRV." CIB at 144. Staff makes a similar argument. SIB at 74-75. Yet, the combination is to add HRV evaluation to AMON's device, not physical activity evaluation to Almen, and as detailed above, AMON recognizes the importance of noting activity level when determining if heart-centric thresholds have been crossed.

Accordingly, this limitation would have been obvious over AMON in light of Almen as alleged.

ii. [11(e)(v)] "alert said first user to record an electrocardiogram using said mobile computing device"

As to "alert said first user to record an electrocardiogram using said mobile computing device," Apple argues it is both disclosed and obvious. RIB at 119. Within AMON, Apple points to statements regarding out of range parameters:

> Dr. Stultz made clear that AMON discloses alerting a user to record an ECG, because "if a parameter is out of range, the user is informed and additional measurements are required, and one of those measurements can be an ECG, and the user is informed to their own status and that of the device." Tr. (Stultz) at 1143:7-14; RDX-3.99. AMON's clinical algorithm also notes in steps 1 and 3 that if the pulse is irregular (outside the normal range), then the user is asked to take an ECG measurement. *Id.* at 420. The user has to actively record the ECG because AMON states "the patient must touch the RA with his left hand" and the RL lead to the abdomen. *Id.* [at] 418; RDX-3.99.

Id. Apple also reminds of AMON's disclosure that "'each step [of the algorithm], the result is displayed . . .' to the user." RRB at 71 (citing RX-0419 at 6). If not disclosed, it is obvious, according to Apple, in combination with Kotzin:

> To the extent that AMON does not expressly disclose an alert, a POSITA would have been motivated to create an alert based on the disclosures in Kotzin that if a preliminary event (*e.g.*, a pulse or HRV signal) occurred outside the normal range thresholds, then it would be beneficial to alert the user to sense an ECG to indicate if the pulse or HRV is a dangerous condition. Tr. (Stultz) at 1143:15-19. RX-401 (Kotzin) 18:10-24; RDX-3.100.

RRB at 120.

The limitation is at least inherently disclosed in AMON. As noted by Dr. Stultz, AMON discloses a five step algorithm, where in the first step, measured values (*e.g.*, pulse) are compared to risk threshold limits in a look-up table. RX-0419 at 6. The third and fourth steps include:

> Third Step: When previous steps indicate a risk or high-risk zone, determine if and what new measurement set is required.
>
> Fourth Step: Calculate pulse based on two or three different measurements (SpO_2, blood pressure, and ECG). Each measurement is weighted according to its reliability.

Id. In the "System Overview," AMON further explains that when a parameter is out of range, as in the third step, an ECG is called for when appropriate:

> Parameter out of range: A remeasurement is performed. If the outcome is the same as before, the user is informed and additional measurements are required. The wrist-worn device determines the type and initiates the measurement. The type of measurement includes SpO_2, blood pressure, and ECG. Taking into account combined results of all measurements, the system then decides whether to alert the TMC or not.

Id. at 3. If the device determines that an ECG is called for, the device necessarily must do as the present claim limitation recites—that is, alert the user to take an ECG. As AMON notes, the device cannot do this itself because ECGs require users to actively position their body to the sensor pads:

> [D]uring a measurement, the patient must touch the RA with his left hand. The right leg (RL) electrode is placed on top pointing to the wearer; during measurement, this electrode must be in contact with the abdomen. In order to reduce common mode interference, a right leg drive circuit has been chosen with gain set to 39.

Id.

And the device would determine that an ECG is appropriate when the out of range parameter is one that an ECG will measure, as opposed to one that an ECG cannot measure, such as blood oxygen concentration (SpO_2) or blood pressure. So although AMON does not expressly disclose "alert[ing] said first user to record an [ECG]," that step is necessarily present when AMON analyzes HRV as the out of range parameter.

In opposition, ALC first argues that because the preamble of claim 11 is limiting, "any alert would necessarily require some connection to the limitation of 'detecting the presence of an arrhythmia.'" CIB at 145 (citing *Eli Lilly & Co. v. Teva Pharms. Int'l GmbH*, 8 F.4th 1331, 1345 (Fed. Cir. 2021)). And because AMON does not use the word "arrhythmia," it cannot meet this limitation either, according to ALC. *Id.*; CRB at 71. But the broad construction of "arrhythmia" which encompasses *any* irregularity in electrical activity of the heart, including HRV. Order No. 12 at 12.

Accordingly, Apple has shown independent and intervening claim 11 would have been obvious over AMON in view of Almen; Kotzin need not be considered.

b. Claim 16

Claim 16 recites, "[t]he system of claim 11, wherein said mobile computing device comprises a smartwatch." 499 patent at cl. 16. For this claim, Apple refers to its discussion of preambles in both claim 12 of the 941 patent and claim 1 of the 731 patent. RIB at 120 (citing Hr'g Tr. (Stultz) at 1143:23-1144:1). ALC only contests claim 16 to the extent it depends on claim 11. *See* CIB at 145; CRB at 71. Staff finds the limitation disclosed in AMON. SIB at 75.

Accordingly, claim 16 would have been prima facie obvious over AMON in view of Almen.

c. Claim 17

Claim 17 recites, "[t]he system of claim 11, wherein said computer program further causes said processor to determine a presence of said arrhythmia using a machine learning algorithm." 499 patent at cl. 17. For this claim, Apple contends AMON discloses it and refers to its discussion of claim 5 of the 731 patent. RIB at 120 (citing Hr'g Tr. (Stultz) at 1143:23-1144:1). ALC similarly contests claim 17 on the same ground as claims 3 and 5 of the 731 patent. CRB at 71. The Staff finds the limitation is not disclosed in AMON and not otherwise obvious based on Kotzin. SIB at 76 ("It is not clear that Kotzin even describes a machine learning algorithm, but even if it did, Kotzin fails to teach or suggest using any such algorithm for the detection of arrhythmia.").

As determined in connection with claims 3 and 5 of the 731 patent, the machine learning limitation is not disclosed in either AMON or Almen, and Apple does not identify any teaching in Kotzin of a machine learning algorithm, or of any motivation to combine Kotzin, AMON, and Almen. *See* RIB at 120.

Accordingly, claim 17 is not disclosed by AMON, and no prima facie case of obviousness has been shown.

d. Summary

Apple has not made out a prima facie case of obviousness as to claim 17, so it is not invalid on that basis. The KBS embodies claim 16, so ALC is entitled to a presumption of nexus to the secondary considerations of non-obviousness, and Apple offers no evidence to rebut that presumption. *See* RIB at 120. Essentially for the same reasons as discussed above for claims 12, 16, 20, 22, and 23 of the 941 patent, the secondary considerations here also outweigh the other *Graham* factors, such that claim 16 would not have been obvious over AMON in view of Almen.

Accordingly, Apple has not proven claim 16 or 17 to have been obvious.

3. Enforceability as to Experimental Use

As with the 941 and 731 patents, Apple argues that "[its] experimental use does not give rise to infringement liability under the '499 patent." RIB at 120. As determined above, ALC's infringement theory does not implicate any Apple experimental activity. Accordingly, experimental use has not been shown to preclude any finding of infringement in this investigation.

VII. DOMESTIC INDUSTRY - ECONOMIC PRONG

In a patent-based complaint, a violation of Section 337 can be found "only if an industry in the United States, relating to the articles protected by the patent ... concerned, exists or is in the process of being established." 19 U.S.C. § 1337(a)(2). Under Commission precedent, this "domestic industry requirement" of Section 337 consists of an economic prong and a technical prong. *Stringed Instruments*, Inv. No. 337-TA-586, Comm'n Op. at 12-14. The complainant bears the burden of establishing that the domestic industry requirement is satisfied. *See Certain Set-Top Boxes and Components Thereof*, Inv. No. 337-TA-454, Initial Determination at 294 (June 21, 2002) (not reviewed in relevant part).

The economic prong of the domestic industry requirement is defined in subsection (a)(3) of Section 337 as follows:

> (3) For purposes of paragraph (2), an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark or mask work concerned --
>
> (A) Significant investment in plant and equipment;
>
> (B) Significant employment of labor or capital; or
>
> (C) Substantial investment in its exploitation, including engineering, research and development, or licensing.

19 U.S.C. § 1337(a)(3). The economic prong of the domestic industry requirement is satisfied by meeting the criteria of any one of the three factors listed above. Importantly, the Commission has

clarified that investments in plant and equipment, labor, and capital that may fairly be considered investments in research and development are eligible for consideration under subsections (A) and (B), in addition to subsection (C). *See Certain Solid State Storage Drives, Stacked Electronics Components, and Products Containing Same*, Inv. No. 337-TA-1097, Comm'n Op. at 14 (June 29, 2018) ("*Solid State Storage*").

In this investigation, ALC contends economic prong is met under each of subsections (A), (B), and (C) for each Asserted Patent through its investments in "design, development, regulatory, and customer support work." CIB at 146. More specifically, ALC contends a domestic industry "exists" through the KBS, [redacted] products; and there is also a domestic industry "in the process of being established" through the [redacted] products. *Id.* at 149, 164.

Overall, ALC has shown a domestic industry "exists" for the 941, 731, and 499 patents under subsection (C). ALC has not shown a domestic industry "exists" under subsections (A) or (B). ALC has not shown a domestic industry is "in the process of being established" for any of subsections (A), (B), or (C).

A. Domestic Industry in Existence

1. Qualifying Expenditures

As noted above, ALC claims economic prong is met through subsections (A), (B), and (C). The appropriate amount of investment to be considered under each subsection is discussed below.

a. Subsection (A) – Plant and Equipment

Considering subsection (A), "significant investment in plant and equipment," ALC first presents company-wide investment amounts from April 2016 to the filing of the complaint, April 2021. CIB at 153-154. ALC reports: [redacted] in rent for a Mountain View, CA facility; [redacted] in additional repairs, utilities, and maintenance; [redacted] in equipment expenses, including software, hardware, and office equipment (and, in addition "regulatory, and customer

support teams"); and [redacted] in tooling expenses from "U.S.-based contractors related to KBS." *Id.* ALC argues its "engineers, regulatory specialists, and customer support specialists work on the DI Products" at this facility. *See id.* at 153.

To arrive at investment figures specifically directed to the DI Products, as opposed to others, ALC identified all employees at the facility and the amount of time each worked on the DI Products. *See* CIB at 154-156. This information is sourced from the knowledge and testimony of ALC's founder, Dr. Albert, ALC's current Chief Technology Officer, Mr. Somayajula, ALC's then regulatory manager, Mr. Raghavan, and ALC's Director of Customer Care, Mr. White. *See id.* To support the reliability of these estimates, ALC contends:

> All of these estimates were prepared carefully and diligently. Tr. (Albert) at 96:9-97:24; Tr. (Somayajula) at 222:25-226:8; Tr. (Raghavan) at 574:3-576:22. Mr. Somayajula is AliveCor's current Chief Technology Officer, and he oversees AliveCor's current development work. Tr. (Somayajula) at 193:6-18. Dr. Albert is a company founder, who is familiar with all of AliveCor's development projects going back to 2016. JX-223C (Albert) at 237:7-238:21. Mr. Raghavan is AliveCor's former Vice President of Regulatory and current regulatory consultant, and he personally oversaw or consulted on the applications at issue in his allocation. Tr. (Raghavan) at 571:22-574:11. . . . Even Apple's expert agreed that Mr. Somayajula and Dr. Albert are knowledgeable about AliveCor's R&D activities and that Mr. Raghavan is knowledgeable about AliveCor's regulatory activities. Tr. (Vander Veen) at 1035:12-20.

Id. at 154-155. For customer support, ALC asserts it "maintains data showing the products to which each incoming customer support ticket relates." *Id.* at 155 (citing CPX-053C). Thus, uniquely for this activity, ALC relies on "how many tickets within a time frame it had for that specific thing, based on our coding." *Id.* (citing JX-0227C (White) at 141:6-12).

The end result, as calculated by ALC's expert, Dr. Akemann, is "a relative headcount of AliveCor employees who work on DI Products at AliveCor's California Headquarters each year." CIB at 155 (citing Hr'g Tr. (Akemann) at 647:13-657:14). The tabulated results are below:

	2016	2017	2018	2019	2020	2021
DI % of Headcount (HQ)	[redacted]					
DI % of Software Headcount						
DI % of Hardware Headcount						
DI % of Regulatory Headcount						
DI % of Customer Support Headcount						

Id. at 156 (citing Hr'g Tr. (Akemann) at 645:10-657:14; CDX-0001C.9; CDX-0001C.10; CPX-047C; CPX-050C; CPX-052C; CX-0920C; CX-0922C).

When these allocations are applied to the company-wide plant and equipment totals presented above, the total amount of alleged subsection (A) investment is as follows:

	2016	2017	2018	2019	2020	2021	Total
Allocated Facilities Expenses	[redacted]						
Allocated Equipment Expenses							

Id. (citing Hr'g Tr. (Akemann) at 645:10-657:14; CDX-0001C.9; CDX-0001C.11; CPX-047C; RX-0484C; JX-227C; JX-225C; CPX-050C; CPX-053C; CX-0918C; CX-0919C; CX-0920C).

In its reply brief, ALC expresses its view that its continuing investments in the technologies shared between KBS, [redacted] allow for consideration of the full six years of plant and equipment investment. CRB at 73-75 (discussing SmartRhythm and KardiaAI), 77-78 ("AliveCor has engaged in continuous efforts to exploit its patented technology through multiple form factors"), 80 ("Even adopting Apple's view—which is contrary to the evidence—that investments in the technology used in the KBS are somehow entirely distinct from investments in the technology in the [redacted] the customer support and software update evidence is

undisputed or unrebutted evidence of continuing, qualify[ing] investments in the KBS."). ALC states in summary, "[t]he KBS is a DI Product. The KBS did not exist before AliveCor developed it. And that last point alone establishes nexus." *Id.* at 75 (citing *Certain Non-Volatile Memory Devices and Products Containing the Same*, Inv. No. 337-TA-1046, Comm'n Op., 2018 WL 6012622, at *25 n.11 (Oct. 26, 2018) ("*Non-Volatile Memory*"); *Certain Electronic Digital Media Devices and Components Thereof*, Inv. No. 337-TA-796, Initial Determination at 454 (Sept. 14, 2012)).

ALC also takes issue with ignoring, or setting aside, investments in the [redacted] when determining if an industry "exists." ALC repeats its view that "the [redacted] are articles for which the technical prong of domestic industry requirement can be evaluated." CRB at 82 n. 19. It matters not, according to ALC, that the products are not ready for commercialization. *Id.* (citing *Non-Volatile Memory*, Inv. No. 337-TA-1046, Comm'n Op., 2018 WL 6012622, at *20). All that matters, allegedly, is that the articles "exist":

> The physical embodiments of the [redacted] that were produced during this investigation qualify as protected articles under the Commission's reasoning in *Non-Volatile Memory Devices*. *Because the articles exist*, and because AliveCor is relying on investments that had been made at the time the complaint was filed, Apple's various arguments about when prototypes first existed and which prototypes are currently be worked on are irrelevant. *See id.* at *27 ("Simply because Macronix has not yet arrived at the final stages of commercializing the [article] does not mean that Macronix does not have a domestic industry in the process of being established with respect to [an article] protected by the asserted patents.").

Id. (emphasis added). Similar to the discussion of past investment, ALC contends, "these investments relate to technology that was implemented in the KBS, which existed at the time the complaint was filed." *Id.* at 83; *see id.* ("But as every AliveCor fact witness explained, the work on [redacted] was continuing development work on the same technologies implemented in the

KBS."). ALC summarizes, "[t]he work does not erase the practicing article that indisputably existed at the time of the complaint." *Id.*

Additionally, ALC disputes that its allocations are unreasonable to the extent Apple has made that argument for subsection (A). ALC asserts, "time estimates from knowledgeable individuals" has been successfully relied upon in prior investigations" (CRB at 85 (citing *Certain Light-Emitting Diode Products, Systems, and Components Thereof (III)*, Inv. No. 337-TA-1168, ID at 121-22 (June 26, 2020))) and also that a precise accounting is not necessary as "most people do not document their daily affairs in contemplation of possible litigation" (*id.* (citing *Stringed Instruments*, Inv. No. 337-TA-586, Comm'n Op. at 26)). ALC then addresses those specific indicia of allocation unreliability proffered by Apple. *See generally id.* at 85-89.

The Staff agrees with ALC. SIB at 81-82; SRB at 39-42. "With respect to allocations," the Staff explains, "AliveCor's allocations appear reasonable . . . and it is not clear that there is a better approach that AliveCor could have taken." SIB at 81. The Staff views Apple's "primary criticism" as that the [redacted] products are not "presently on the market" (SRB at 38) and, for the same reasons as ALC, argues commercialization is not a necessity (*id.* (citing, *inter alia*, *Non-Volatile Memory*, Inv. No. 337-TA-1046, Comm'n Op. at 41-42)). More specifically, the Staff argues the [redacted] hardware status at the time of the complaint was "sufficient":

> As explained above, the designs of the [redacted] products were sufficient before the filing of the Complaint to determine that those designs would implement the next generation SmartRhythm software based on what was originally included as part of the KardiaBand System that worked with the Apple watch. At the time of the filing of the Complaint, implementation of the design had begun but working prototypes in the intended form factor were not yet developed. With respect to the technical prong, the Staff relies on the Complainant's expert's analysis of products in which the hardware aspects were improved in the course of the investigation. While not all design work had been completed, sufficient design work had been completed such that the Commission can determine that those designs practice the claimed invention, *i.e.*, that the hardware would include PPG and ECG sensors, and a processor to run SmartRhythm. With respect to the economic prong, the Staff

> relies on Complainant's expert's analysis of investments made relating to these products up to the time the Complaint was filed. Accordingly, references to investments made in 2021 herein are to investments made in 2021 through the date of the filing of the Complaint.

Id. at 39 n.3. Thus, according to the Staff, "[a]s there is substantial overlap in the investments of KBS, [redacted], all of AliveCor's claimed investments should be considered as a whole," and that subsection (A) figure is [redacted] *Id.*

ALC's investment figures for subsection (A), plant and equipment, are not reliable. Despite its assertion that technology, efforts, and investment are shared between the KBS on the one hand, and [redacted] on the other, the fact remains that the [redacted] have not been shown to practice any of the asserted patents at the time of the complaint. Thus, any investment directed to these articles under subsection (A) must be allocated out, just as with any other non-practicing products. *Stud Finders*, Inv. No. 337-TA-1221, Comm'n Op. at 48, 50-51 ("[T]his is not the first time that [the Commission] has explained that aggregating investments in articles that *are* protected by a particular patent with investments in articles that *are not* protected by that patent may preclude meaningful consideration of those investments under the statutory framework required by section 337.") (emphasis in original); *Certain Earpiece Devices and Components Thereof*, Inv. No. 337-TA-1121, Comm'n Op. at 17-18 (Nov. 8, 2019); *Certain High-Density Fiber Optic Equipment and Components Thereof*, Inv. No. 337-TA-1194, Comm'n Op. at 61 (Aug. 23, 2021).

The Staff's rationale for keeping [redacted] in the calculus is far from persuasive. They suggest technical prong may be somehow established by product design materials, without actual practice, so long as there has been "sufficient" work completed. SRB at 39 n.3 ("While not all design work had been completed, sufficient design work had been completed such that the Commission can determine that those designs practice the claimed invention."). There is no

precedent for this, and it would defeat the purpose of the statute, which is to ensure "an industry . . . relating to the *articles protected* by the patent . . . exists." 19 U.S.C. § 1337 (emphasis added).

Turning back to ALC's subsection (A) investments, they are the combination of KBS, [redacted] activity. *See* CIB at 154 (citing Hr'g Tr. (Albert) at 96:9-97:24; Hr'g Tr. (Somayajula) at 222:25-226:8); Hr'g Tr. (Akemann) at 644:2-657:14; CDX-0001C.5; CDX-0005C.48. Yet ALC does not provide any means to alternatively subtract out activities spent on [redacted]. *See* CIB at 154; RX-0484C at 112-114, 138-140; CDX-0001C.5. This is a problem according to Commission precedent and may preclude further analysis. With that said, Apple's expert, Dr. Vander Veen, does make an attempt at isolating KBS plant and equipment (RIB at 140 (citing RX-0314C; RX-0323C)) but he acknowledges that the largest year, 2018, cannot reliably be parsed between KBS and [redacted] (Hr'g Tr. (Vander Veen) at 997:11-18). Even then, there is strong evidence that some 2017 investment should be given to [redacted], which Dr. Vander Veen does not do (*see* CIB at 19 [redacted]; CX-0250C.2 ([redacted])), and evidence that some 2018 must be given to [redacted], which he also does not do. As Dr. Albert explains, "I went to one engineer, Miguel Kirsch, who, as you see, came in 2018 and worked on the [redacted] at that time . . . [and] Miguel said, where I said he was [redacted] percent committed, he said I was [redacted] percent committed to [redacted] during those time periods. He said I definitely underestimated him." Hr'g Tr. (Albert) at 97:6-20. Thus, it is reasonable to eliminate the years 2018-2021 from ALC's plant and equipment investments as having an unreliable connection to KBS, leaving only 2016-2017.

The testimony of Dr. Albert raises a separate hurdle that ALC has not overcome. Apple contends the alleged subsection (A) investment (and subsections (B) and (C), as well) is ultimately

based on Dr. Albert's recollection "of the percentage of time each employee spent working on the KBS and [redacted] for each quarter from 2016 to Q1 2021 *solely from memory*." RIB at 133 (emphasis in original). Apple's claim of "solely from memory" is not exaggeration. Dr. Albert consulted no emails, documents, or persons in developing his percentages:

> Q. Turning to CDX-5C.48, this is information taken out of CX-687C, pages 14-15 for identification purposes only, can you tell us, briefly, what you were asked to do in terms of analyzing the amount of time different people at AliveCor have spent on the domestic industry products?
>
> A. Well, as the common denominator in the company since the beginning, and as I'm very involved in new product development, I was asked last year to estimate the contribution of this list of people to KardiaBand, [redacted], and then at the end of this timeline, Q1, [redacted]. And so I was given a list of names and I was given time, different times. And so I had no time sheets, we don't keep time sheets, I had no emails, I consulted no one. I just came up with what I thought, because I know what these people were working on, I know what their jobs were, I came up with estimates of what their contribution was in terms of time spent. And I submitted that. And I guess it's become part of the record.

Hr'g Tr. (Albert) at 96:9-97:2. While it may be true that ALC employees do not keep time sheets, there certainly must be documentation of some type—even emails—that could at least partially corroborate the allocation that is the factual underpinning of ALC's economic prong theory for all of subsections (A), (B), and (C). That Dr. Albert did not review *any* materials or consult with any colleagues—especially for the early 2016-2018 years—greatly diminishes the reliability of his percentages. *See, e.g.*, Hr'g Tr. (Somayajula) at 262:8-11 ("Q. But you do believe that it was appropriate to collect documents to try to have some data to figure out how much time each person spent on a project, correct? A. Correct."). And that reliability is not helped by two employees suggesting to Dr. Albert, after the fact, that their times were underestimations. Hr'g Tr. (Albert) at 97:6-20. The Commission expects more from a complainant seeking to establish the existence of an industry worthy of section 337 protection. *See, e.g.*, *Certain Electronic Candle Products and Components Thereof*, Inv. No. 337-TA-1195, Comm'n Op. at 14 (Sept. 13, 2021) ("*Electronic*

Candles") ("Complainants must provide credible evidence to show these employees engage in cognizable activity despite their job titles if they want to rely on these labor expenditures to show a domestic industry."); *Certain Light-Emitting Diode Products, Systems, and Components Thereof (III)*, Inv. No. 337-TA-1168, Initial Determination at 122 (June 26, 2020) (recognizing from-memory allocation estimates "corroborated . . . with documents from employees, expenditure documents, calendar entries, project documentation, and discussions with current employees regarding their work on the DI Products.").

There are additional reasons to doubt Dr. Albert's from-memory percentages. To start, it should be difficult for anyone to remember the activities of thirteen individuals for each year of a five year period, as in the below table:

Name	2016	2017	2018	2019	2020	2021 (Q1)
[redacted]						

CDX-0005C.48; CX-0932C; RX-0484C at 14-15 (ALC contentions). And these from-memory values are oddly specific, with some individuals reported as contributing [redacted], of their time. CX-0932C. This is indicative of some undisclosed calculation on the part of

Dr. Albert or, if truly taken from memory, an odd deviation from the expected rounding (*i.e.*, it is not reasonable to recall, from five years ago, a person's quarter of a percentage point of time).

It is also not clear how seriously Dr. Albert took the estimation process, because he was seemingly surprised that his estimations would be used for purposes of this investigation's record. Hr'g Tr. at 96:20-97:2 ("I just came up with what I thought, because I know what these people were working on . . .. And I guess it's become part of the record."). Additionally, 2018 is listed as the most intense for purposes of KBS and [redacted] activity. Yet, it appears very little was accomplished for [redacted] between this time and 2020. *Compare* CX-0250C [redacted] project concept document) *with* CX-0252C [redacted] concept document, with similar level of detail). And in a discussion of 2019, Dr. Albert could not recall when the "pivot" from KBS to [redacted] occurred as between 2018 or 2019—even though this is exactly the knowledge needed to provide reliable time estimations. Hr'g Tr. (Albert) at 137:11-140:16.

There was also no confirmation, analysis, or any kind of evaluation of ALC personnel activities by ALC's expert, Dr. Akemann, for any of these times. Hr'g Tr. (Akemann) at 720:8-21 ("Q. And you provided no opinion with respect to nexus, correct? A. That's correct. I assumed AliveCor will be able to demonstrate that here, but I view that largely as a technical issue and I'm not offering any opinions on it. I'm making an assumption that that part of the requirement will be met."). And ALC may have also included the contributions of executives towards the DI Products without also figuring them into total personnel, although it is admittedly unclear if this makes a material difference. See RIB at 135. Taken altogether, there is simply more reason to doubt than to trust this critical allocation.

Accordingly, ALC has not presented sufficiently reliable subsection (A) investment amounts.

Nevertheless, one of Apple's primary arguments should be addressed. Apple contends no investment behind the KBS should be counted at all due to its being abandoned in 2019, with only minimal customer support at the time of the complaint. RIB at 130. Apple highlights ALC's modest [redacted] plant and equipment investment in 2021 as an example of this *de minimis* activity. *See id.* (citing RX-0314C). Apple also cites *Certain Television Sets, Television Receivers, Television Tuners, & Components Thereof*, Inv. No. 337-TA-910, 2015 WL 6755093, at *38-46 (Oct. 30, 2015) ("*Television Sets*"), where the complainant's business surrounding the article no longer existed and domestic industry was denied. Apple reasons, "[t]hus, any domestic industry with respect to KBS ceased to exist after KBS was discontinued." RIB at 131.

Apple is incorrect. The Federal Circuit confirmed the standard in *Television Sets*, which is "'past expenditures may be considered to support a domestic industry claim so long as those investments pertain to the complainant's industry with respect to the articles protected by the asserted [intellectual property] rights and the complainant is continuing to make qualifying investments at the time the complaint is filed.'" *Hyosung TNS Inc. v. Int'l Trade Comm'n*, 926 F.3d 1353, 1361-2 (Fed. Cir. 2019) (citing *Television Sets*, Inv. No. 337-TA-910, 2015 WL 6755093, at *36). There, the complainant had five-to-ten year old research and development investment it wanted to count based on a connection to present-day field service and repair costs. *Id.* The Federal Circuit agreed with the Commission that: (1) this was possible; and (2) appropriate given the sufficient nexus between the old research and new service activities. *Id.*

The situation here is very similar. For the year 2020, the last full calendar preceding the filing of the complaint, Apple acknowledges [redacted] in KBS customer service labor and [redacted] in associated plant and equipment. RIB at 139-140. In the year prior, it was higher still. That the first four months of 2021 saw [redacted] is not all that surprising or dispositive.

And there is substantial evidence that *some* amount of R&D was also occurring at the time of the complaint, including research into, for example, ECG sensors and algorithms (KardiaAI) that has an obvious nexus to the ECG limitations of the asserted claims. CRB at 83 (citing Hr'g Tr. (Raghavan) at 567:10-569:12; Hr'g Tr. (Somayajula) at 198:13-19, 202:3-21; JX-0228C at 45:12-46:3); *see* RIB at 142-143 (denying R&D had nexus to the KBS product, not to asserted patent claims); JX-0096C.5-6; *but see* RRB at 75-76 (complaining that KardiaAI had little discovery and is not mentioned by name and thus cannot be "a key piece of patented technology" to supply nexus). Altogether, this is sufficient activity in April 2021 to justify looking back to 2016 in support of an industry that "exists" even though ALC's exact figures are not particularly reliable. As ALC phrases it, "[t]here is no question that, at the time the complaint was filed, AliveCor was engaged in 'some type of current activities related to the domestic industry.'" CRB at 81; *Hyosung*, 926 F.3d at 1361-2.

b. Subsection (B) – Labor and Capital

Considering subsection (B), "significant employment of labor or capital," ALC contends it "invests in labor and capital in the United States to develop, support, and obtain regulatory clearances related to the DI Products." CIB at 158. ALC first tallies its own company-wide investments in software, hardware, regulatory, and customer support teams from 2016 to 2021, as in the subsection (A) analysis, above. *Id.* (citing Hr'g Tr. (Akemann) at 657:15-660:2). To this amount, it adds costs related to "domestic contractors who performed development work, . . . prepared FDA applications, . . .and performed customer support work . . . related to the DI Products." *Id.* at 158-159. Then ALC applies the same per-employee time allocation used in conjunction with subsection (A) against these company-wide expenditures to arrive at the following labor amounts in support of the DI Products:

	2016	2017	2018	2019	2020	2021	Total
DI Internal Software R&D Labor							
DI Internal Hardware R&D Labor							
DI Contractor R&D Labor							
DI Regulatory Labor							
DI Customer Support Labor							
Total DI Labor Investments							

Id. (citing Hr'g Tr. (Akemann) at 658:13-660:2; CDX-0001C.13; CPX-047C; CPX-048C; CPX-052C; CPX-053C; CX-0924C - CX-0928C).

The first two rows, internal hardware and software personnel, are not sufficiently reliable for a domestic industry that "exists" for the same reasons discussed above for subsection (A). They include labor directed, at least, to the [redacted], which did not exist by the time of the complaint; and they are rooted in the same dubious, from-memory, five-year, [redacted] time allocations provided by Dr. Albert. CX-0924C.

The third row, R&D contractors, appears to be largely undisputed by Apple, however. It is not based on Dr. Albert's recollection but on business records of ALC payments to contractors. CX-0925C (citing CPX-0048C (ALiveITC_00024846) ([redacted])). And Dr. Vander Veen does not challenge the records, but would remove certain projects that he views as [redacted] rather than KBS—within years 2018-2021. This leaves an amount of [redacted]:

AliveCor's Labor and Capital Investments in KardiaBand						
	2016	2017	2018	2019	2020	2021
Software R&D						
Hardware R&D						
Contractor R&D						
Regulatory						
Customer Support						
Total DI						
Total DI Labor vs. Total Labor (%)						

RDX-0004C.44 (annotation in original); *see* RX-0314C (citing "[O] and [W] Expert Report of Dr. Michael P. Akemann, December 22, 2021, at Exhibit 6. Tab 7. Adjusted Dr. Akemann's 2018 DI Contractor R&D Labor figure to exclude expenses related to the '[redacted]' project."). Since removing [redacted] investment is proper, and without any further objection, these contractor R&D amounts are accepted for purposes of subsection (B).

There is much dispute over the fourth row, regulatory investment. Apple argues it is overstated because two ALC witnesses stated regulatory work for KBS ended after it obtained FDA clearance in November 2017. RIB at 135 (citing JX-0225C (Raghavan) at 88:22-89:3 ("A. [redacted]), 170:19-22); Hr'g Tr. (Albert) at 141:9-24 ("[redacted]")). Apple also argues a time-estimate allocation developed by Mr. Raghavan, similar to Dr. Albert's, is unreliable and cannot support any of the amounts including 2016-2017. *See id.* at 136-137.

As with the other categories, Apple is persuasive to the extent the investment should be limited to activity in support of KBS as opposed to other, non-practicing products. This indisputably includes the FDA submissions of 2016-2017, as none were made for [redacted] during this time. It would also likely include a portion of 2018, as this was the year the KardiaAI FDA

submission was filed, and KardiaAI is used in the KBS. CIB at 147; RRB at 74; Hr'g Tr. (Raghavan) at 575:19-23. Yet it is unclear what that portion should be. Mr. Raghavan estimated [redacted] which must be excluded. So to be conservative, 2018 is excluded entirely. And while Apple suggests that 2016-2017 is not reliable because "AliveCor was also working on regulatory submissions for [redacted]" (RIB at 136), the cited testimony only refers generally to "regulatory activities" (JX-0225C (Raghavan) at 92:12-23). Mr. Raghavan's testimony likely referred to the group's quality function ([redacted]) and not FDA submission function. Hr'g Tr. (Raghavan) at 573:16-22 (two functions, regulatory and quality), 575:1-3 ([redacted]); *see* CRB at 86. ALC's figures, and allocation percentages, of 2016-2017 are otherwise reliable.

In reply, ALC contends the full set of 2016-2021 is appropriate because "[Apple] never disputes—or even mentions—[redacted] CRB at 86 (citing Hr'g Tr. (Raghavan) at 568:19-569:12). Yet it is undisputed the KBS production was cancelled in 2019, such that this FDA submission cannot possibly be in support of it as a product.

As for the final row, customer support, there is no dispute that the cancellation of the KBS in 2019 does not affect these amounts, because previous purchasers continued to have service issues. And, since [redacted] have not been released, no amounts tied to these two products need be removed. Apple continues to contend the investment figures are overstated and unreliable, however. RIB at 137. Specifically, Apple argues the [redacted] and should not be credited to KBS. *Id.* (citing JX-0227C (White) at 148:24-149:11, 150:3-6, 151:9-12, 148:24-

149:11; Hr'g Tr. (Vander Veen) at 1001:8-22). Apple also complains that very few of the tickets appear to concern SmartRhythm, which is a necessary feature to practice the claims, and suggests ALC's customer service contractor, [redacted], must be considered differently than ALC's internal team. *See id.* at 137-138.

Apple is partially persuasive. Its expert, Dr. Vander Veen, does more to explain why the hardware unknown tickets should not be counted than ALC's expert, Dr. Akemann, explains why they should. Hr'g Tr. (Vander Veen) at 1000:18-1001:22 ("the hardware unknown tickets do not appear to tie to the KardiaBand specifically"); Hr'g Tr. (Akemann) at 652:21-25 ("in some cases they don't know the product type and they record that too"). So they are removed from consideration, but as ALC notes, this makes little difference. CRB at 87 (removal changes allocation from [redacted]). Apple's other points are not accepted. It is not clear why [redacted] contractor costs require an allocation distinct from the one used for ALC's internal personnel; once KBS is shown to practice a claim of an asserted patent (above), customer support activities related to any part of that article can be counted—not just those associated with SmartRhythm. The following customer support costs are therefore included in ALC's subsection (B) calculus: [redacted]

Accordingly, the total amounts to be considered for significance, for an industry that "exists" under subsection (B), are as follows, with 2021 removed because data for just Q1 (up to the filing of the complaint) does not appear to be available, and with allocation percentages involving "Unknown Hardware" removed:

	2016	2017	2018	2019	2020	2021	Total
DI Contractor R&D Labor							
DI Regulatory Labor							
DI Customer Support Labor							
Total DI Labor Investments							

See generally CX-0930C (customer support).

c. Subsection (C) – Licensing and Research and Development

Considering subsection (C), "substantial investment in its exploitation, including engineering, research and development, or licensing," ALC contends its R&D has always been in "critical components of a DI Product" such as KardiaAI, the KardiaApp, and SmartRhythm. *See* CIB at 162-163; *see* CRB at 74-75. ALC argues that investments in such critical components qualify. CIB at 163 (citing *Certain Beverage Brewing Capsules, Components Thereof, and Products Containing the Same*, Inv. No. 337-TA-929, Comm'n Op. at 82 (April 5, 2016); *Certain Electronic Digital Media Devices and Components Thereof*, Inv. No. 337-TA-796, Comm'n Op. at 99-100 (Sept. 6, 2013)); CRB at 83-84. ALC presents the following amounts for subsection (C) consideration:

	2016	2017	2018	2019	2020	2021	Total
Allocated R&D Expenses							

CIB at 163 (citing, *inter alia*, Hr'g Tr. (Akemann) at 659:25-660:18; CX-0918C; CX-0920C; CX-0924C; CX-0925C). Dr. Akemann explains how these figures are simply the sums of previously calculated subsection (A) and (B) values:

> This shows the allocated R&D expenses in each year. It shows the derivation of the [redacted] figure in the far right corner, which maps to the first slide of numbers that I put on the screen. So this shows the plant and equipment and labor expenses that just relate to the R&D group post-allocation, focusing in on a fraction of those expenses that I think are reasonably related to the three DI products at issue in this investigation.

Hr'g Tr. (Akemann) at 660:10-18.

In opposition, and on subsection (C) specifically, Apple argues all 2019-2021 figures must be eliminated because of testimony from Dr. Albert that "there was no investment in KBS after 2018." RIB at 141 (citing JX-0223 (Albert) at 249:16-20, 254:15-18, 255:21-24), 142-143. Apple also argues that ALC has failed to show sufficient nexus between the alleged investments and the asserted patents. *Id.* at 142 (citing *Certain Integrated Circuit Chips and Products Containing Same*, Inv. No. 337-TA-859, Comm'n Op., 2014 WL 12796437, at *22 (Aug. 22, 2014)). Apple highlights Dr. Akemann's admission that he has no opinion on the matter, and simply assumed nexus existed. *Id.* (citing Hr'g Tr. (Akemann) at 720:15-21).

ALC has not shown that a majority of its alleged investments for subsection (C) are sufficiently reliable. Unlike subsections (A) and (B), where a connection is made between an alleged investment and a patent-practicing product, a subsection (C) analysis requires a connection between the R&D investment and the asserted patents (*i.e.*, nexus). *See Electronic Candles*, Inv. No. 337-TA-1195, Comm'n Op. at 15-17 ("On remand, Complainants must show a nexus between the investments and the patented features of its candles specifically if they seek to show a domestic industry under subsection 337(a)(3)(C).")). The record certainly evidences a qualitative effort on the part of ALC to refine and improve features like SmartRhythm and KardiaAI—which have a

clear nexus to the heart rate and ECG analysis limitations recited in the Asserted Claims of the 941, 731, and 499 patents. *See, e.g.*, CIB at 162-163 (referring to work on "KardiaAI, the Kardia App, and SmartRhythm" as components of products).

But the *quantitative* amounts presented for ALC's subsection (C) theory are not derived from records or testimony concerning the amount of work ALC puts into these features. Rather, they are generated from the same per-employee, per-DI Product time estimates provided by Dr. Albert and found deficient above. *See* CIB at 163 ("Dr. Akemann calculated AliveCor's research and development investments using the same allocation methods discussed above."); *see also* CX-0918C (detailing facility investments for R&D using Dr. Albert's headcount estimates); CX-0920C (same for equipment); CX-0923 (same for hardware labor and software labor).

And a close review of ALC's evidence demonstrates why Dr. Albert's estimates are particularly not reliable for R&D. CX-0932C, a worksheet taken from the expert report of Dr. Akemann, displays Dr. Albert's employee time estimations (2016 – Q1 2021) alongside the estimations of Mr. Somayajula (Q2/Q3 2021). For those individuals working on the DI Products for both time periods, there is a marked decrease in the portion of their time spent as between the two estimations.

Name	Dept.	2016	2017	2018	2019	2020	2021 Q1	2021 Q2 - 2021 Q3	2021
[redacted]									

[redacted]. *Id.* ALC may argue these drops are due to the conservative calculus Mr. Somayajula applied (*see* Hr'g Tr. (Somayajula) at 223:17-225:21 (describing email/meeting records review with strict limits)), which is probably a contributing factor. But that Mr. Somayajula's methodology may actually be appropriate only casts more doubt over Dr. Albert's knowledge on the matter.

Adding to the dubiousness of ALC's numbers is the general lack of familiarity Dr. Albert displayed at the hearing concerning the development and status of the [redacted] products, despite being someone allegedly "very involved in new product development":

> Well, as the common denominator in the company since the beginning, and as I'm very involved in new product development, I was asked last year to estimate the contribution of this list of people to KardiaBand, [redacted].

Hr'g Tr. (Albert) at 96:14-19. When asked about the basic existence of any manufacturing agreements [redacted], he had no knowledge and indicated he would not even be the correct person to ask:

> Q. Okay. So AliveCor has not signed any manufacturing agreements [redacted], correct?
>
> A. I don't – you're talking to the wrong person on that one. I'm sorry.
>
> Q. You just don't know?
>
> A. yes, sir.
>
> Q. Okay. And you also don't know if [redacted] is going to be the manufacturer of the [redacted] product, correct?
>
> A. You're right, I do not know about that either.

Id. at 143:25-144:10. Dr. Albert also did not have firsthand knowledge of how the [redacted] started or its current status:

> Q. AliveCor has not found any suitable customers for the [redacted] correct?

A. [redacted], to be honest with you.

Q. Okay.

A. [redacted] So that's my understanding.

Q. Thank you, Dr. Albert. If you could just answer my question, sir, I'll move on. It is a fact that AliveCor has not found any [redacted]

A. I have no idea actually.

Q. Okay. You know that [redacted] correct?

A. I have no knowledge of that whatsoever.

Id. at 149:18-150:5; *see id.* at 185:7-17. Even though the [redacted]—*i.e.*, the time period Dr. Albert was not asked to estimate—how the project started and its current status should be basic knowledge for one who is "the common denominator in the company since the beginning, and . . . very involved in new product development."

Dr. Albert even suggested he has never communicated with [redacted] or other matters: "Q. Well, you recognize that the product that you put on your slide is called [redacted] right? A. No, I did not know that. I wasn't directly involved with the names of the contracts, so I don't interface [redacted]" Hr'g Tr. (Albert) at 151:14-19. [redacted]. Hr'g Tr. (Somayajula) at 206:4-7, 257:8-18. But despite all this lack of knowledge, Dr. Albert later claimed to somehow know that AliveCor helped [redacted]. *Id.* at 154:11-21.

Perhaps most tellingly, when shown a CAD image for a [redacted] —presented by ALC as evidence of the completeness of the design—Dr. Albert had no idea what it was:

> Q. Let me try a different one. Can I have slide 44? You recall this one, right, Dr. Albert?
>
> A. Yes.
>
> Q. This is a 3D printed device, correct?
>
> A. I don't know that that's what it is, but you've told me that's what it is, so I'll say yes.
>
> Q. Well, sir, unfortunately I don't get to testify.
>
> A. Well, the truth is, I've seen – I saw this device for the first time the day before yesterday, at least it brought down from our facility in Mountain View. So what I will tell you is I don't know how it was manufactured.

Hr'g Tr. (Albert) at 154:22-155:7. In confirmation of his lack of first-hand knowledge on this project, Dr. Albert testified, again, that he was the wrong person to ask questions about the status of the prototype:

Q. In fact, as of the date of the complaint, AliveCor did not have any [redacted], correct?

A. You're talking to the wrong person for that. You'd have to get somebody who knows that hardware part more than I do, that would have greater detail than I do, sir.

Q. So you just don't know one way or the other [redacted]

A. You're correct, I do not.

Id. at 170:16-25. And, following all of this testimony, Dr. Albert re-confirmed the estimations at the heart of ALC's subsection (A), (B), and (C) calculations were "simply my knowledge of the projects we had going at the time and what I thought those – how much of their time they were spending on the KardiaBand project or the [redacted]. That's what I was asked to comment on." *Id.* at 186:22-187:1.

In sum, the most logical inference to draw is that Dr. Albert's estimations, on their own, are not sufficiently reliable for determining the quantitative value of ALC's R&D activities as they concern the Asserted Patents. Thus, the hardware labor, software labor, facilities, and equipment amounts in ALC's subsection (C) totals are disregarded.

This leaves payments made to R&D contractors, with those payments having been recorded in CPX-0048C and summed by Dr. Akemann. *See* CX-09236C (presenting totals for "DI Contractor R&D Labor" and citing "Exhibit 7b"); CX-0925C ("Exhibit 7b" and citing, via Bates Number, CPX-0048C). These are not tied to Dr. Albert's percentages, and unlike hardware labor, software labor, facilities, and equipment, CPX-0048C provides at least some description of the activity behind each cost that *suggests* a nexus to sensors, circuitry, and housing structure:

See CPX-0048C (Tabs "2017 QB," "NS 2018-2020"). And while no ALC witness explained any of these projects or relationships, and Dr. Akemann made clear he conducted no analysis on nexus (Hr'g Tr. (Akemann) at 720:8-21), Apple's expert, Dr. Vander Veen, also did not opine that any of these expenses have no nexus to the Asserted Claims (*see* Hr'g Tr. (Vander Veen) at 1012:9-16 (opinion limited to Dr. Akemann's lack of opinion)). Thus, the contractor R&D expenses are accepted.

Accordingly, the total amounts to be considered for substantiality, for an industry that "exists" under subsection (C), are as follows:

	2016	2017	2018	2019	2020	2021	Total
Total DI R&D							

See CX-0923C (DI Contractor R&D Labor).

2. "Significant" or "Substantial"

The next step in the evaluation of domestic industry is to determine if the investment amounts identified above are "significant," as in subsections (A) and (B), or "substantial," as in subsection (C). The most recent precedential decision by the Court of Appeals for the Federal Circuit addressing this determination is *Lelo*, which restated law applicable to a number of issues surrounding the economic prong of domestic industry. *See* 786 F.3d at 883-85. In particular, the Federal Circuit held that the statutory terms "'significant' and 'substantial' refer to an increase in quantity, or to a benchmark in numbers," and "[a]n 'investment in plant and equipment' therefore is characterized quantitatively, *i.e.*, by the amount of money invested in the plant and equipment." *Lelo*, 786 F.3d at 883. Continuing, the Federal Circuit held "[a]ll of the foregoing requires a quantitative analysis in order to determine whether there is a 'significant' increase or attribution by virtue of the claimant's asserted commercial activity in the United States." *Id.* In short, "[q]ualitative factors cannot compensate for quantitative data that indicate insignificant investment and employment." *Id.* at 885. The Commission has since made clear that some sort of comparative analysis must be made before significant or substantial can be found. *See, e.g.*, *Gas Spring Nailers*, Inv. No. 337-TA-1082, Notice of Comm'n Determination at 3 (Dec. 12, 2019); *Certain Carburetors and Products Containing Such Carburetors*, Inv. No. 337-TA-1123, Comm'n Op. at 17-19 (Oct. 28, 2019) ("*Carburetors*").

As determined above, ALC has not presented sufficiently reliable figures for subsection (A) such that no determination need be made on significance. *Stud Finders*, Inv. No. 337-TA-1221, Comm'n Op. at 48, 50-51. The amounts established for subsections (B) and (C) above, however, are considered.

a. Subsection (B) – Labor and Capital

ALC argues its labor and capital expenditures in "a hardware development team, software development team, AI team, regulatory team, and customer support team" are qualitatively and quantitatively significant. CIB at 159-160. ALC presents its [redacted] figure from 2016 to 2021 as "approximately [redacted] of the total AliveCor labor and capital investments from 2016 to 2020" and refers to the testimony of Dr. Akemann to explain why this is "a significant percentage." *Id.* at 160 (citing, *inter alia*, Hr'g Tr. (Akemann) at 663:7-664:5). Alternatively, ALC argues for significance based on sales of KBS which "[f]rom 2018 to 2019 . . . accounted for [redacted] of AliveCor's hardware revenues and [redacted] of AliveCor's total revenues" and as compared to [redacted] in payments to [redacted] for development of the [redacted]. *See id.* at 160-161. With that said, ALC disputes that foreign development/manufacturing costs even need to be considered since "AliveCor's operations do not include manufacturing." CIB at 148 (citing *Certain Movable Barrier Operator Systems and Components Thereof*, Inv. No. 337-TA-1118, Comm'n Op. at 26 (Jan. 12, 2021) ("*Movable Barriers*"), 161 n.18 (same); *see* CRB at 90. And in reply, ALC points to the year 2018 "which, according to charts in Apple's brief, amounted to over [redacted] of AliveCor's overall labor and capital spend that year and over [redacted] of overall plant and equipment spend that year." CRB at 77.

Using the same quantitative contexts provided by ALC, significance has not been shown under subsection (B). ALC's labor of [redacted] of 2016-2021 is closer to [redacted] of its total labor and capital investments from 2016 to 2020, instead of ALC's calculated [redacted]. *See* CIB at 160. This is not a significant percentage on its own. And even though there is bound to be some additional domestic labor from currently uncounted ALC personnel due to Dr. Albert's otherwise-discounted estimation, it would not have made a material difference. ALC would have an internal labor investment (hardware and software) of [redacted] from 2016-2017. CIB at 159. Adding this

to ALC's accepted labor of [redacted] creates [redacted]n, which is still only [redacted] of ALC's total labor and capital investment for 2016-2020.

More importantly, ALC's comparative approach is barely even relevant, because the fact that "a complainant may have substantial sales of other products is not pertinent to this analysis." *Carburetors*, Inv. No. 337-TA-1123, Comm'n Op at 28. A large company with many products may have a domestic industry based on one such product, even though it only accounts for a tiny percentage of the company's expenses; conversely, a small company with a single qualifying product may not have a domestic industry if the bulk of its investments are overseas. And in both cases, the most commonly accepted approach to proving a domestic industry is by substantiating either "the value added to the article in the United States by the domestic activities," or "the relative domestic contribution to the protected article by comparing complainant's product-related domestic activities to its product-related foreign activities." *Id*. at 19. Comparing DI labor and capital expenses to total ALC labor and capital expenses addresses neither of these metrics.

That the thousands of KBS products sold were likely manufactured overseas (*see* Hr'g Tr. (Akemann) at 646:6-12) makes ALC's comparison especially inapt, because it raises the possibility that ALC was a "mere importer[]." *Electronic Candles*, Inv. No. 337-TA-1195, Comm'n Op. at 8, 19; *Movable Barriers*, Inv. No. 337-TA-1118, Comm'n Op., Separate Views of Chair Kearns Regarding Economic Prong Issues at 2 (Jan. 12, 2021). This is so despite ALC's argument that manufacturing costs need not be considered. CIB at 161 n.18. Its cited case, *Movable Barriers*, merely held that a complainant's economic prong case does not automatically fail if the complainant fails to include foreign manufacturing costs:

> [W]hile foreign manufacturing costs may be relevant to proving that a complainant's investments are significant or substantial, Nortek has provided no authority that compels a finding that domestic investments cannot satisfy the

> domestic industry requirement in the absence of presenting a comparison of foreign manufacturing costs to a complainant's U.S. investments.

Inv. No. 337-TA-1118, Comm'n Op. at 24. Yet the Commission also made clear that when manufacturing is entirely overseas (as with KBS) foreign investment is certainly relevant. *Id.* at 24, 26 n.10 ("This is not to say that foreign manufacturing data is irrelevant. Such evidence may be useful in evaluating the significance of a complainant's domestic activities where, [[ ]], the DI products are manufactured primarily (or exclusively) overseas."). In view of the payments [redacted], the foreign manufacturing expenses for KBS may have been in [redacted]. *See* CIB at 161; JPX-0012C. Equally relevant are any foreign labor expenditures for development of the product, which in this case have not been called out clearly. *See, e.g.*, CPX-0048C ([redacted]); CX-0925 ([redacted]).

On the whole, then, it is fair to infer that foreign labor investment, if proven, would weigh against a finding of significance. ALC's remaining quantitative context, the percentage of ALC total revenue provided by KBS, is not material because it does not involve investment at all, and is for a limited range of years. *See* CIB at 160 (highlighting that in 2018-2019, KBS supplied "[redacted] of AliveCor's hardware revenues and [redacted] of AliveCor's total revenues.").

Accordingly, it has not been shown that ALC's investment in domestic labor in support of the KBS (and, therefore, the Asserted Patents) is "significant."

b. Subsection (C) – Licensing and Research and Development

For the related question of a "substantial" domestic industry through its R&D activities, ALC contends its 2016 – Q1 2021 total is closer to [redacted], and that this is substantial "for many of the same reasons the investments are significant under subprongs (A) and (B)." CIB at 164. ALC also offers that the amount is "approximately [redacted] of total AliveCor R&D expenses

over the period at issue." *Id.* (citing, *inter alia*, CX-0941C). As with labor and capital under subsection (B), this comparison is not helpful.

Nonetheless, there is circumstantial quantitative evidence suggesting that ALC's R&D labor expenses overall, including for the DI Products, are mostly domestic. Dr. Akemann opines that over the entire DI period [redacted] of ALC's total headcount was domestic, of which [redacted] worked in software and hardware R&D. *See* CDX-0001C.16. His underlying computation supports his opinion:

Exhibit 15
AliveCor Headcount by Team vs International Headcount by Team

U.S.		2016	2017	2018	2019	2020	2021	2016 - 2021
Software Team	[A]	[redacted]						
Hardware Team	[B]							
Regulatory Team	[C]							
Customer Support	[D]							
Other	[E]							
DI Teams	[F]=SUM([A]:[D])							
Total	[G]=SUM([A]:[E])							
International								
Total	[H]							
DI Teams U.S. %	[I]=[F]/([F]+[H])							
Total U.S. %	[J]=[G]/([G]+[H])							

CX-0937C. After comparing domestic and foreign R&D headcount, especially for the period 2016-19, it is likely that ALC's internal R&D labor expenses for KBS were overwhelmingly domestic, even without allocation.

This conclusion is weakened only slightly by considering the R&D contractor expenses allocated to the DI Products of [redacted], which were incurred almost entirely over the same period, as well as the 2020 - Q1 2021 headcount. *See* CX-0925C. Converting [redacted] to headcount by conservatively assuming it is all for labor, and then dividing it by ALC's "Average Salary" in 2020, approximately [redacted] were dedicated to DI-related contractor R&D between 2016 and 2020. *See* CX-0050C (Tab "Salaries – All YE 20" (row 145)).

Even treating these contractor costs as foreign, it is still likely the DI-related R&D labor costs were substantially domestic, because the total domestic headcount of the software and

hardware teams for 2016-19 totaled [redacted]. *See* CX-0937C. As for 2020 - Q1 2021, although "international" headcount jumped dramatically, domestic R&D headcount also increased, and in 2020 remained larger even than total international headcount ([redacted]). *See id*. And contractor costs for 2020 – Q1 2021 were negligible. *See* CX-0925C. Moreover, while ALC's record of R&D contractor payments do suggest a material amount of foreign payments towards the DI Products in 2016-2020 that have otherwise gone unaddressed in ALC's briefing (see CPX-0048C (Tabs "2016 PCH," "2017 QB, "NS 2018-2020 (see payments to PCH International)); CX-0935C (note: "Excludes expenses with Vendor Name of PCH International"), they only add up to [redacted]). If this is the true extent of foreign R&D payments over this time and dedicated to the DI Products, then it only further supports the substantiality of the [redacted] domestic spend.

On balance, therefore, ALC has demonstrated economic prong under subsection (C) by a preponderance of the evidence. Apple's argument in opposition largely rests on accepting the near-zero research and development costs in the KBS after 2018 as dispositive, as opposed to addressing whether or not the ALC's quantitative evidence is "substantial." *See* RIB at 141-143; Hr'g Tr. (Vander Veen) at 1012:2-22. Because ALC likely had a substantial domestic headcount relative to its foreign R&D labor expenses, Apple's argument is not persuasive.

The overall analysis here is troubling, to be sure. It is no secret that a domestic-to-foreign comparison is at least the preferred method of proving economic prong. *See Carburetors*, Inv. No. 337-TA-1123, Comm'n Op at 17-19. The parties were even warned at the end of the evidentiary hearing that "you need to compare foreign and domestic investments." Hr'g Tr. at 1312:17-18. For whatever reason, however, ALC has seemingly taken the position that no such comparison is needed. Fortunately for ALC, Dr. Akemann assembled a sufficiently detailed and pertinent

headcount comparison showing it more likely than not that DI-related R&D labor expenses were substantially domestic.

Accordingly, ALC has met the economic prong under subsection (C) for a domestic industry that "exists."

B. Domestic Industry in the Process of Being Established

ALC contends, "if AliveCor does not have an ongoing domestic industry, its investments related to [redacted] demonstrate an industry in the process of being established." CIB at 164. ALC continues:

> A domestic industry is in the process of being established when the complainant "demonstrate[s] that [it] is taking the necessary tangible steps to establish an industry" and that there is a "significant likelihood that the industry requirement will be satisfied in the future." *Certain Stringed Musical Instruments*, Inv. No. 337-TA-586, Comm'n Op., at 13 (May 16, 2008) (quotation marks omitted). The complainant need not establish that its practicing article is a product that has been or will be commercialized. *See Certain Non-Volatile Memory Devices*, Inv. No. 337-TA-1046, Comm'n Op., at 40-44 (Oct. 26, 2018). Past research and development investments combined with evidence of "further planned work to be undertaken in order to bring [an] industry to fruition within the foreseeable future" is sufficient. *Id.* at 44.

Id. at 164-165. ALC concentrates on investments from 2018-2021 to demonstrate the work that has already been done for the domestic industry in the process of being established. *Id.* at 165, 167-169 (broken out per subsection (A), (B), (C)). ALC adds that the 2018-2021 amounts are "significant" or "substantial" for generally the same reasons as the previous 2016-2021 amounts. *See id.* CIB at 167-169.

Referring back to the standard, ALC points to the "tangible steps" it presently takes to achieve prototype [redacted] that run the KardiaApp (with KardiaAI), and those arrangements it has made for future FDA submissions. *See* CIB at 165-166; CRB at 91 ("all of the components on the [redacted]."), 93. As for a likelihood of success, ALC points to its timelines for moving from [redacted]

[redacted], among other documentary evidence. *See* CIB at 166.

In response to Apple, ALC disputes that it has provided no "'financial forecast, sales projection, budget, planned investment, marketing plan, or manufacturing agreement for the [redacted]'" and points to the press release frequently asked questions (PRFAQ) document it created, a development plan, "a plan specific to [redacted]" and a purchase order for EVT and PVT work [redacted] CRB at 92 (citing, *inter alia*, JX-0095C; JX-0090C; JX-0096C; CX-0485C). ALC rejects any contention that its materials amount to one or two CAD drawings, as the Commission has found insufficient in the past. *Id.* at 93 (citing *Thermoplastic Motors*, 2019 WL 9596564, at *8). ALC concludes that even if the [redacted] projects take years to commercialize, those years will be filled with relevant, recognizable investment. *See id.* at 94.

ALC has not shown a domestic industry is "in the process of being established." Much like its approach to a domestic industry that "exists," ALC pins its case on investments in support of certain patent-practicing products—in this case, the [redacted]—as opposed to investments in research and development work with direct nexus to the Asserted Patents—*e.g.*, KardiaAI or SmartRhythm. This is problematic, because the evidence as of the complaint filing (April 20, 2021) does not convincingly demonstrate "a significant likelihood that the industry requirement will be satisfied in the future" for either product. *Thermoplastic Motors*, Inv. No. 337-TA-1073, Comm'n Op. at 11 (citing *Stringed Instruments*, Inv. No. 337-TA-1073, Comm'n Op. at 13).

This can be seen by examining ALC's contentions. For subsection (A) it refers to an amount of [redacted] spent from 2018 up to the complaint and argues, "it is reasonable to expect plant and equipment investments in the [redacted] to continue in the future given the

concrete plans to continue product development and regulatory submission work." CIB at 167. Even if this number were reliable, which it is not per Dr. Albert's estimations, it is not clear that the amount would constitute a significant value-add to the [redacted] products. Both of these products, if commercialized, are expected to be manufactured overseas. Hr'g Tr. (Akemann) at 686:22-4 ([redacted]), 700:2-12 ([redacted]); JX-0095C.1. If, for example, $4.5 million is spent in facilities and equipment to produce these products over three years, then ALC's domestic contribution comes to approximately [redacted] This value-add is of questionable significance.

Even then, it is not clear the efforts of ALC personnel (leading to time estimations, which provide facility and equipment values) will continue as alleged. ALC's plan for [redacted], in particular, [redacted]—the equivalent of a license. *See* JX-0095C (PRFAQ document). Such activities shortly before filing the complaint (JX-0008) certainly constitute a "necessary tangible" step, but it cannot be said there is a "significant likelihood" that economic prong will be satisfied given ALC's current plans.

ALC witness testimony, contractor invoices, and project summary reports overwhelmingly show that "necessary tangible" steps to developing the [redacted] were taken across 2018 - Q1 2021. *See, e.g.*, Hr'g Tr. (Somayajula) at 2015:9-206:7; Hr'g Tr. (Raghavan) at 568:16-570:15; CPX-0048C (Tabs "2017 QB," "NS 2018-2020"); JX-0152C; JX-096C. Yet, at the time of the complaint, the product did not even [redacted]. Thus, a substantial, further, amount of research and development is needed before [redacted] can be entered into a study, qualified by the FDA, or marketed, among other things. *See* RIB at 147 (citing Hr'g Tr. (Albert) at 185:7-23, 158:8-15; Hr'g Tr. (Somayajula) at 252:18-22), 149.

Whether or not ALC will undertake this effort, and whether or not it takes place domestically—as evaluated at the time of the complaint—is unclear. ALC's expenses show it has R&D contacts overseas (CPX-0048C) and its internal time estimations indisputably show fewer and fewer of its own employees working on the project (CDX-0005C.48). Indeed, not one person dedicates [redacted] to getting this new product off the ground (*see* CDX-0005C.48) , and it appears in 2020 that ALC has begun a concerted push to hire substantially more foreign personnel (*see* CX-0937C; CPX-0048C (Tab "Salaries-all YE 20")). And as Dr. Vander Veen persuasively testified, without dispute from Dr. Akemann, there are no records of planned investment or forecasting revenue for the project:

> Here what I think is really important is what you would expect to see in terms of business plans or financial plans for -- if there were to be significant investments, you know, in the future.
>
> If there were plans for -- if there were going to be significant investments for this domestic industry, I would expect to see that there would be plans for those investments, and, even more than that, that there would be management review, approval, and even potential board approval of such investments.
>
> We don't see any planned investments or documents to support investments here related to [redacted]
>
> [redacted] We don't see approved budgets for this ongoing or future work. There's no financial forecast or sales forecasts. [redacted] -- there's been no public announcement of either of these products or launch of these products.
>
> [redacted]
>
> So I think, as we look at this, these factors, it doesn't -- it doesn't support that there's a significant likelihood of domestic industry for these two products that are in the process of being established. I think this is true both at the time of the filing of the complaint and all of these elements appear to be true even today.

Hr'g Tr. (Vander Veen) at 1013:7-25; *see* Hr'g Tr. (Akemann) at 686:5-10 ("I don't recall seeing any financial planning documents that project out investments, for example, that's correct.").

These documents would have been the exact "concrete plans" ALC alleges exist. CIB at 167. The more reasonable inference, then, is that [redacted] is in more of an exploration phase as opposed to a planned commitment. *See* JX-0152C [redacted] defining "product definition, feature expectations, and product risks"). Thus, ALC has not shown—at the time of the complaint—a "significant likelihood" economic prong will be met through [redacted].

Accordingly, it has not been shown that a domestic industry under subsection (A) is "in the process of being established" through the [redacted]

The same determination is warranted for subsection (B). Here, ALC refers to [redacted] in labor that it spent from 2018 – Q1 2021, and reasons, again, that it "expect[s] these investments to continue in the future given the concrete plans to continue product development and regulatory submission work." CIB at 168. Not only is this amount not reliable as built upon Dr. Albert's time estimations, but it does not overcome the overall plan for [redacted]

Similarly, for subsection (C), ALC points to [redacted] it spent on R&D from 2018 – Q1 2021. CIB at 169. Although not stated, it is assumed ALC contends a similar amount can be expected to be further invested as in subsections (A) and (B). Again, this number is not particularly reliable, and in any event it is not clear that the amount previously spent will be spent again going forward, within the United States by ALC, or overseas by ALC or by a contractor.

Accordingly, it has not been shown that a domestic industry under subsections (A), (B), or (C) is "in the process of being established" through the [redacted].

VIII. CONCLUSIONS OF LAW

1. ALC has proven infringement of claims 12, 13, 19, 20, 21, 22, and 23 of U.S. Patent No. 10,683,941 by the Accused Products.

2. ALC has proven infringement of claims 1, 3, 5, 8, 9, 10, 12, 15, and 16 of U.S. Patent No. 10,595,731 by the Accused Products.

3. ALC has not proven infringement of claims 16 or 17 of U.S. Patent No. 9,572,499 by the Accused Products.

4. Apple has not proven any claim of U.S. Patent No. 10,683,941 invalid.

5. Apple has proven claims 1, 8, 12, and 16 of U.S. Patent No. 10,595,731 are invalid as obvious under 35 U.S.C. § 103, and otherwise has not proven any claim invalid.

6. Apple has proven claim 17 of U.S. Patent No. 9,572,499 is invalid for lack of patentable subject matter under 35 U.S.C. § 101, and otherwise has not proven any claim invalid.

7. ALC has proven the existence of a domestic industry as required by 19 U.S.C. § 1337(a)(2) for U.S. Patent Nos. 10,683,941, 10,595,731, and 9,572,499, in that it has proven that a domestic industry exists that practices at least one valid claim of each patent.

8. There is a violation of section 337 with respect to U.S. Patent No. 10,683,941.

9. There is a violation of section 337 with respect to U.S. Patent No. 10,595,731.

10. There is no violation of section 337 with respect to U.S. Patent No. 9,572,499.

IX. RECOMMENDED DETERMINATION ON REMEDY AND BOND

The Commission's Rules provide that subsequent to an initial determination on the question of violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, the administrative law judge shall issue a recommended determination concerning the appropriate remedy in the event that the Commission finds a violation of section 337, and the amount of bond to be posted by respondent during Presidential review of the Commission action under section 337(j). *See* 19 C.F.R. § 210.42(a)(1)(ii).

The Commission has broad discretion in selecting the form, scope, and extent of the remedy in a section 337 proceeding. *Viscofan, S.A. v. Int'l Trade Comm'n*, 787 F.2d 544, 548 (Fed. Cir. 1986). Under Section 337(d)(1), if the Commission determines as a result of an investigation that there is a violation of section 337, the Commission is authorized to enter either a limited or a general exclusion order. 19 U.S.C. § 1337(d)(1). A limited exclusion order instructs the U.S. Customs and Border Protection ("CBP") to exclude from entry all articles that are covered by the patent at issue and that originate from a named respondent in the investigation. A general exclusion order instructs the CBP to exclude from entry all articles that are covered by the patent at issue, without regard to source. *Certain Purple Protective Gloves*, Inv. No. 337-TA-500, Comm'n Op. at 5 (Dec. 22, 2004). Under section 337(f)(1), the Commission may issue a cease and desist order in addition to, or instead of, an exclusion order. 19 U.S.C. § 1337(f)(1). The Commission generally issues a cease and desist order directed to a domestic respondent when there is a "commercially significant" amount of infringing, imported product in the United States that could be sold, thereby undercutting the remedy provided by an exclusion order. *See Certain Crystalline Cefadroxil Monohydrate*, Inv. No. 337-TA-293, USITC Pub. 2391, Comm'n Op. on Remedy, the Public Interest and Bonding at 37-42 (June 1991); *Certain Condensers, Parts Thereof*

and Prods. Containing Same, Including Air Conditioners for Automobiles, Inv. No. 337-TA-334 (Remand), Comm'n Op. at 26-28 (Sept. 10, 1997).

Additionally, during the 60-day period of Presidential review under 19 U.S.C. § 1337(j), "articles directed to be excluded from entry under subsection (d) . . . shall . . . be entitled to entry under bond prescribed by the Secretary in an amount determined by the Commission to be sufficient to protect the complainant from any injury." *See* 19 U.S.C. § 1337(j)(3). "The Commission typically sets the bond based on the price differential between the imported infringing product and the domestic industry article or based on a reasonable royalty. However, where the available pricing or royalty information is inadequate, the bond may be set at one hundred (100) percent of the entered value of the infringing product." *Certain Industrial Automation Systems and Components Thereof Including Control Systems, Controllers, Visualization Hardware, Motion and Motor Control Systems, Networking Equipment, Safety Devices, and Power Supplies*, Inv. No. 337-TA-1074, Comm'n Op. at 13 (Apr. 23, 2019) ("*Automation Systems*") (public version) (citation omitted).

A. Limited Exclusion Order

Should a violation be found, there is no dispute that a limited exclusion order ("LEO") should issue against Apple. *See* CIB at 171 ("cover[ing] all infringing products imported by or on behalf of Apple or its agents"); *see generally* RIB at 167-169, 173-175; RRB at 95-98, 99-100; SIB at 88. Apple argues the order should, however, include a standard certification provision (RIB at 169) and a number of other modifications.

First, Apple seeks a stay of any remedial order until two conditions are met:

> (1) the PTAB has issued its final written decision in the now-instituted IPRs Apple filed on the Asserted Patents, and (2) AliveCor submits evidence that it has a protectable domestic industry product that has been FDA cleared and has commercially launched in the U.S. so as to avoid harming consumers.

RIB at 167-168, 173-175; RRB at 99-100. This request is denied. Apple's cited case, *Certain Laparoscopic Surgical Staplers, Reload Cartridges, and Components Thereof*, concerned an issued final written decision, not the mere institution of an IPR as is the present situation. Inv. No. 337-TA-1167, Comm'n Op. at 64 (Dec. 20, 2021). And the proposed domestic industry/FDA restriction goes well beyond a more typical reporting requirement and is otherwise vague. To the extent it is justified by public interest considerations (RIB at 174-175 ("it is U.S. consumers who will suffer . . .")), those have not been delegated to this proceeding and are reserved for Commission review. *See* 86 Fed. Reg. 28382 (May 26, 2021).

Second, Apple seeks an exception for repair, replacement, and warranty, with mention of additional public interest considerations. RIB at 168; RRB at 95-97; *see* RIB at 169-170. This too is reserved for Commission review. *See* 86 Fed. Reg. 28382 (May 26, 2021).

Third, Apple seeks an exemption "where the ECG app is either not used in or removed from the accused products because such products would be noninfringing products." RIB at 168. Apple also proposes any use or purchase by persons under 22 be exempt because the ECG feature is not meant for that group. *Id.* at 168-169. All of these requests are denied. Apple has not even attempted to show why a product which has not been used—or used, but by persons under the age of 22, or purchasers under 22—would not continue to infringe the asserted claims. Very likely, they would. Even then, once-infringing products modified to avoid infringement are intended for full fact gathering under section 337 modification proceedings. 19 C.F.R. § 210.76; *Certain Laparoscopic Surgical Staplers, Reload Cartridges, and Components Thereof*, Inv. No. 337-TA-1167, Comm'n Op. at 60 (Dec. 20, 2021).

Fourth, Apple seeks a standard certification provision without opposition. RIB at 169; *see* SIB at 92; *see generally* CIB; CRB. Certification provisions are known to "aid U.S. Customs and

Border Protection ('CBP') in enforcing Commission orders but 'do not mandate that CBP accept certification as proof that the articles in question are not covered' by the limited exclusion order." *Certain Robotic Vacuum Cleaning Devices and Components Thereof Such as Spare Parts*, Inv. No. 337-TA-1057, Comm'n Op. at 55 (Feb. 1, 2019). As "it has been Commission practice for the past several years to include certification provisions in its exclusion orders to aid CBP" (*see Certain Road Milling Machines and Components Thereof*, Inv. No. 337-TA-1067, Comm'n Op. at 15, 15 n. 5 (July 18, 2019) (citations omitted)), it is therefore recommended that in the event a limited exclusion order issues, it should include the Commission's standard certification provision.

B. Cease and Desist Order

Should a violation be found, ALC argues a cease and desist order ("CDO") should issue. CIB at 172. ALC references a stipulation from Apple that it "'will not dispute that it currently maintains a commercially significant inventory of the Accused Apple Products in the United States at the time hearing evidence is submitted in this Investigation.'" *Id.* at 173 (citing CX-0904C.3). Per that stipulation, ALC reports "a domestic inventory of [redacted] units that cumulatively value at over [redacted]" and argues it is "commercially significant" as well as an underestimation. *See id.* at 173. As with the LEO, ALC contends Apple's requested modifications to the CDO are inappropriate. *See* CRB at 94-95. The Staff agrees with ALC. SIB at 88; SRB at 89. Apple does not contest the issuance of a CDO but urges its list of LEO modifications should apply. *See* RIB at 167-170, 173-175; RRB at 95-98, 99-100.

Complainants bear the burden on the issue of cease and desist orders. *Certain Microfluidic Devices*, Inv. No. 337-TA-1068, Comm'n Op. at 23 (Jan. 10, 2020). Such orders "are generally issued when, with respect to the imported infringing products, respondents maintain commercially significant inventories in the United States or have significant domestic operations that could

undercut the remedy provided by an exclusion order." *Id.* at 22-23 (citations omitted). Given the stipulation referenced above, this inventory requirement is certainly met for Apple, and it is my recommendation that a cease and desist order issue against this respondent. *See* CX-0904C.3.

C. Bond

The Commission has held that "[t]he complainant bears the burden of establishing the need for a bond" during the Presidential Review period. *See Robotic Vacuums*, Inv. No. 337-TA-1057, Comm'n Op. at 68. The amount of the bond is, generally, set "to be sufficient to protect the complainant from any injury." 19 U.S.C. § 1337(e)(1), (j3).

ALC argues a bond is necessary. CIB at 173. ALC refers to Apple internal documents showing Apple believes ALC's products are competitive with Apple Watches and reasons, "[t]he injury to AliveCor is plain." *Id.* at 173-174; *see* CRB at 96. ALC explains, however, that a direct price comparison is impractical due to the nature of the KBS product being an accessory to unaccused Apple Watch models, with the accused products being whole Apple Watch products themselves. *See* CIB at 174 (citing Hr'g Tr. (Akemann) at 638:18-639:15). Thus, ALC looks to licensing evidence—in particular, the [redacted]—which it alleges supports an [redacted] $13 per-unit bond. *Id.*; CRB at 96.

Apple rejects any bond. RIB at 170. Apple argues that a bond is not meant as punishment or a deterrent to importation, but solely to offset any competitive advantage the respondent may have by virtue of the offending imports. *See id.* at 170-171 (collecting cases); RRB at 98. Apple continues:

> Should the Commission issue a bond, it should be set at zero because AliveCor does not compete with the accused Apple Watches, and has failed to prove that it would be injured by the importation of the accused Apple Watches, or that Apple enjoys a competitive advantage resulting from its alleged infringement.

CONFIDENTIAL MATERIAL OMITTED

RIB at 171 (citing Hr'g Tr. (Vander Veen) at 1021:6-14, 1050:21-1051:4). Like ALC, Apple cites to ALC internal documents suggesting ALC and Apple are not competitors in this space (*id.* at 172; RRB at 98), and otherwise argues ALC's $13 royalty is inappropriate based on the terms of the [redacted]

The Staff agrees with Apple, finding the evidence fails to support a $13 bond rate due, in part, to [redacted] SIB at 94 (citing JX-0008C.4; Hr'g Tr. (Vander Veen) at 1049:11-25); SRB at 52 ("AliveCor has not offered any evidence or set forth any arguments as to what portion of the [redacted] is attributable [redacted] as opposed to the asserted patents."). Thus, according to the Staff, the bond rate should be zero. SIB at 94; SRB at 52.

ALC has not met its burden for a bond requirement. The presidential review period is short (60 days), compared to the possible lifetime of an LEO or CDO (years). It is entirely unclear what competitive harm ALC will face during this time as the KBS product has not been sold for some time (Hr'g Tr. (Albert) at 135:14-136:22) and [redacted] are, at best, in development. And as for a reasonable royalty, Staff persuasively argues that the [redacted] (JX-0008C.1-3 ("2.1 [redacted])) in addition to a right to use the asserted patents. In fact, if ALC's contentions surrounding its contributions to the art are to be believed, then [redacted] must be of significant value. *See, e.g.*, CIB at 67 (referring to ALC's ground breaking and unconventional "configuration of sensors and algorithmic instructions"); CRB at 47 (alleging copying through [redacted]). With Apple using its own software, the $13 rate is demonstrably too high. As ALC has not offered alternative proposals reflecting this

reality, it has not met its burden. It is therefore recommended no bond should issue in the event of a violation.

X. INITIAL DETERMINATION AND ORDER

Based on the foregoing,[1] it is my Initial Determination that there is a violation of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain wearable electronic devices with ECG functionality and components thereof in connection with the asserted claims of U.S. Patent Nos. 10,638,941 and 10,595,731. There has been no violation of U.S. Patent No. 9,572,499.

The undersigned hereby certifies to the Commission this Initial Determination, together with the Record of the hearing in this investigation consisting of the following: the transcript of the evidentiary hearing, with appropriate corrections as may hereafter be ordered; and the exhibits accepted into evidence in this investigation.[2]

Pursuant to 19 C.F.R. § 210.42(h), this Initial Determination shall become the determination of the Commission sixty (60) days after the date of service of the Initial Determination, unless a party files a petition for review of the Initial Determination within twelve (12) days after service of the Initial Determination pursuant to 19 C.F.R. § 210.43(a) or the Commission, pursuant to 19 C.F.R. § 210.44, orders on its own motion, a review of the Initial Determination or certain issues therein. Any issue or argument not raised in a petition for review,

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[1] The failure to discuss any matter raised by the parties or any portion of the Record herein does not indicate that said matter was not considered. Rather, any such matter(s) or portion(s) of the Record has/have been determined to be irrelevant, immaterial or meritless. Arguments made on brief which were otherwise unsupported by Record evidence or legal precedent have been accorded no weight.

[2] The pleadings of the parties filed with the Secretary need not be certified as they are already in the Commission's possession in accordance with Commission rules.

or response thereto, will be deemed to have been abandoned and may be disregarded by the Commission in reviewing the Initial Determination pursuant to 19 C.F.R. § 210.43(b) and (c).

Confidentiality Notice:

This Initial Determination is being issued as confidential, and a public version will be issued pursuant to Commission Rule 210.5(f). Within seven (7) days of the date of this Initial Determination, the parties shall jointly submit: (1) a proposed public version of this opinion with any proposed redactions bracketed in red; and (2) a written justification for any proposed redactions specifically explaining why the piece of information sought to be redacted is confidential and why disclosure of the information would be likely to cause substantial harm or likely to have the effect of impairing the Commission's ability to obtain such information as is necessary to perform its statutory functions.[3]

SO ORDERED.

Cameron Elliot
Administrative Law Judge

[3] Under Commission Rules 210.5 and 201.6(a), confidential business information includes: information which concerns or relates to the trade secrets, processes, operations, style of works, or apparatus, or to the production, sales, shipments, purchases, transfers, identification of customers, inventories, or amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or other organization, or other information of commercial value, the disclosure of which is likely to have the effect of either impairing the Commission's ability to obtain such information as is necessary to perform its statutory functions, or causing substantial harm to the competitive position of the person, firm, partnership, corporation, or other organization from which the information was obtained, unless the Commission is required by law to disclose such information. *See* 19 C.F.R. § 201.6(a). Thus, to constitute confidential business information the disclosure of the information sought to be designated confidential must likely have the effect of either: (1) impairing the Commission's ability to obtain such information as is necessary to perform its statutory functions; or (2) causing substantial harm to the competitive position of the person, firm, partnership, corporation, or other organization from which the information was obtained.

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of **CERTAIN WEARABLE ELECTRONIC DEVICES WITH ECG FUNCTIONALITY AND COMPONENTS THEREOF**	**Inv. No. 337-TA-1266**

ORDER NO. 12: CONSTRUING THE TERMS OF THE ASSERTED CLAIMS OF THE PATENTS AT ISSUE

(November 4, 2021)

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I. INTRODUCTION

This investigation was instituted by the Commission on May 20, 2021 to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain wearable electronic devices with ECG functionality and components thereof by reason of infringement of one or more of claims 1-23 of U.S. Patent No. 10,638,941 ("the 941 patent"), claims 1-30 of U.S. Patent No. 10,595,731 ("the 731 patent"), and claims 1-4, 6-14, and 16-20 of U.S. Patent No. 9,572,499 ("the 499 patent"). *See* 86 Fed. Reg. 28382 (May 26, 2021). The Complainant is AliveCor, Inc. ("AliveCor"), the Respondent is Apple Inc. ("Apple"), and the Office of Unfair Import Investigations ("Staff") is a party. *See id*.

No *Markman* hearing was held. However, the parties filed joint proposed claim construction charts setting forth a limited set of terms to be construed, and also filed claim construction briefs.[1]

II. IN GENERAL

The claim terms addressed below are construed for the purposes of this investigation, and those terms not in dispute need not be construed. *See Vanderlande Indus. Nederland BV v. Int'l Trade Comm'n*, 366 F.3d 1311, 1323 (Fed. Cir. 2004) (noting that the administrative law judge need only construe disputed claim terms). The meaning of any claim terms not presently disputed will be addressed in connection with the evidentiary hearing.

[1] For convenience, the briefs and chart submitted by the parties are referred to as:

CIMB	Complainant's Initial Markman Brief
CRMB	Complainant's Reply Markman Brief
RIMB	Respondent's Initial Markman Brief
RRMB	Respondent's Reply Markman Brief
SIMB	Staff's Initial Markman Brief
JC	Joint Disclosure of Proposed Claim Constructions

III. RELEVANT LAW

"An infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (*en banc*) (internal citations omitted), *aff'd*, 517 U.S. 370 (1996). Claim construction is a "matter of law exclusively for the court." *Id.* at 970-71. "The construction of claims is simply a way of elaborating the normally terse claim language in order to understand and explain, but not to change, the scope of the claims." *Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1347 (Fed. Cir. 2000).

Claim construction focuses on the intrinsic evidence, which consists of the claims themselves, the specification, and the prosecution history. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (*en banc*); *see also Markman*, 52 F.3d at 979. As the Federal Circuit in *Phillips* explained, courts must analyze each of these components to determine the "ordinary and customary meaning of a claim term" as understood by a person of ordinary skill in art at the time of the invention. 415 F.3d at 1313. "Such intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language." *Bell Atl. Network Servs., Inc. v. Covad Commc'ns Grp., Inc.*, 262 F.3d 1258, 1267 (Fed. Cir. 2001).

"It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Phillips*, 415 F.3d at 1312 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)); *see Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) ("In construing claims, the analytical focus must begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to 'particularly point [ ] out and

distinctly claim [ ] the subject matter which the patentee regards as his invention."). The context in which a term is used in an asserted claim can be "highly instructive." *Phillips*, 415 F.3d at 1314. Additionally, other claims in the same patent, asserted or unasserted, may also provide guidance as to the meaning of a claim term. *Id*. "Courts do not rewrite claims; instead, we give effect to the terms chosen by the patentee." *K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1364 (Fed. Cir. 1999).

The specification "is always highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed term." *K-2 Corp.,* 191 F.3d at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). "[T]he specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." 191 F.3d at 1316. "In other cases, the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor." *Id.* As a general rule, however, the particular examples or embodiments discussed in the specification are not to be read into the claims as limitations. *Id.* at 1323. In the end, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be . . . the correct construction." *Id.* at 1316 (quoting *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998)).

In addition to the claims and the specification, the prosecution history should be examined, if in evidence. *Id.* at 1317; *see Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 913 (Fed. Cir. 2004). The prosecution history can "often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Phillips*, 415 F.3d at 1317; *see Chimie v. PPG Indus. Inc.*, 402 F.3d 1371, 1384 (Fed. Cir.

2005) ("The purpose of consulting the prosecution history in construing a claim is to exclude any interpretation that was disclaimed during prosecution.").

When the intrinsic evidence does not establish the meaning of a claim, then extrinsic evidence (*i.e.*, all evidence external to the patent and the prosecution history, including dictionaries, inventor testimony, expert testimony, and learned treatises) may be considered. *Phillips*, 415 F.3d at 1317. Extrinsic evidence is generally viewed as less reliable than the patent itself and its prosecution history in determining how to define claim terms. *Id*. "The court may receive extrinsic evidence to educate itself about the invention and the relevant technology, but the court may not use extrinsic evidence to arrive at a claim construction that is clearly at odds with the construction mandated by the intrinsic evidence." *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 977 (Fed. Cir. 1999).

The construction of a claim term is generally guided by its ordinary meaning. However, courts may deviate from the ordinary meaning when: (1) "the intrinsic evidence shows that the patentee distinguished that term from prior art on the basis of a particular embodiment, expressly disclaimed subject matter, or described a particular embodiment as important to the invention;" or (2) "the patentee acted as his own lexicographer and clearly set forth a definition of the disputed claim term in either the specification or prosecution history." *Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1329 (Fed. Cir. 2009); *see also GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1309 (Fed. Cir. 2014) ("the specification and prosecution history only compel departure from the plain meaning in two instances: lexicography and disavowal."); *Omega Eng'g, Inc, v. Raytek Corp.*, 334 F.3d 1314, 1324 (Fed. Cir. 2003) ("[W]here the patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender."); *Rheox,*

Inc. v. Entact, Inc., 276 F.3d 1319, 1325 (Fed. Cir. 2002) ("The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution."). Nevertheless, there is a "heavy presumption that a claim term carries its ordinary and customary meaning." *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002) (citations omitted). The standard for deviating from the plain and ordinary meaning is "exacting" and requires "a clear and unmistakable disclaimer." *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1366-67 (Fed. Cir. 2012); *see Epistar Corp. v. Int'l Trade Comm'n*, 566 F.3d 1321, 1334 (Fed. Cir. 2009) (requiring "expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope" to deviate from the ordinary meaning) (citation omitted). As the Federal Circuit has explained, "[w]e do not read limitations from the specification into claims; we do not redefine words. Only the patentee can do that." *Thorner*, 669 F.3d at 1366.

Courts are not required to construe every claim limitation of an asserted patent. *See O2 Micro Intern. Ltd. v. Beyond Innovation Technology Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008) (citations omitted). Rather, "claim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement." *Id.* at 1362 (quoting *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997)); *see also Embrex*, 216 F.3d at 1347 ("The construction of claims is simply a way of elaborating the normally terse claim language in order to understand and explain, but not to change, the scope of the claims.") (citation omitted). In addition, "[a] determination that a claim term 'needs no construction' or has the 'plain and ordinary meaning' may be inadequate when a term has more than one 'ordinary' meaning or when reliance on a term's 'ordinary' meaning does not resolve the parties' dispute." *O2 Micro*, 521 F.3d at 1361. Claim construction, however, is not an "obligatory exercise in redundancy." *U.S. Surgical Corp.*, 103 F.3d

at 1568. "[M]erely rephrasing or paraphrasing the plain language of a claim by substituting synonyms does not represent genuine claim construction." *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 863 (Fed. Cir. 2004).

A claim must also be definite. Pursuant to pre-AIA 35 U.S.C. § 112, second paragraph: "The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112, ¶ 2. In *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120 (2014), the Supreme Court held that § 112, ¶ 2 requires "that a patent's claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty." *Id.* at 2129. A claim is required to "provide objective boundaries for those of skill in the art," and a claim term is indefinite if it "might mean several different things and no informed and confident choice is among the contending definitions." *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014). A patent claim that is indefinite is invalid. 35 U.S.C. § 282(b)(3)(A).

If, after a review of the intrinsic and extrinsic evidence, a claim term remains ambiguous, the claim should be construed so as to maintain its validity. *Phillips*, 415 F.3d at 1327. Claims, however, cannot be judicially rewritten in order to fulfill the axiom of preserving their validity. *See Rhine v. Casio, Inc.*, 183 F.3d 1342, 1345 (Fed. Cir. 1999). Thus, "if the only claim construction that is consistent with the claim's language and the written description renders the claim invalid, then the axiom does not apply and the claim is simply invalid." *Id.*

IV. OVERVIEW OF THE ART AND THE LEVEL OF ORDINARY SKILL

The three patents in suit relate to systems, devices, and methods for monitoring cardiac health and managing cardiac disease. *See* 941 patent at 1:26-33; 731 patent at 1:29-33. The specific cardiac condition addressed by all the asserted claims is arrhythmia, or abnormal heart rhythm. *See*

941 patent at 4:9-10; 499 patent at cl. 1 (preamble). The devices recited in the claims, including in the method claims, are either a smartwatch (for the 941 and 731 patents) or a mobile computing device (for the 499 patent). The smartwatch claims require an electrocardiogram (ECG) sensor and at least one other sensor. *E.g.*, 941 patent at cl. 1; 731 patent at cl. 25. For most asserted smartwatch claims one of the other sensors is a photoplethysmogram (PPG) sensor, which detects heart rate optically. *See* 731 patent at 8:51-55. The mobile computing device claims require an ECG sensor, a heart rate sensor, and a motion sensor. *E.g.*, 499 patent at cls. 1, 11. Whether reciting a method or apparatus, the asserted independent claims generally involve monitoring heart rate (*e.g.*, "sensing a heart rate" (499 patent at cl. 1)), detecting or determining possible arrhythmia or irregularity in heart rate variability (*e.g.*, "detect, based on the PPG data, the presence of an arrythmia" (731 patent at cl. 1)), and either performing an ECG or alerting the user that an ECG is called for (*e.g.*, "receive electric signals of the user from the ECG sensor to confirm the presence of the arrythmia" (941 patent at cl. 12)).

A person of ordinary skill in such art would likely have an engineering education and experience with cardiac-related equipment, diagnostics, and signal processing. And the parties agree that a skilled artisan at the time of the invention would have had a "bachelor of science degree in electrical engineering, mechanical engineering, biomedical engineering, computer science, or a related discipline, with at least two years of relevant work experience designing wearable devices and/or sensors for measuring physiological signals or parameters of mammals." SIMB at 6; *see* CIMB at 5; RIMB at 3. This is reasonable and is adopted.

Respondent additionally proposes that a skilled artisan at the time of the invention could have had a medical degree (M.D. or D.O.) and at least two years of work experience using biomedical sensors and/or analyzing their data, including in clinical practice treating patients. *See*

RIMB at 3. But it is not enough for a skilled artisan to be able to use the claimed invention; the skilled artisan must also be able to make it. *See Amgen Inc. v. Sanofi, Aventisub LLC*, 987 F.3d 1080, 1084 (Fed. Cir. 2021). A physician might know how to use the claimed inventions, but there is no reason to expect that a physician in clinical practice would be able to make them without substantially more experience and training than two years using biomedical sensors or analyzing their data.

Therefore, a person of ordinary skill in the art at the time of the invention would have had either (1) a bachelor of science degree in electrical engineering, mechanical engineering, biomedical engineering, computer science, or a related discipline, with at least two years of relevant work experience designing wearable devices and/or sensors for measuring physiological signals or parameters of mammals, or (2) a medical degree and at least five years of relevant work experience designing wearable devices and/or sensors for measuring physiological signals or parameters of mammals. Also, relevant experience could substitute for education and vice versa for both categories of skilled artisan.

V. THE ASSERTED PATENTS

Although various dependent claims have been asserted, the parties' claim construction disputes all pertain to terms found in the independent claims, as well as to some preambles and the order of method steps. *See* JC at 2-4. Therefore, only the independent claims are reproduced below.

A. The 499 Patent

The 499 patent, entitled "Methods and Systems for Arrhythmia Tracking and Scoring," issued February 21, 2017, to Gopalakrishnan, et al., and is assigned on its face to Complainant. It claims priority to provisional application No. 61/915,113, filed on December 12, 2013. *See generally* 499 patent.

The 499 patent has 20 claims, of which claims 1-4, 6-14, and 16-20 are asserted. Claims 1 and 11 are independent, and the disputed terms are highlighted in **bold.**

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.

11. A system for determining the presence of an arrhythmia of a first user, comprising

a **heart rate sensor** coupled to said first user;

a mobile computing device comprising a processor, wherein said mobile computing device is coupled to said **heart rate sensor**, and wherein said mobile computing device is configured to sense an electrocardiogram of said first user; and

a motion sensor

a non-transitory computer readable medium encoded with a computer program including instructions executable by said processor to cause said processor to receive a heart rate of said first user from said **heart rate sensor**, sense an activity level of said first user from said motion sensor, determine a heart rate variability of said first user based on said heart rate of said first user, compare and activity level of said first user to said heart rate variability of said first user, and **alert** said first user to record an electrocardiogram using said mobile computing device.

B. The 731 Patent

The 731 patent, entitled "Methods and Systems for Arrhythmia Tracking and Scoring," issued March 24, 2020, to Gopalakrishnan, et al., and is assigned on its face to Complainant. It derives from a series of continuation applications, one of which issued as the 499 patent, and claims priority to the same provisional application as the 499 patent. As a result, it appears to have substantially the same specification as the 499 patent. *See generally* 731 patent.

The 731 patent has 30 claims, all of which are asserted. Claims 1, 17 and 25 are independent, and the disputed term are highlighted in **bold**:

> **1.** A smart watch to detect the presence of an arrhythmia of a user, comprising:
>
> a processing device;
>
> a photoplethysmography ("PPG") sensor operatively coupled to the processing device;
>
> an ECG sensor, comprising two or more ECG electrodes, the ECG sensor operatively coupled to the processing device;
>
> a display operatively coupled to the processing device; and
>
> a memory, operatively coupled to the processing device, the memory having instructions stored thereon that, when executed by the processing device, cause the processing device to:
>
> receive PPG data from the PPG sensor;
>
> detect, based on the PPG data, the presence of an arrhythmia;
>
> receive ECG data from the ECG sensor; and
>
> **confirm the presence of the arrhythmia based on the ECG data**.
>
> **17.** A method to detect the presence of an arrhythmia of a user on a smart watch, comprising:
>
> receiving PPG data from a PPG sensor of the smartwatch;

detecting by a processing device, based on the PPG data, the presence of an arrhythmia;

receiving ECG data from an ECG sensor of the smartwatch; and

confirming the presence of the arrhythmia based on the ECG data.

25. A non-transitory computer-readable storage medium including instructions that, when executed by a processing device, cause the processing device to:

receive PPG data from a PPG sensor of the smartwatch;

detect by the processing device, based on the PPG data, the presence of an arrhythmia;

receive ECG data from an ECG sensor of the smartwatch; and

confirm the presence of the arrhythmia based on the ECG data.

C. The 941 Patent

The 941 patent, entitled "Discordance Monitoring," issued May 5, 2020, to Albert, et al., and is assigned on its face to Complainant. It claims priority to provisional application No. 62/161,092, filed on May 13, 2015. *See generally* 941 patent.

The 941 patent has 23 claims, all of which are asserted. Claims 1 and 12 are independent, and the disputed terms are highlighted in **bold.**

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.

12. A smartwatch, comprising:

a processor;

a first sensor configured to sense an activity level value of a user, wherein the first sensor is coupled to the processor;

a photoplethysmogram ("PPG") sensor configured to sense a heart rate parameter of the user **when the activity level value is resting**, wherein the PPG sensor is coupled to the processor;

an electrocardiogram ("ECG") sensor configured to sense electrical signals of a heart, wherein the ECG sensor comprises a first electrode and a second electrode, and wherein the ECG sensor is coupled to the processor; and

a non-transitory computer readable storage medium encoded with a computer program including instructions executable by the processor to cause the processor to:

determine if a **discordance** is present between the activity level value of the user and the heart rate parameter of the user;

based on the presence of the **discordance**, indicate to the user a possibility of an arrhythmia being present; and

receive electric signals of the user from the ECG sensor to **confirm the presence of the arrhythmia**.

VI. CLAIM CONSTRUCTION

A. Construction of the Agreed-Upon Claim Term

The parties agree that the term "arrhythmia," which appears in all independent claims, means "a cardiac condition in which the electrical activity of the heart is irregular or is faster or slower than normal." JC at 4. This construction is consistent with the plain and ordinary meaning of the term and with the intrinsic evidence. *See* 731 patent at 1:40-42 ("Arrhythmia is a cardiac condition in which the electrical activity of the heart is irregular or is faster (tachycardia) or slower (bradycardia)

than normal."); 941 patent at 4:9-10 (arrhythmia is "an abnormality of rhythm"). It is therefore adopted.

B. Construction of the Disputed Claim Terms

The disputed claim terms are summarized in the parties' Joint Disclosure of Proposed Claim Constructions. *See generally* JC.

1. 499 Patent – Preambles

Claims	AliveCor's Proposed Construction	Staff's Proposed Construction	Apple's Proposed Construction
499 patent: preambles	The preambles are not limiting.	The preambles of the asserted claims are limiting.	The preambles of claims 1 and 11 are limiting.

JC at 2.

The only place in the independent claims of the 499 patent that the term "arrhythmia" appears is in the preambles. *See* 499 patent at cls. 1 ("an arrhythmia of a first user"), 11 (same). Claim 7, which depends from claim 1, and claim 17, which depends from claim 11, further recites the step of "determining a presence of said arrhythmia" and the operation of "determine a presence of said arrhythmia," respectively. *See id*. at cls. 7, 17. Respondent argues, among other points, that the preambles are limiting because they provide an antecedent basis for "said arrhythmia." RIMB at 10-13. Staff agrees. *See* SIMB at 8. Complainant, relying principally on examples from District Court cases, argues that "the fact that the antecedent basis for a term in the body of some dependent claims is found in the preamble of the independent claims does not require a preamble to be limiting." CIMB at 7.

In one respect, at least, the preambles are undoubtedly limiting. The body of claim 1 does not describe a structurally complete method for "alerting said first user to sense an electrocardiogram . . . in response to an irregularity of said heart rate variability of said first user."

See 499 patent at 26:36-39. This is because the antecedent basis for "said first user" appears in the preamble. *See id*. at 26:27-28. Claim 11 similarly fails to describe a structurally complete invention, albeit a system rather than a method. *See id*. at 27:19-24 ("determine a heart rate variability of said first user . . . and alert said first user to record an electrocardiogram"). So the preambles are limiting to the extent they provide antecedent bases for "said first user."

Whether they are limiting with respect to "arrhythmia," however, is a different question. *See TomTom, Inc. v. Adolph*, 790 F.3d 1315, 1323 (Fed. Cir. 2015) (finding one part of a preamble limiting but not another part). Nothing in the body of claims 1 or 11 requires "determining [a/the] presence of an arrhythmia," because the recited methods stop at alerting the user to "sense" or "record" an ECG. 499 patent at cls. 1, 11. So on the surface, determining the presence of arrhythmia is just the "purpose or intended use for the invention." *Catalina Marketing Int'l, Inc. v. Coolsavings.com, Inc*., 289 F.3d 801, 808 (Fed. Cir. 2002).

Claims 7 and 17, however, use the term "said arrhythmia," which would be expected to require an antecedent basis. *See Catalina Marketing*, 289 F.3d at 808. Moreover, claims 7 and 17 reiterate an entire clause of the relevant preamble, almost verbatim, before adding one limitation. Specifically, claim 1 recites "using a machine learning algorithm" for "determining a presence of an arrhythmia," while claim 7 recites the same for "determining a presence of said arrhythmia," and claim 11 recites "using a machine learning algorithm" for "determining the presence of an arrhythmia," while claim 17 recites the same to "determine a presence of said arrhythmia." 499 patent at cls. 1, 7, 11, 17.

Such repetition of the preamble, combined with the use of the term "said," indicates that the "arrhythmia" portion of each preamble is limiting, and is not just the purpose or intended use of each claimed invention. Admittedly, there are instances in the case law where a preamble has been

found limiting for a dependent claim and not limiting for the associated independent claim. *See* CIMB at 7-9 (collecting cases); CRMB at 1-2 (same); *see also Energizer Holdings, Inc. v. ITC*, 435 F.3d 1366, 1370 (Fed. Cir. 2006) (an antecedent basis need be express if it is "present by implication"). But the weight of authority is that if a preamble is limiting for a dependent claim, it is also limiting for the associated independent claim, because a dependent claim possesses all the elements of the claim from which it depends. *See Catalina Marketing*, 289 F.3d at 808; *Monsanto Co. v. Syngenta Seeds, Inc*., 503 F.3d 1352, 1359 (Fed. Cir. 2007) ("claims in dependent form include all the limitations of the claim" from which they depend). And it may be true that if claims 7 and 17 had been drafted without using "said" and without repeating the language of the preambles of claims 1 and 11 (and the bodies of claims 1 and 11 had not used the term "said first user"), then the preambles would not be limiting. *See* CRMB at 3. But the claims were not so drafted, and the claim language must instead be considered as it is actually written.

On balance, therefore, the preambles of claims 1 and 11 of the 499 patent are limiting.

2. 499 Patent – "alerting said first user to sense an electrocardiogram"/ "alert"

Claims	AliveCor's Proposed Construction	Staff's Proposed Construction	Apple's Proposed Construction
499 patent: "alerting said first user to sense an electrocardiogram" [cl. 1]; "alert" [cl. 11]	No construction required. Alternatively, "notifying said first user to sense an electrocardiogram"/ "notify"	No construction necessary. If construed, "informing the first user to take an electrocardiogram"/ "inform"	"informing the first user to take an electrocardiogram"/ "inform"

JC at 2.

Respondent most clearly explains the nature of the dispute in its reply brief. *See* RRMB at 5-8. Respondent argues that: (1) its proposed construction will "aid . . . in understanding the term as it is used in the claimed invention"; (2) references to performing an ECG in the specification use the term "take" or some variation of it; (3) the claim language suggests an affirmative act by the user (as in "taking" an ECG) rather than mere passive sensing of a parameter (as in "sensing a heart rate"); and (4) the specification contemplates a "trigger message to inform the user" to get an ECG, rather than some less informative "alert." *Id*.

These points offer insufficient reason to deviate from the plain and ordinary meaning of the claim language. First, the prosecution history does not appear to be relevant. *See* RIMB at 16-17. As for the specification, the term "sense" in reference to obtaining an ECG clearly has a broad meaning, including "take" (*e.g.*, 499 patent at 6:64), "record" (*id*. at cl. 11), and "measure" (*id*. at Table 1). Construing "sense" to mean just one of these actions is not warranted, and does not clarify anything about the claim language. And to the extent the term "sense" is ambiguous, the specification explains what it means: "the ECG device includes an electrode assembly configured to sense heart-related signals upon contact with a user's skin, and to convert the sensed heart-related signals to an ECG electric signal." *Id*. at 25:29-33. Moreover, the claims are directed to determining whether or not an ECG is appropriate, and then "alerting" the user to that fact; substituting "to take" for "to sense" does not clarify anything about whether "to sense" the ECG requires an affirmative act by the user.

As for "alert" and "alerting," the plain and ordinary meaning is similarly broad, and includes "notify" (499 patent at 5:12), "instruct" (*id*. at 20:59), "indicate" (*id*. at 23:21), and "generate and send notification signals" (*id*. at 25:2-3). In fact, one purpose of the disclosed invention is to "minimize[] false alarms," suggesting that an "alarm" (i.e., an audible tone) may qualify as an

"alert." *Id*. at 25:24. The proposed term "inform," by contrast, appears nowhere in the specification, and the term "informing" appears only once, in disclosing the optional feature of "informing the patient" of "behaviors, habits . . . and the like" associated with abnormal ECG readings, instead of "informing the patient" of the need for an ECG. *Compare id*. at 16:42-46 *with id*. at cl. 11. So inasmuch as "inform" implies a message of some sort, and excludes a non-linguistic method of alerting, it is clearly too narrow.

Therefore, the terms "alerting said first user to sense an electrocardiogram" and "alert" are accorded their plain and ordinary meaning, the "alert" is not limited to a message, and the terms need not otherwise be construed.

3. 499 Patent – "heart rate sensor"

Claims	**AliveCor's Proposed Construction**	**Staff's Proposed Construction**	**Apple's Proposed Construction**
499 patent: "heart rate sensor" [cls. 1, 11]	No construction necessary. Alternatively: "a sensor for measuring heart rate"	No construction necessary. If construed: "a sensor for measuring heart rate"	"A sensor that directly measures heart rate"

JC at 2.

Claims 1 and 11 of the 499 patent require a "heart rate sensor coupled to [a] first user." 499 patent at cls. 1, 11. In method claim 1, the heart rate is "sens[ed]," and the heart rate variability is then "determine[ed] . . . based on said heart rate." *Id*. at cl. 1. In system claim 11, a processor "receive[s] a heart rate . . . from said heart rate sensor," and the processor then determines the heart rate variability "based on said heart rate." *Id*. at cl. 11.

The specification does not limit the nature of the heart rate sensor. It may be a "portable computing device" executing an "application," an "accessory usable with the portable computing device," an "accessory device" including "Garmin's Vivofit Fitness Band, Fitbit, Polar Heart Rate

Monitors . . . and the like," an "[ECG] in communication with the portable computing device or accessory," an "on-board heart rate sensor of the portable computing device," or "[PPG] implemented by an imaging source and a light source of the portable computing device." 499 patent at 8:28-53; *see also id*. at 25:13-16 ("an optical sensor to detect the fluctuation of blood flow"), 25:38-39 ("[t]he ECG can be further processed using algorithms to calculate heart rate"). In fact, although the specification incorporates by reference the application resulting in U.S. Patent No. 9,649,042, which discloses a stethoscope, a device which Respondent argues "measure[s] heart rate directly," the 499 patent's specification does not expressly teach this well-known "heart rate sensor." RIMB at 18 & Ex. 3.

Therefore, Respondent's argument that the specification distinguishes between different kinds of heart rate sensors, and in particular between "heart rate sensors" on the one hand and PPG and ECG sensors on the other, is not supported by the specification. *See* RIMB at 17-18. Nor is the prosecution history Apple cites especially relevant. *See id*. at 1819. If there was disavowal, at most it was of using "ECG data only" and "determining [heart rate variability] from peak to peak interval data taken from a sensed ECG," as opposed to "use of a heart rate sensor" and then computing heart rate variability. *See id*., Ex. 4 at 6-7 (emphasis omitted). Lastly, Respondent's expert opined that a skilled artisan would understand "heart rate sensor" narrowly, but his opinion was based on arguments that duplicate Respondent's legal arguments; it is accordingly inconsistent with the intrinsic evidence and is accorded no weight. *See* RIMB, Ex. 1 (Stultz Decl.) at ¶¶ 67-69.

Therefore, the term "heart rate sensor" is accorded its plain and ordinary meaning, and in particular is construed to mean heart rate sensors that sense heart rate both directly and indirectly, and is not otherwise construed.

4. 499 Patent – Order of Method Steps

Claims	AliveCor's Proposed Construction	Staff's Proposed Construction	Apple's Proposed Construction
499 patent: order of steps [cl. 1]	While some ordering is dictated by logic, the limitations of the claim may be performed in different order than recited.	While some ordering is dictated by logic, the limitations of the claim may be performed in different order than recited.	Should be performed in the order listed.

JC at 2.

Claim 1 covers a method with six basic steps: (1) sensing the user's heart rate; (2) transmitting the heart rate to a mobile computing device; (3) determining heart rate variability; (4) sensing the user's activity level; (5) comparing the heart rate variability to the activity level; and (6) alerting the user to sense an ECG in response to an irregularity in heart rate variability. *See* 499 patent at cl. 1. The parties' disagreement is over whether step (4), sensing an activity level, may be performed before or simultaneously with steps (1), (2), or (3), or whether it must be performed only after step (3). *See* RIMB at 21-22; SIMB at 19; CIMB at 18-19.

Generally, "[u]nless the steps of a method actually recite an order, the steps are not ordinarily construed to require one." *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1342 (Fed. Cir. 2001). Claim 1 does not expressly recite any particular order of steps, so presumptively there is none. *See* 499 patent at cl. 1. Contrary to Respondent's suggestion, the fact that in step (5) the heart rate variability is compared to the activity level, rather than the other way around, does not grammatically or logically require that one parameter be measured before the other, because what the step requires is simply a comparison. *See* RRMB at 10.

Nor does anything in the specification require a particular order. Respondent's assertion that "in all the disclosed examples, heart rate and [heart rate variability] are always analyzed first" is incorrect, because the cited examples do not even disclose measuring activity level. RIMB at 22

(citing 499 patent at 22:56-65, 23:12-26); *see* RRMB at 10-11 (citing 499 patent at 19:42-46 & Fig. 6). In short, "[t]he only order mandated by the claim language" – and in this case the specification, as well – "is the conditional language in several of the steps," and that conditional language does not logically mandate that step (4) be performed only after steps (1), (2), and (3). *Altiris, Inc. v. Symantec Corp*., 318 F.3d 1363, 1370 (Fed. Cir. 2003).

Therefore, claim 1 of the 499 patent is construed such that the step of "sensing an activity level of said first user with a motion sensor" need not be performed after the step of "determining, using said mobile device, a heart rate variability of said first user based on said heart rate of said first user."

5. 731 Patent – "confirm the presence of the arrhythmia based on the ECG data" / "confirming the presence of the arrhythmia based on the ECG data"

Claims	AliveCor's Proposed Construction	Staff's Proposed Construction	Apple's Proposed Construction
731 patent: "confirm[ing] the presence of the arrhythmia based on the ECG data" [cls. 1, 17, 25]	No construction required. Alternatively: "identify[ing] the occurrence of the arrhythmia based on the ECG data"	No construction necessary. These claims do not require verifying the arrhythmia by comparing the ECG sensor data to the PPG sensor data. If construed: "verify[ing] the occurrence of the arrhythmia based on the ECG data"	"verify[ing] the arrhythmia by comparing the ECG sensor data to the PPG sensor data"

JC at 3.

Claims 1, 17, and 25 of the 731 patent cover, respectively, a "smart watch" comprising a processing device that executes instructions to perform certain operations, a method of using a

smartwatch, and a "non-transitory computer-readable storage medium including instructions that . . . cause [a] processing device to" perform certain operations based on smartwatch data. *See* 731 patent at cls. 1, 17, 25. The method of claim 17 and the operations of claims 1 and 25 are in substance the same: (1) receive PPG data from the smartwatch's PPG sensor; (2) detect the presence of an arrhythmia based on the PPG data; (3) receive ECG data from the smartwatch's ECG sensor; and (4) confirm the presence of the arrhythmia based on the ECG data. *See id*.

There are two disputes over the last element of the claim. First, Respondent argues that "confirm" (cls. 1 and 25) and "confirming" (cl. 17) should be construed as "verify" and "verifying." *See* RIMB at 23-25. It is true that the specification sometimes uses the synonymous term "verify," but it also uses the term "identify." 731 patent at 15:19, 21:7, 25:47. Respondent offers no reason to prefer one of these terms over any other, and in any event "confirm" and "confirming" have plain and ordinary meanings even to a layperson. *See* RIMB at 23-25.

Second, Respondent argues that "there must necessarily be a comparison of the ECG data to the PPG data to verify that [the arrhythmia] is indeed the same condition." RIMB at 26. But the claims do not say "detect a type of arrhythmia," or otherwise require detecting or confirming a particular species of arrhythmia; they instead merely require "detecting . . . the presence of an arrhythmia" and "confirming the presence of the arrhythmia." 731 patent at cl. 17. It is not clear that detecting, say, atrial fibrillation, followed by confirming, say, tachycardia, would fall outside the scope of the claims, because both conditions are arrhythmias. *See id*. at 1:40-45. Even assuming as a matter of construction that the two arrhythmias must be the same condition – an interpretation the parties have not squarely briefed or addressed – Respondent offers no intrinsic evidence that the only way to confirm that fact is by comparing ECG sensor data to PPG sensor data. *See* RIMB at 26. The specification says nothing about such a comparison. Indeed, a skilled artisan could

seemingly practice the claims by programming a smartwatch to apply a machine learning algorithm to the heart rate data from the PPG, output a "recognize[d]" species of "detected" arrhythmia, and then send only that species identification, without the underlying data, to the smartwatch processor as an input to the ECG "confirmation" analysis. *See* 731 patent at 4:6-9 ("the machine learning algorithm may recognize atrial fibrillation from the continuously measured heart rate data of a new user who has not yet been identified as having atrial fibrillation"). Finally, Respondent's expert's opinion on this point is either conclusory or relies on statements in the specification that do not even reference PPG. *See id*., Ex. 1 at ¶¶ 75-79.

Therefore, the terms "confirm the presence of the arrhythmia based on the ECG data" and "confirming the presence of the arrhythmia based on the ECG data" are accorded their plain and ordinary meaning, with no requirement of a comparison of the ECG data to the PPG data.

6. 731 Patent – Order of Method Steps

Claims	AliveCor's Proposed Construction	Staff's Proposed Construction	Apple's Proposed Construction
731 patent: order of steps [cl. 17]	While some ordering is dictated by logic, the limitations of the claim may be performed in different order than recited.	While some ordering is dictated by logic, the limitations of the claim may be performed in different order than recited.	Should be performed in the order listed.

JC at 3.

Again, claim 17 covers a method with four basic steps: (1) receiving PPG data from the smartwatch's PPG sensor; (2) detecting the presence of an arrhythmia based on the PPG data; (3) receiving ECG data from the smartwatch's ECG sensor; and (4) confirming the presence of the arrhythmia based on the ECG data. *See* 731 patent at cl. 17. The parties' disagreement is over whether steps (3) and (4) (which the parties agree must be consecutive) may be performed before

or simultaneously with steps (1) and (2) (which the parties agree must be consecutive). *See* RIMB at 26-27; SIMB at 24-25; CIMB at 24-25.

Claim 17 does not expressly recite any particular order of steps, so presumptively there is none. *Interactive Gift Express*, 256 F.3d at 1342. The specification discloses continuous ECG monitoring. *See* 731 at 14:14 ("[t]he ECG signal data can be continuously recorded"), 16:16-19 ("[a]nalysis of the time before the abnormality . . . may allow the system to identify patterns or correlations of various ECG features that precede the occurrence of the abnormality"). Similarly, the specification discloses continuous PPG monitoring. *See id*. at 2:42-57 ("heart rate may be measured by . . . imaging and lighting sources"), 8:54-55 (PPG is "implemented by an imaging source and a light source"). Nothing in the specification rules out commencing PPG monitoring after commencing ECG monitoring, so Respondent's assertion that "there is no disclosure that ECG data can be taken prior to a PPG measurement" is unpersuasive. RRMB at 15. At minimum, therefore, step (3) (receiving the ECG data) may occur before or simultaneously with steps (1) and (2).

Respondent advances two additional points. First, it argues that "the arrhythmia" confirmed by the ECG must be the same arrhythmia detected by the PPG. *See* RIMB at 27. Again, this issue is not squarely addressed by the parties, but even assuming that the two arrhythmias must be the same condition, "an arrhythmia" in the PPG "detecting" step merely provides antecedent basis for "the arrythmia" in the ECG "confirming" step, it does not necessarily imply a temporal order.

Second, Respondent argues that "one must first detect . . . before one can confirm" the arrhythmia's presence. RRMB at 15. To be sure, the specification discloses an embodiment where "continuous monitoring may allow a subject to be alerted immediately upon an indication of the potential problem," which suggests that the "indication," or detection, triggers the measurement of

an ECG. 731 patent at 23:13-15. But that same embodiment then discloses simultaneous monitoring: "This may allow the coupling of continuous HR monitoring with ECG recording and analysis." *Id*. at 23:16-18. Moreover, it is undisputed that an ECG (as opposed to a PPG) is "the required standard of care for use in diagnosing cardiac arrhythmias," because it can "confirm or refute the suspected irregularity." RIMB, Ex. 1 (Stultz Decl.) at ¶¶ 59-60. So "confirming," as relevant here, means "obtaining sufficient data for a diagnosis," rather than simply "confirming what was previously detected" or "double-checking." And although such a confirmation would seemingly render subsequent detection by PPG monitoring superfluous, continuous ECG monitoring is plainly taught by the specification. In short, Respondent points to nothing in the intrinsic evidence that requires detection before confirmation, or otherwise bars practicing the "confirming" step before the "detecting" step.

Therefore, claim 17 of the 731 patent is construed such that the step of "receiving PPG data from a PPG sensor of the smartwatch" must be performed before the step of "detecting by a processing device, based on the PPG data, the presence of an arrhythmia," and the step of "receiving ECG data from an ECG sensor of the smartwatch" must be performed before the step of "confirming the presence of the arrhythmia based on the ECG data," but there is otherwise no restriction on the order of the steps.

7. 941 Patent – "to confirm a presence of the arrhythmia" / "to confirm the presence of the arrhythmia"

Claims	AliveCor's Proposed Construction	Staff's Proposed Construction	Apple's Proposed Construction
941 patent: "to confirm a presence of the arrhythmia" / "to confirm	No construction required. Alternatively:	No construction necessary. These claims do not require verifying the arrhythmia by	"to verify the arrhythmia by comparing the ECG sensor results to the discordance determination"

the presence of the arrhythmia" [cls. 1, 12]	"to identify an occurrence of the arrhythmia"	comparing the ECG sensor data to the PPG sensor data. If construed: "to verify a presence of the arrhythmia" (claim 1) / "to verify the presence of the arrhythmia" (claim 12)	

JC at 4; CIMB at 25; RIMB at 28.

Independent claim 1 of the 941 patent covers a method where the final step, in pertinent part, is "receiving electric signals of the user from [a smartwatch ECG sensor] to confirm a presence of the arrhythmia." 941 patent at cl. 1. Independent claim 12 covers a smartwatch comprising a processor programmed to "receive electric signals of the user from the ECG sensor to confirm the presence of the arrhythmia." *Id*. at cl. 12. As with the corresponding limitation of the independent claims of the 731 patent, Respondent argues that "confirm" should be construed as "verify." *See* RIMB at 29. In contrast to the 731 patent, however, the term "verify" appears nowhere in the 941 patent. *See* SIMB at 27 (collecting specification citations where only "confirm" is used). And again, "confirm" has a plain and ordinary meaning even to a layperson.

Respondent's other argument varies somewhat from the corresponding one advanced regarding the 731 patent. Unlike the 731 patent, the independent claims of the 941 patent require "sensing an activity level," "sensing a heart rate parameter" when the activity level is resting, and then "determining . . . that a discordance is present between the activity level value and the heart rate parameter." 941 patent at cl. 1; *see id*. at cl. 12. The claims then require "based on the presence of the discordance, indicate to the user a possibility of an arrhythmia being present," followed by the ECG confirmation step. *Id*. at cl. 12; *see id*. at cl. 1.

Respondent argues that the claimed invention "must necessarily compare the results of the ECG sensor to the results of the previous discordance determination." RIMB at 29. Certainly one embodiment disclosed in the specification works that way. *See* 941 patent at 13:60-14:18. But the disclosed embodiments associated with Figure 7 (a decision tree describing various combinations of measurements and their associated diagnoses) say nothing about such a comparison. *See id*. at 14:59-15:59 & Fig. 7. In fact, the most natural reading of the claim language is that the only use for "determin[ing] . . . a discordance" is to "indicate . . . a possibility of an arrhythmia being present." *Id*. at cl. 12. Respondent's prosecution history evidence has no clear relevance to this issue, and its expert evidence merely repeats the arguments made in its brief without substantial elaboration. *See* RIMB at 30 (citing RIMB, Ex. 1 (Stultz Decl.) at ¶¶ 84-86; Ex. 5 at 5). Lastly, to the extent "the arrhythmia" must be the same "an arrhythmia" previously found to be "a possibility," the discordance determination itself does not necessarily result in any diagnostic conclusions, because such conclusions may instead result from a machine learning algorithm. *See* 941 patent at 13:60-14:18; RIMB at 29. Similarly to the 731 patent, then, it stands to reason that a skilled artisan could practice the claimed inventions without using any discordance data as a direct input to the ECG analysis.

Therefore, the terms "to confirm a presence of the arrhythmia" and "to confirm the presence of the arrhythmia" are accorded their plain and ordinary meaning, with no requirement of a comparison of the ECG sensor results to the discordance determination.

8. 941 Patent – "when the activity level is resting" / "when the activity level value is resting"

Claims	AliveCor's Proposed Construction	Staff's Proposed Construction	Apple's Proposed Construction
941 patent: "when the activity level is resting" / "when the activity level value is resting" [cls. 1, 12]	Not indefinite.	Not indefinite.	Indefinite.

JC at 4.

Independent claim 1 of the 941 patent covers a method comprising "sensing an activity level of a user," and then, "when the activity level is resting, sensing a heart rate parameter of the user." 941 patent at cl. 1. If there is a discordance between the sensed data, "a possibility of an arrhythmia being present" is "indicat[ed] to the user." *Id*. Independent claim 12 covers a smartwatch comprising a processor programmed to perform substantially the same method, including sensing a heart rate parameter "when the activity level value is resting." *Id*. at cl. 12.

Respondent argues that a skilled artisan cannot adequately discern the scope of the terms "activity level is resting" and "activity level value is resting," and the claims are therefore indefinite. *See* RIMB at 31-34. It is true that the specification seemingly equates "resting" with "normal." *E.g*., 941 patent at 16:6. It is also true that "what is considered resting for one person, is not necessarily resting for another person." RIMB, Ex. 1 (Stultz Decl.) at ¶ 93. The specification acknowledges this: "an activity level [that] is determined to be increased in a 70 year old user [] would not be increased in a 7 year old user." 941 patent at 16:10-12. Respondent's expert accordingly opines that the 941 patent "provides no guidance on what would be considered a resting activity level other than to say that it would be determined for each individual separately." RIMB, Ex. 1 (Stultz Decl.) at ¶ 93.

Respondent has not met its burden of proving indefiniteness. Three teachings of the patent are especially pertinent. First, "resting" and "normal" have different plain and ordinary meanings, and the claims use the term "resting." In the absence of lexicography (and the cited passages fall short of it) the meaning of "resting" controls. Moreover, nothing in the claims requires measuring the degree of activity level; instead, the user's activity level must be "sense[d]," and "when the activity level value is resting" a heart rate parameter is sensed. 941 patent at cl. 12. So the trigger for heart rate parameter sensing is binary – resting or not resting – and the example of "increased" activity varying between persons of different ages is therefore not especially relevant. *Id*. at 16:10-12.

Second, the only "activity level" sensors disclosed are an accelerometer and a gyroscope, that is, motion sensors. *See* 941 patent at 2:57-58. The specification makes clear that a "resting" activity level measured by such devices corresponds to a lack of motion. *See id*. at 15:64-65 ("resting activity level as sensed by an accelerometer which measures that the individual is traveling at 0 miles/hr"). And again, the activity level does not have to be measured or quantified, it just has to be "sense[d]" as resting, and presumably both an accelerometer and a gyroscope sense a resting state by sensing a lack of motion. *Id*. at cl. 12. In other words, the user does not actually have to be resting, the sensor just has to detect the user as resting, or "simply not moving." RIMB, Ex. 1 (Stultz Decl.) at ¶ 95.

Third, if the sensor detects motion, the sensed activity level is "not resting," and the claims are not practiced. As the specification explains, if "an increased heart rate is sensed together with an increased activity level . . . no discordance is present, and an ECG is not recorded as the individual is probably exercising." 941 patent at 15:44-48. By extension, the claims are also not practiced in the situation Respondent hypothesizes, because it involves a false positive discordance: "a user can

be 'motionless' – e.g., traveling at 0 miles/hour – and yet not resting, if they are exercising (on a stationary bike) or agitated." RIMB at 34. In such a case, there may be a discordance but there is no arrhythmia, so the claimed invention may "indicate . . . a possibility of an arrhythmia being present," but any ECG will not confirm the arrhythmia (and the user may even not initiate the ECG).

In view of these disclosures, "when the activity level is resting" is not fatally ambiguous to a skilled artisan. If the activity level sensor detects "not resting," that is, the sensor detects motion, the processor does not determine that a discordance is present and the claims are not practiced. If the activity level sensor detects "resting," that is, no motion, but the user is not actually resting and one or more heart rate parameters are discordant with "resting," a possible arrhythmia is (erroneously) indicated but the ECG measurement either does not occur or cannot confirm the arrhythmia, and the claims are not practiced. If the activity level sensor detects "resting," the user is actually resting, and the sensed heart rate parameter is not discordant with resting, the discordance is not determined and a possible arrhythmia is not indicated, so the claims are not practiced. Lastly, if the activity level sensor detects "resting," the user is actually resting, and the sensed heart rate parameter is discordant with resting, a possible arrhythmia is indicated and the ECG is taken to confirm the arrhythmia; only in this last case are the claims practiced.

So a skilled artisan should be able to discern when the claim limitations are satisfied and when they are not. The specification and claims do, therefore, sufficiently define the metes and bounds of the claimed inventions, and claims 1 and 12 are not indefinite because of the "activity level [value] is resting" language.

9. 941 Patent – "discordance"

Claims	AliveCor's Proposed Construction	Staff's Proposed Construction	Apple's Proposed Construction
941 patent: "discordance" [cls. 1, 12]	No construction required.	"inconsistency"	"inconsistency"

JC at 4.

The parties' dispute regarding the term "discordance" is mystifying. The term is admittedly uncommon, but it has a customary meaning, and neither Staff nor Apple offer any reason why substituting "inconsistency" clarifies anything. *See* SIMB at 32-33; RIMB at 35-38. To the extent any doubt exists about its meaning, it is used in numerous passages of the specification without any apparent lexicography, so it should not be difficult to ascertain the scope of the claims in practice. *E.g.*, 941 patent at 1:61-2:1, 12:47-65. Therefore, the term "discordance" is accorded its plain and ordinary meaning.

10. 941 Patent – Order of Method Steps

Claims	AliveCor's Proposed Construction	Staff's Proposed Construction	Apple's Proposed Construction
941 patent: order of steps [cl. 1]	While some ordering is dictated by logic, the limitations of the claim may be performed in different order than recited.	While some ordering is dictated by logic, the limitations of the claim may be performed in different order than recited.	Should be performed in the order listed.

JC at 4.

Independent claim 1 covers a method with five basic steps: (1) sensing an activity level; (2) sensing a heart rate parameter when the activity level is resting; (3) determining the presence of a discordance between the activity level and the heart rate parameter; (4) indicating the possibility of an arrhythmia based on the presence of the discordance; and (5) confirming the presence of the arrhythmia using an ECG. *See* 941 patent at cl. 1. As with the other asserted method claims, claim

1 of the 941 patent does not expressly recite any particular order of steps, so presumptively there is none. *Interactive Gift Express*, 256 F.3d at 1342. The parties nonetheless have two disagreements over order.

First, Respondent argues that step (2) must be performed only after step (1), while Complainant and Staff argue that the two steps may be performed simultaneously. *See* RRMB at 22-23; CIMB at 36-37; SIMB at 34-35. As Respondent acknowledges, the specification discloses an embodiment in which both activity level and heart rate are "continuously and simultaneously sensed." *See* RRMB at 22 n.11 (citing 941 patent at 5:27-31). In such an embodiment, whenever the activity level is sensed as resting, the heart rate (which qualifies as a heart rate parameter) is necessarily sensed simultaneously. So step (2) may be performed simultaneously with step (1).

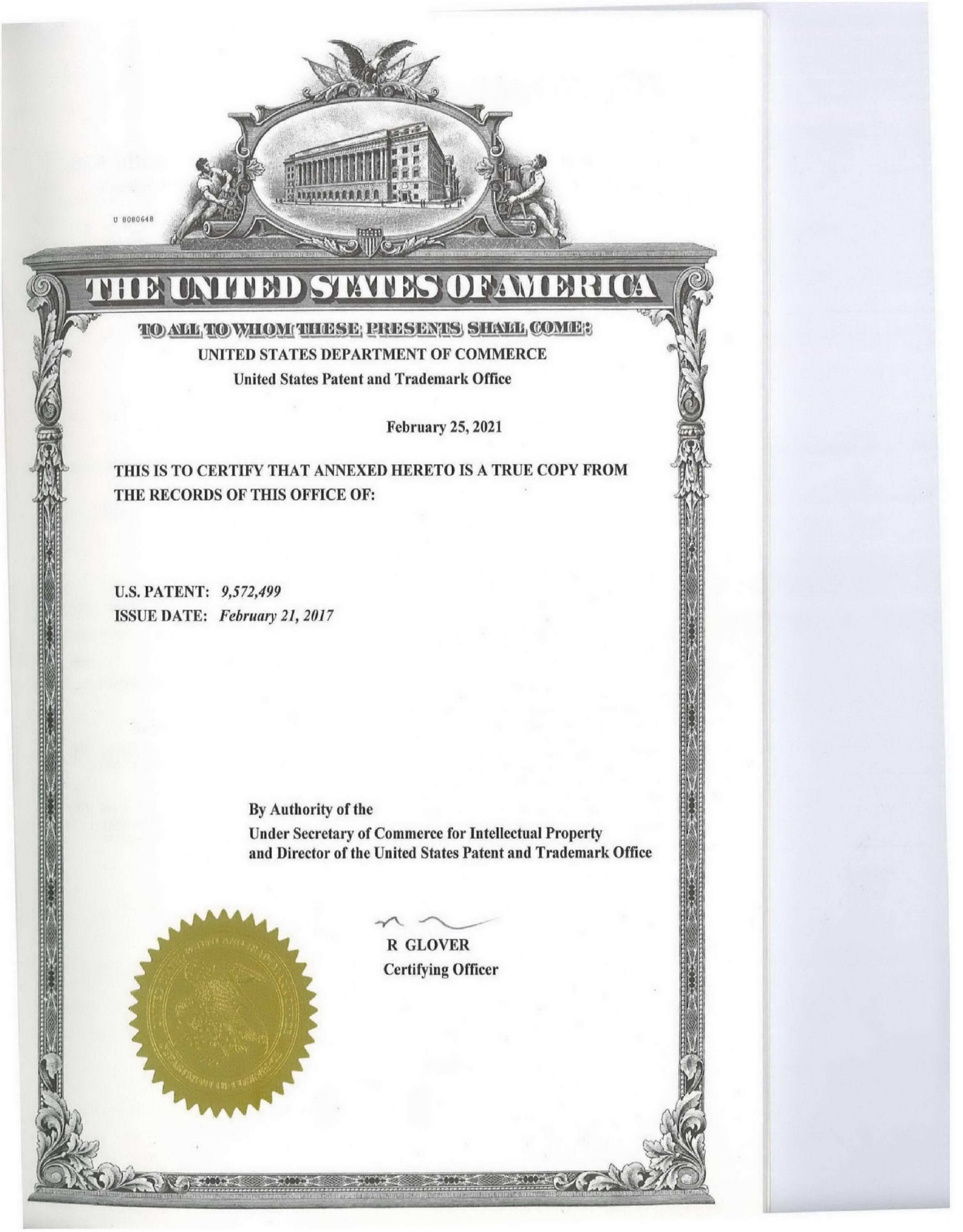
Second, Respondent contends that step (5), the ECG measurement, must occur last. *See* RIMB at 38-39. Here, too, the specification refutes Respondent's contention: "In some embodiments, an intermittently sensed [ECG] is caused to be sensed in response to both a continuously measured heart rate and a continuously measured activity level." 941 patent at 11:35-38; *see generally id*. at 11:22-42. In such an embodiment the ECG "electric signals" could easily be "receiv[ed]" before both the discordance is determined and the possible arrhythmia is indicated; certainly nothing in the specification rules out the possibility. *See id*. at cl. 1. So step (5) need not be performed last.

Therefore, method claim 1 of the 941 patent is construed such that the step of "when the activity level is resting, sensing a heat rate parameter of the user with a second sensor on the smartwatch" may be performed after or simultaneously with the step of "sensing an activity level of a user with a first sensor on a smartwatch worn by the user," and the step of "receiving electric

signals of the user from an [ECG] on the smartwatch to confirm a presence of the arrhythmia" need not be performed last.

SO ORDERED.

Cameron Elliot
Administrative Law Judge



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ISSUE DATE: *February 21, 2017*

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(12) **United States Patent**
Gopalakrishnan et al.

(10) **Patent No.: US 9,572,499 B2**
(45) **Date of Patent: *Feb. 21, 2017**

(54) **METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING**

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This patent is subject to a terminal disclaimer.

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(58) **Field of Classification Search**
USPC 600/508–509
See application file for complete search history.

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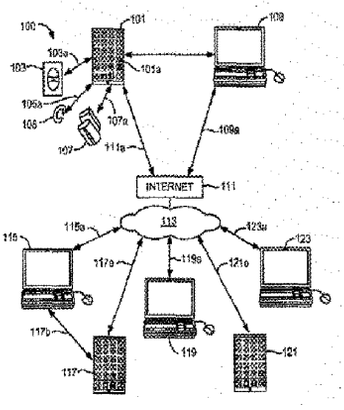
(57) **ABSTRACT**

A dashboard centered around arrhythmia or atrial fibrillation tracking is provided. The dashboard includes a heart or cardiac health score that can be calculated in response to data from the user such as their ECG and other personal information and cardiac health influencing factors. The dashboard also provides to the user recommendations or goals, such as daily goals, for the user to meet and thereby improve their heart or cardiac health score. These goals and recommendations may be set by the user or a medical professional and routinely updated as his or her heart or
(Continued)



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cardiac health score improves or otherwise changes. The dashboard is generally displayed from an application provided on a smartphone or tablet computer of the user.

20 Claims, 16 Drawing Sheets

Related U.S. Application Data

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A61B 5/024	(2006.01)
A61B 5/0245	(2006.01)
A61B 5/046	(2006.01)
A61B 5/00	(2006.01)
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A61B 5/0452	(2006.01)
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G06F 19/00	(2011.01)

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CPC ***A61B 5/02405*** (2013.01); ***A61B 5/02416*** (2013.01); ***A61B 5/046*** (2013.01); ***A61B 5/6898*** (2013.01); ***A61B 5/7264*** (2013.01); ***A61B 5/7275*** (2013.01); ***G06F 19/3418*** (2013.01); *A61B 5/021* (2013.01); *A61B 5/02438* (2013.01); *A61B 5/0452* (2013.01); *A61B 5/1118* (2013.01); *A61B 5/681* (2013.01); *G06F 19/322* (2013.01); *G06F 19/3487* (2013.01)

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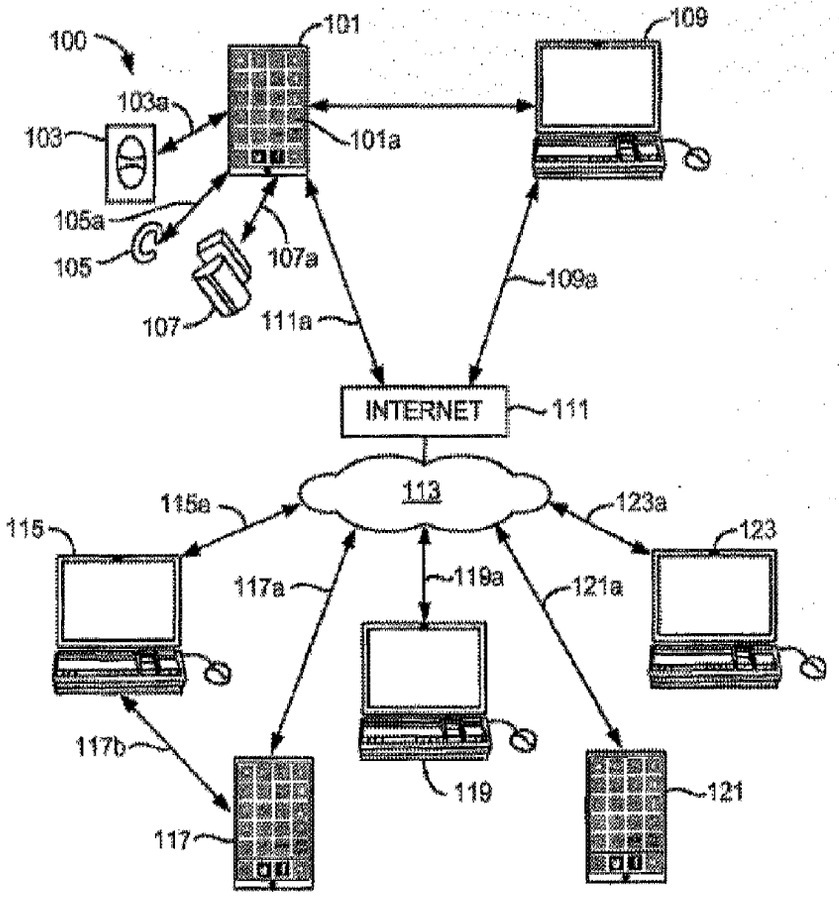

FIG. 1

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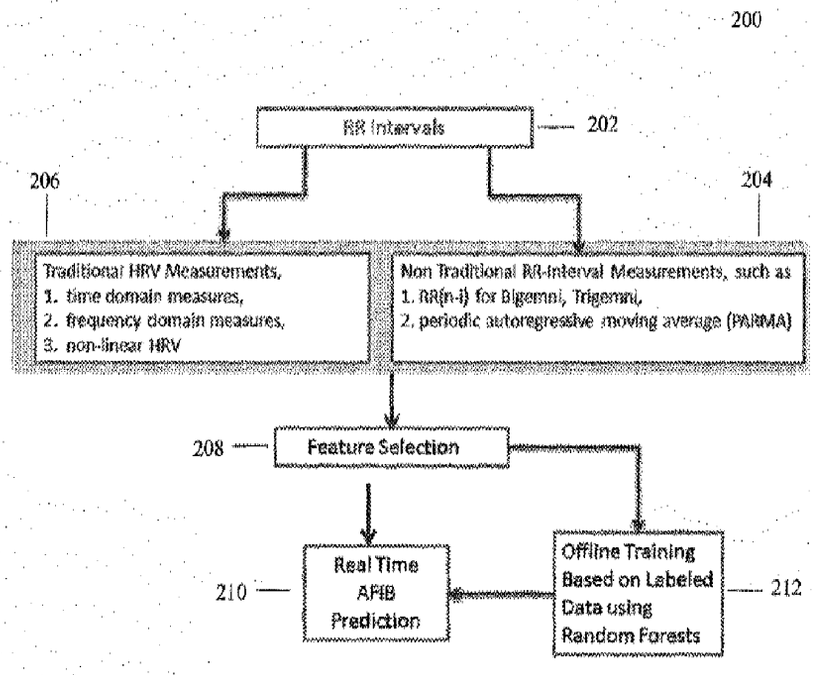

FIG. 2

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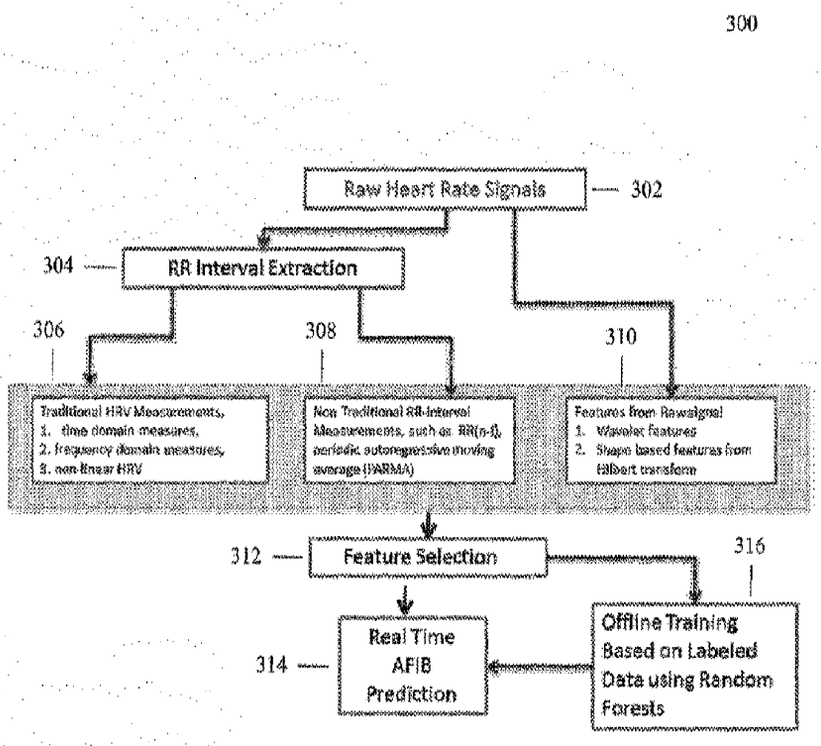

FIG. 3

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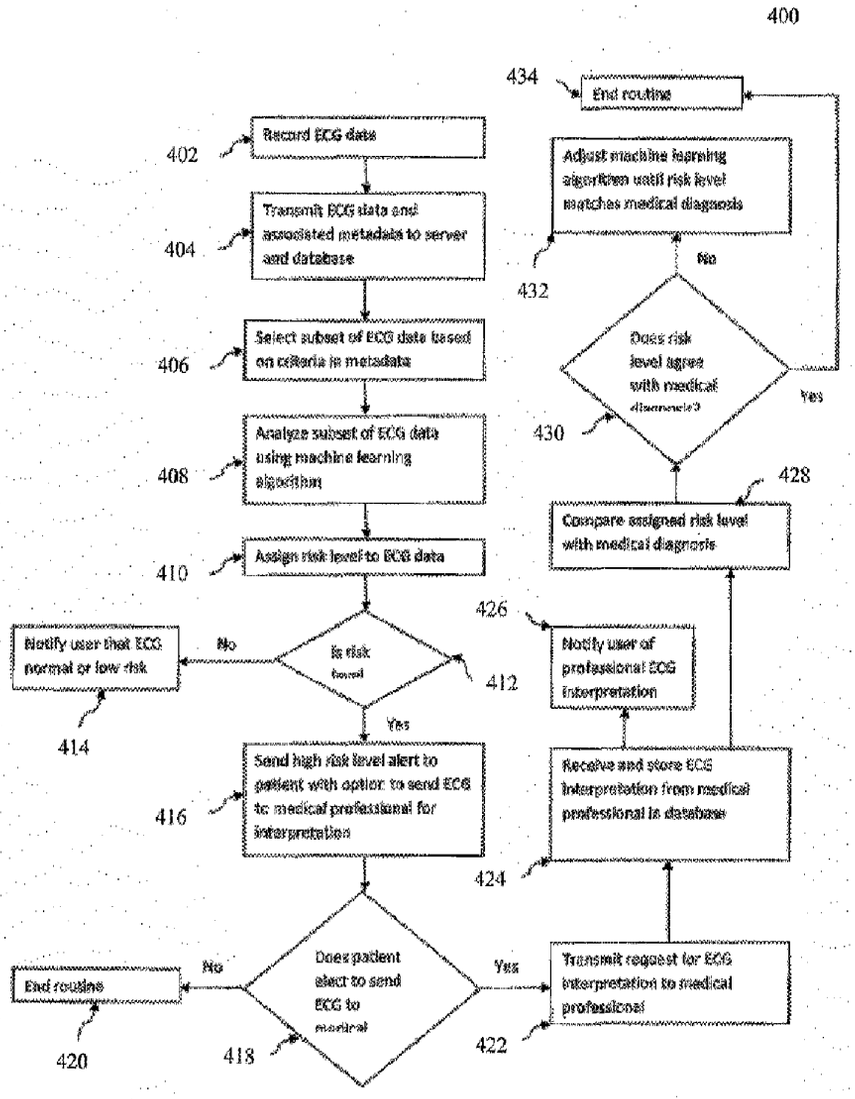

FIG. 4

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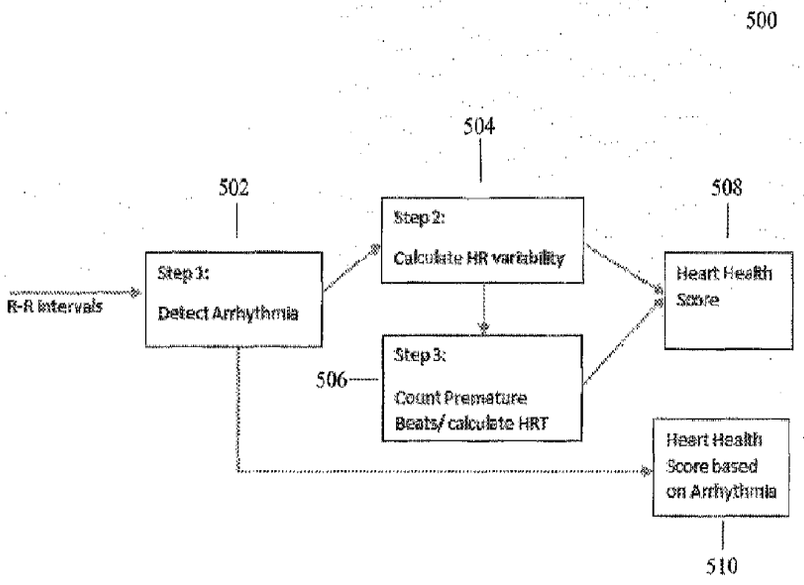

FIG. 5

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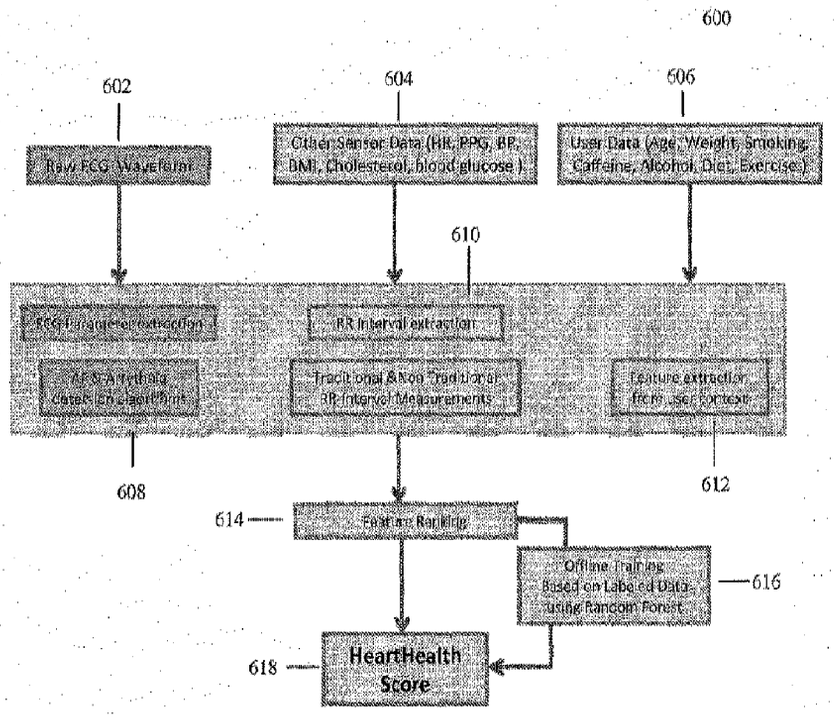

FIG. 6

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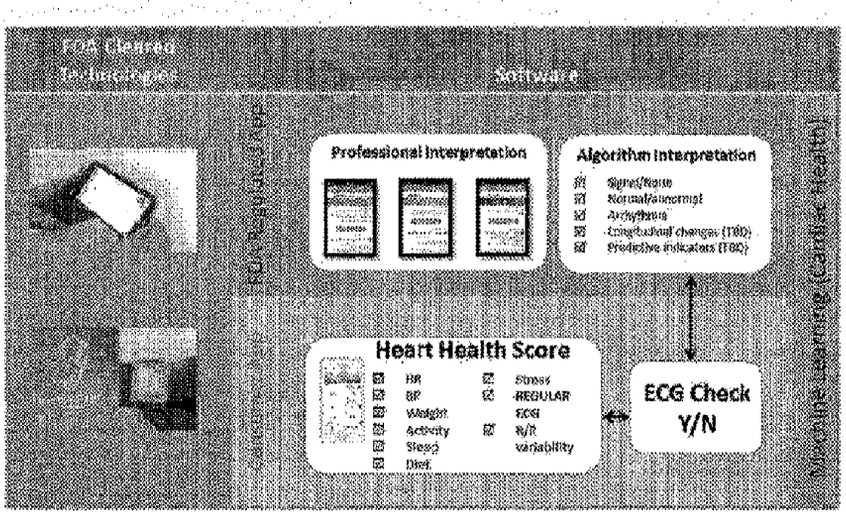

FIG. 7

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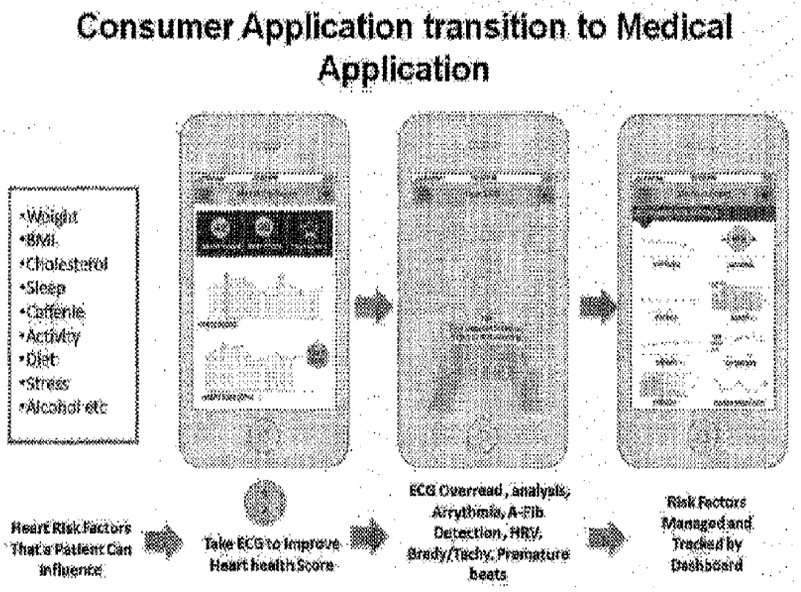

FIG. 8

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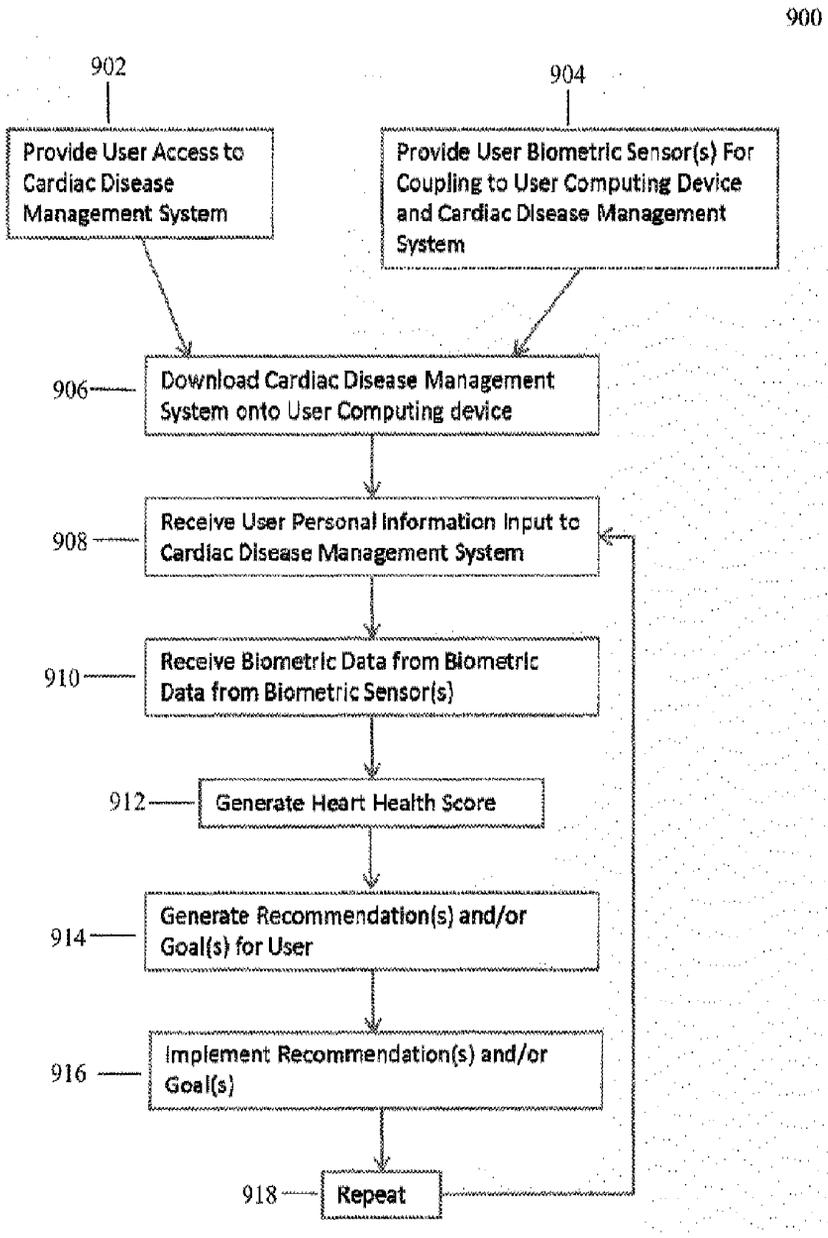

FIG. 9

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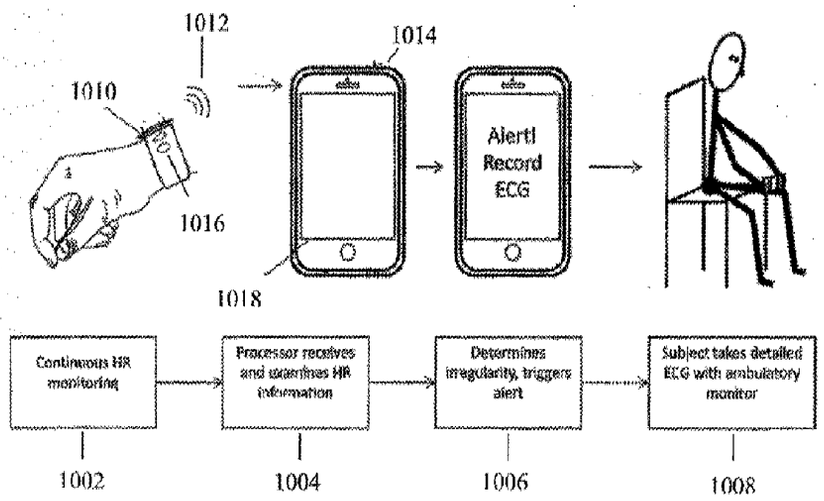

FIG. 10

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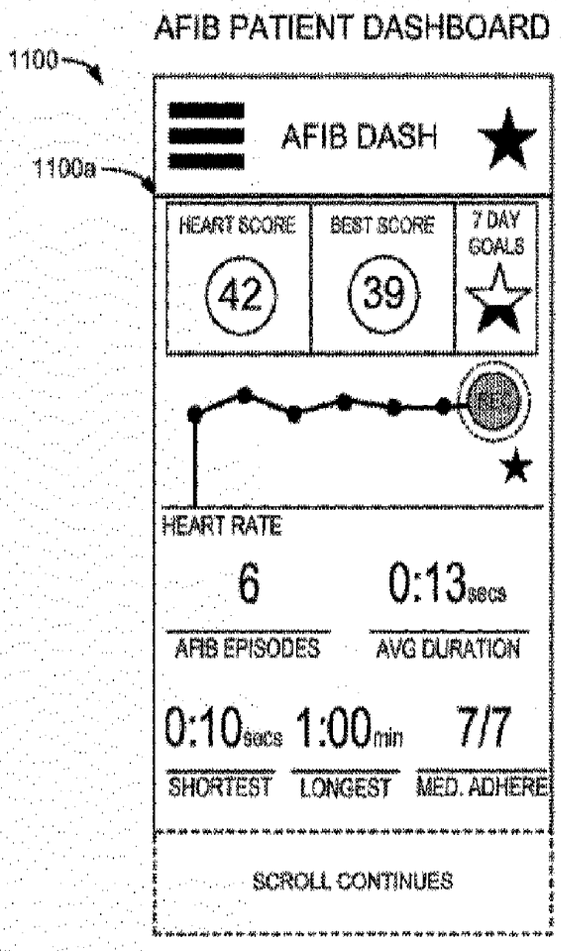

FIG. 11

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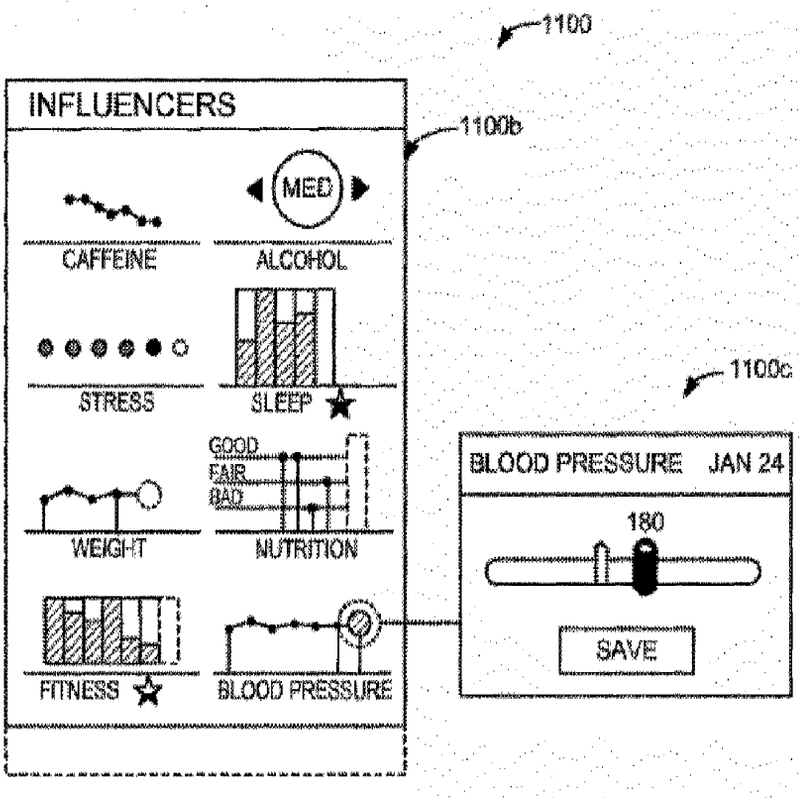

FIG. 11A

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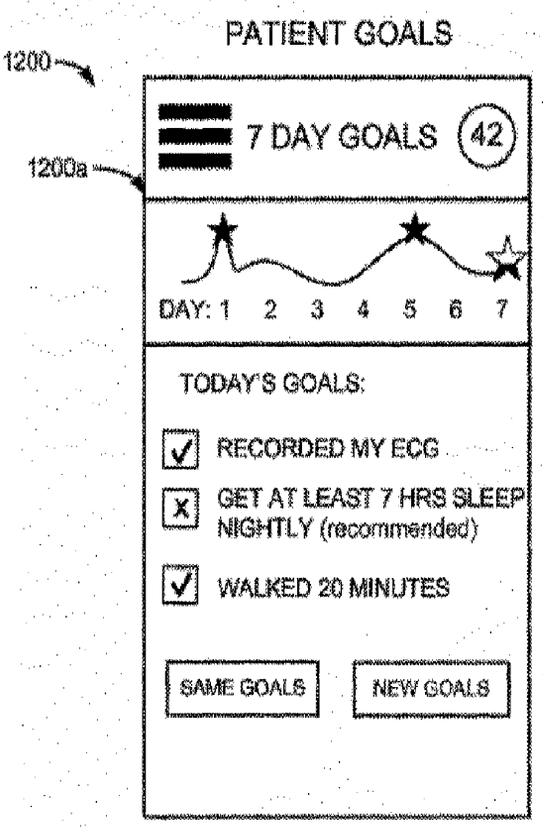

FIG. 12

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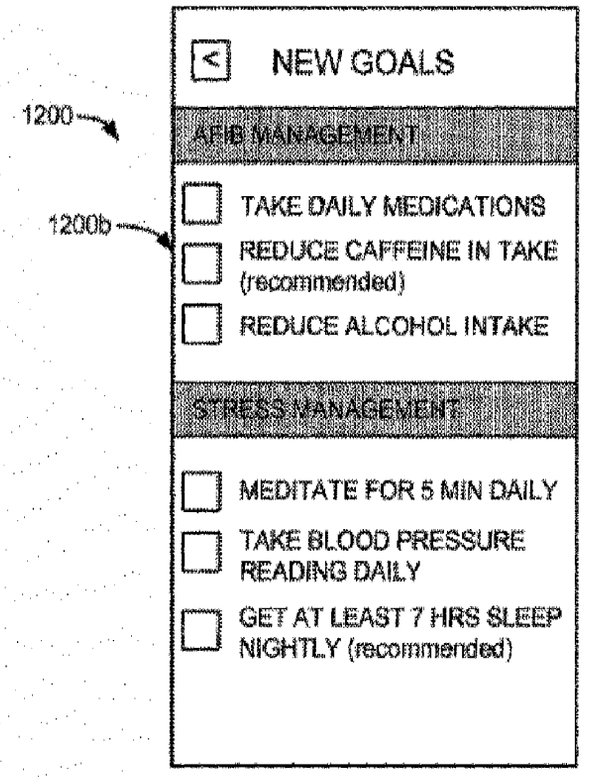

FIG. 12A

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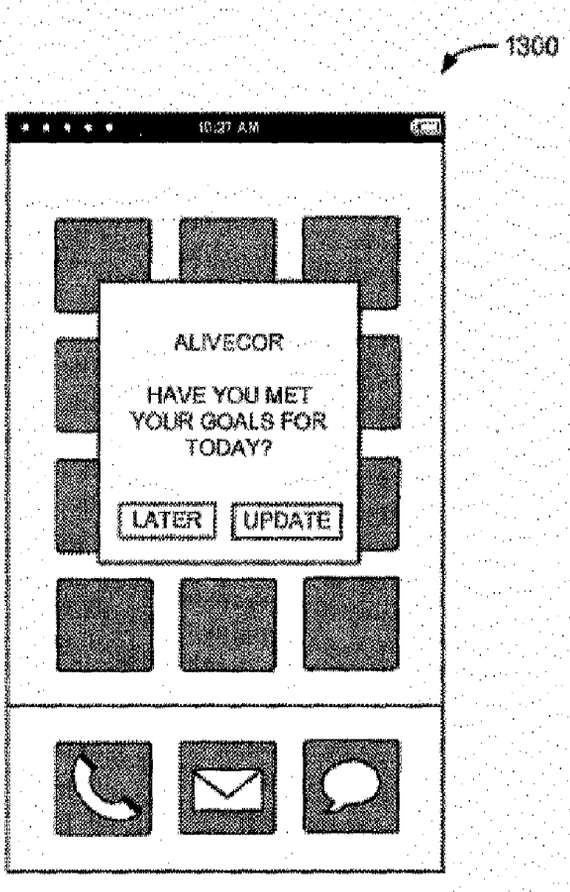

FIG. 13

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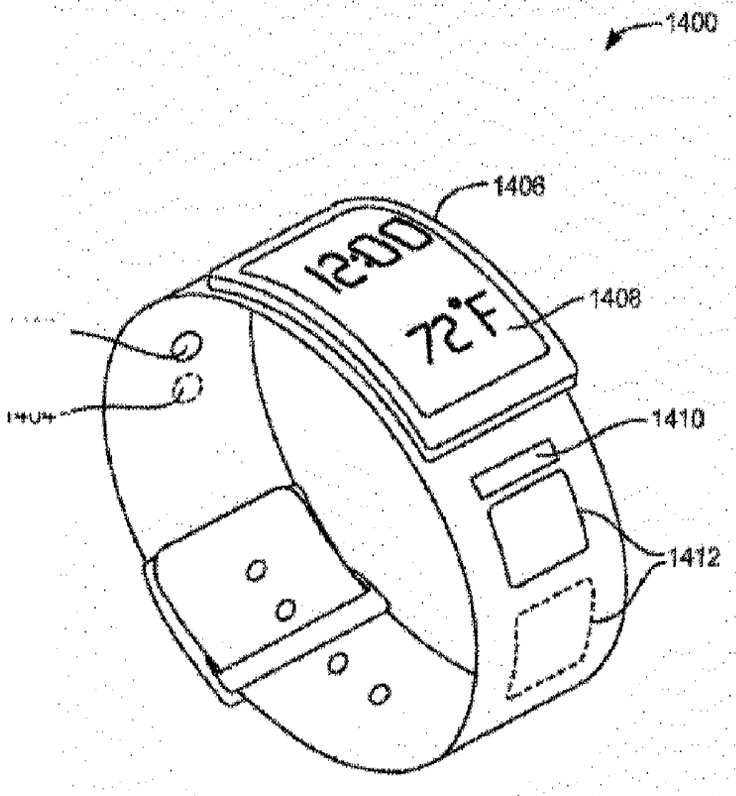

FIG. 14

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METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING

CROSS-REFERENCE

This application is a continuation of U.S. application Ser. No. 14/569,513 filed Dec. 12, 2014, which claims the benefit of U.S. Provisional Application No. 61/915,113, filed Dec. 12, 2013, which application is incorporated herein by reference, U.S. Provisional Application No. 61/953,616 filed Mar. 14, 2014, U.S. Provisional Application No. 61/969,019, filed Mar. 21, 2014, U.S. Provisional Application No. 61/970,551 filed Mar. 26, 2014 which application is incorporated herein by reference, and U.S. Provisional Application No. 62/014,516, filed Jun. 19, 2014, which application is incorporated herein by reference.

BACKGROUND

The present disclosure relates to medical devices, systems, and methods. In particular, the present disclosure relates to methods and systems for managing health and disease such as cardiac diseases including arrhythmia and atrial fibrillation.

Cardiovascular diseases are the leading cause of death in the world. In 2008, 30% of all global death can be attributed to cardiovascular diseases. It is also estimated that by 2030, over 23 million people will die from cardiovascular diseases anually. Cardiovascular diseases are prevalent in the populations of high-income and low-income countries alike.

Arrhythmia is a cardiac condition in which the electrical activity of the heart is irregular or is faster (tachycardia) or slower (bradycardia) than normal. Although many arrhythmias are not life-threatening, some can cause cardiac arrest and even sudden cardiac death. Atrial fibrillation is the most common cardiac arrhythmia. In atrial fibrillation, electrical conduction through the ventricles of heart is irregular and disorganized. While atrial fibrillation may cause no symptoms, it is often associated with palpitations, shortness of breath, fainting, chest, pain or congestive heart failure. Atrial fibrillation is also associated with atrial clot formation, which is associated with clot migration and stroke.

Atrial fibrillation is typically diagnosed by taking an electrocardiogram (ECG) of a subject, which shows a characteristic atrial fibrillation waveform.

To treat atrial fibrillation, a patient may take medications to slow heart rate or modify the rhythm of the heart. Patients may also take anticoagulants to prevent atrial clot formation and stroke. Patients may even undergo surgical intervention including cardiac ablation to treat atrial fibrillation.

Often, a patient with arrhythmia or atrial fibrillation is monitored for extended periods of time to manage the disease. For example, a patient may be provided with a Holter monitor or other ambulatory electrocardiography device to continuously monitor a patient's heart rate and rhythm for at least 24 hours.

Current ambulatory electrocardiography devices such as Holter monitors, however, are typically bulky and difficult for subjects to administer without the aid of a medical professional. For example, the use of Holter monitors requires a patient to wear a bulky device on their chest and precisely place a plurality of electrode leads on precise locations on their chest. These requirements can impede the activities of the subject, including their natural movement, bathing, and showering. Once an ECG is generated, the ECG is sent to the patient's physician who may analyze the ECG and provide a diagnosis and other recommendations. Currently, this process often must be performed through hospital administrators and health management organizations and many patients do not receive feedback in an expedient manner.

SUMMARY

Disclosed herein are devices, systems, and methods for managing health and disease such as cardiac diseases, including arrhythmia and atrial fibrillation. In particular, a cardiac disease and/or rhythm management system, according to aspects of the present disclosure, allows a user to conveniently document their electrocardiograms (ECG) and other biometric data and receive recommendation(s) and/or goal(s) generated by the system or by a physician in response to the documented data. The cardiac disease and/or rhythm management system can be loaded onto a local computing device of the user, where biometric data can be conveniently entered onto the system while the user may continue to use the local computing device for other purposes. A local computing device may comprise, for example, a computing device worn on the body (e.g. a head-worn computing device such as a Google Glass, a wrist-worn computing device such as a Samsung Galaxy Gear Smart Watch, etc.), a tablet computer (e.g. an Apple iPad, an Apple iPod, a Google Nexus tablet, a Samsung Galaxy Tab, a Microsoft Surface, etc.), a smartphone (e.g. an Apple iPhone, a Google Nexus phone, a Samsung Galaxy phone, etc.)

A portable computing device or an accessory thereof may be configured to continuously measure one or more physiological signals of a user. The heart rate of the user may be continuously measured. The continuously measurement may be made with a wrist or arm band or a patch in communication with the portable computing device. The portable computing device may have loaded onto (e.g. onto a non-transitory computer readable medium of the computing device) and executing thereon (e.g. by a processor of the computing device) an application for one or more of receiving the continuously measured physiological signal(s), analyzing the physiological signal(s), sending the physiological signal(s) to a remote computer for further analysis and storage, and displaying to the user analysis of the physiological signal(s). The heart rate may be measured by one or more electrodes provided on the computing device or accessory, a motion sensor provided on the computing device or accessory, or by imaging and lighting sources provided on the computing device or accessory. In response to the continuous measurement and recordation of the heart rate of the user, parameters such as heart rate (HR), heart rate variability (R-R variability or HRV), and heart rate turbulence (HRT) may be determined. These parameters and further parameters may be analyzed to detect and/or predict one or more of atrial fibrillation, tachycardia, bradycardia, bigeminy, trigeminy, or other cardiac conditions. A quantitative heart health score may also be generated from the determined parameters. One or more of the heart health score, detected heart conditions, or recommended user action items based on the heart health score may be displayed to the user through a display of the portable computing device.

The biometric data may be uploaded onto a remote server where one or more cardiac technicians or cardiac specialists may analyze the biometric data and provide ECG interpretations, diagnoses, recommendations such as lifestyle recommendations, and/or goals such as lifestyle goals for subject. These interpretations, diagnoses, recommendations,

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and/or goals may be provided to the subject through the cardiac disease and/or rhythm management system on their local computing device. The cardiac disease and/or rhythm management system may also include tools for the subject to track their biometric data and the associated interpretations, diagnoses, recommendations, and/or goals from the cardiac technicians or specialists.

An aspect of the present disclosure includes a dashboard centered around arrhythmia or atrial fibrillation tracking. The dashboard includes a heart score that can be calculated in response to data from the user such as their ECG and other personal information such as age, gender, height, weight, body fat, disease risks, etc. The main driver of this heart score will often be the incidence of the user's atrial fibrillation. Other drivers and influencing factors include the aforementioned personal information. The heart score will be frequently related to output from a machine learning algorithm that combines and weights many if not all of influencing factors.

The dashboard will often display and track many if not all of the influencing factors. Some of these influencing factors may be entered directly by the user or may be input by the use of other mobile health monitoring or sensor devices. The user may also use the dashboard as an atrial fibrillation or arrhythmia management tool to set goals to improve their heart score.

The dashboard may also be accessed by the user's physician (e.g. the physician prescribing the system to the user, another regular physician, or other physician) to allow the physician to view the ECG and biometric data of the user, view the influencing factors of the user, and/or provide additional ECG interpretations, diagnoses, recommendations, and/or goals.

Another aspect of the present disclosure provides a method for managing cardiac health. Biometric data of a user may be received. A cardiac health score may be generated in response to the received biometric data. One or more recommendations or goals for improving the generated cardiac health score may be displayed to the user. The biometric data may comprise one or more of an electrocardiogram (ECG), dietary information, stress level, activity level, gender, height, weight, age, body fat percentage, blood pressure, results from imaging scans, blood chemistry values, or genotype data. The recommendations or goals may be updated in response to the user meeting the displayed recommendations or goals. The user may be alerted if one or more recommendations or goals have not been completed by the user; for example if the user has not completed one or more recommendations or goals for the day.

The analysis applied may be through one or more of the generation of a heart health score or the application of one or more machine learning algorithms. The machine learning algorithms may be trained using population data of heart rate. The population data may be collected from a plurality of the heart rate monitoring enabled portable computing devices or accessories provided to a plurality of users. The training population of users may have been previously identified as either having atrial fibrillation or not having atrial fibrillation prior to the generation of data for continuously measured heart rate. The data may be used to train the machine learning algorithm to extract one or more features from any continuously measured heart rate data and identify atrial fibrillation or other conditions therefrom. After the machine learning algorithm has been trained, the machine learning algorithm may recognize atrial fibrillation from the continuously measured heart rate data of a new user who has not yet been identified as having atrial fibrillation or other heart conditions. One or more of training population data or the trained machine learning algorithm may be provided on a central computing device (e.g. be stored on a non-transitory computer readable medium of a server) which is in communication with the local computing devices of the users and the application executed thereon (e.g. through an Internet or an intranet connection.)

A set of instructions for managing cardiac health may be downloaded from the Internet. These set of instructions may be configured to automatically generate the cardiac health score. The cardiac health score may be generated using a machine learning algorithm. The machine learning algorithm may generate the cardiac health score of the user and/or the recommendations and/or goals in response to biometric data from a plurality of users. The set of instructions may be configured to allow a medical professional to access the received biometric data. The cardiac health score and/or the recommendations and/or goals may be generated by the medical professional.

The set of instructions may be stored on a non-transitory computer readable storage medium of one or more of a body-worn computer, a tablet computer, a smartphone, or other computing device. These set of instructions may be capable of being executed by the computing device. When executed, the set of instructions may cause the computing device to perform any of the methods described herein, including the method for managing cardiac health described above.

Another aspect of the present disclosure provides a system for managing cardiac health. The system may comprise a sensor for recording biometric data of a user and a local computing device receiving the biometric data from the sensor. The local computing device may be configured to display a cardiac health score and one or more recommendations or goals for the user to improve the cardiac health score in response to the received biometric data.

The system may further comprise a remote server receiving the biometric data from the local computing device. One or more of the local computing device or the remote server may comprise a machine learning algorithm which generates one or more of the cardiac health score or the one or more recommendations or goals for the user. The remote server may be configured for access by a medical professional. Alternatively or in combination, one or more of the cardiac health score or one or more recommendations or goals may be generated by the medical professional and provided to the local computing device through the remote server.

The sensor may comprise one or more of a hand-held electrocardiogram (ECG) sensor, a wrist-worn activity sensor, a blood pressure monitor, a personal weighing scale, a body fat percentage sensor, a personal thermometer, a pulse oximeter sensor, or any mobile health monitor or sensor. Often, the sensor is configured to be in wireless communication with the local computing device. The local computing device comprises one or more of a personal computer, a laptop computer, a palmtop computer, a tablet computer, a smartphone, a body-worn computer, or the like. The biometric data may comprise one or more of an electrocardiogram (ECG), dietary information, stress level, activity level, gender, height, weight, age, body fat percentage, or blood pressure.

Other physiological signals or parameters such as physical activity, heart sounds, blood pressure, blood oxygenation, blood glucose, temperature, activity, breath composition, weight, hydration levels, an electroencephalograph (EEG), an electromyography (EMG), a mechanomyogram (MMG), an electrooculogram (EOG), etc. may also be

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monitored. The user may also input user-related health data such as age, height, weight, body mass index (BMI), diet, sleep levels, rest levels, or stress levels. One or more of these physiological signals and/or parameters may be combined with the heart rate data to detect atrial fibrillation or other conditions. The machine learning algorithm may be configured to identify atrial fibrillation or other conditions in response to heart rate data in combination with one or more of the other physiological signals and/or parameters for instance. Triggers or alerts may be provided to the user in response to the measured physiological signals and/or parameters. Such triggers or alerts may notify the user to take corrective steps to improve their health or monitor other vital signs or physiological parameters. The application loaded onto and executed on the portable computing device may provide a health dash board integrating and displaying heart rate information, heart health parameters determined in response to the heart rate information, other physiological parameters and trends thereof, and recommended user action items or steps to improve health.

INCORPORATION BY REFERENCE

All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the subject matter disclosed herein are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present disclosure will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the disclosure are utilized, and the accompanying drawings of which:

FIG. **1** shows a system for cardiac disease and rhythm management;

FIG. **2** shows a flow chart of a method **200** for predicting and/or detecting atrial fibrillation from R-R interval measurements;

FIG. **3** shows a flow chart of a method for predicting and/or detecting atrial fibrillation from R-R interval measurements and for predicting and/or detecting atrial fibrillation from raw heart rate signals;

FIG. **4** shows an embodiment of the system and method of the ECG monitoring described herein;

FIG. **5** shows a flow chart of an exemplary method to generate a heart health score in accordance with many embodiments;

FIG. **6** shows an exemplary method of generating a heart score;

FIG. **7** shows a schematic diagram of the executed application described herein;

FIG. **8** shows exemplary screenshots of the executed application;

FIG. **9** shows an exemplary method for cardiac disease and rhythm management;

FIG. **10** shows an exemplary method for monitoring a subject to determine when to record an electrocardiogram (ECG);

FIG. **11** shows an exemplary screenshot of a first aspect of a dashboard application;

FIG. **11A** shows an exemplary screenshot of a second aspect of a dashboard application;

FIG. **12** shows an exemplary screenshot of a first aspect of a goals and recommendations page of the cardiac disease and rhythm management system interface or mobile app;

FIG. **12A** shows an exemplary screenshot of a second aspect of a goals and recommendations page of the cardiac disease and rhythm management system interface or mobile app;

FIG. **13** shows an exemplary screenshot of a user's local computing device notifying the user with a pop-up notice to meet their daily recommendations and goals; and

FIG. **14** shows an embodiment comprising a smart watch which includes at least one heart rate monitor and at least one activity monitor.

DETAILED DESCRIPTION

Devices, systems, and methods for managing health and disease such as cardiac diseases, including arrhythmia and atrial fibrillation, are disclosed. In particular, a cardiac disease and/or rhythm management system, according to aspects of the present disclosure, allows a user to conveniently document their electrocardiograms (ECG) and other biometric data and receive recommendation(s) and/or goal(s) generated by the system or by a physician in response to the documented data.

The term "atrial fibrillation," denoting a type of cardiac arrhythmia, may also be abbreviated in either the figures or description herein as "AFIB."

FIG. **1** shows a system **100** for cardiac disease and rhythm management. The system **100** may be prescribed for use by a user or subject such as being prescribed by the user or subject's regular or other physician or doctor. The system **100** may comprise a local computing device **101** of the user or subject. The local computing device **101** may be loaded with a user interface, dashboard, or other sub-system of the cardiac disease and rhythm management system **100**. For example, the local computing device **101** may be loaded with a mobile software application ("mobile app") **101***a* for interfacing with the system **100**. The local computing device may comprise a computing device worn on the body (e.g. a head-worn computing device such as a Google Glass, a wrist-worn computing device such as a Samsung Galaxy Gear Smart Watch, etc.), a tablet computer (e.g. an Apple iPad, an Apple iPod, a Google Nexus tablet, a Samsung Galaxy Tab, a Microsoft Surface, etc.), a smartphone (e.g. an Apple iPhone, a Google Nexus phone, a Samsung Galaxy phone, etc.).

The local computing device **101** may be coupled to one or more biometric sensors. For example, the local computing device **101** may be coupled to a handheld ECG monitor **103**. The handheld ECG monitor **103** may be in the form of a smartphone case as described in co-owned U.S. patent application Ser. No. 12/796,188 (now U.S. Pat. No. 8,509,882), Ser. Nos. 13/107,738, 13/420,520 (now U.S. Pat. No. 8,301,232), Ser. Nos. 13/752,048, 13/964,490, 13/969,445, 14/015,303, and 14/076,076, the contents of which are incorporated herein by reference.

In some embodiments, the handheld ECG monitor **103** may be a handheld sensor coupled to the local computing device **101** with an intermediate protective case/adapter as described in U.S. Provisional Application No. 61/874,806, filed Sep. 6, 2013, the contents of which are incorporated herein by reference. The handheld ECG monitor **103** may be used by the user to take an ECG measurement which the handheld ECG monitor **103** may send to the local computing device by connection **103***a*. The connection **103***a* may comprise a wired or wireless connection (e.g. a WiFi con-

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nection, a Bluetooth connection, a NFC connection, an ultrasound signal transmission connection, etc.). The mobile software application **101***a* may be configured to interface with the one or more biometric sensors including the hand-held ECG monitor **103**.

The local computing device **101** may be coupled to a wrist-worn biometric sensor **105** through a wired or wireless connection **105***a* (e.g. a WiFi connection, a Bluetooth connection, a NFC connection, an ultrasound signal transmission connection, etc.). The wrist-worn biometric sensor **105** may comprise an activity monitor such as those available from Fitbit Inc. of San Francisco, Calif. or a Nike FuelBand available from Nike, Inc. of Oregon. The wrist-worn biometric sensor **105** may also comprise an ECG sensor such as that described in co-owned U.S. Provisional Application No. 61/872,555, the contents of which is incorporated herein by reference.

The local computing device **101** may be coupled to other biometric devices as well such as a personal scale or a blood pressure monitor **107**. The blood pressure monitor **107** may communicate with the local device **101** through a wired or wireless connection **107***a* (e.g. a WiFi connection, a Bluetooth connection, a NFC connection, an ultrasound signal transmission connection, etc.).

The local computing device **101** may directly communicate with a remote server or cloud-based service **113** through the Internet **111** via a wired or wireless connection **111***a* (e.g. a WiFi connection, a cellular network connection, a DSL Internet connection, a cable Internet connection, a fiber optic Internet connection, a T1 Internet connection, a T3 Internet connection, etc.). Alternatively or in combination, the local computing device **101** may first couple with another local computing device **109** of the user, such as a personal computer of the user, which then communicates with the remote server or cloud-based service **113** via a wired or wireless connection **109***a* (e.g. a WiFi connection, a cellular network connection, a DSL Internet connection, a cable Internet connection, a fiber optic Internet connection, a T1 Internet connection, a T3 Internet connection, etc.) The local computing device **109** may comprise software or other interface for managing biometric data collected by the local computing device **101** or the biometric data dashboard loaded on the local computing device **101**.

Other users may access the patient data through the remote server or cloud-based service **113**. These other users may include the user's regular physician, the user's prescribing physician who prescribed the system **100** for use by the user, other cardiac technicians, other cardiac specialists, and system administrators and managers. For example, a first non-subject user may access the remote server or cloud-based service **113** with a personal computer or other computing device **115** through an Internet connection **115***a* (e.g. a WiFi connection, a cellular network connection, a DSL Internet connection, a cable Internet connection, a fiber optic Internet connection, a T1 Internet connection, a T3 Internet connection, etc.). Alternatively or in combination, the first non-subject user may access the remote server or cloud-based service **113** with a local computing device such as a tablet computer or smartphone **117** through an Internet connection **117***a*. The tablet computer or smartphone **117** of the first non-subject user may interface with the personal computer **115** through a wired or wireless connection **117***b* (e.g. a WiFi connection, a Bluetooth connection, a NFC connection, an ultrasound signal transmission connection, etc.). Further, a second non-subject user may access the remote server or cloud-based service **113** with a personal computer or other computing device **119** through an Internet connection **119***a* (e.g. a WiFi connection, a cellular network connection, a DSL Internet connection, a cable Internet connection, a fiber optic Internet connection, a T1 Internet connection, a T3 Internet connection, etc.). Further, a third non-subject user may access the remote server or cloud-based service **113** with a tablet computer or smartphone **121** through an Internet connection **121***a* (e.g. a WiFi connection, a cellular network connection, a DSL Internet connection, a cable Internet connection, a fiber optic Internet connection, a T1 Internet connection, a T3 Internet connection, etc.). Further, a fourth non-subject user may access the remote server or cloud-based service **113** with a personal computer or other computing device **123** through an Internet connection **123***a* (e.g. a WiFi connection, a cellular network connection, a DSL Internet connection, a cable Internet connection, a fiber optic Internet connection, a T1 Internet connection, a T3 Internet connection, etc.). The first non-subject user may comprise an administrator or manager of the system **100**. The second non-subject user may comprise a cardiac technician. The third non-subject user may comprise a regular or prescribing physician of the user or subject. And, the fourth non-subject user may comprise a cardiac specialist who is not the user or subject's regular or prescribing physician. Generally, many if not all of the communication between various devices, computers, servers, and cloud-based services will be secure and HIPAA-compliant.

Aspects of the present disclosure provide systems and methods for detecting and/or predicting atrial fibrillation or other arrhythmias of a user by applying one or more machine learning-based algorithms. A portable computing device (or an accessory usable with the portable computing device) may provide R-R intervals and/or raw heart rate signals as input to an application loaded and executed on the portable computing device. The raw heart rate signals may be provided using an electrocardiogram (ECG) in communication with the portable computing device or accessory such as described in U.S. Ser. No. 13/964,490 filed Aug. 12, 2013, Ser. No. 13/420,520 filed Mar. 14, 2013, Ser. No. 13/108,738 filed May 16, 2011, and Ser. No. 12/795,188 filed Jun. 8, 2010. Alternatively or in combination, the raw heart rate signals may be provided using an on-board heart rate sensor of the portable computing device or by using photoplethysmography implemented by an imaging source and a light source of the portable computing device. Alternatively or in combination, the raw heart rate signals may be from an accessory device worn by the user or attached to the user (e.g. a patch) and which is in communication with the portable computing device. Such wearable accessory devices may include Garmin's Vivofit Fitness Band, Fitbit, Polar Heart Rate Monitors, New Balance's Balance Watch, Basis B1 Band, MIO Alpha, Withings Pulse, LifeCORE Heart Rate Monitor strap, and the like.

R-R intervals may be extracted from the raw heart rate signals. The R-R intervals may be used to calculate heart rate variability (HRV) which may be analyzed in many ways such as using time-domain methods, geometric methods, frequency-domain methods, non-linear methods, long term correlations, or the like as known in the art. Alternatively or in combination, the R-R intervals may be used for non-traditional measurements such as (i) determining the interval between every other or every three R-waves to evaluate for bigeminy or trigeminy or (ii) the generation of a periodic autoregressive moving average (PARMA).

The machine learning based algorithm(s) may allow software application(s) to identify patterns and/or features of the R-R interval data and/or the raw heart rate signals or data to

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predict and/or detect atrial fibrillation or other arrhythmias. These extracted and labelled features may be features of HRV as analyzed in the time domain such as SDNN (the standard deviation of NN intervals calculated over a 24 hour period), SDANN (the standard deviation of the average NN intervals calculated over short periods), RMSSD (the square root of the mean of the sum of the squares of the successive differences between adjacent NNs), SDSD (the standard deviation of the successive differences between adjacent NNs), NN50 (the number of pairs of successive NNs that differ by more than 50 ms), pNN50 (the proportion of NN50 divided by total number of NNs), NN20 (the number of pairs of successive NNs that differ by more than 20 ms), pNN20 (the proportion of NN20 divided by the total number of NNs), EBC (estimated breath cycle), NNx (the number of pairs of successive NNs that differ by more than x ms), pNNx (the proportion of NNx divided by the number of NNs), or other features known in the art. Alternatively or in combination, the extracted and labelled features may comprise a nonlinear transform of R-R ratio or R-R ratio statistics with an adaptive weighting factor. Alternatively or in combination, the extracted and labelled features may be features of HRV as analyzed geometrically such as the sample density distribution of NN interval durations, the sample density distribution of differences between adjacent NN intervals, a Lorenz plot of NN or RR intervals, degree of skew of the density distribution, kurtosis of the density distribution, or other features known in the art. Alternatively or in combination, the extracted and labelled features may be features of HRV in the frequency domain such as the power spectral density of different frequency bands including a high frequency band (HF, from 0.15 to 0.4 Hz), low frequency band (LF, from 0.04 to 0.15 Hz), and the very low frequency band (VLF, from 0.0033 to 0.04 Hz), or other frequency domain features as known in the art. Alternatively or in combination, the extracted and labelled features may be non-linear features such as the geometric shapes of a Poincaré plot, the correlation dimension, the nonlinear predictability, the pointwise correlation dimension, the approximate entropy, and other features as known in the art. Other features from the raw heart rate signals and data may also be analyzed. These features include for example a generated autoregressive (AR) model, a ratio of consecutive RR intervals, a normalized ratio of consecutive RR intervals, a standard deviation of every 2, 3, or 4 RR intervals, or a recurrence plot of the raw HR signals, among others.

The features of the analysis and/or measurement may be selected, extracted, and labelled to predict atrial fibrillation or other arrhythmias in real time, e.g. by performing one or more machine learning operation. Such operations can be selected from among an operation of ranking the feature(s), classifying the feature(s), labelling the feature(s), predicting the feature(s), and clustering the feature(s). Alternatively or in combination, the extracted features may be labelled and saved for offline training of a machine learning algorithm or set of machine learning operations. For example, the operations may be selected from any of those above. Any number of machine learning algorithms or methods may be trained to identify atrial fibrillation or other conditions such as arrhythmias. These may include the use of decision tree learning such as with a random forest, association rule learning, artificial neural network, inductive logic programming, support vector machines, clustering, Bayesian networks, reinforcement learning, representation learning, similarity and metric learning, sparse dictionary learning, or the like.

The systems and methods for detecting and/or predicting atrial fibrillation or other conditions such as arrhythmias described herein may be implemented as software provided as a set of instructions on a non-transitory computer readable medium. A processor of a computing device (e.g. a tablet computer, a smartphone, a smart watch, a smart band, a wearable computing device, or the like) may execute this set of instructions to receive the input data and detect and/or predict atrial fibrillation therefrom. The software may be downloaded from an online application distribution platform such as the Apple iTunes or App Store, Google Play, Amazon App Store, and the like. A display of the computing device may notify the user whether atrial fibrillation or other arrhythmias has been detected and/or if further measurements are required (e.g. to perform a more accurate analysis). The software may be loaded on and executed by the portable computing device of the user such as with the processor of the computing device.

The machine learning-based algorithms or operations for predicting and/or detecting atrial fibrillation or other arrhythmias may be provided as a service from a remote server which may interact or communicate with a client program provided on the computing device of the user, e.g. as a mobile app. The interaction or communication may be through an Application Program Interface (API). The API may provide access to machine learning operations for ranking, clustering, classifying, and predicting from the R-R interval and/or raw heart rate data, for example.

The machine learning-based algorithms or operations, provided through a remote server and/or on a local application on a local computing device, may operate on, learn from, and make analytical predictions from R-R interval data or raw heart rate data, e.g. from a population of users. The R-R interval or raw heart rate data may be provided by the local computing device itself or an associated accessory, such as described in U.S. Ser. No. 13/964,490 filed Aug. 12, 2013, Ser. No. 13/420,520 filed Mar. 14, 2013, Ser. No. 13/108,738 filed May 16, 2011, and Ser. No. 12/796,188 filed Jun. 8, 2010. Thus, atrial fibrillation and other arrhythmias or other heart conditions can be in a convenient, user-accessible way.

FIG. **2** shows a flow chart of a method **200** for predicting and/or detecting atrial fibrillation from R-R interval measurements. In a step **202**, an R-R interval of a user is obtained. In a step **204**, the obtained R-R interval is analyzed using one or more traditional heart rate variability measurements such as, for example, time domain measures, frequency domain measures, and non-linear heart rate variability. In a step **206**, the obtained R-R interval is analyzed using one or more non-traditional heart rate variability measurements such as, for example, RR (n-i) for Bigeminy and Trigeminy detection, and the generation of a periodic autoregressive moving average (PARMA). In a step **208**, a feature selection occurs. In a step **210**, a real time prediction or detection of atrial fibrillation, and/or in a step **212**, the heart rate variability measurements may be labelled and saved for offline training of a machine learning algorithm or set of machine learning operations, and then may be subsequently used to make a real time prediction and/or detection of atrial fibrillation.

FIG. **3** shows a flow chart of a method **300** for predicting and/or detecting atrial fibrillation from R-R interval measurements and for predicting and/or detecting atrial fibrillation from raw heart rate signals. In a step **302**, raw heart rate signals are obtained from, for example, an ECG of a user. In a step **304**, R-R intervals are obtained from the obtained raw hearth signals. In a step **306**, the obtained R-R

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interval is analyzed using one or more traditional heart rate variability measurements such as, for example, time domain measures, frequency domain measures, and non-linear heart rate variability. In a step **308**, the obtained R-R interval is analyzed using one or more non-traditional heart rate variability measurements such as, for example, RR (n-i) for bigeminy and trigeminy detection, and the generation of a periodic autoregressive moving average (PARMA). In a step **310**, features from the obtained heart rate features are analyzed using one or more of wavelet features and shape based features from a Hilbert transform. In a step **312**, a feature selection occurs. In a step **314**, a real time prediction or detection of atrial fibrillation, and/or in a step **316**, the heart rate variability measurements may be labelled and saved for offline training of a machine learning algorithm or set of machine learning operations, and then may be subsequently used to make a real time prediction and/or detection of atrial fibrillation.

Although the above steps show methods **200** and **300** in accordance with many embodiments, a person of ordinary skill in the art will recognize many variations based on the teaching described herein. The steps may be completed in a different order. Steps may be added or deleted. Some of the steps may comprise sub-steps. Many of the steps may be repeated as often as beneficial to the user or subject.

One or more of the steps of method **200** and **300** may be performed with circuitry, for example, one or more of a processor or a logic circuitry such as a programmable array logic for a field programmable gate array. The circuitry may be programmed to provide one or more of the steps of methods **200** and **300**, and the program may comprise program instructions stored on a non-transitory computer readable medium or memory or programmed steps of the logic circuitry such as the programmable array logic or the field programmable gate array, for example.

Aspects of the present disclosure provide systems and methods for monitoring one or more physiological parameters and providing a trigger message to the user if the one or more physiological parameter meets a pre-determined or learned threshold(s). Two or more of the physiological parameters may be combined to provide a trigger message. That is, a particular trigger message may be provided to the user if two or more pre-determined threshold(s) for the physiological parameter(s) are met.

Table 1 below shows an exemplary table of physiological parameters that may be measured (left column), features of interest to be measured or threshold types to be met (middle column), and exemplary trigger messages (right column).

TABLE 1

Physiological Parameter	Measurements/Threshold	Sample Trigger Messages
Heart Rate	Heart Rate Variability (HRV), Non-linear Transformation of RR Intervals	Measure ECG; See Your Doctor
Heart Sound	Sound Features	Abnormal Heart Sound; Measure ECG; See Your Doctor
Blood Pressure	Upper and Lower Thresholds	High/Low Blood Pressure; Take BP Medication; Exercise; See Your Doctor
Blood Oxygenation	O2 Saturation, O2 Saturation Variability	High Risk of Hypoventilation; High Risk of Sleep Disorder such as Apnea; See Your Doctor
Blood Glucose	Upper and Lower Thresholds	High Risk of Hypoglycemia; See Your Doctor
Temperature	Temperature, Temperature Changes	Fever; Take OTC Fever Medication; See Your Doctor
Physical Activity (accelerometer data)	Gait, Chest Compressions, Speed, Distance	Monitor Senior or Infant Posture, e.g. if senior/infant has fallen
Electrocardiogram (ECG)	ECG Features (E.g. QT, QRS, PR intervals, HRV, etc.	High Risk of Certain Cardiac Diseases; Sleep apnea; See Your Doctor
Breath Content (Breathalyzer data)	Percentage of the Certain Chemicals	High Risk of Certain Dental Disease, Diabetes, etc.; See Your Doctor

The machine learning based algorithms or operations as described herein may be used to determine the appropriate trigger thresholds in response to the raw physiological data input and/or user-input physiological parameters (e.g. age, height, weight, gender, etc.). Features of the raw physiological data input may be selected, extracted, labelled, clustered, and/or analyzed. These processed features may then be analyzed using one or more machine learning operation such as ranking the feature(s), classifying the feature(s), predicting the feature(s), and clustering the feature(s). The various machine learning algorithms described herein may be used to analyze the features to detect and predict health conditions and generate recommendations or user action items to improve the health of the user. For instance, the machine learning algorithms may be trained to identify atrial fibrillation or other conditions in response to the non-heart rate physiological parameter(s) such as age, gender, body mass index (BMI), activity level, diet, and others in combination with the raw heart rate data and HRV that can be extracted therefrom.

The systems and methods for monitoring one or more physiological parameters and providing a trigger message to the user if the one or more physiological parameter meets a pre-determined threshold(s) described herein may be implemented as software provided as a set of instructions on a non-transitory computer readable medium. A processor of a computing device (e.g. a tablet computer, a smartphone, a smart watch, a smart band, a wearable computing device, or the like) may execute this set of instructions to receive the input data and detect and/or predict atrial fibrillation therefrom. The software may be downloaded from an online application distribution platform such as the Apple iTunes or App Store, Google Play, Amazon App Store, and the like.

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The software may be loaded on and executed by the portable computing device of the user such as with the processor of the computing device. The software may also provide both the triggering application described herein and the heart rate monitoring and analysis for detecting atrial fibrillation or other heart conditions described herein.

In an embodiment, a method and system for longitudinal monitoring of a patient's or any consumer's (after referred to as "patient") health using various ECG monitoring devices is described herein. The ECG monitoring devices generate ECG signal data which can be stored in a database for further analysis. The ECG data, which can be stored in a database along with other patient information, can be analyzed by a processing device, such as a computer or server, using various algorithms.

Various ECG monitoring or recording devices, hereinafter referred to as ECG monitoring devices, can be used to record the ECG data. For example, the ECG monitoring device can be a handheld, portable, or wearable smartphone based device, as described in U.S. Pat. No. 8,301,232, which is herein incorporated by reference in its entirety for all purposes. A smartphone based device, or a device having wireless or cellular telecommunication capabilities, can transmit the ECG data to a database or server directly through the internet. These types of ECG monitoring devices as well as other ECG monitoring devices include portable devices, wearable recording devices, event recorders, and Holter monitors. Clinical or hospital based ECG recording devices can also be used and integrated into the system. Such devices may be able to transmit stored ECG data through a phone line or wirelessly through the internet or cellular network, or may need to be sent to a data collection center for data collection and processing. The ECG data can be tagged with the type of ECG monitoring device used to record the data by, for example, including it in metadata for indexing and searching purposes.

The ECG monitoring devices can be single lead devices or multiple lead devices, where each lead generally terminates with an electrode. Some embodiments may even be leadless and have electrodes that are integrated with the body or housing of the device, and therefore have a predetermined relationship with each other, such as a fixed spacing apart from each other. The orientation and positioning of the single lead in a single lead device or of each lead of the multiple lead device or of the electrodes of the leadless device can be transmitted with the ECG data. The lead and/or electrode placement may be predetermined and specified to the patient in instructions for using the device. For example, the patient may be instructed to position the leads and/or electrodes with references to one or more anatomical landmarks on the patient's torso. Any deviation from the predetermined lead and/or electrode placement can be notated by the patient or user when transmitting the ECG data. The lead and electrode placement may be imaged using a digital camera, which may be integrated with a smart phone, and transmitted with the ECG data and stored in the database. The lead and electrode placement may be marked on the patient's skin for imaging and for assisting subsequent placement of the leads and electrodes. The electrodes can be attached to the skin using conventional methods which may include adhesives and conducting gels, or the electrodes may simply be pressed into contact with the patient's skin. The lead and electrode placement may be changed after taking one recording or after recording for a predetermined or variable amount of time. The ECG data can be tagged with the numbers of leads and/or electrodes and the lead and/or electrode placement, including whether adhesives and/or conducting gels were used. Again, this information can be including in metadata for indexing and searching purposes.

The ECG signal data can be continuously recorded over a predetermined or variable length of time. Continuous ECG recording devices can record for up to 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, or 14 days. Alternatively or additionally, the ECG data can be recorded on demand by the patient at various discrete times, such as when the patient feels chest pains or experiences other unusual or abnormal feelings. The on demand ECG recorder can have a memory buffer that can record a predetermined amount of ECG data on a rolling basis, and when activated by the patient to record a potential event, a predetermined amount of ECG data can be saved and/or transmitted. The predetermined amount of ECG data can include a predetermined amount of ECG data before activation and a predetermined amount of ECG data after activation such that a window of ECG data is captured that encompasses the potential event. The time period between ECG recordings may be regular or irregular. For example, the time period may be once a day, once a week, once a month, or at some other predetermined interval. The ECG recordings may be taken at the same or different times of days, under similar or different circumstances, as described herein. One or more baseline ECGs can be recorded while the patient is free of symptoms. The baseline ECGs can be periodically recorded and predetermined intervals and/or on-demand. The same ECG recording device or different ECG recording devices may be used to record the various ECG of a particular patient. All this information may be tagged to or associated with the ECG data by, for example, including it in the metadata for indexing and searching purposes.

The ECG data can be time stamped and can be annotated by the patient or health care provider to describe the circumstances during which the ECG was recorded, preceding the ECG recording, and/or following the ECG recording. For example, the system and device can have an user interface for data entry that allows the patient to enter in notes regarding the conditions and circumstances surrounding the ECG recording. This additional data can be also included as metadata for indexing and searching purposes. For example, location, food, drink, medication and/or drug consumption, exercise, rest, sleep, feelings of stress, anxiety, pain or other unusual or abnormal feelings, or any other circumstance that may affect the patient's ECG signal can all be inputted into the device, smart phone, computer or other computing device to be transmitted to the server or database along with the ECG data. The annotated data can also include the patient's identity or unique identifier as well as various patient characteristics including age, sex, race, ethnicity, and relevant medical history. The annotated data can also be time stamped or tagged so that the ECG data can be matched or correlated with the activity or circumstance of interest. This also allows comparison of the ECG before, after and during the activity or circumstance so that the effect on the ECG can be determined.

The ECG data and the associated metadata can be transmitted from the device to a server and database for storage and analysis. The transmission can be real-time, at regular intervals such as hourly, daily, weekly and any interval in between, or can be on demand. The metadata facilitates the searching, organizing, analyzing and retrieving of ECG data. Comparison and analysis of a single patient's ECG data can be performed, and/or comparison of ECG data between patients can be performed. For example, the metadata can be used to identify and select a subset of ECG data where an

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activity or circumstance, such as the taking of medication, occurred within a predetermined amount of time to the ECG data. The components of the ECG signal data, such as the P wave, T wave, and QRS complex and the like, the amplitudes of the components, the ratios between the components, the width of the components, and the delay or time separation between the components, can be extracted, compared, analyzed, and stored as ECG features. For example, the P wave and heart rate can be extracted and analyzed to identify atrial fibrillation, where the absence of P waves and/or an irregular heart rate may indicate atrial fibrillation. The extracted ECG features can also be included in the metadata for indexing and searching.

The changes in the ECG signal over time in view of the activities and circumstances can be compared with changes over time and circumstances observed within a database of ECG's. Comparisons may include any comparison of data derived from any other ECG signal or any database of ECG's or any subset of ECG data, or with data derived from any database of ECG's. Changes in any feature of the ECG signal over time may be used for a relative comparison with similar changes in any ECG database or with data derived from an ECG database. The ECG data from the baseline ECG and the ECG data from a potential adverse event can be compared to determine the changes or deviations from baseline values. In addition, both the baseline ECG and the ECG data recorded from the patient can be compared to one or more predetermined template ECGs which can represent a normal healthy condition as well as various diseased conditions, such as myocardial infarction and arrhythmias.

The comparisons and analysis described herein can be used to draw conclusions and insights into the patient's health status, which includes potential health issues that the patient may be experiencing at the time of measurement or at future times. Conclusions and determinations may be predictive of future health conditions or diagnostic of conditions that the patient already has. The conclusions and determinations may also include insights into the effectiveness or risks associated with drugs or medications that the patient may be taking, have taken or may be contemplating taking in the future. In addition, the comparisons and analysis can be used to determine behaviors and activities that may reduce or increase risk of an adverse event. Based on the comparisons and analysis described herein, the ECG data can be classified according to a level of risk of being an adverse event. For example, the ECG data can be classified as normal, low risk, moderate risk, high risk, and/or abnormal. The normal and abnormal designation may require health care professional evaluation, diagnosis, and/or confirmation.

Diagnosis and determination of an abnormality, an adverse event, or a disease state by physicians and other health care professionals can be transmitted to the servers and database to be tagged with and associated with the corresponding ECG data. The diagnosis and determination may be based on analysis of ECG data or may be determined using other tests or examination procedures. Professional diagnosis and determinations can be extracted from the patient's electronic health records, can be entered into the system by the patient, or can be entered into the system by the medical professional. The conclusions and determinations of the system can be compared with actual diagnosis and determinations from medical professions to validate and/or refine the machine learning algorithms used by the system. The time of occurrence and duration of the abnormality, adverse event or disease state can also be included in the database, such that the ECG data corresponding with the occurrence and/or the ECG data preceding and/or following the abnormality, adverse event or disease state can be associated together and analyzed. The length of time preceding or following the abnormality may be predetermined and be up to 1 to 30 days, or greater than 1 to 12 months. Analysis of the time before the abnormality, adverse event or disease state may allow the system to identify patterns or correlations of various ECG features that precede the occurrence of the abnormality, adverse event or disease state, thereby providing advance detection or warning of the abnormality, adverse event or disease state. Analysis of the time following the abnormality, adverse event or disease state can provide information regarding the efficacy of treatments and/or provide the patient or physician information regarding disease progression, such as whether the patient's condition in improving, worsening or staying the same. The diagnosis and determination can also be used for indexing by, for example, including it in the metadata associated with the corresponding ECG data.

As described herein, various parameters may be included in the database along with the ECG data. These may include the patient's age, gender, weight, blood pressure, medications, behaviors, habits, activities, food consumption, drink consumption, drugs, medical history and other factors that may influence a patient's ECG signal. The additional parameters may or may not be used in the comparison of the changes in ECG signal over time and circumstances.

The conclusions, determinations, and/or insights into the patient's health generated by the system may be communicated to the patient directly or via the patient's caregiver (doctor or other healthcare professional). For example, the patient can be sent an email or text message that is automatically generated by the system. The email or text message can be a notification which directs the patient to log onto a secure site to retrieve the full conclusion, determination or insight, or the email or text message can include the conclusion, determination or insight. Alternatively or additionally, the email or text message can be sent to the patient's caregiver. The notification may also be provided via an application on a smartphone, tablet, laptop, desktop or other computing device.

As described herein, the system can identify behaviors, habits, activities, foods, drinks, medications, drugs, and the like which are associated with the patient's abnormal ECG readings. In addition to informing the patient of these associations, the system can provide instructions or recommendations to the patient to avoid these behaviors, habits, activities, foods, drinks, medications, drugs, and the like which are associated with the patient's abnormal ECG readings. Similarly, the system can identify behaviors, habits, activities, foods, drinks, medications, drugs, and the like which are associated with normal or improving ECG readings, and can instruct or recommend that the patient perform these behaviors, habits, and activities and/or consume these foods, drinks, medications, and drugs. The patient may avoid a future healthcare issue, as instructed or recommended by the system, by modifying their behavior, habits or by taking any course of action, including but not limited to taking a medication, drug or adhering to a diet or exercise program, which may be a predetermined course of action recommended by the system independent of any analysis of the ECG data, and/or may also result from insights learned through this system and method as described herein. In addition, the insights of the system may relate to general fitness and or mental wellbeing.

The ECG data and the associated metadata and other related data as described herein can be stored in a central

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database, a cloud database, or a combination of the two. The data can be indexed, searched, and/or sorted according to any of the features, parameters, or criteria described herein. The system can analyze the ECG data of a single patient, and it can also analyze the ECG data of a group of patients, which can be selected according to any of the features, parameters or criteria described herein. When analyzing data from a single patient, it may be desirable to reduce and/or correct for the intra-individual variability of the ECG data, so that comparison of one set of ECG data taken at one particular time with another set of ECG data taken at another time reveals differences resulting from changes in health status and not from changes in the type of ECG recording device used, changes in lead and electrode placement, changes in the condition of the skin (i.e. dry, sweaty, conductive gel applied or not applied), and the like. As described above, consistent lead and electrode placement can help reduce variability in the ECG readings. The system can also retrieve the patient's ECG data that were taken under similar circumstances and can analyze this subset of ECG data.

FIG. **4** illustrates an embodiment of the system and method **400** of ECG monitoring described herein. The system can be implemented on a server or computer having a processor for executing the instructions described herein, which can be stored in memory. In step **402**, ECG data can be recorded using any of the devices described herein for one or more patients. In step **404**, the ECG data is transmitted along with associated metadata to a server and database that stores the ECG data. In step **406**, a subset of the ECG data can be selected based on criteria in the metadata, such as user identity, time, device used to record the ECG data, and the like. In step **408**, the subset of ECG data can be analyzed using a machine learning algorithm, which can assign a risk level to the ECG data in step **410**. The system can then determine whether the risk level is high, as shown in step **412**. If the risk level is low, the user can be notified that the ECG is normal or low risk, as shown in step **414**. If the risk level is high, a high risk level alert can be sent to the patient with the option of sending the ECG to the medical professional for interpretation, as shown in step **416**. The system then waits for the user's response to determine whether the patient elects to send the ECG to the medical professional for interpretation, as shown in step **418**. If the patient does not wish to send the ECG to the medical professional for interpretation, the system can end the routine at this point, as shown in **420**. If the patient does elect to send the ECG to the medical professional for interpretation, the request can be transmitted to the medical professional in step **422**. The request to the medical professional can be sent to a workflow auction system as described in U.S. Provisional Application No. 61/800,879, filed Mar. 15, 2013, which is herein incorporated by reference in its entirety for all purposes. Once the medical professional has interpreted the ECG, the system can receive and store the ECG interpretation from the medical professional in the database, as shown in step **424**. The system can then notify the user of the professional ECG interpretation, which can be sent to or accessed by the user, as shown in step **426**. Additionally, the system can compare the assigned risk level with the medical diagnosis in step **428** and can determine whether the risk level determined by the system agrees with the medical diagnosis in step **430**. If the risk level does not agree with the medical diagnosis, the machine learning algorithm can be adjusted until the risk level matches the medical diagnosis, as shown in step **432**. If the risk level does agree with the medical diagnosis, the routine can be ended as shown in step **434**.

Although the above steps show a method **400** in accordance with many embodiments, a person of ordinary skill in the art will recognize many variations based on the teaching described herein. The steps may be completed in a different order. Steps may be added or deleted. Some of the steps may comprise sub-steps. Many of the steps may be repeated as often as beneficial to the user or subject.

One or more of the steps of a method **400** may be performed with circuitry, for example, one or more of a processor or a logic circuitry such as a programmable array logic for a field programmable gate array. The circuitry may be programmed to provide one or more of the steps of a method **400**, and the program may comprise program instructions stored on a non-transitory computer readable medium or memory or programmed steps of the logic circuitry such as the programmable array logic or the field programmable gate array, for example.

Aspects of the present disclosure provide systems and methods for generating a heart health score in response to continuously measured or monitored physiological parameter(s). The score may be given a quantitative value such as be graded from A to F or 0 to 100 for example (e.g. a great score may be an A or 100, a good score may be a B or 75, a moderate score may be a C or 50, a poor score may be a D or 25, and a failing score may be an F or 0.) If an arrhythmia is detected, the score may be below 50 for example. Other scoring ranges such as A to Z, 1 to 5, 1 to 10, 1 to 1000, etc. may also be used. Arrhythmia may be detecting using the machine learning based operations or algorithms described herein.

FIG. **5** shows a flow chart of an exemplary method **500** to generate a heart health score in accordance with many embodiments.

In a step **502**, an arrhythmia is detected. If an arrhythmia is detected (e.g. using the methods and/or algorithms disclosed herein), then the heart health score generated will be below 50. Depending on the severity of the arrhythmia detected, the heart score may be calculated or assigned within the ranges according to the table below in Table 2.

TABLE 2

Arrhythmia	Heart Health score
ATRIAL FIBRILLATION, HR below 100	30-45
ATRIAL FIBRILLATION, HR above 100	15-30
Sinus Tachycardia	20-40
Supraventricular Tachycardia	20-40
Bradycardia	20-40
Bigeminy, Trigeminy	30-50
Short runs of High Heart Rate (VTACH suspect)	10-30

In a step **504** a Heart Rate Variability (HRV) is calculated. HRV can be an indicator of heart health. The value for HRV value for a healthy heart is typically higher than HRV for an unhealthy heart. Also, HRV typically declines with age and may be affected by other factors, like stress, lack of physical activity, etc. HRV may be measured and analyzed using the methods described above. HRV may be calculated in the absence of arrhythmia, which may improve the accuracy of the HRV measurement. HRV may be determined and further analyzed as described above.

In a step **506**, premature beats are counted and Heart Rate Turbulence (HRT) is calculated. Premature beats in the sequence of R-R intervals may be detected. Also, R-R

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intervals typically tend to recover at a certain pace after a premature beat. Using these two parameters (prematurity and pace of R-R recovery), HRT parameters may be calculated. There may be known deviations of HRT parameters associated with patients with risk of Congestive Heart Failure (CHF). These deviations, however, may be used to estimate an inverse measure. The number of premature beats per day (or per hour) may also be used as a measure of heart health. A low number of premature beats may indicate better heart health. In summary, the heart health score may be generated by combining at least heart rate variability (HRV), the number of premature beats, and heart rate turbulence (HRT). This combination (in the absence of arrhythmia) may provide an accurate estimate of how healthy the heart of the user is.

In a step **508**, a heart health score is generated, and in a step **510**, a hearth health score is generated based on an arrhythmia. To initially generate the score, a few hours (e.g. 2-5 hours) of measured R-R intervals may be required. A more accurate score may be generated after a week of continuous R-R interval measurements. Longer data sets may be required to detect significant arrhythmias as they may usually be detected within the first 7-8 days of monitoring.

Although the above steps show a method **500** in accordance with many embodiments, a person of ordinary skill in the art will recognize many variations based on the teaching described herein. The steps may be completed in a different order. Steps may be added or deleted. Some of the steps may comprise sub-steps. Many of the steps may be repeated as often as beneficial to the user or subject.

One or more of the steps of a method **500** may be performed with circuitry, for example, one or more of a processor or a logic circuitry such as a programmable array logic for a field programmable gate array. The circuitry may be programmed to provide one or more of the steps of a method **500**, and the program may comprise program instructions stored on a non-transitory computer readable medium or memory or programmed steps of the logic circuitry such as the programmable array logic or the field programmable gate array, for example.

FIG. **6** shows a further method **600** of generating a heart score. In addition to the parameters which may be derived from the heart rate data described above, the heart health score may also be generated in response to further physiological parameters as shown in FIG. **6**.

In a step **602**, a raw ECG waveform is obtained. In a step **608**, ECG parameters are extracted from the raw ECG waveform data and arrhythmia prediction and/or detection algorithms are run to analyze the obtained raw ECG waveform data.

In a step **604**, physiological parameters may be measured using a sensor of the user's local computing device or an accessory thereof. Such measured physiological parameters may include blood pressure, user activity and exercise level, blood oxygenation levels, blood sugar levels, an electrocardiogram, skin hydration or the like of the user. These physiological parameters may be measured over time such as over substantially the same time scale or length as the measurement of heart rate. In a step **610**, an R-R interval is extracted and both traditional and non-traditional heart rate measures are used to analyze the measured heart rate and physiological parameters.

In a step **606**, additional physiological parameters for determining the heart health score may be input by the user. These parameters may include the age, the gender, the weight, the height, the body type, the body mass index (BMI), the personal medical history, the family medical history, the exercise and activity level, the diet, the hydration level, the amount of sleep, the cholesterol level, the alcohol intake level, the caffeine intake level, the smoking status, and the like of the user. For example, the heart health score may be weighted by age and/or gender to provide the user an accurate assessment of his or her heart health in response to the heart rate data. In a step **612**, feature extraction is used to analyze the inputted physiological parameters.

In a step **614** feature ranking and/or feature selection occurs. In a step **618**, a real time prediction or detection of atrial fibrillation, and/or in a step **616**, the heart rate variability measurements may be labelled and saved for offline training of a machine learning algorithm or set of machine learning operations, and then may be subsequently used to make a real time prediction and/or detection of atrial fibrillation. A plurality of heart health scores may be generated by a plurality of users to generate a set of population data. This population data may be used to train the machine learning algorithms described herein such that the trained algorithm may be able to detect and predict atrial fibrillation or other health conditions from user data.

Although the above steps show a method **600** in accordance with many embodiments, a person of ordinary skill in the art will recognize many variations based on the teaching described herein. The steps may be completed in a different order. Steps may be added or deleted. Some of the steps may comprise sub-steps. Many of the steps may be repeated as often as beneficial to the user or subject.

One or more of the steps of a method **600** may be performed with circuitry, for example, one or more of a processor or a logic circuitry such as a programmable array logic for a field programmable gate array. The circuitry may be programmed to provide one or more of the steps of a method **600**, and the program may comprise program instructions stored on a non-transitory computer readable medium or memory or programmed steps of the logic circuitry such as the programmable array logic or the field programmable gate array, for example.

The systems and methods for generating a heart health score in response to continuously measured or monitored physiological parameter(s) may comprise a processor of a computing device and software. A processor of a computing device (e.g. a tablet computer, a smartphone, a smart watch, a smart band, a wearable computing device, or the like) may execute this set of instructions to receive the input data and detect and/or predict atrial fibrillation therefrom. The software may be downloaded from an online application distribution platform such as the Apple iTunes or App Store, Google Play, Amazon App Store, and the like. A display of the computing device may notify the user of the calculated heart health score and/or if further measurements are required (e.g. to perform a more accurate analysis).

FIG. **7** shows a schematic diagram of the executed application described herein. The heart health score may be provided on a software application such as a mobile app downloaded from an application distribution platform and executed on a local computing device of the user as described above. This executed application may instruct the user to take active steps in response to a poor or moderate heart health score. For example, the instructions to the user may be to make a corrective measure such as to modify his or her diet, exercise pattern, sleep pattern, or the like. Alternatively or in combination, the instructions to the user may be to take a further step such as to take an electrocardiogram (e.g. to verify the presence of an arrhythmia), enroll in an electrocardiogram over-read service, or schedule an

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appointment with a physician or other medical specialist. If the heart health score is below a desired threshold for good heart health, the executed application may link the user to a second execute application with further application features. Alternatively or in combination, these further features may be unlocked on the first executed application if the heart health score is below the threshold. In at least some cases, a prescription or verification from a medical professional may also be required to unlock the further application features.

FIG. **8** shows screenshots of the executed application. The further features unlocked may include the ability to read electrocardiogram (ECG) data from a sensor coupled to the local computing device and display the electrocardiogram (ECG) in real-time and/or detect and alert for atrial fibrillation based on the electrocardiogram (ECG) in real-time (e.g. as described in U.S. application Ser. Nos. 12/796,188, 13/108,738, 13/420,540, and 13/964,490). As shown in FIG. **8**, these further features may include an electrocardiogram (ECG) over-read service such as that described in U.S. application Ser. No. 14/217,032. The first executed application may comprise a consumer software application and the second executed application may comprise a medical professional or regulated software application or set of features of the first executed application. As described herein and shown in FIG. **8**, the executed application may provide a dash board to track the heart health of the user and show risk factors which may be monitored and tracked by the user. The dash board may be provided with further features such as that described in U.S. Ser. No. 61/915,113 (filed Dec. 12, 2013).

FIG. **9** shows a method **900** for cardiac disease and rhythm management, which may, for example, be implemented with the system **100** described herein. In a step **902**, a user or subject is provided access to a cardiac disease and/or rhythm management system such as system **100**. Step **902** may comprise prescribing the use of the system **100** for the user or subject. In a step **904**, the user or subject is provided one or more biometric sensors. These biometric sensor(s) may couple to a computing device of the user or subject, e.g. a personal desktop computer, a laptop computer, a tablet computer, a smartphone, etc., and associated software loaded thereon.

In a step **906**, the user or subject downloads the cardiac disease and/or rhythm management system software onto their computing device. For example, the system software may comprise a mobile software application ("mobile app") downloaded from the Apple App Store, Google Play, Amazon Appstore, BlackBerry World, Nokia Store, Windows Store, Windows Phone Store, Samsung Apps Store, and the like. The downloaded system software, e.g. mobile app **101***a*, may be configured to interface with the biometric sensors provided to the user or subject in the step **154**.

In a step **908**, personal information input to the cardiac disease management system is received. For example, the user or subject may enter his or her gender, height, weight, diet, disease risk factors, etc. into the mobile app **101***a*. Alternatively or in combination, this personal information may be input on behalf of the user or subject, for example, by a physician of the user or subject.

In a step **910**, biometric data is received from the biometric sensors provided to the user or subject. For example, the system **100** and the mobile app **101***a* may receive ECG data and heart rate from handheld sensor **103**, activity data from wrist-worn activity sensor **105**, blood pressure and heart rate data from mobile blood pressure monitor **107***a*, and other data such as weight and body fat percentage data from a "smart" scale in communication with the local computing device **101**.

In a step **912**, a cardiac health score is generated. The cardiac health score can be generated by considering and weighing one or more influencing factors including the incidence of atrial fibrillation or arrhythmia as detected by the handheld ECG monitor, the heart rate of the user or subject, the activity of the user or subject, hours of sleep and rest of the user or subject, blood pressure of the user or subject, etc. Often, the incidence of atrial fibrillation or arrhythmia will be weighed the most. The cardiac health score may be generated by a physician or a machine learning algorithm provided by the remote server or cloud-based service **113**, for example. A plurality of users and subject may concurrently use the cardiac health and/or rhythm management system **100** and the machine learning algorithm may, for example, consider population data and trends to generate an individual user or subject's cardiac health score.

In a step **914**, one or more recommendations or goals is generated for the user or subject based on or in response to the generated cardiac health score. These recommendation(s) and/or goal(s) may be generated automatically based on or in response to the biometric and personal information of the user or subject. For example, the machine learning algorithm may generate these recommendation(s)/goal(s). Alternatively or in combination, a physician or other medical specialist may generate the recommendation(s) and/or goal(s), for example, based on or in response to the biometric and personal information of the user or subject. The physician or other medical professional may access the patient data through the Internet as described above.

In a step **916**, the patient implements many if not all of the recommendation(s) and/or goal(s) provided to him or her. And in a step **916**, steps **908** to **916** may be repeated such that the user or subject may iteratively improve their cardiac health score and their overall health.

Although the above steps show method **900** of managing cardiac disease and/or rhythm in accordance with many embodiments, a person of ordinary skill in the art will recognize many variations based on the teaching described herein. The steps may be completed in a different order. Steps may be added or deleted. Some of the steps may comprise sub-steps. Many of the steps may be repeated as often as beneficial to the user or subject.

One or more of the steps of the method **900** may be performed with circuitry, for example, one or more of a processor or a logic circuitry such as a programmable array logic for a field programmable gate array. The circuitry may be programmed to provide one or more of the steps of the method **900**, and the program may comprise program instructions stored on a non-transitory computer readable medium or memory or programmed steps of the logic circuitry such as the programmable array logic or the field programmable gate array, for example.

In some embodiments, the heart rate information (or an extracted portion of HR information) may be used to compare to a database of similar information that has been correlated with cardiac events. For example, heart rate information may be compared to a database of HR information extracted for ECG recordings of patients known to be experiencing cardiac problems. Thus, patterns of heart rate information taken from a subject may be compared to patterns of cardiac information in a database. If there is a match (or a match within a reasonable closeness of fit), the patient may be instructed to record an ECG, e.g. using an ambulatory ECG monitor. This may then provide a more

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detailed view of the heart. This method may be particularly useful, as it may allow recording and/or transmission and/or analysis of detailed electrical information about the heart at or near the time (or shortly thereafter) when a clinically significant cardiac event is occurring. Thus, the continuous monitoring may allow a subject to be alerted immediately upon an indication of the potential problem (e.g. an increase in HRV suggestive of a cardiac dysfunction). This may allow the coupling of continuous HR monitoring with ECG recording and analysis for disease diagnosis and disease management.

FIG. **10** illustrates one variation of a method for monitoring a subject to determine when to record an electrocardiogram (ECG). In FIG. **10**, a subject is wearing a continuous heart rate monitor (configured as a watch **1010**, including electrodes **1016**), shown in step **1002**. The heart rate monitor transmits (wirelessly **1012**) heart rate information that is received by the smartphone **1018**, as shown in step **1004**. The smartphone includes a processor that may analyze the heart rate information **1004**, and when an irregularity is determined, may indicate **1006** to the subject that an ECG should be recorded. In FIG. **10**, an ambulatory ECG monitor **1014** is attached (as a case having electrodes) to the phone **1018**. The user may apply the ECG monitor as to their body (e.g. chest, between arms, etc.) **1008** to record ECGs that can then be saved and/or transmitted for analysis.

FIGS. **11** and **11A** show screenshots of an atrial fibrillation dashboard **1100** of a user interface for the cardiac disease and/or rhythm management system **100**. FIG. **11** shows a top portion **1100***a* of the atrial fibrillation dashboard **1100** while FIG. **10A** shows a bottom portion **1100***b* of the atrial fibrillation dashboard **1100**.

The top portion **1100***a* of the atrial fibrillation dashboard **1100** as shown in FIG. **10** may display the current cardiac health score of the user or subject, a recent best cardiac health score of the user or subject, and a completion percentage of recommendation(s) and/or goal(s) for the user or subject. The user or subject may tap any one of the cardiac health score displays or the recommendation(s) and/or goal(s) displays to access more detailed information regarding the calculated health score(s) or recommendation(s) and/or goal(s), respectively. The top portion **1100***a* may also show an ECG of the user or subject and a button which may be tapped to record the ECG of the user or subject for the day. As discussed with reference to FIG. **1**, the ECG may be recorded with a handheld sensor **103** in communication with the local computing device **100**. The top portion **1000***a* may also show the number of atrial fibrillation episodes and the average duration of these atrial fibrillation episodes. This number and duration may be generated automatically by software or logic of the mobile app **101***a* based on or in response to the ECG measurements taken by the user or subject. Alternatively or in combination, a physician may access the atrial fibrillation dashboard **1100** of an individual user or subject, evaluate his or her ECGs, and provide the number of atrial fibrillation episodes and their duration to the mobile app **101***a* or other software loaded on the local computing device **101** of the user or subject. The shortest and longest durations of the atrial fibrillation episodes may also be shown by the top portion **1100***a* as well as the user or subject's daily adherence to a medication regime.

The bottom portion **1100***b* of the atrial fibrillation dashboard **1100** as shown in FIG. **10A** may display one or more influencers which influence how the cardiac health score is generated. These influencers may include, for example, caffeine intake, alcohol intake, stress levels, sleep levels, weight, nutrition, fitness and activity levels, and blood pressure. Data for these influencers may be input automatically by one or more biometric sensors coupled to the local computing device **101** and/or the mobile app **101***a*. Alternatively or in combination, the data for these influencers may be input manually by the user or subject by tapping on the respective influencer display. For example, tapping on the blood pressure display area may cause a slider input **1100***c* for blood pressure to pop up. The user or subject may use the slider to enter and save his or her blood pressure for the day. Similar pop-ups or user-selected inputs may be provided for the other influencers. For example, the user or subject may enter his or her daily caffeine or alcohol intake, stress and sleep levels, nutrition levels, or activity and fitness levels (e.g. low/bad, medium/so-so, or high/good based on the user's age, gender, height, weight, etc. as can be indicated by an instruction page of the mobile app **101***a*). The influencer displays may also show the goal progression of the user or subject.

FIGS. **12** and **12A** show screenshots of a goals and recommendations page **1200** of the cardiac disease and rhythm management system interface or mobile app **101***a*. A top portion **1200***a* of the goals and recommendations page **1100** may comprise a listing of 7-day goals for the user or subject. The top portion **1200***a* may further comprise everyday goals for the user or subject which often cannot be removed or changed. The user or subject can check off these goals or recommendations as he or she meets them. The top portion **1200***a* may track goal completion percentage over a 7-day period. The user or subject can set the same goals for the next day and/or set new goals.

A bottom portion **1200***b* of the goals and recommendations page **1200** may comprise a listing of new goals which the user or subject may add. The new goals may be categorized into goals or recommendations for atrial fibrillation management, stress management, and/or other categories. For example, goals for atrial fibrillation management may include taking daily medications, reducing caffeine intake, and reducing alcohol intake. And, goals for stress management may include meditate for 5 minutes daily, take blood pressure reading daily, and getting at least 7 hours of sleep nightly. Using the goals and recommendations page **1200**, the user or subject can set their goals for the week. One or more of these goals may be automatically recommended to the user or subject or be recommended by a physician having access to the dashboard **1100**. For example, goals may be recommended based on last week's progress. The completion of recommended goals can result in the user or subject earning more "points," in effect gamifying health and cardiac rhythm management for the user or subject. Alternatively or in combination, the goals may be set by a physician having access to the dashboard **1100**.

FIG. **13** shows a screenshot of a user's local computing device notifying the user with a pop-up notice **1300** to meet their daily recommendations and goals. By tapping on the pop-up notice, **1300**, the user or subject can be taken to the atrial fibrillation dashboard where the user or subject can update or otherwise manage their cardiac health.

FIG. **14** shows an embodiment comprising a smart watch **1400** which includes at least one heart rate monitor **1402** and at least one activity monitor **1404**. One or more processors are coupled to one or more non-transitory memories of the smart watch and configured to communicate with the heart rate monitor **1402** and the activity monitor **1404**. The one or more processors are further coupled to an output device **1408**. Processor executable code is stored on the one or more memories and when executed by the one or more processors causes the one or more processors to determine if heart rate

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and activity measurements represent an advisory condition for recording an ECG, and generate and send notification signals through the output device **1408** when an advisory condition for recording an ECG is determined.

For example, presently available smart watches include motion sensors such as pedometers. Pedometers can be based on an accelerometer or electromechanical mechanism such as a pendulum, magnetic reed proximity switch, and a spring suspended lever arm with metal-on-metal contact. Modern accelerometers are often small micro electro-mechanical systems and are well known by those skilled in the art. Heart rate monitors are readily available with smart phones as well as smart watches. One type uses an optical sensor to detect the fluctuation of blood flow. The signal can be amplified further using, for example, a microcontroller to count the rate of fluctuation, which is actually the heart rate.

An advisory condition for recording an ECG may occur due to, for example, large continuing fluctuations in heart rate. An advisory condition for recording an ECG can also occur when a measured heart rate increases rapidly without a corresponding increase in activity monitored by, for example, an accelerometer. By comparing measured heart rate changes with measured activity changes, the presently disclosed software or "app" minimizes false alarms are minimized. ECG devices are described in U.S. Ser. No. 12/796,188, filed Jun. 8, 2010, now U.S. Pat. No. 8,509,882, hereby expressly incorporated herein by reference in its entirety. The ECG device can be present in a smart watch band or a smart phone. In one embodiment, the ECG device includes an electrode assembly configured to sense heart-related signals upon contact with a user's skin, and to convert the sensed heart-related signals to an ECG electric signal. The ECG device transmits an ultrasonic frequency modulated ECG signal to a computing device such as, for example, a smartphone. Software running on the computing device or smartphone digitizes and processes the audio in real-time, where the frequency modulated ECG signal is demodulated. The ECG can be further processed using algorithms to calculate heart rate and identify arrhythmias. The ECG, heart rate, and rhythm information can be displayed on the computer or smartphone, stored locally for later retrieval, and/or transmitted in real-time to a web server via a 2G/3G/4G, WiFi or other Internet connection. In addition to the display and local processing of the ECG data, the computer or smartphone can transmit, in real-time, the ECG, heart rate and rhythm data via a secure web connection for viewing, storage and further analysis via a web browser interface.

In another embodiment, the converter assembly of an ECG device is integrated with, and electrically connected to the electrode assembly and is configured to convert the electric ECG signal generated by electrode assembly to a frequency modulated ECG ultrasonic signal having a carrier frequency in the range of from about 18 kHz to about 24 kHz. It is sometimes desirable to utilize a carrier frequency in the 20 kHz to 24 kHz range. The ultrasonic range creates both a lower noise and a silent communication between the acquisition electronics and the computing device such as the smartphone, notebook, smart watch and the like.

A kit can include downloadable software such as an "app" for detecting an advisory condition for recording an ECG and an ECG device. The ECG device can be present on a watch band for replacing a specific band on a smart watch. The ECG device can also be provided on a smart phone back plate for replacing an existing removable smartphone back. In another configuration, the ECG device is usable as a smartphone protective case.

Software on the smartphone or smart watch can also combine data and signals from other sensors built into the smartphone or smart watch such as a GPS.

While preferred embodiments of the present disclosure have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the subject matter described herein. It should be understood that various alternatives to the embodiments of the subject matter described herein may be employed in practicing the subject matter described herein. It is intended that the following claims define the scope of the disclosure and that methods and structures within the scope of these claims and their equivalents be covered thereby.

What is claimed is:

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.

2. The method of claim **1**, wherein said heart rate sensor comprises one or more of a patch, a wristband, and an armband.

3. The method of claim **1**, further comprising receiving biometric data of said first user from a biometric data sensor coupled to said first user.

4. The method claim **3**, wherein said biometric data comprises one or more of a temperature of said first user, a blood pressure of said first user, and inertial data of said first user.

5. The method of claim **1**, wherein said mobile computing device comprises a smartphone.

6. The method of claim **1**, wherein said mobile computing device comprises a smartwatch.

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

8. The method of claim **7**, wherein said machine learning algorithm stores heart rate and heart rate variability data previously associated with arrhythmias in said first user and determines said presence of said arrhythmia based on said stored heart and heart rate variability data.

9. The method of claim **7**, wherein said machine learning algorithm stores heart rate and heart rate variability data associated with arrhythmias in a second user and determines said presence of said arrhythmia in said first user based on said stored heart and heart rate variability data associated with arrhythmias in said second user.

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10. The method of claim 1, wherein an irregularity comprises an increase in said heart rate variability of said first user without a corresponding increase in said activity level of said first user.

11. A system for determining the presence of an arrhythmia of a first user, comprising

a heart rate sensor coupled to said first user;

a mobile computing device comprising a processor, wherein said mobile computing device is coupled to said heart rate sensor, and wherein said mobile computing device is configured to sense an electrocardiogram of said first user; and

a motion sensor

a non-transitory computer readable medium encoded with a computer program including instructions executable by said processor to cause said processor to receive a heart rate of said first user from said heart rate sensor, sense an activity level of said first user from said motion sensor, determine a heart rate variability of said first user based on said heart rate of said first user, compare and activity level of said first user to said heart rate variability of said first user, and alert said first user to record an electrocardiogram using said mobile computing device.

12. The system of claim 11, wherein said heart rate sensor comprises one or more of a patch, a wristband, and an armband.

13. The system of claim 11, wherein said system further comprises a biometric data sensor, and wherein said computer program including instructions executable by said processor further causes said processor to sense biometric data of said first user from said biometric data sensor.

14. The system claim 13, wherein said biometric data comprises one or more of a temperature of said first user, a blood pressure of said first user, and inertial data of said first user.

15. The system of claim 11, wherein said mobile computing device comprises a smartphone.

16. The system of claim 11, wherein said mobile computing device comprises a smartwatch.

17. The system of claim 11, wherein said computer program further causes said processor to determine a presence of said arrhythmia using a machine learning algorithm.

18. The system of claim 17, wherein said machine learning algorithm stores heart rate and heart rate variability data previously associated with arrhythmias in said first user and determines said presence of said arrhythmia based on said stored heart and heart rate variability data.

19. The system of claim 18, wherein said machine learning algorithm stores heart rate and heart rate variability data associated with arrhythmias in a second user and determines said presence of said arrhythmia in said first user based on said stored heart and heart rate variability data associated with arrhythmias in said second user.

20. The system of claim 11, wherein an irregularity comprises an increase in said heart rate variability of said first user without a corresponding increase in said activity level of said first user.

* * * * *

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 9,572,499 B2
APPLICATION NO. : 14/730122
DATED : February 21, 2017
INVENTOR(S) : Ravi Gopalakrishnan et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Claims

Column 27, Claim 11, should read as follows:

11. A system for determining the presence of an arrhythmia of a first user, comprising
a heart rate sensor coupled to said first user;
a mobile computing device comprising a processor,
wherein said mobile computing device is coupled to said heart rate sensor, and wherein said mobile computing device is configured to sense an electrocardiogram of said first user; and
a motion sensor
a non-transitory computer readable medium encoded with
a computer program including instructions executable by said processor to cause said processor to receive a heart rate of said first user from said heart rate sensor, sense an activity level of said first user from said motion sensor, determine a heart rate variability of said first user, based on said heart rate of said first user, compare said activity level of said first user to said heart rate variability of said first user, and alert said first user to record an electrocardiogram using said mobile computing device.

Signed and Sealed this
Twentieth Day of June, 2017

Joseph Matal

Joseph Matal
Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office

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February 25, 2021

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U.S. PATENT: *10,595,731*

ISSUE DATE: *March 24, 2020*

By Authority of the

Under Secretary of Commerce for Intellectual Property

and Director of the United States Patent and Trademark Office

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Certifying Officer

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JX-002.1

(12) **United States Patent**
Gopalakrishnan et al.

(10) **Patent No.: US 10,595,731 B2**
(45) **Date of Patent: Mar. 24, 2020**

(54) **METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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(65) **Prior Publication Data**

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A61B 5/024 (2006.01)
A61B 5/0205 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 5/02055*** (2013.01); ***A61B 5/0022*** (2013.01); ***A61B 5/0245*** (2013.01); ***A61B 5/02405*** (2013.01); ***A61B 5/02416*** (2013.01); ***A61B 5/046*** (2013.01); ***A61B 5/681*** (2013.01); ***A61B 5/6898*** (2013.01);
(Continued)

(58) **Field of Classification Search**
USPC 600/508–509
See application file for complete search history.

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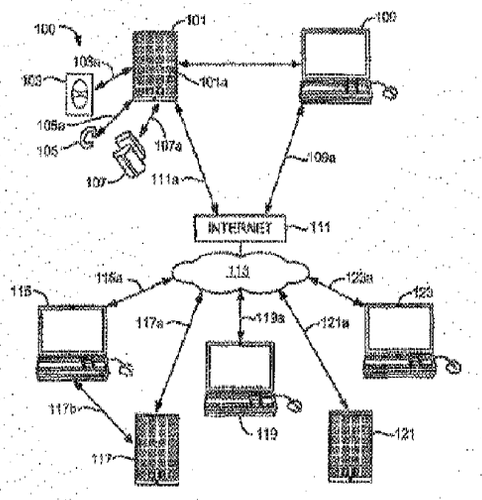
(57) **ABSTRACT**

A dashboard centered around arrhythmia or atrial fibrillation tracking is provided. The dashboard includes a heart or cardiac health score that can be calculated in response to data from the user such as their ECG and other personal information and cardiac health influencing factors. The dashboard also provides to the user recommendations or goals, such as daily goals, for the user to meet and thereby improve their heart or cardiac health score. These goals and recommendations may be set by the user or a medical professional and routinely updated as his or her heart or cardiac health score improves or otherwise changes. The dashboard is generally displayed from an application provided on a smartphone or tablet computer of the user.

30 Claims, 16 Drawing Sheets



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Related U.S. Application Data

continuation of application No. 15/393,077, filed on Dec. 28, 2016, now Pat. No. 10,159,415, which is a continuation of application No. 14/730,122, filed on Jun. 3, 2015, now Pat. No. 9,572,499, which is a continuation of application No. 14/569,513, filed on Dec. 12, 2014, now Pat. No. 9,420,956.

(60) Provisional application No. 62/014,516, filed on Jun. 19, 2014, provisional application No. 61/970,551, filed on Mar. 26, 2014, provisional application No. 61/969,019, filed on Mar. 21, 2014, provisional application No. 61/953,616, filed on Mar. 14, 2014, provisional application No. 61/915,115, filed on Dec. 12, 2013.

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G16H 40/63	(2018.01)
G16H 15/00	(2018.01)
G16H 10/60	(2018.01)
A61B 5/021	(2006.01)
A61B 5/0452	(2006.01)
A61B 5/11	(2006.01)
G16H 50/30	(2018.01)

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CPC ***A61B 5/7264*** (2013.01); ***A61B 5/7275*** (2013.01); ***A61B 5/746*** (2013.01); ***G16H 20/40*** (2018.01); ***G16H 40/67*** (2018.01); *A61B 5/021* (2013.01); *A61B 5/02438* (2013.01); *A61B 5/0452* (2013.01); *A61B 5/1118* (2013.01); *G16H 10/60* (2018.01); *G16H 15/00* (2018.01); *G16H 40/63* (2018.01); *G16H 50/30* (2018.01)

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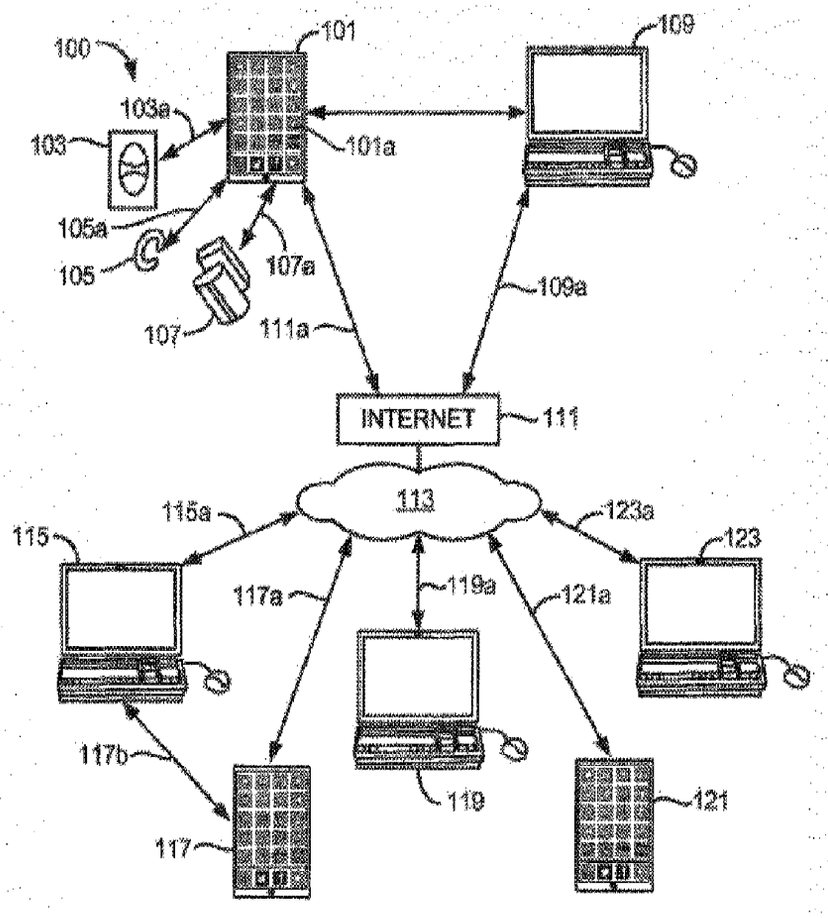

FIG. 1

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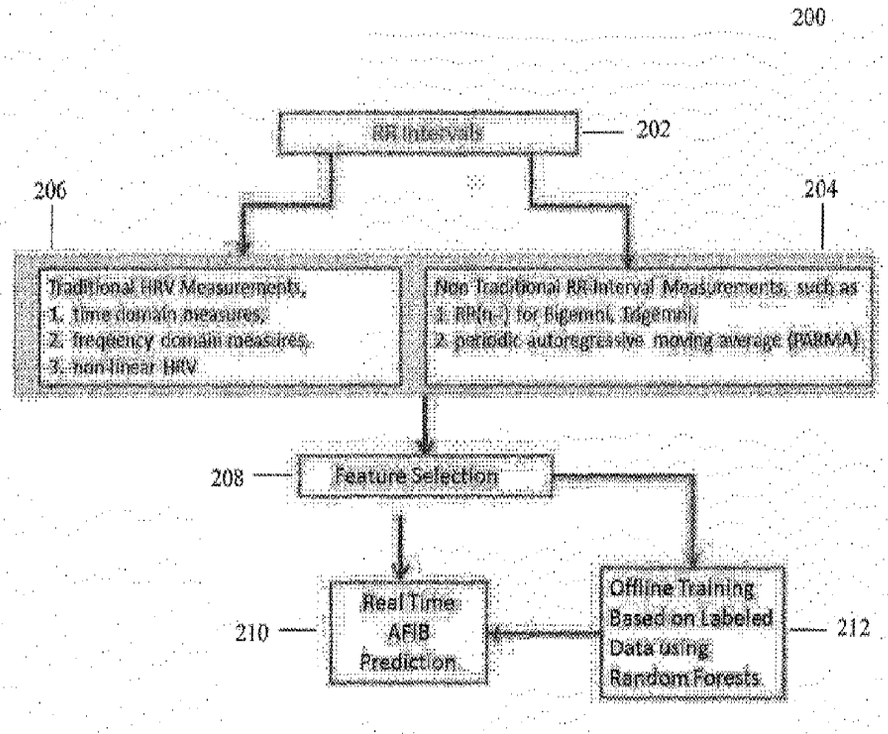

FIG. 3

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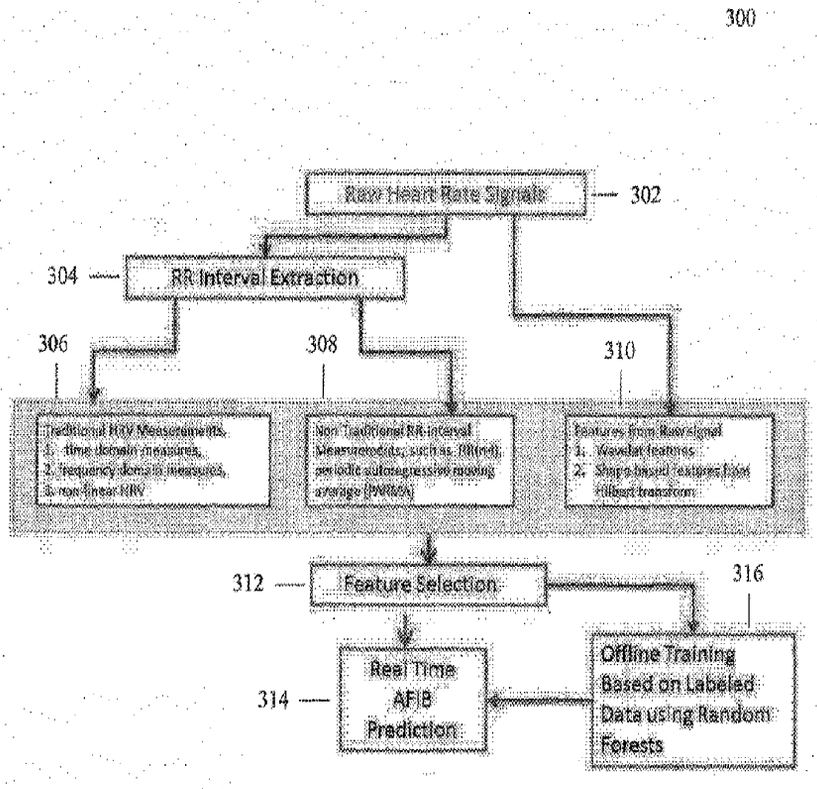

FIG. 3

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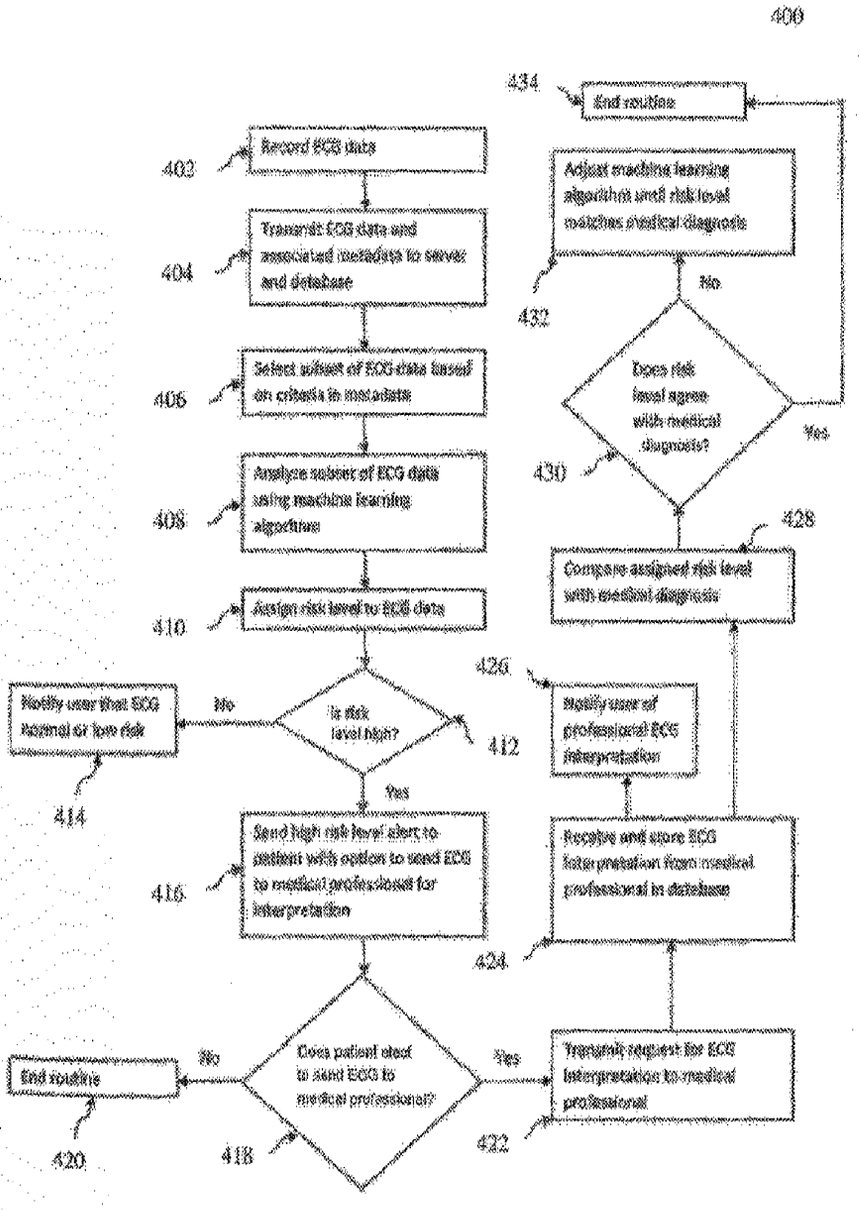

FIG. 4

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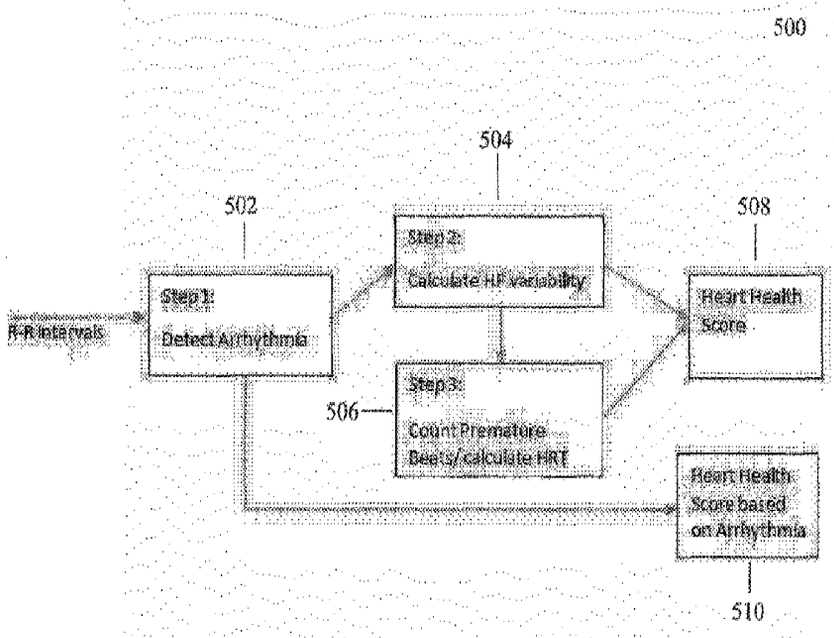

FIG. 5

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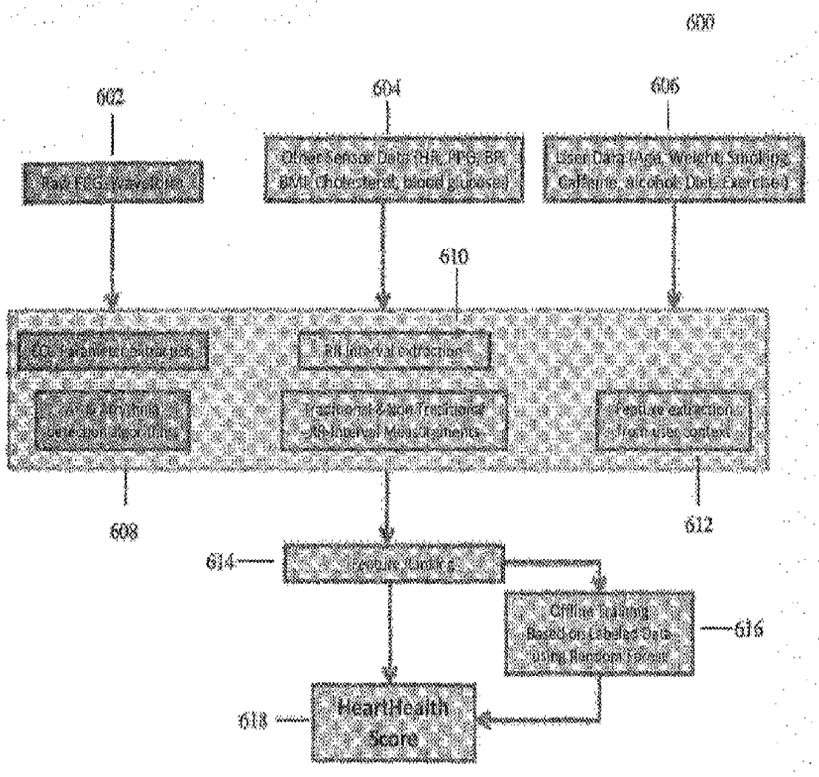

FIG. 6

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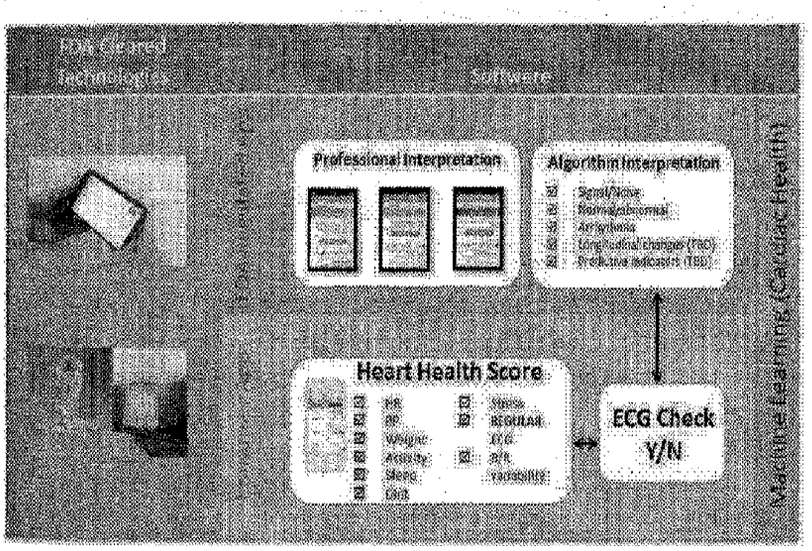

FIG. 7

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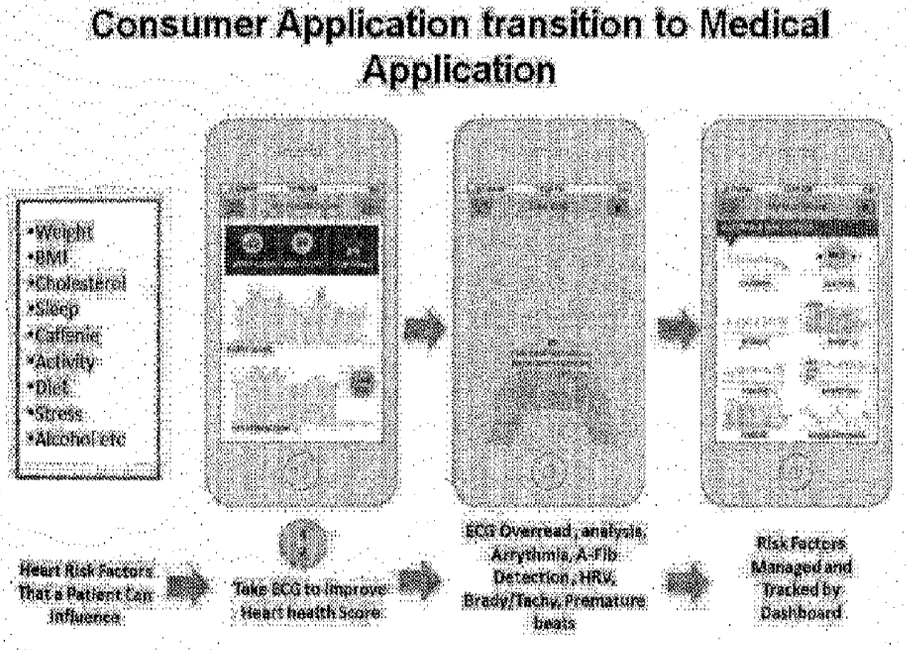

FIG. 8

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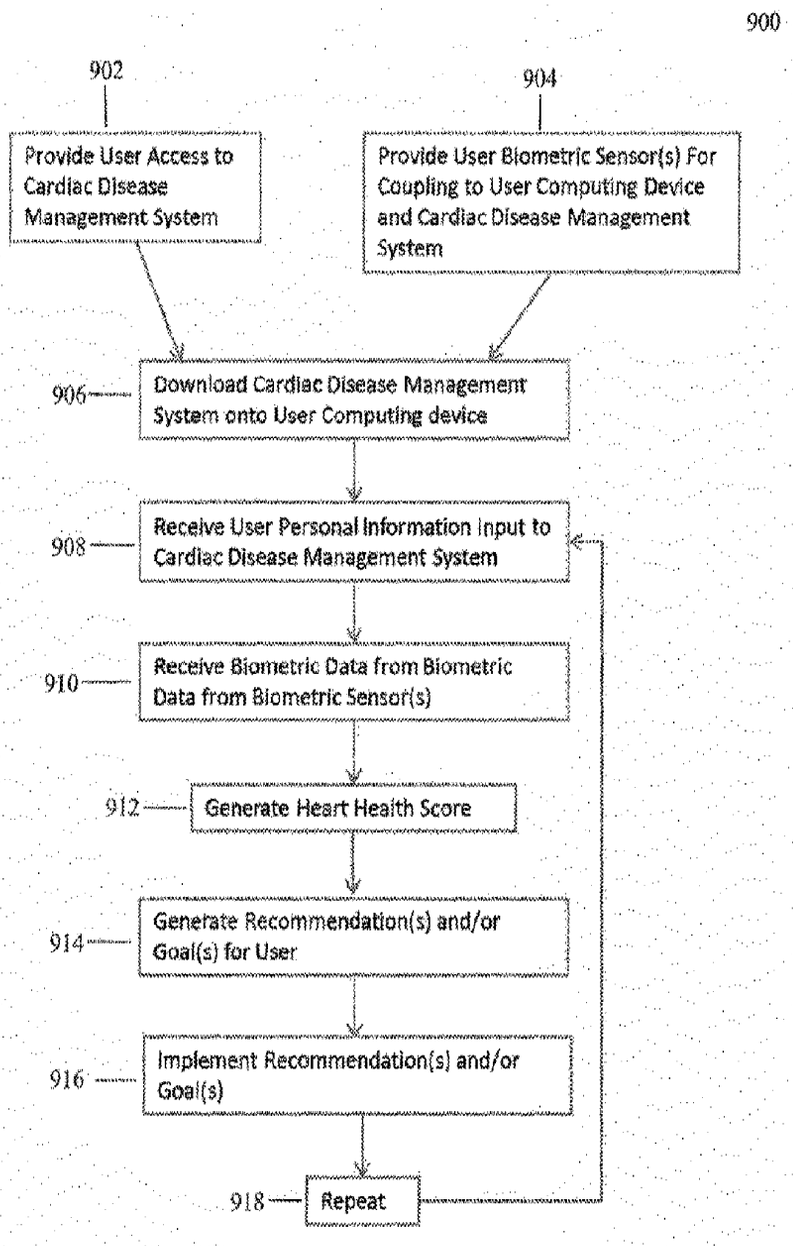

FIG. 9

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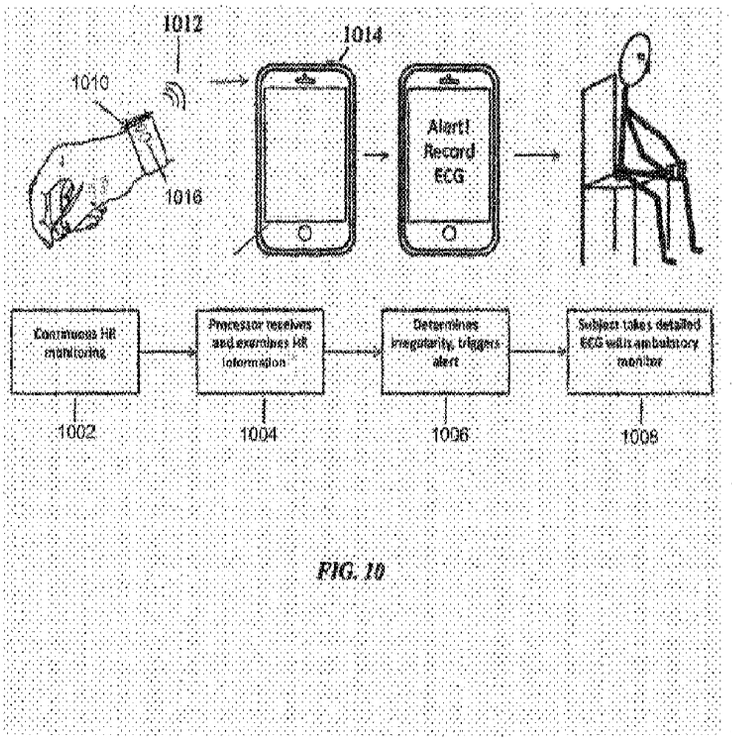

FIG. 10

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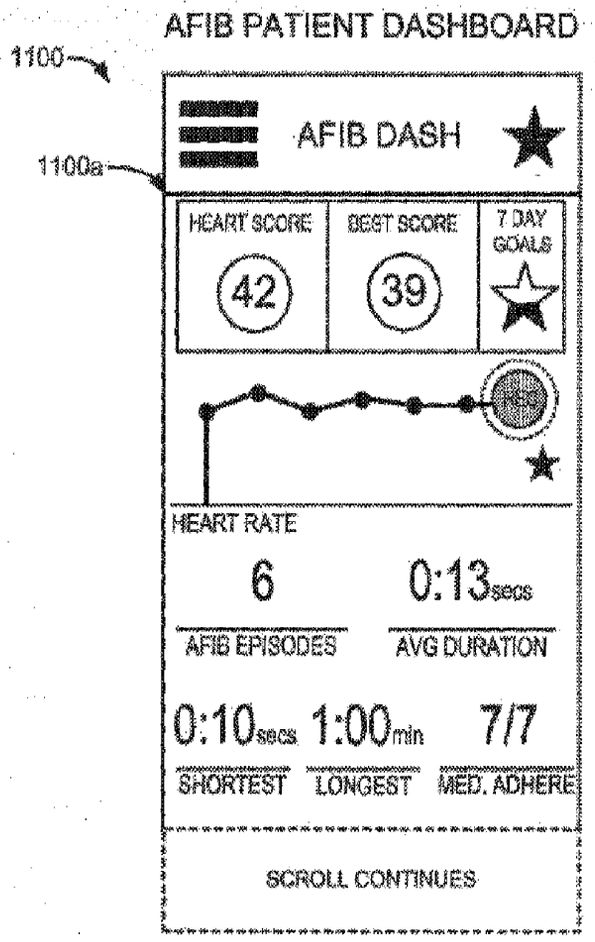

FIG. 11

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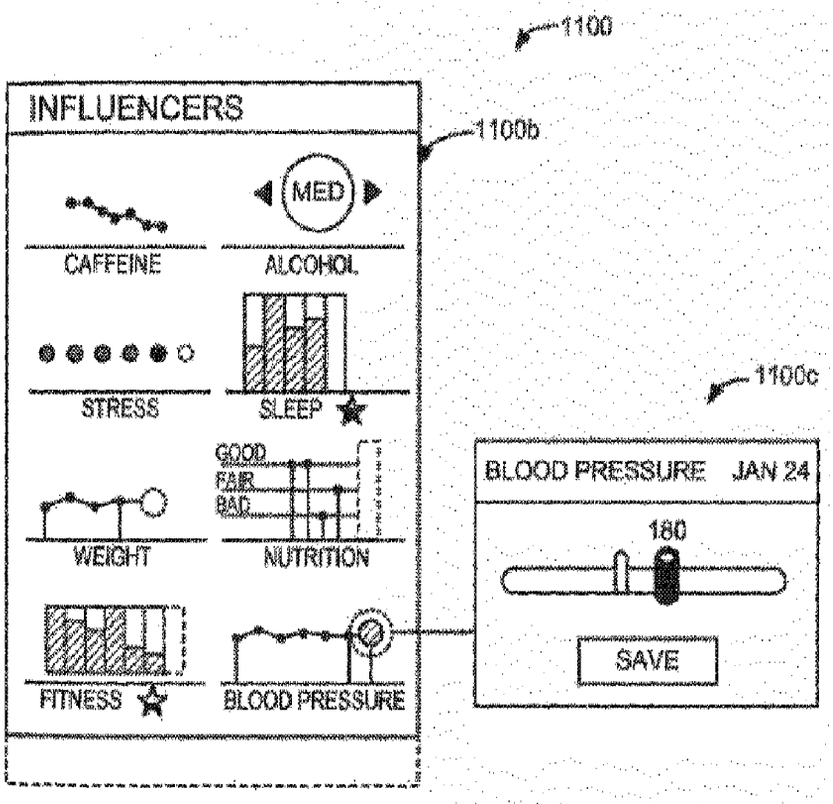

FIG. 11A

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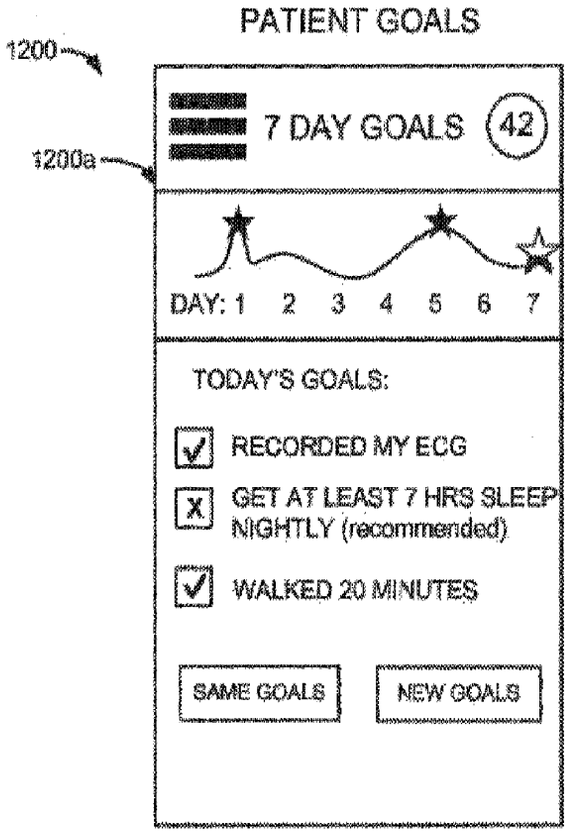

FIG. 12

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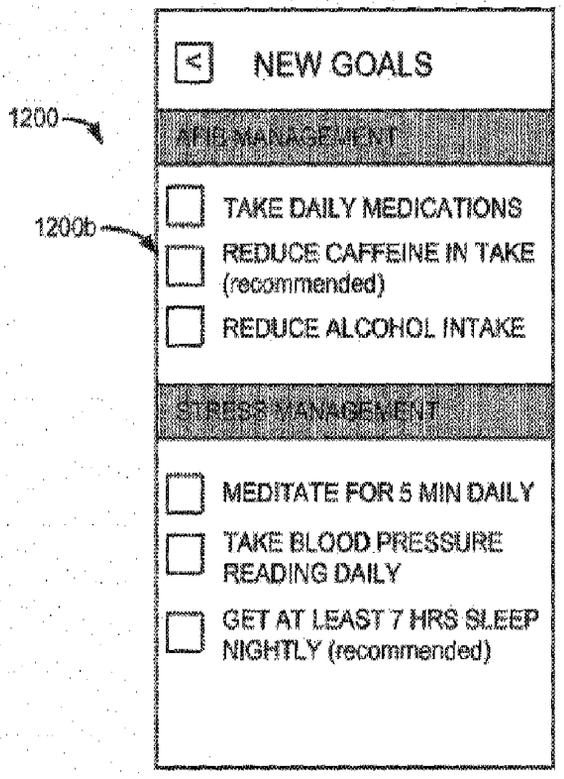

FIG. 12A

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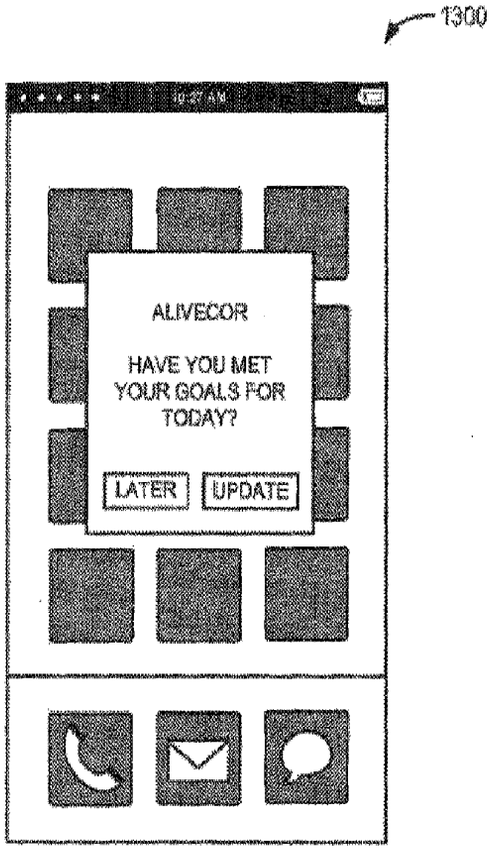

FIG. 13

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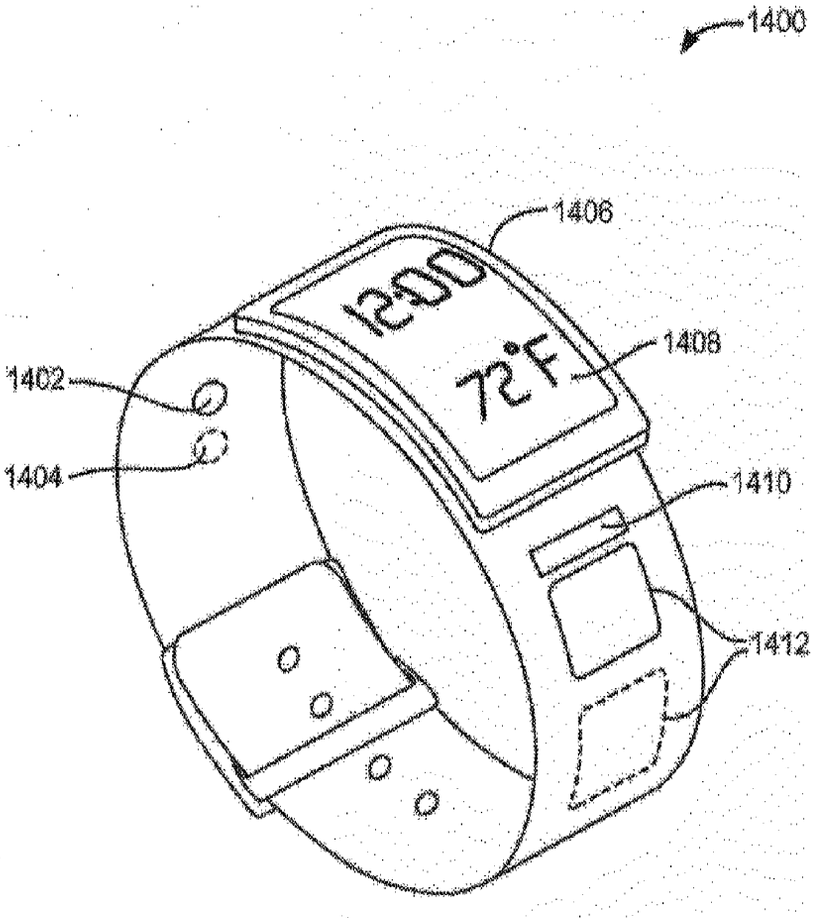

FIG. 14

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METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 16/153,446, filed Oct. 5, 2018, now U.S. Pat. No. 10,426,359, issued Oct. 1, 2019, which is a continuation of U.S. application Ser. No. 15/393,077, filed Dec. 28, 2016, now U.S. Pat. No. 10,159,415, issued Dec. 25, 2018, which is a continuation of U.S. application Ser. No. 14/730,122, filed Jun. 3, 2015, now U.S. Pat. No. 9,572,499, issued Feb. 21, 2017, which is a continuation of U.S. application Ser. No. 14/569,513 filed Dec. 12, 2014, now U.S. Pat. No. 9,420,956, issued Aug. 23, 2016, which claims the benefit of U.S. Provisional Application No. 61/915,113, filed Dec. 12, 2013, which application is incorporated herein by reference, U.S. Provisional Application No. 61/953,616 filed Mar. 14, 2014, U.S. Provisional Application No. 61/969,019, filed Mar. 21, 2014, U.S. Provisional Application No. 61/970,551 filed Mar. 26, 2014 which application is incorporated herein by reference, and U.S. Provisional Application No. 62/014,516, filed Jun. 19, 2014, which application is incorporated herein by reference.

BACKGROUND

The present disclosure relates to medical devices, systems, and methods. In particular, the present disclosure relates to methods and systems for managing health and disease such as cardiac diseases including arrhythmia and atrial fibrillation.

Cardiovascular diseases are the leading cause of death in the world. In 2008, 30% of all global death can be attributed to cardiovascular diseases. It is also estimated that by 2030, over 23 million people will die from cardiovascular diseases annually. Cardiovascular diseases are prevalent in the populations of high-income and low-income countries alike.

Arrhythmia is a cardiac condition in which the electrical activity of the heart is irregular or is faster (tachycardia) or slower (bradycardia) than normal. Although many arrhythmias are not life-threatening, some can cause cardiac arrest and even sudden cardiac death. Atrial fibrillation is the most common cardiac arrhythmia. In atrial fibrillation, electrical conduction through the ventricles of heart is irregular and disorganized. While atrial fibrillation may cause no symptoms, it is often associated with palpitations, shortness of breath, fainting, chest, pain or congestive heart failure. Atrial fibrillation is also associated with atrial clot formation, which is associated with clot migration and stroke.

Atrial fibrillation is typically diagnosed by taking an electrocardiogram (ECG) of a subject, which shows a characteristic atrial fibrillation waveform

To treat atrial fibrillation, a patient may take medications to slow heart rate or modify the rhythm of the heart. Patients may also take anticoagulants to prevent atrial clot formation and stroke. Patients may even undergo surgical intervention including cardiac ablation to treat atrial fibrillation.

Often, a patient with arrhythmia or atrial fibrillation is monitored for extended periods of time to manage the disease. For example, a patient may be provided with a Holter monitor or other ambulatory electrocardiography device to continuously monitor a patient's heart rate and rhythm for at least 24 hours.

Current ambulatory electrocardiography devices such as Holter monitors, however, are typically bulky and difficult for subjects to administer without the aid of a medical professional. For example, the use of Holter monitors requires a patient to wear a bulky device on their chest and precisely place a plurality of electrode leads on precise locations on their chest. These requirements can impede the activities of the subject, including their natural movement, bathing, and showering. Once an ECG is generated, the ECG is sent to the patient's physician who may analyze the ECG and provide a diagnosis and other recommendations. Currently, this process often must be performed through hospital administrators and health management organizations and many patients do not receive feedback in an expedient manner.

SUMMARY

Disclosed herein are devices, systems, and methods for managing health and disease such as cardiac diseases, including arrhythmia and atrial fibrillation. In particular, a cardiac disease and/or rhythm management system, according to aspects of the present disclosure, allows a user to conveniently document their electrocardiograms (ECG) and other biometric data and receive recommendation(s) and/or goal(s) generated by the system or by a physician in response to the documented data. The cardiac disease and/or rhythm management system can be loaded onto a local computing device of the user, where biometric data can be conveniently entered onto the system while the user may continue to use the local computing device for other purposes. A local computing device may comprise, for example, a computing device worn on the body (e.g. a head-worn computing device such as a Google Glass, a wrist-worn computing device such as a Samsung Galaxy Gear Smart Watch, etc.), a tablet computer (e.g. an Apple iPad, an Apple iPod, a Google Nexus tablet, a Samsung Galaxy Tab, a Microsoft Surface, etc.), a smartphone (e.g. an Apple iPhone, a Google Nexus phone, a Samsung Galaxy phone, etc.)

A portable computing device or an accessory thereof may be configured to continuously measure one or more physiological signals of a user. The heart rate of the user may be continuously measured. The continuously measurement may be made with a wrist or arm band or a patch in communication with the portable computing device. The portable computing device may have loaded onto (e.g. onto a non-transitory computer readable medium of the computing device) and executing thereon (e.g. by a processor of the computing device) an application for one or more of receiving the continuously measured physiological signal(s), analyzing the physiological signal(s), sending the physiological signal(s) to a remote computer for further analysis and storage, and displaying to the user analysis of the physiological signal(s). The heart rate may be measured by one or more electrodes provided on the computing device or accessory, a motion sensor provided on the computing device or accessory, or by imaging and lighting sources provided on the computing device or accessory. In response to the continuous measurement and recordation of the heart rate of the user, parameters such as heart rate (HR), heart rate variability (R-R variability or HRV), and heart rate turbulence (HRT) may be determined. These parameters and further parameters may be analyzed to detect and/or predict one or more of atrial fibrillation, tachycardia, bradycardia, bigeminy, trigeminy, or other cardiac conditions. A quantitative heart health score may also be generated from the determined parameters. One or more of the heart health score, detected heart conditions, or recommended user

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action items based on the heart health score may be displayed to the user through a display of the portable computing device.

The biometric data may be uploaded onto a remote server where one or more cardiac technicians or cardiac specialists may analyze the biometric data and provide ECG interpretations, diagnoses, recommendations such as lifestyle recommendations, and/or goals such as lifestyle goals for subject. These interpretations, diagnoses, recommendations, and/or goals may be provided to the subject through the cardiac disease and/or rhythm management system on their local computing device. The cardiac disease and/or rhythm management system may also include tools for the subject to track their biometric data and the associated interpretations, diagnoses, recommendations, and/or goals from the cardiac technicians or specialists.

An aspect of the present disclosure includes a dashboard centered around arrhythmia or atrial fibrillation tracking. The dashboard includes a heart score that can be calculated in response to data from the user such as their ECG and other personal information such as age, gender, height, weight, body fat, disease risks, etc. The main driver of this heart score will often be the incidence of the user's atrial fibrillation. Other drivers and influencing factors include the aforementioned personal information. The heart score will be frequently related to output from a machine learning algorithm that combines and weights many if not all of influencing factors.

The dashboard will often display and track many if not all of the influencing factors. Some of these influencing factors may be entered directly by the user or may be input by the use of other mobile health monitoring or sensor devices. The user may also use the dashboard as an atrial fibrillation or arrhythmia management tool to set goals to improve their heart score.

The dashboard may also be accessed by the user's physician (e.g. the physician prescribing the system to the user, another regular physician, or other physician) to allow the physician to view the ECG and biometric data of the user, view the influencing factors of the user, and/or provide additional ECG interpretations, diagnoses, recommendations, and/or goals.

Another aspect of the present disclosure provides a method for managing cardiac health. Biometric data of a user may be received. A cardiac health score may be generated in response to the received biometric data. One or more recommendations or goals for improving the generated cardiac health score may be displayed to the user. The biometric data may comprise one or more of an electrocardiogram (ECG), dietary information, stress level, activity level, gender, height, weight, age, body fat percentage, blood pressure, results from imaging scans, blood chemistry values, or genotype data. The recommendations or goals may be updated in response to the user meeting the displayed recommendations or goals. The user may be alerted if one or more recommendations or goals have not been completed by the user, for example if the user has not completed one or more recommendations or goals for the day.

The analysis applied may be through one or more of the generation of a heart health score or the application of one or more machine learning algorithms. The machine learning algorithms may be trained using population data of heart rate. The population data may be collected from a plurality of the heart rate monitoring enabled portable computing devices or accessories provided to a plurality of users. The training population of users may have been previously identified as either having atrial fibrillation or not having atrial fibrillation prior to the generation of data for continuously measured heart rate. The data may be used to train the machine learning algorithm to extract one or more features from any continuously measured heart rate data and identify atrial fibrillation or other conditions therefrom. After the machine learning algorithm has been trained, the machine learning algorithm may recognize atrial fibrillation from the continuously measured heart rate data of a new user who has not yet been identified as having atrial fibrillation or other heart conditions. One or more of training population data or the trained machine learning algorithm may be provided on a central computing device (e.g. be stored on a non-transitory computer readable medium of a server) which is in communication with the local computing devices of the users and the application executed thereon (e.g. through an Internet or an intranet connection.)

A set of instructions for managing cardiac health may be downloaded from the Internet. These set of instructions may be configured to automatically generate the cardiac health score. The cardiac health score may be generated using a machine learning algorithm. The machine learning algorithm may generate the cardiac health score of the user and/or the recommendations and/or goals in response to biometric data from a plurality of users. The set of instructions may be configured to allow a medical professional to access the received biometric data. The cardiac health score and/or the recommendations and/or goals may be generated by the medical professional.

The set of instructions may be stored on a non-transitory computer readable storage medium of one or more of a body-worn computer, a tablet computer, a smartphone, or other computing device. These set of instructions may be capable of being executed by the computing device. When executed, the set of instructions may cause the computing device to perform any of the methods described herein, including the method for managing cardiac health described above.

Another aspect of the present disclosure provides a system for managing cardiac health. The system may comprise a sensor for recording biometric data of a user and a local computing device receiving the biometric data from the sensor. The local computing device may be configured to display a cardiac health score and one or more recommendations or goals for the user to improve the cardiac health score in response to the received biometric data.

The system may further comprise a remote server receiving the biometric data from the local computing device. One or more of the local computing device or the remote server may comprise a machine learning algorithm which generates one or more of the cardiac health score or the one or more recommendations or goals for the user. The remote server may be configured for access by a medical professional. Alternatively, or in combination, one or more of the cardiac health score or one or more recommendations or goals may be generated by the medical professional and provided to the local computing device through the remote server.

The sensor may comprise one or more of a hand-held electrocardiogram (ECG) sensor, a wrist-worn activity sensor, a blood pressure monitor, a personal weighing scale, a body fat percentage sensor, a personal thermometer, a pulse oximeter sensor, or any mobile health monitor or sensor. Often, the sensor is configured to be in wireless communication with the local computing device. The local computing device comprises one or more of a personal computer, a laptop computer, a palmtop computer, a tablet computer, a smartphone, a body-worn computer, or the like. The biometric data may comprise one or more of an electrocardio-

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gram (ECG), dietary information, stress level, activity level, gender, height, weight, age, body fat percentage, or blood pressure.

Other physiological signals or parameters such as physical activity, heart sounds, blood pressure, blood oxygenation, blood glucose, temperature, activity, breath composition, weight, hydration levels, an electroencephalograph (EEG), an electromyography (EMG), a mechanomyogram (MMG), an electrooculogram (EOG), etc. may also be monitored. The user may also input user-related health data such as age, height, weight, body mass index (BMI), diet, sleep levels, rest levels, or stress levels. One or more of these physiological signals and/or parameters may be combined with the heart rate data to detect atrial fibrillation or other conditions. The machine learning algorithm may be configured to identify atrial fibrillation or other conditions in response to heart rate data in combination with one or more of the other physiological signals and/or parameters for instance. Triggers or alerts may be provided to the user in response to the measured physiological signals and/or parameters. Such triggers or alerts may notify the user to take corrective steps to improve their health or monitor other vital signs or physiological parameters. The application loaded onto and executed on the portable computing device may provide a health dash board integrating and displaying heart rate information, heart health parameters determined in response to the heart rate information, other physiological parameters and trends thereof, and recommended user action items or steps to improve health.

INCORPORATION BY REFERENCE

All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the subject matter disclosed herein are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present disclosure will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the disclosure are utilized, and the accompanying drawings of which:

FIG. **1** shows a system for cardiac disease and rhythm management;

FIG. **2** shows a flow chart of a method **200** for predicting and/or detecting atrial fibrillation from R-R interval measurements;

FIG. **3** shows a flow chart of a method for predicting and/or detecting atrial fibrillation from R-R interval measurements and for predicting and/or detecting atrial fibrillation from raw heart rate signals;

FIG. **4** shows an embodiment of the system and method of the ECG monitoring described herein;

FIG. **5** shows a flow chart of an exemplary method to generate a heart health score in accordance with many embodiments;

FIG. **6** shows an exemplary method of generating a heart score;

FIG. **7** shows a schematic diagram of the executed application described herein;

FIG. **8** shows exemplary screenshots of the executed application;

FIG. **9** shows an exemplary method for cardiac disease and rhythm management;

FIG. **10** shows an exemplary method for monitoring a subject to determine when to record an electrocardiogram (ECG);

FIG. **11** shows an exemplary screenshot of a first aspect of a dashboard application;

FIG. **11A** shows an exemplary screenshot of a second aspect of a dashboard application;

FIG. **12** shows an exemplary screenshot of a first aspect of a goals and recommendations page of the cardiac disease and rhythm management system interface or mobile app;

FIG. **12A** shows an exemplary screenshot of a second aspect of a goals and recommendations page of the cardiac disease and rhythm management system interface or mobile app;

FIG. **13** shows an exemplary screenshot of a user's local computing device notifying the user with a pop-up notice to meet their daily recommendations and goals; and

FIG. **14** shows an embodiment comprising a smart watch which includes at least one heart rate monitor and at least one activity monitor.

DETAILED DESCRIPTION

Devices, systems, and methods for managing health and disease such as cardiac diseases, including arrhythmia and atrial fibrillation, are disclosed. In particular, a cardiac disease and/or rhythm management system, according to aspects of the present disclosure, allows a user to conveniently document their electrocardiograms (ECG) and other biometric data and receive recommendation(s) and/or goal(s) generated by the system or by a physician in response to the documented data.

The term "atrial fibrillation," denoting a type of cardiac arrhythmia, may also be abbreviated in either the figures or description herein as "AFIB."

FIG. **1** shows a system **100** for cardiac disease and rhythm management. The system **100** may be prescribed for use by a user or subject such as being prescribed by the user or subject's regular or other physician or doctor. The system **100** may comprise a local computing device **101** of the user or subject. The local computing device **101** may be loaded with a user interface, dashboard, or other sub-system of the cardiac disease and rhythm management system **100**. For example, the local computing device **101** may be loaded with a mobile software application ("mobile app") **101***a* for interfacing with the system **100**. The local computing device may comprise a computing device worn on the body (e.g. a head-worn computing device such as a Google Glass, a wrist-worn computing device such as a Samsung Galaxy Gear Smart Watch, etc.), a tablet computer (e.g. an Apple iPad, an Apple iPod, a Google Nexus tablet, a Samsung Galaxy Tab, a Microsoft Surface, etc.), a smartphone (e.g. an Apple iPhone, a Google Nexus phone, a Samsung Galaxy phone, etc.).

The local computing device **101** may be coupled to one or more biometric sensors. For example, the local computing device **101** may be coupled to a handheld ECG monitor **103**. The handheld ECG monitor **103** may be in the form of a smartphone case as described in co-owned U.S. patent application Ser. No. 12/796,188 (now U.S. Pat. No. 8,509,882), Ser. Nos. 13/107,738, 13/420,520 (now U.S. Pat. No. 8,301,232), Ser. Nos. 13/752,048, 13/964,490, 13/969,446, 14/015,303, and 14/076,076, the contents of which are incorporated herein by reference.

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In some embodiments, the handheld ECG monitor **103** may be a handheld sensor coupled to the local computing device **101** with an intermediate protective case/adapter as described in U.S. Provisional Application No. 61/874,806, filed Sep. 6, 2013, the contents of which are incorporated herein by reference. The handheld ECG monitor **103** may be used by the user to take an ECG measurement which the handheld ECG monitor **103** may send to the local computing device by connection **103***a*. The connection **103***a* may comprise a wired or wireless connection (e.g. a Wi-Fi connection, a Bluetooth connection, a NFC connection, an ultrasound signal transmission connection, etc.). The mobile software application **101***a* may be configured to interface with the one or more biometric sensors including the handheld ECG monitor **103**.

The local computing device **101** may be coupled to a wrist-worn biometric sensor **105** through a wired or wireless connection **105***a* (e.g. a Wi-Fi connection, a Bluetooth connection, a NFC connection, an ultrasound signal transmission connection, etc.). The wrist-worn biometric sensor **105** may comprise an activity monitor such as those available from Fitbit Inc. of San Francisco, Calif. or a Nike FuelBand available from Nike, Inc. of Oregon. The wrist-worn biometric sensor **105** may also comprise an ECG sensor such as that described in co-owned U.S. Provisional Application No. 61/872,555, the contents of which is incorporated herein by reference.

The local computing device **101** may be coupled to other biometric devices as well such as a personal scale or a blood pressure monitor **107**. The blood pressure monitor **107** may communicate with the local device **101** through a wired or wireless connection **107***a* (e.g. a Wi-Fi connection, a Bluetooth connection, a NFC connection, an ultrasound signal transmission connection, etc.).

The local computing device **101** may directly communicate with a remote server or cloud-based service **113** through the Internet **111** via a wired or wireless connection **111***a* (e.g. a Wi-Fi connection, a cellular network connection, a DSL Internet connection, a cable Internet connection, a fiber optic Internet connection, a T1 Internet connection, a T3 Internet connection, etc.). Alternatively, or in combination, the local computing device **101** may first couple with another local computing device **109** of the user, such as a personal computer of the user, which then communicates with the remote server or cloud-based service **113** via a wired or wireless connection **109***a* (e.g. a Wi-Fi connection, a cellular network connection, a DSL Internet connection, a cable Internet connection, a fiber optic Internet connection, a T1 Internet connection, a T3 Internet connection, etc.) The local computing device **109** may comprise software or other interface for managing biometric data collected by the local computing device **101** or the biometric data dashboard loaded on the local computing device **101**.

Other users may access the patient data through the remote server or cloud-based service **113**. These other users may include the user's regular physician, the user's prescribing physician who prescribed the system **100** for use by the user, other cardiac technicians, other cardiac specialists, and system administrators and managers. For example, a first non-subject user may access the remote server or cloud-based service **113** with a personal computer or other computing device **115** through an Internet connection **115***a* (e.g. a Wi-Fi connection, a cellular network connection, a DSL Internet connection, a cable Internet connection, a fiber optic Internet connection, a T1 Internet connection, a T3 Internet connection, etc.). Alternatively, or in combination, the first non-subject user may access the remote server or cloud-based service **113** with a local computing device such as a tablet computer or smartphone **117** through an Internet connection **117***a*. The tablet computer or smartphone **117** of the first non-subject user may interface with the personal computer **115** through a wired or wireless connection **117***b* (e.g. a Wi-Fi connection, a Bluetooth connection, a NFC connection, an ultrasound signal transmission connection, etc.). Further, a second non-subject user may access the remote server or cloud-based service **113** with a personal computer or other computing device **119** through an Internet connection **119***a* (e.g. a Wi-Fi connection, a cellular network connection, a DSL Internet connection, a cable Internet connection, a fiber optic Internet connection, a T1 Internet connection, a T3 Internet connection, etc.). Further, a third non-subject user may access the remote server or cloud-based service **113** with a tablet computer or smartphone **121** through an Internet connection **121***a* (e.g. a Wi-Fi connection, a cellular network connection, a DSL Internet connection, a cable Internet connection, a fiber optic Internet connection, a T1 Internet connection, a T3 Internet connection, etc.). Further, a fourth non-subject user may access the remote server or cloud-based service **113** with a personal computer or other computing device **123** through an Internet connection **123***a* (e.g. a Wi-Fi connection, a cellular network connection, a DSL Internet connection, a cable Internet connection, a fiber optic Internet connection, a T1 Internet connection, a T3 Internet connection, etc.). The first non-subject user may comprise an administrator or manager of the system **100**. The second non-subject user may comprise a cardiac technician. The third non-subject user may comprise a regular or prescribing physician of the user or subject. And, the fourth non-subject user may comprise a cardiac specialist who is not the user or subject's regular or prescribing physician. Generally, many if not all of the communication between various devices, computers, servers, and cloud-based services will be secure and HIPAA-compliant.

Aspects of the present disclosure provide systems and methods for detecting and/or predicting atrial fibrillation or other arrhythmias of a user by applying one or more machine learning-based algorithms. A portable computing device (or an accessory usable with the portable computing device) may provide R-R intervals and/or raw heart rate signals as input to an application loaded and executed on the portable computing device. The raw heart rate signals may be provided using an electrocardiogram (ECG) in communication with the portable computing device or accessory such as described in U.S. Ser. No. 13/964,490 filed Aug. 12, 2013, Ser. No. 13/420,520 filed Mar. 14, 2013, Ser. No. 13/108,738 filed May 16, 2011, and Ser. No. 12/796,188 filed Jun. 8, 2010. Alternatively, or in combination, the raw heart rate signals may be provided using an on-board heart rate sensor of the portable computing device or by using photoplethysmography implemented by an imaging source and a light source of the portable computing device. Alternatively, or in combination, the raw heart rate signals may be from an accessory device worn by the user or attached to the user (e.g. a patch) and which is in communication with the portable computing device. Such wearable accessory devices may include Garmin's Vivofit Fitness Band, Fitbit, Polar Heart Rate Monitors, New Balance's Balance Watch, Basis BI Band, MIO Alpha, Withings Pulse, LifeCORE Heart Rate Monitor strap, and the like.

R-R intervals may be extracted from the raw heart rate signals. The R-R intervals may be used to calculate heart rate variability (HRV) which may be analyzed in many ways such as using time-domain methods, geometric methods,

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frequency-domain methods, non-linear methods, long term correlations, or the like as known in the art. Alternatively, or in combination, the R-R intervals may be used for non-traditional measurements such as (i) determining the interval between every other or every three R-waves to evaluate for bigeminy or trigeminy or (ii) the generation of a periodic autoregressive moving average (PARMA).

The machine learning based algorithm(s) may allow software application(s) to identify patterns and/or features of the R-R interval data and/or the raw heart rate signals or data to predict and/or detect atrial fibrillation or other arrhythmias. These extracted and labelled features may be features of HRV as analyzed in the time domain such as SDNN (the standard deviation of NN intervals calculated over a 24 hour period), SDANN (the standard deviation of the average NN intervals calculated over short periods), RMSSD (the square root of the mean of the sum of the squares of the successive differences between adjacent NNs), SDSD (the standard deviation of the successive differences between adjacent NNs), NN50 (the number of pairs of successive NNs that differ by more than 50 ms), pNN50 (the proportion of NN50 divided by total number of NNs), NN20 (the number of pairs of successive NNs that differ by more than 20 ms), pNN20 (the proportion of NN20 divided by the total number of NNs), EBC (estimated breath cycle), NNx (the number of pairs of successive NNs that differ by more than x ms), pNNx (the proportion of NNx divided by the number of NNs), or other features known in the art. Alternatively, or in combination, the extracted and labelled features may comprise a nonlinear transform of R-R ratio or R-R ratio statistics with an adaptive weighting factor. Alternatively, or in combination, the extracted and labelled features may be features of HRV as analyzed geometrically such as the sample density distribution of NN interval durations, the sample density distribution of differences between adjacent NN intervals, a Lorenz plot of NN or RR intervals, degree of skew of the density distribution, kurtosis of the density distribution, or other features known in the art. Alternatively, or in combination, the extracted and labelled features may be features of HRV in the frequency domain such as the power spectral density of different frequency bands including a high frequency band (HF, from 0.15 to 0.4 Hz), low frequency band (LF, from 0.04 to 0.15 Hz), and the very low frequency band (VLF, from 0.0033 to 0.04 Hz), or other frequency domain features as known in the art. Alternatively, or in combination, the extracted and labelled features may be non-linear features such as the geometric shapes of a Poincare plot, the correlation dimension, the nonlinear predictability, the pointwise correlation dimension, the approximate entropy, and other features as known in the art. Other features from the raw heart rate signals and data may also be analyzed. These features include for example a generated autoregressive (AR) model, a ratio of consecutive RR intervals, a normalized ratio of consecutive RR intervals, a standard deviation of every 2, 3, or 4 RR intervals, or a recurrence plot of the raw HR signals, among others.

The features of the analysis and/or measurement may be selected, extracted, and labelled to predict atrial fibrillation or other arrhythmias in real time, e.g. by performing one or more machine learning operation. Such operations can be selected from among an operation of ranking the feature(s), classifying the feature(s), labelling the feature(s), predicting the feature(s), and clustering the feature(s). Alternatively, or in combination, the extracted features may be labelled and saved for offline training of a machine learning algorithm or set of machine learning operations. For example, the operations may be selected from any of those above. Any number of machine learning algorithms or methods may be trained to identify atrial fibrillation or other conditions such as arrhythmias. These may include the use of decision tree learning such as with a random forest, association rule learning, artificial neural network, inductive logic programming, support vector machines, clustering, Bayesian networks, reinforcement learning, representation learning, similarity and metric learning, sparse dictionary learning, or the like.

The systems and methods for detecting and/or predicting atrial fibrillation or other conditions such as arrhythmias described herein may be implemented as software provided as a set of instructions on a non-transitory computer readable medium. A processor of a computing device (e.g. a tablet computer, a smartphone, a smart watch, a smart band, a wearable computing device, or the like) may execute this set of instructions to receive the input data and detect and/or predict atrial fibrillation therefrom. The software may be downloaded from an online application distribution platform such as the Apple iTunes or App Store, Google Play, Amazon App Store, and the like. A display of the computing device may notify the user whether atrial fibrillation or other arrhythmias has been detected and/or if further measurements are required (e.g. to perform a more accurate analysis). The software may be loaded on and executed by the portable computing device of the user such as with the processor of the computing device.

The machine learning-based algorithms or operations for predicting and/or detecting atrial fibrillation or other arrhythmias may be provided as a service from a remote server which may interact or communicate with a client program provided on the computing device of the user, e.g. as a mobile app. The interaction or communication may be through an Application Program Interface (API). The API may provide access to machine learning operations for ranking, clustering, classifying, and predicting from the R-R interval and/or raw heart rate data, for example.

The machine learning-based algorithms or operations, provided through a remote server and/or on a local application on a local computing device, may operate on, learn from, and make analytical predictions from R-R interval data or raw heart rate data, e.g. from a population of users. The R-R interval or raw heart rate data may be provided by the local computing device itself or an associated accessory, such as described in U.S. Ser. No. 13/964,490 filed Aug. 12, 2013, Ser. No. 13/420,520 filed Mar. 14, 2013, Ser. No. 13/108,738 filed May 16, 2011, and Ser. No. 12/796,188 filed Jun. 8, 2010. Thus, atrial fibrillation and other arrhythmias or other heart conditions can be in a convenient, user-accessible way.

FIG. **2** shows a flow chart of a method **200** for predicting and/or detecting atrial fibrillation from R-R interval measurements. In a step **202**, an R-R interval of a user is obtained. In a step **204**, the obtained R-R interval is analyzed using one or more traditional heart rate variability measurements such as, for example, time domain measures, frequency domain measures, and non-linear heart rate variability. In a step **206**, the obtained R-R interval is analyzed using one or more non-traditional heart rate variability measurements such as, for example, RR (n-i) for Bigeminy and Trigeminy detection, and the generation of a periodic autoregressive moving average (PARMA). In a step **208**, a feature selection occurs. In a step **210**, a real time prediction or detection of atrial fibrillation, and/or in a step **212**, the heart rate variability measurements may be labelled and saved for offline training of a machine learning algorithm or set of

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machine learning operations, and then may be subsequently used to make a real time prediction and/or detection of atrial fibrillation.

FIG. **3** shows a flow chart of a method **300** for predicting and/or detecting atrial fibrillation from R-R interval measurements and for predicting and/or detecting atrial fibrillation from raw heart rate signals. In a step **302**, raw heart rate signals are obtained from, for example, an ECG of a user. In a step **304**, R-R intervals are obtained from the obtained raw hearth signals. In a step **306**, the obtained R-R interval is analyzed using one or more traditional heart rate variability measurements such as, for example, time domain measures, frequency domain measures, and non-linear heart rate variability. In a step **308**, the obtained R-R interval is analyzed using one or more non-traditional heart rate variability measurements such as, for example, RR (n-i) for bigeminy and trigeminy detection, and the generation of a periodic autoregressive moving average (PARMA). In a step **310**, features from the obtained heart rate features are analyzed using one or more of wavelet features and shape based features from a Hilbert transform. In a step **312**, a feature selection occurs. In a step **314**, a real time prediction or detection of atrial fibrillation, and/or in a step **316**, the heart rate variability measurements may be labelled and saved for offline training of a machine learning algorithm or set of machine learning operations, and then may be subsequently used to make a real time prediction and/or detection of atrial fibrillation.

Although the above steps show methods **200** and **300** in accordance with many embodiments, a person of ordinary skill in the art will recognize many variations based on the teaching described herein. The steps may be completed in a different order. Steps may be added or deleted. Some of the steps may comprise sub-steps. Many of the steps may be repeated as often as beneficial to the user or subject.

One or more of the steps of method **200** and **300** may be performed with circuitry, for example, one or more of a processor or a logic circuitry such as a programmable array logic for a field programmable gate array. The circuitry may be programmed to provide one or more of the steps of methods **200** and **300**, and the program may comprise program instructions stored on a non-transitory computer readable medium or memory or programmed steps of the logic circuitry such as the programmable array logic or the field programmable gate array, for example.

Aspects of the present disclosure provide systems and methods for monitoring one or more physiological parameters and providing a trigger message to the user if the one or more physiological parameter meets a pre-determined or learned threshold(s). Two or more of the physiological parameters may be combined to provide a trigger message. That is, a particular trigger message may be provided to the user if two or more pre-determined threshold(s) for the physiological parameter(s) are met.

Table 1 below shows an exemplary table of physiological parameters that may be measured (left column), features of interest to be measured or threshold types to be met (middle column), and exemplary trigger messages (right column).

TABLE 1

Physiological Parameter	Measurements/Threshold	Sample Trigger Messages
Heart Rate	Heart Rate Variability (HRV), Non-linear Transformation of RR Intervals	Measure ECG; See Your Doctor
Heart Sound	Sound Features	Abnormal Heart Sound; Measure ECG; See Your Doctor
Blood Pressure	Upper and Lower Thresholds	High/Low Blood Pressure; Take BP Medication; Exercise; See Your Doctor
Blood Oxygenation	O2 Saturation, O2 Saturation Variability	High Risk of Hypoventilation; High Risk of Sleep Disorder such as Apnea; See Your Doctor
Blood Glucose	Upper and Lower Thresholds	High Risk of Hypoglycemia; See Your Doctor
Temperature	Temperature, Temperature Changes	Fever; Take OTC Fever Medication; See Your Doctor
Physical Activity (accelerometer data)	Gait, Chest Compressions, Speed, Distance	Monitor Senior or Infant Posture, e.g. if senior/infant has fallen
Electrocardiogram (ECG)	ECG Features (E.g. QT, QRS, PR intervals, HRV, etc.	High Risk of Certain Cardiac Diseases; Sleep apnea; See Your Doctor
Breath Content (Breathalyzer data)	Percentage of the Certain Chemicals	High Risk of Certain Dental Disease, Diabetes, etc.; See Your Doctor

The machine learning based algorithms or operations as described herein may be used to determine the appropriate trigger thresholds in response to the raw physiological data input and/or user-input physiological parameters (e.g. age, height, weight, gender, etc.). Features of the raw physiological data input may be selected, extracted, labelled, clustered, and/or analyzed. These processed features may then be analyzed using one or more machine learning operation such as ranking the feature(s), classifying the feature(s), predicting the feature(s), and clustering the feature(s). The various machine learning algorithms described herein may be used to analyze the features to detect and predict health conditions and generate recommendations or user action items to improve the health of the user. For instance, the machine learning algorithms may be trained to identify atrial fibrillation or other conditions in response to the non-heart rate physiological parameter(s) such as age, gender, body mass index (BMI), activity level, diet, and others in combination with the raw heart rate data and HRV that can be extracted therefrom.

The systems and methods for monitoring one or more physiological parameters and providing a trigger message to the user if the one or more physiological parameter meets a

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pre-determined threshold(s) described herein may be implemented as software provided as a set of instructions on a non-transitory computer readable medium. A processor of a computing device (e.g. a tablet computer, a smartphone, a smart watch, a smart band, a wearable computing device, or the like) may execute this set of instructions to receive the input data and detect and/or predict atrial fibrillation therefrom. The software may be downloaded from an online application distribution platform such as the Apple iTunes or App Store, Google Play, Amazon App Store, and the like. The software may be loaded on and executed by the portable computing device of the user such as with the processor of the computing device. The software may also provide both the triggering application described herein and the heart rate monitoring and analysis for detecting atrial fibrillation or other heart conditions described herein.

In an embodiment, a method and system for longitudinal monitoring of a patient's or any consumer's (after referred to as "patient") health using various ECG monitoring devices is described herein. The ECG monitoring devices generate ECG signal data which can be stored in a database for further analysis. The ECG data, which can be stored in a database along with other patient information, can be analyzed by a processing device, such as a computer or server, using various algorithms.

Various ECG monitoring or recording devices, hereinafter referred to as ECG monitoring devices, can be used to record the ECG data. For example, the ECG monitoring device can be a handheld, portable, or wearable smartphone based device, as described in U.S. Pat. No. 8,301,232, which is herein incorporated by reference in its entirety for all purposes. A smartphone based device, or a device having wireless or cellular telecommunication capabilities, can transmit the ECG data to a database or server directly through the internet. These types of ECG monitoring devices as well as other ECG monitoring devices include portable devices, wearable recording devices, event recorders, and Holter monitors. Clinical or hospital based ECG recording devices can also be used and integrated into the system. Such devices may be able to transmit stored ECG data through a phone line or wirelessly through the internet or cellular network, or may need to be sent to a data collection center for data collection and processing. The ECG data can be tagged with the type of ECG monitoring device used to record the data by, for example, including it in metadata for indexing and searching purposes.

The ECG monitoring devices can be single lead devices or multiple lead devices, where each lead generally terminates with an electrode. Some embodiments may even be leadless and have electrodes that are integrated with the body or housing of the device, and therefore have a predetermined relationship with each other, such as a fixed spacing apart from each other. The orientation and positioning of the single lead in a single lead device or of each lead of the multiple lead device or of the electrodes of the leadless device can be transmitted with the ECG data. The lead and/or electrode placement may be predetermined and specified to the patient in instructions for using the device. For example, the patient may be instructed to position the leads and/or electrodes with references to one or more anatomical landmarks on the patient's torso. Any deviation from the predetermined lead and/or electrode placement can be notated by the patient or user when transmitting the ECG data. The lead and electrode placement may be imaged using a digital camera, which may be integrated with a smart phone, and transmitted with the ECG data and stored in the database. The lead and electrode placement may be marked on the patient's skin for imaging and for assisting subsequent placement of the leads and electrodes. The electrodes can be attached to the skin using conventional methods which may include adhesives and conducting gels, or the electrodes may simply be pressed into contact with the patient's skin. The lead and electrode placement may be changed after taking one recording or after recording for a predetermined or variable amount of time. The ECG data can be tagged with the numbers of leads and/or electrodes and the lead and/or electrode placement, including whether adhesives and/or conducting gels were used. Again, this information can be including in metadata for indexing and searching purposes.

The ECG signal data can be continuously recorded over a predetermined or variable length of time. Continuous ECG recording devices can record for up to 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, or 14 days. Alternatively, or additionally, the ECG data can be recorded on demand by the patient at various discrete times, such as when the patient feels chest pains or experiences other unusual or abnormal feelings. The on demand ECG recorder can have a memory buffer that can record a predetermined amount of ECG data on a rolling basis, and when activated by the patient to record a potential event, a predetermined amount of ECG data can be saved and/or transmitted. The predetermined amount of ECG data can include a predetermined amount of ECG data before activation and a predetermined amount of ECG data after activation such that a window of ECG data is captured that encompasses the potential event. The time period between ECG recordings may be regular or irregular. For example, the time period may be once a day, once a week, once a month, or at some other predetermined interval. The ECG recordings may be taken at the same or different times of days, under similar or different circumstances, as described herein. One or more baseline ECGs can be recorded while the patient is free of symptoms. The baseline ECGs can be periodically recorded and predetermined intervals and/or on-demand. The same ECG recording device or different ECG recording devices may be used to record the various ECG of a particular patient. All this information may be tagged to or associated with the ECG data by, for example, including it in the metadata for indexing and searching purposes.

The ECG data can be time stamped and can be annotated by the patient or health care provider to describe the circumstances during which the ECG was recorded, preceding the ECG recording, and/or following the ECG recording. For example, the system and device can have a user interface for data entry that allows the patient to enter in notes regarding the conditions and circumstances surrounding the ECG recording. This additional data can be also included as metadata for indexing and searching purposes. For example, location, food, drink, medication and/or drug consumption, exercise, rest, sleep, feelings of stress, anxiety, pain or other unusual or abnormal feelings, or any other circumstance that may affect the patient's ECG signal can all be inputted into the device, smart phone, computer or other computing device to be transmitted to the server or database along with the ECG data. The annotated data can also include the patient's identity or unique identifier as well as various patient characteristics including age, sex, race, ethnicity, and relevant medical history. The annotated data can also be time stamped or tagged so that the ECG data can be matched or correlated with the activity or circumstance of interest. This also allows comparison of the ECG before, after and during the activity or circumstance so that the effect on the ECG can be determined.

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The ECG data and the associated metadata can be transmitted from the device to a server and database for storage and analysis. The transmission can be real-time, at regular intervals such as hourly, daily, weekly and any interval in between, or can be on demand. The metadata facilitates the searching, organizing, analyzing and retrieving of ECG data. Comparison and analysis of a single patient's ECG data can be performed, and/or comparison of ECG data between patients can be performed. For example, the metadata can be used to identify and select a subset of ECG data where an activity or circumstance, such as the taking of medication, occurred within a predetermined amount of time to the ECG data. The components of the ECG signal data, such as the P wave, T wave, and QRS complex and the like, the amplitudes of the components, the ratios between the components, the width of the components, and the delay or time separation between the components, can be extracted, compared, analyzed, and stored as ECG features. For example, the P wave and heart rate can be extracted and analyzed to identify atrial fibrillation, where the absence of P waves and/or an irregular heart rate may indicate atrial fibrillation. The extracted ECG features can also be included in the metadata for indexing and searching.

The changes in the ECG signal over time in view of the activities and circumstances can be compared with changes over time and circumstances observed within a database of ECG's. Comparisons may include any comparison of data derived from any other ECG signal or any database of ECG's or any subset of ECG data, or with data derived from any database of ECG's. Changes in any feature of the ECG signal over time may be used for a relative comparison with similar changes in any ECG database or with data derived from an ECG database. The ECG data from the baseline ECG and the ECG data from a potential adverse event can be compared to determine the changes or deviations from baseline values. In addition, both the baseline ECG and the ECG data recorded from the patient can be compared to one or more predetermined template ECGs which can represent a normal healthy condition as well as various diseased conditions, such as myocardial infarction and arrhythmias.

The comparisons and analysis described herein can be used to draw conclusions and insights into the patient's health status, which includes potential health issues that the patient may be experiencing at the time of measurement or at future times. Conclusions and determinations may be predictive of future health conditions or diagnostic of conditions that the patient already has. The conclusions and determinations may also include insights into the effectiveness or risks associated with drugs or medications that the patient may be taking, have taken or may be contemplating taking in the future. In addition, the comparisons and analysis can be used to determine behaviors and activities that may reduce or increase risk of an adverse event. Based on the comparisons and analysis described herein, the ECG data can be classified according to a level of risk of being an adverse event. For example, the ECG data can be classified as normal, low risk, moderate risk, high risk, and/or abnormal. The normal and abnormal designation may require health care professional evaluation, diagnosis, and/or confirmation.

Diagnosis and determination of an abnormality, an adverse event, or a disease state by physicians and other health care professionals can be transmitted to the servers and database to be tagged with and associated with the corresponding ECG data. The diagnosis and determination may be based on analysis of ECG data or may be determined using other tests or examination procedures. Professional diagnosis and determinations can be extracted from the patient's electronic health records, can be entered into the system by the patient, or can be entered into the system by the medical professional. The conclusions and determinations of the system can be compared with actual diagnosis and determinations from medical professions to validate and/or refine the machine learning algorithms used by the system. The time of occurrence and duration of the abnormality, adverse event or disease state can also be included in the database, such that the ECG data corresponding with the occurrence and/or the ECG data preceding and/or following the abnormality, adverse event or disease state can be associated together and analyzed. The length of time preceding or following the abnormality may be predetermined and be up to 1 to 30 days, or greater than 1 to 12 months. Analysis of the time before the abnormality, adverse event or disease state may allow the system to identify patterns or correlations of various ECG features that precede the occurrence of the abnormality, adverse event or disease state, thereby providing advance detection or warning of the abnormality, adverse event or disease state. Analysis of the time following the abnormality, adverse event or disease state can provide information regarding the efficacy of treatments and/or provide the patient or physician information regarding disease progression, such as whether the patient's condition in improving, worsening or staying the same. The diagnosis and determination can also be used for indexing by, for example, including it in the metadata associated with the corresponding ECG data.

As described herein, various parameters may be included in the database along with the ECG data. These may include the patient's age, gender, weight, blood pressure, medications, behaviors, habits, activities, food consumption, drink consumption, drugs, medical history and other factors that may influence a patient's ECG signal. The additional parameters may or may not be used in the comparison of the changes in ECG signal over time and circumstances.

The conclusions, determinations, and/or insights into the patient's health generated by the system may be communicated to the patient directly or via the patient's caregiver (doctor or other healthcare professional). For example, the patient can be sent an email or text message that is automatically generated by the system. The email or text message can be a notification which directs the patient to log onto a secure site to retrieve the full conclusion, determination or insight, or the email or text message can include the conclusion, determination or insight. Alternatively, or additionally, the email or text message can be sent to the patient's caregiver. The notification may also be provided via an application on a smartphone, tablet, laptop, desktop or other computing device.

As described herein, the system can identify behaviors, habits, activities, foods, drinks, medications, drugs, and the like which are associated with the patient's abnormal ECG readings. In addition to informing the patient of these associations, the system can provide instructions or recommendations to the patient to avoid these behaviors, habits, activities, foods, drinks, medications, drugs, and the like which are associated with the patient's abnormal ECG readings. Similarly, the system can identify behaviors, habits, activities, foods, drinks, medications, drugs, and the like which are associated with normal or improving ECG readings, and can instruct or recommend that the patient perform these behaviors, habits, and activities and/or consume these foods, drinks, medications, and drugs. The patient may avoid a future healthcare issue, as instructed or recommended by the system, by modifying their behavior, habits

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or by taking any course of action, including but not limited to taking a medication, drug or adhering to a diet or exercise program, which may be a predetermined course of action recommended by the system independent of any analysis of the ECG data, and/or may also result from insights learned through this system and method as described herein. In addition, the insights of the system may relate to general fitness and or mental wellbeing.

The ECG data and the associated metadata and other related data as described herein can be stored in a central database, a cloud database, or a combination of the two. The data can be indexed, searched, and/or sorted according to any of the features, parameters, or criteria described herein. The system can analyze the ECG data of a single patient, and it can also analyze the ECG data of a group of patients, which can be selected according to any of the features, parameters or criteria described herein. When analyzing data from a single patient, it may be desirable to reduce and/or correct for the intra-individual variability of the ECG data, so that comparison of one set of ECG data taken at one particular time with another set of ECG data taken at another time reveals differences resulting from changes in health status and not from changes in the type of ECG recording device used, changes in lead and electrode placement, changes in the condition of the skin (i.e. dry, sweaty, conductive gel applied or not applied), and the like. As described above, consistent lead and electrode placement can help reduce variability in the ECG readings. The system can also retrieve the patient's ECG data that were taken under similar circumstances and can analyze this subset of ECG data.

FIG. **4** illustrates an embodiment of the system and method **400** of ECG monitoring described herein. The system can be implemented on a server or computer having a processor for executing the instructions described herein, which can be stored in memory. In step **402**, ECG data can be recorded using any of the devices described herein for one or more patients. In step **404**, the ECG data is transmitted along with associated metadata to a server and database that stores the ECG data. In step **406**, a subset of the ECG data can be selected based on criteria in the metadata, such as user identity, time, device used to record the ECG data, and the like. In step **408**, the subset of ECG data can be analyzed using a machine learning algorithm, which can assign a risk level to the ECG data in step **410**. The system can then determine whether the risk level is high, as shown in step **412**. If the risk level is low, the user can be notified that the ECG is normal or low risk, as shown in step **414**. If the risk level is high, a high risk level alert can be sent to the patient with the option of sending the ECG to the medical professional for interpretation, as shown in step **416**. The system then waits for the user's response to determine whether the patient elects to send the ECG to the medical professional for interpretation, as shown in step **418**. If the patient does not wish to send the ECG to the medical professional for interpretation, the system can end the routine at this point, as shown in **420**. If the patient does elect to send the ECG to the medical professional for interpretation, the request can be transmitted to the medical professional in step **422**. The request to the medical professional can be sent to a workflow auction system as described in U.S. Provisional Application No. 61/800,879, filed Mar. 15, 2013, which is herein incorporated by reference in its entirety for all purposes. Once the medical professional has interpreted the ECG, the system can receive and store the ECG interpretation from the medical professional in the database, as shown in step **424**. The system can then notify the user of the professional ECG interpretation, which can be sent to or accessed by the user, as shown in step **426**. Additionally, the system can compare the assigned risk level with the medical diagnosis in step **428** and can determine whether the risk level determined by the system agrees with the medical diagnosis in step **430**. If the risk level does not agree with the medical diagnosis, the machine learning algorithm can be adjusted until the risk level matches the medical diagnosis, as shown in step **432**. If the risk level does agree with the medical diagnosis, the routine can be ended as shown in step **434**.

Although the above steps show a method **400** in accordance with many embodiments, a person of ordinary skill in the art will recognize many variations based on the teaching described herein. The steps may be completed in a different order. Steps may be added or deleted. Some of the steps may comprise sub-steps. Many of the steps may be repeated as often as beneficial to the user or subject.

One or more of the steps of a method **400** may be performed with circuitry, for example, one or more of a processor or a logic circuitry such as a programmable array logic for a field programmable gate array. The circuitry may be programmed to provide one or more of the steps of a method **400**, and the program may comprise program instructions stored on a non-transitory computer readable medium or memory or programmed steps of the logic circuitry such as the programmable array logic or the field programmable gate array, for example.

Aspects of the present disclosure provide systems and methods for generating a heart health score in response to continuously measured or monitored physiological parameter(s). The score may be given a quantitative value such as be graded from A to F or 0 to 100 for example (e.g. a great score may be an A or 100, a good score may be a B or 75, a moderate score may be a C or 50, a poor score may be a D or 25, and a failing score may be an F or 0.) If an arrhythmia is detected, the score may be below 50 for example. Other scoring ranges such as A to Z, 1 to 5, 1 to 10, 1 to 1000, etc. may also be used. Arrhythmia may be detecting using the machine learning based operations or algorithms described herein.

FIG. **5** shows a flow chart of an exemplary method **500** to generate a heart health score in accordance with many embodiments.

In a step **502**, an arrhythmia is detected. If an arrhythmia is detected (e.g. using the methods and/or algorithms disclosed herein), then the heart health score generated will be below 50. Depending on the severity of the arrhythmia detected, the heart score may be calculated or assigned within the ranges according to the table below in Table 2.

TABLE 2

Arrhythmia	Heart Health score
ATRIAL FIBRILLATION, HR below 100	30-45
ATRIAL FIBRILLATION, HR above 100	15-30
Sinus Tachycardia	20-40
Supraventricular Tachycardia	20-40
Bradycardia	20-40
Bigeminy, Trigeminy	30-50
Short runs of High Heart Rate (VTACH suspect)	10-30

In a step **504** a Heart Rate Variability (HRV) is calculated. HRV can be an indicator of heart health. The value for HRV value for a healthy heart is typically higher than HRV for an unhealthy heart. Also, HRV typically declines with age and may be affected by other factors, like stress, lack of physical

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activity, etc. HRV may be measured and analyzed using the methods described above. HRV may be calculated in the absence of arrhythmia, which may improve the accuracy of the HRV measurement. HRV may be determined and further analyzed as described above.

In a step **506**, premature beats are counted and Heart Rate Turbulence (HRT) is calculated. Premature beats in the sequence of R-R intervals may be detected. Also, R-R intervals typically tend to recover at a certain pace after a premature beat. Using these two parameters (prematurity and pace of R-R recovery), HRT parameters may be calculated. There may be known deviations of HRT parameters associated with patients with risk of Congestive Heart Failure (CHF). These deviations, however, may be used to estimate an inverse measure. The number of premature beats per day (or per hour) may also be used as a measure of heart health. A low number of premature beats may indicate better heart health. In summary, the heart health score may be generated by combining at least heart rate variability (HRV), the number of premature beats, and heart rate turbulence (HRT). This combination (in the absence of arrhythmia) may provide an accurate estimate of how healthy the heart of the user is.

In a step **508**, a heart health score is generated, and in a step **510**, a hearth health score is generated based on an arrhythmia. To initially generate the score, a few hours (e.g. 2-5 hours) of measured R-R intervals may be required. A more accurate score may be generated after a week of continuous R-R interval measurements. Longer data sets may be required to detect significant arrhythmias as they may usually be detected within the first 7-8 days of monitoring.

Although the above steps show a method **500** in accordance with many embodiments, a person of ordinary skill in the art will recognize many variations based on the teaching described herein. The steps may be completed in a different order. Steps may be added or deleted. Some of the steps may comprise sub-steps. Many of the steps may be repeated as often as beneficial to the user or subject.

One or more of the steps of a method **500** may be performed with circuitry, for example, one or more of a processor or a logic circuitry such as a programmable array logic for a field programmable gate array. The circuitry may be programmed to provide one or more of the steps of a method **500**, and the program may comprise program instructions stored on a non-transitory computer readable medium or memory or programmed steps of the logic circuitry such as the programmable array logic or the field programmable gate array, for example.

FIG. **6** shows a further method **600** of generating a heart score. In addition to the parameters which may be derived from the heart rate data described above, the heart health score may also be generated in response to further physiological parameters as shown in FIG. **6**.

In a step **602**, a raw ECG waveform is obtained. In a step **608**, ECG parameters are extracted from the raw ECG waveform data and arrhythmia prediction and/or detection algorithms are run to analyze the obtained raw ECG waveform data.

In a step **604**, physiological parameters may be measured using a sensor of the user's local computing device or an accessory thereof. Such measured physiological parameters may include blood pressure, user activity and exercise level, blood oxygenation levels, blood sugar levels, an electrocardiogram, skin hydration or the like of the user. These physiological parameters may be measured over time such as over substantially the same time scale or length as the measurement of heart rate. In a step **610**, an R-R interval is extracted and both traditional and non-traditional heart rate measures are used to analyze the measured heart rate and physiological parameters.

In a step **606**, additional physiological parameters for determining the heart health score may be input by the user. These parameters may include the age, the gender, the weight, the height, the body type, the body mass index (BMI), the personal medical history, the family medical history, the exercise and activity level, the diet, the hydration level, the amount of sleep, the cholesterol level, the alcohol intake level, the caffeine intake level, the smoking status, and the like of the user. For example, the heart health score may be weighted by age and/or gender to provide the user an accurate assessment of his or her heart health in response to the heart rate data. In a step **612**, feature extraction is used to analyze the inputted physiological parameters.

In a step **614** feature ranking and/or feature selection occurs. In a step **618**, a real time prediction or detection of atrial fibrillation, and/or in a step **616**, the heart rate variability measurements may be labelled and saved for offline training of a machine learning algorithm or set of machine learning operations, and then may be subsequently used to make a real time prediction and/or detection of atrial fibrillation. A plurality of heart health scores may be generated by a plurality of users to generate a set of population data. This population data may be used to train the machine learning algorithms described herein such that the trained algorithm may be able to detect and predict atrial fibrillation or other health conditions from user data.

Although the above steps show a method **600** in accordance with many embodiments, a person of ordinary skill in the art will recognize many variations based on the teaching described herein. The steps may be completed in a different order. Steps may be added or deleted. Some of the steps may comprise sub-steps. Many of the steps may be repeated as often as beneficial to the user or subject.

One or more of the steps of a method **600** may be performed with circuitry, for example, one or more of a processor or a logic circuitry such as a programmable array logic for a field programmable gate array. The circuitry may be programmed to provide one or more of the steps of a method **600**, and the program may comprise program instructions stored on a non-transitory computer readable medium or memory or programmed steps of the logic circuitry such as the programmable array logic or the field programmable gate array, for example.

The systems and methods for generating a heart health score in response to continuously measured or monitored physiological parameter(s) may comprise a processor of a computing device and software. A processor of a computing device (e.g. a tablet computer, a smartphone, a smart watch, a smart band, a wearable computing device, or the like) may execute this set of instructions to receive the input data and detect and/or predict atrial fibrillation therefrom. The software may be downloaded from an online application distribution platform such as the Apple iTunes or App Store, Google Play, Amazon App Store, and the like. A display of the computing device may notify the user of the calculated heart health score and/or if further measurements are required (e.g. to perform a more accurate analysis).

FIG. **7** shows a schematic diagram of the executed application described herein. The heart health score may be provided on a software application such as a mobile app downloaded from an application distribution platform and executed on a local computing device of the user as described above. This executed application may instruct the

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user to take active steps in response to a poor or moderate heart health score. For example, the instructions to the user may be to make a corrective measure such as to modify his or her diet, exercise pattern, sleep pattern, or the like. Alternatively, or in combination, the instructions to the user may be to take a further step such as to take an electrocardiogram (e.g. to verify the presence of an arrhythmia), enroll in an electrocardiogram over-read service, or schedule an appointment with a physician or other medical specialist. If the heart health score is below a desired threshold for good heart health, the executed application may link the user to a second execute application with further application features. Alternatively, or in combination, these further features may be unlocked on the first executed application if the heart health score is below the threshold. In at least some cases, a prescription or verification from a medical professional may also be required to unlock the further application features.

FIG. **8** shows screenshots of the executed application. The further features unlocked may include the ability to read electrocardiogram (ECG) data from a sensor coupled to the local computing device and display the electrocardiogram (ECG) in real-time and/or detect and alert for atrial fibrillation based on the electrocardiogram (ECG) in real-time (e.g. as described in U.S. application Ser. Nos. 12/796,188, 13/108,738, 13/420,540, and 13/964,490). As shown in FIG. **8**, these further features may include an electrocardiogram (ECG) over-read service such as that described in U.S. application Ser. No. 14/217,032. The first executed application may comprise a consumer software application and the second executed application may comprise a medical professional or regulated software application or set of features of the first executed application. As described herein and shown in FIG. **8**, the executed application may provide a dash board to track the heart health of the user and show risk factors which may be monitored and tracked by the user. The dash board may be provided with further features such as that described in U.S. Ser. No. 61/915,113 (filed Dec. 12, 2013).

FIG. **9** shows a method **900** for cardiac disease and rhythm management, which may, for example, be implemented with the system **100** described herein. In a step **902**, a user or subject is provided access to a cardiac disease and/or rhythm management system such as system **100**. Step **902** may comprise prescribing the use of the system **100** for the user or subject. In a step **904**, the user or subject is provided one or more biometric sensors. These biometric sensor(s) may couple to a computing device of the user or subject, e.g. a personal desktop computer, a laptop computer, a tablet computer, a smartphone, etc., and associated software loaded thereon.

In a step **906**, the user or subject downloads the cardiac disease and/or rhythm management system software onto their computing device. For example, the system software may comprise a mobile software application ("mobile app") downloaded from the Apple App Store, Google Play, Amazon Appstore, BlackBerry World, Nokia Store, Windows Store, Windows Phone Store, Samsung Apps Store, and the like. The downloaded system software, e.g. mobile app **101***a*, may be configured to interface with the biometric sensors provided to the user or subject in the step **154**.

In a step **908**, personal information input to the cardiac disease management system is received. For example, the user or subject may enter his or her gender, height, weight, diet, disease risk factors, etc. into the mobile app **101***a*. Alternatively, or in combination, this personal information may be input on behalf of the user or subject, for example, by a physician of the user or subject.

In a step **910**, biometric data is received from the biometric sensors provided to the user or subject. For example, the system **100** and the mobile app **101***a* may receive ECG data and heart rate from handheld sensor **103**, activity data from wrist-worn activity sensor **105**, blood pressure and heart rate data from mobile blood pressure monitor **107***a*, and other data such as weight and body fat percentage data from a "smart" scale in communication with the local computing device **101**.

In a step **912**, a cardiac health score is generated. The cardiac health score can be generated by considering and weighing one or more influencing factors including the incidence of atrial fibrillation or arrhythmia as detected by the handheld ECG monitor, the heart rate of the user or subject, the activity of the user or subject, hours of sleep and rest of the user or subject, blood pressure of the user or subject, etc. Often, the incidence of atrial fibrillation or arrhythmia will be weighed the most. The cardiac health score may be generated by a physician or a machine learning algorithm provided by the remote server or cloud-based service **113**, for example. A plurality of users and subject may concurrently use the cardiac health and/or rhythm management system **100** and the machine learning algorithm may, for example, consider population data and trends to generate an individual user or subject's cardiac health score.

In a step **914**, one or more recommendations or goals is generated for the user or subject based on or in response to the generated cardiac health score. These recommendation(s) and/or goal(s) may be generated automatically based on or in response to the biometric and personal information of the user or subject. For example, the machine learning algorithm may generate these recommendation(s)/goal(s). Alternatively, or in combination, a physician or other medical specialist may generate the recommendation(s) and/or goal(s), for example, based on or in response to the biometric and personal information of the user or subject. The physician or other medical professional may access the patient data through the Internet as described above.

In a step **916**, the patient implements many if not all of the recommendation(s) and/or goal(s) provided to him or her. And in a step **916**, steps **908** to **916** may be repeated such that the user or subject may iteratively improve their cardiac health score and their overall health.

Although the above steps show method **900** of managing cardiac disease and/or rhythm in accordance with many embodiments, a person of ordinary skill in the art will recognize many variations based on the teaching described herein. The steps may be completed in a different order. Steps may be added or deleted. Some of the steps may comprise sub-steps. Many of the steps may be repeated as often as beneficial to the user or subject.

One or more of the steps of the method **900** may be performed with circuitry, for example, one or more of a processor or a logic circuitry such as a programmable array logic for a field programmable gate array. The circuitry may be programmed to provide one or more of the steps of the method **900**, and the program may comprise program instructions stored on a non-transitory computer readable medium or memory or programmed steps of the logic circuitry such as the programmable array logic or the field programmable gate array, for example.

In some embodiments, the heart rate information (or an extracted portion of HR information) may be used to compare to a database of similar information that has been correlated with cardiac events. For example, heart rate

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information may be compared to a database of HR information extracted for ECG recordings of patients known to be experiencing cardiac problems. Thus, patterns of heart rate information taken from a subject may be compared to patterns of cardiac information in a database. If there is a match (or a match within a reasonable closeness of fit), the patient may be instructed to record an ECG, e.g. using an ambulatory ECG monitor. This may then provide a more detailed view of the heart. This method may be particularly useful, as it may allow recording and/or transmission and/or analysis of detailed electrical information about the heart at or near the time (or shortly thereafter) when a clinically significant cardiac event is occurring. Thus, the continuous monitoring may allow a subject to be alerted immediately upon an indication of the potential problem (e.g. an increase in HRV suggestive of a cardiac dysfunction). This may allow the coupling of continuous HR monitoring with ECG recording and analysis for disease diagnosis and disease management.

FIG. **10** illustrates one variation of a method for monitoring a subject to determine when to record an electrocardiogram (ECG). In FIG. **10**, a subject is wearing a continuous heart rate monitor (configured as a watch **1010**, including electrodes **1016**), shown in step **1002**. The heart rate monitor transmits (wirelessly **1012**) heart rate information that is received by the smartphone **1018**, as shown in step **1004**. The smartphone includes a processor that may analyze the heart rate information **1004**, and when an irregularity is determined, may indicate **1006** to the subject that an ECG should be recorded. In FIG. **10**, an ambulatory ECG monitor **1014** is attached (as a case having electrodes) to the phone **1018**. The user may apply the ECG monitor as to their body (e.g. chest, between arms, etc.) **1008** to record ECGs that can then be saved and/or transmitted for analysis.

FIGS. **11** and **11A** show screenshots of an atrial fibrillation dashboard **1100** of a user interface for the cardiac disease and/or rhythm management system **100**. FIG. **11** shows a top portion **1100***a* of the atrial fibrillation dashboard **1100** while FIG. **10A** shows a bottom portion **1100***b* of the atrial fibrillation dashboard **1100**.

The top portion **1100***a* of the atrial fibrillation dashboard **1100** as shown in FIG. **10** may display the current cardiac health score of the user or subject, a recent best cardiac health score of the user or subject, and a completion percentage of recommendation(s) and/or goal(s) for the user or subject. The user or subject may tap any one of the cardiac health score displays or the recommendation(s) and/or goal(s) displays to access more detailed information regarding the calculated health score(s) or recommendation(s) and/or goal(s), respectively. The top portion **1100***a* may also show an ECG of the user or subject and a button which may be tapped to record the ECG of the user or subject for the day. As discussed with reference to FIG. **1**, the ECG may be recorded with a handheld sensor **103** in communication with the local computing device **100**. The top portion **1000***a* may also show the number of atrial fibrillation episodes and the average duration of these atrial fibrillation episodes. This number and duration may be generated automatically by software or logic of the mobile app **101***a* based on or in response to the ECG measurements taken by the user or subject. Alternatively, or in combination, a physician may access the atrial fibrillation dashboard **1100** of an individual user or subject, evaluate his or her ECGs, and provide the number of atrial fibrillation episodes and their duration to the mobile app **101***a* or other software loaded on the local computing device **101** of the user or subject. The shortest and longest durations of the atrial fibrillation episodes may also be shown by the top portion **1100***a* as well as the user or subject's daily adherence to a medication regime.

The bottom portion **1100***b* of the atrial fibrillation dashboard **1100** as shown in FIG. **10A** may display one or more influencers which influence how the cardiac health score is generated. These influencers may include, for example, caffeine intake, alcohol intake, stress levels, sleep levels, weight, nutrition, fitness and activity levels, and blood pressure. Data for these influencers may be input automatically by one or more biometric sensors coupled to the local computing device **101** and/or the mobile app **101***a*. Alternatively, or in combination, the data for these influencers may be input manually by the user or subject by tapping on the respective influencer display. For example, tapping on the blood pressure display area may cause a slider input **1100***c* for blood pressure to pop up. The user or subject may use the slider to enter and save his or her blood pressure for the day. Similar pop-ups or user-selected inputs may be provided for the other influencers. For example, the user or subject may enter his or her daily caffeine or alcohol intake, stress and sleep levels, nutrition levels, or activity and fitness levels (e.g. low/bad, medium/so-so, or high/good based on the user's age, gender, height, weight, etc. as can be indicated by an instruction page of the mobile app **101***a*). The influencer displays may also show the goal progression of the user or subject.

FIGS. **12** and **12A** show screenshots of a goals and recommendations page **1200** of the cardiac disease and rhythm management system interface or mobile app **101***a*. A top portion **1200***a* of the goals and recommendations page **1100** may comprise a listing of 7-day goals for the user or subject. The top portion **1200***a* may further comprise everyday goals for the user or subject which often cannot be removed or changed. The user or subject can check off these goals or recommendations as he or she meets them. The top portion **1200***a* may track goal completion percentage over a 7-day period. The user or subject can set the same goals for the next day and/or set new goals.

A bottom portion **1200***b* of the goals and recommendations page **1200** may comprise a listing of new goals which the user or subject may add. The new goals may be categorized into goals or recommendations for atrial fibrillation management, stress management, and/or other categories. For example, goals for atrial fibrillation management may include taking daily medications, reducing caffeine intake, and reducing alcohol intake. And, goals for stress management may include meditate for 5 minutes daily, take blood pressure reading daily, and getting at least 7 hours of sleep nightly. Using the goals and recommendations page **1200**, the user or subject can set their goals for the week. One or more of these goals may be automatically recommended to the user or subject or be recommended by a physician having access to the dashboard **1100**. For example, goals may be recommended based on last week's progress. The completion of recommended goals can result in the user or subject earning more "points," in effect gamifying health and cardiac rhythm management for the user or subject. Alternatively, or in combination, the goals may be set by a physician having access to the dashboard **1100**.

FIG. **13** shows a screenshot of a user's local computing device notifying the user with a pop-up notice **1300** to meet their daily recommendations and goals. By tapping on the pop-up notice, **1300**, the user or subject can be taken to the atrial fibrillation dashboard where the user or subject can update or otherwise manage their cardiac health.

FIG. **14** shows an embodiment comprising a smart watch **1400** which includes at least one heart rate monitor **1402** and

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at least one activity monitor **1404**. One or more processors are coupled to one or more non-transitory memories of the smart watch and configured to communicate with the heart rate monitor **1402** and the activity monitor **1404**. The one or more processors are further coupled to an output device **1408**. Processor executable code is stored on the one or more memories and when executed by the one or more processors causes the one or more processors to determine if heart rate and activity measurements represent an advisory condition for recording an ECG, and generate and send notification signals through the output device **1408** when an advisory condition for recording an ECG is determined.

For example, presently available smart watches include motion sensors such as pedometers. Pedometers can be based on an accelerometer or electromechanical mechanism such as a pendulum, magnetic reed proximity switch, and a spring suspended lever arm with metal-on-metal contact. Modern accelerometers are often small micro electro-mechanical systems and are well known by those skilled in the art. Heart rate monitors are readily available with smart phones as well as smart watches. One type uses an optical sensor to detect the fluctuation of blood flow. The signal can be amplified further using, for example, a microcontroller to count the rate of fluctuation, which is actually the heart rate.

An advisory condition for recording an ECG may occur due to, for example, large continuing fluctuations in heart rate. An advisory condition for recording an ECG can also occur when a measured heart rate increases rapidly without a corresponding increase in activity monitored by, for example, an accelerometer. By comparing measured heart rate changes with measured activity changes, the presently disclosed software or "app" minimizes false alarms are minimized. ECG devices are described in U.S. Ser. No. 12/796,188, filed Jun. 8, 2010, now U.S. Pat. No. 8,509,882, hereby expressly incorporated herein by reference in its entirety. The ECG device can be present in a smart watch band or a smart phone. In one embodiment, the ECG device includes an electrode assembly configured to sense heart-related signals upon contact with a user's skin, and to convert the sensed heart-related signals to an ECG electric signal. The ECG device transmits an ultrasonic frequency modulated ECG signal to a computing device such as, for example, a smartphone. Software running on the computing device or smartphone digitizes and processes the audio in real-time, where the frequency modulated ECG signal is demodulated. The ECG can be further processed using algorithms to calculate heart rate and identify arrhythmias. The ECG, heart rate, and rhythm information can be displayed on the computer or smartphone, stored locally for later retrieval, and/or transmitted in real-time to a web server via a 2G/3G/4G, Wi-Fi or other Internet connection. In addition to the display and local processing of the ECG data, the computer or smartphone can transmit, in real-time, the ECG, heart rate and rhythm data via a secure web connection for viewing, storage and further analysis via a web browser interface.

In another embodiment, the converter assembly of an ECG device is integrated with, and electrically connected to the electrode assembly and is configured to convert the electric ECG signal generated by electrode assembly to a frequency modulated ECG ultrasonic signal having a carrier frequency in the range of from about 18 kHz to about 24 kHz. It is sometimes desirable to utilize a carrier frequency in the 20 kHz to 24 kHz range. The ultrasonic range creates both a lower noise and a silent communication between the acquisition electronics and the computing device such as the smartphone, notebook, smart watch and the like.

A kit can include downloadable software such as an "app" for detecting an advisory condition for recording an ECG and an ECG device. The ECG device can be present on a watch band for replacing a specific band on a smart watch. The ECG device can also be provided on a smart phone back plate for replacing an existing removable smartphone back. In another configuration, the ECG device is usable as a smartphone protective case.

Software on the smartphone or smart watch can also combine data and signals from other sensors built into the smartphone or smart watch such as a GPS.

While preferred embodiments of the present disclosure have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the subject matter described herein. It should be understood that various alternatives to the embodiments of the subject matter described herein may be employed in practicing the subject matter described herein. It is intended that the following claims define the scope of the disclosure and that methods and structures within the scope of these claims and their equivalents be covered thereby.

What is claimed is:

1. A smart watch to detect the presence of an arrhythmia of a user, comprising:

a processing device;

a photoplethysmography ("PPG") sensor operatively coupled to the processing device;

an ECG sensor, comprising two or more ECG electrodes, the ECG sensor operatively coupled to the processing device;

a display operatively coupled to the processing device; and

a memory, operatively coupled to the processing device, the memory having instructions stored thereon that, when executed by the processing device, cause the processing device to:

receive PPG data from the PPG sensor;

detect, based on the PPG data, the presence of an arrhythmia;

receive ECG data from the ECG sensor; and

confirm the presence of the arrhythmia based on the ECG data.

2. The smart watch of claim 1, further comprising a motion sensor operatively coupled to the processing device, wherein to detect the presence of the arrhythmia, the processing device is configured to:

receive motion sensor data from the motion sensor; and

determine, from motion sensor data, that the user is at rest.

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.

4. The smart watch of claim 2, wherein to detect the presence of the arrhythmia, the processing device is configured to:

determine heartrate variability ("HRV") data from the PPG data; and

detect, based on the HRV data, the presence of the arrhythmia.

5. The smart watch of claim 4, wherein to detect the presence of the arrhythmia, the processing device is configured to input the HRV data into a machine learning algorithm trained to detect arrhythmias.

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6. The smart watch of claim 5, wherein to detect the presence of the arrhythmia, the processing device is further configured to input the motion sensor data with the HRV data into the machine learning algorithm trained to detect arrhythmias.

7. The smart watch of claim 1, wherein the processing device is further configured to:

extract one or more features from the PPG data; and

detect, based on the one or more features, the presence of the arrhythmia.

8. The smart watch of claim 7, wherein the one or more features correspond to an HRV signal analyzed in a time domain.

9. The smart watch of claim 7, wherein the one or more features comprise a nonlinear transform of R-R ratio or R-R ratio statistics with an adaptive weighting factor.

10. The smart watch of claim 7, wherein the one or more features are features of an HRV signal analyzed geometrically.

11. The smart watch of claim 7, wherein the one or more features are features of an HRV signal analyzed in the frequency domain.

12. The smart watch of claim 1, wherein the processing device is further configured to generate a notification of the detected arrhythmia.

13. The smart watch of claim 1, further comprising a biometric data sensor, wherein the processing device is further configured to:

receive biometric data of the user from the biometric data sensor; and

detect, based on the biometric data, the presence of the arrhythmia.

14. The smart watch of claim 13, wherein the biometric data comprises at least one of: a temperature, a blood pressure, or an inertial data of the user.

15. The smart watch of claim 1, the processing device further configured to display an ECG rhythm strip from the ECG data.

16. The smart watch of claim 1, the processing device further to receive the ECG data from the ECG sensor in response to receiving an indication of a user action.

17. A method to detect the presence of an arrhythmia of a user on a smart watch, comprising:

receiving PPG data from a PPG sensor of the smartwatch;

detecting by a processing device, based on the PPG data, the presence of an arrhythmia;

receiving ECG data from an ECG sensor of the smartwatch; and

confirming the presence of the arrhythmia based on the ECG data.

18. The method of claim 17, wherein detecting the presence of the arrhythmia comprises:

receiving motion sensor data from a motion sensor of the smartwatch; and

determine, from motion sensor data, that the user is at rest.

19. The method of claim 18, wherein detecting the presence of the arrhythmia comprises inputting the PPG data into a machine learning algorithm trained to detect arrhythmias.

20. The method of claim 18, wherein detecting the presence of the arrhythmia comprises:

determining heartrate variability ("HRV") data from the PPG data; and

detecting, based on the HRV data, the presence of the arrhythmia.

21. The method of claim 20, wherein detecting the presence of the arrhythmia comprises inputting the HRV data into a machine learning algorithm trained to detect arrhythmias.

22. The method of claim 21, wherein detecting the presence of the arrhythmia comprises inputting the motion sensor data with the HRV data into the machine learning algorithm trained to detect arrhythmias.

23. The method of claim 17, further comprising generating a notification of the detected arrhythmia.

24. The method of claim 17, further comprising receiving the ECG data from the ECG sensor in response to receiving an indication of a user action.

25. A non-transitory computer-readable storage medium including instructions that, when executed by a processing device, cause the processing device to:

receive PPG data from a PPG sensor of the smartwatch;

detect by the processing device, based on the PPG data, the presence of an arrhythmia;

receive ECG data from an ECG sensor of the smartwatch; and

confirm the presence of the arrhythmia based on the ECG data.

26. The non-transitory computer-readable storage medium of claim 25, wherein the processing device is further configured to:

extract one or more features from the PPG data; and

detect, based on the one or more features, the presence of the arrhythmia.

27. The non-transitory computer-readable storage medium of claim 26, wherein the one or more features correspond to an HRV signal analyzed in a time domain.

28. The non-transitory computer-readable storage medium of claim 26, wherein the one or more features comprise a nonlinear transform of R-R ratio or R-R ratio statistics with an adaptive weighting factor.

29. The non-transitory computer-readable storage medium of claim 26, wherein the one or more features are features of an HRV signal analyzed geometrically or in the frequency domain.

30. The non-transitory computer-readable storage medium of claim 25, the processing device further to receive the ECG data from the ECG sensor in response to receiving an indication of a user action.

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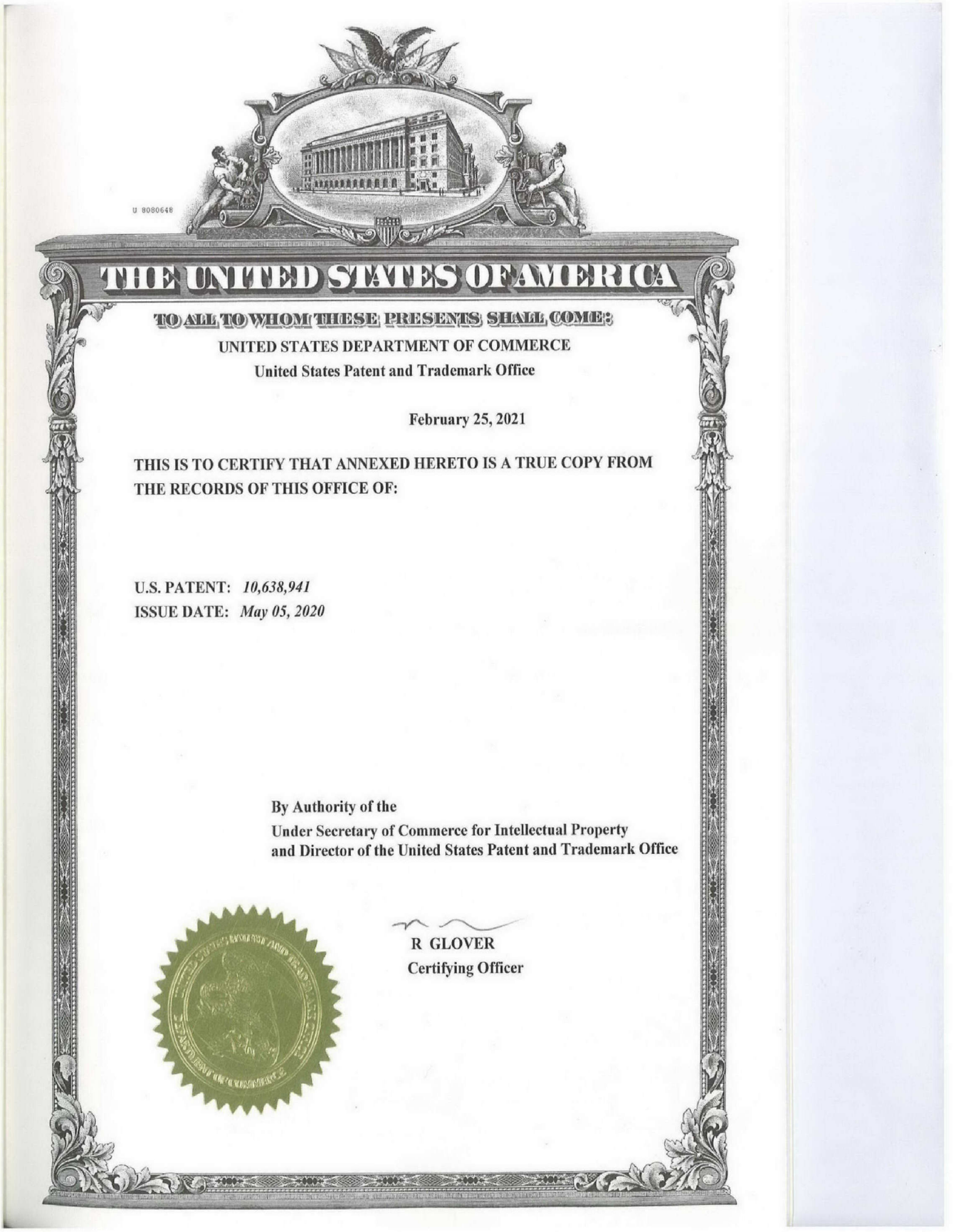

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ISSUE DATE: *May 05, 2020*

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(12) **United States Patent**
Albert et al.

(10) **Patent No.: US 10,638,941 B2**
(45) **Date of Patent: *May 5, 2020**

(54) **DISCORDANCE MONITORING**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

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(63) Continuation of application No. 15/656,745, filed on Jul. 21, 2017, now Pat. No. 10,537,250, which is a continuation of application No. 15/154,849, filed on May 13, 2016, now Pat. No. 9,839,363.

(60) Provisional application No. 62/161,092, filed on May 13, 2015.

(51) **Int. Cl.**

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A61B 5/024	(2006.01)
A61B 5/11	(2006.01)
A61B 5/046	(2006.01)
A61B 5/0464	(2006.01)
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CPC ***A61B 5/0205*** (2013.01); ***A61B 5/681*** (2013.01); ***A61B 5/7267*** (2013.01); *A61B 5/02405* (2013.01); *A61B 5/02438* (2013.01); *A61B 5/046* (2013.01); *A61B 5/0464* (2013.01); *A61B 5/04085* (2013.01); *A61B 5/1118* (2013.01); *A61B 2562/0219* (2013.01)

(58) **Field of Classification Search**

None

See application file for complete search history.

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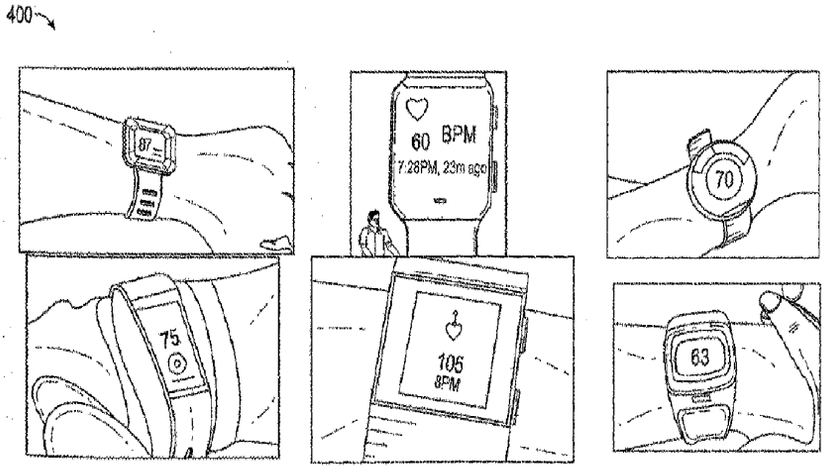
(57) **ABSTRACT**

Described herein are systems, devices, and methods for cardiac monitoring. In particular, the systems, devices, and methods described herein may be used to conveniently sense the presence of an intermittent arrhythmia in an individual. The systems, devices, and methods described herein may be further configured to sense an electrocardiogram.

23 Claims, 7 Drawing Sheets



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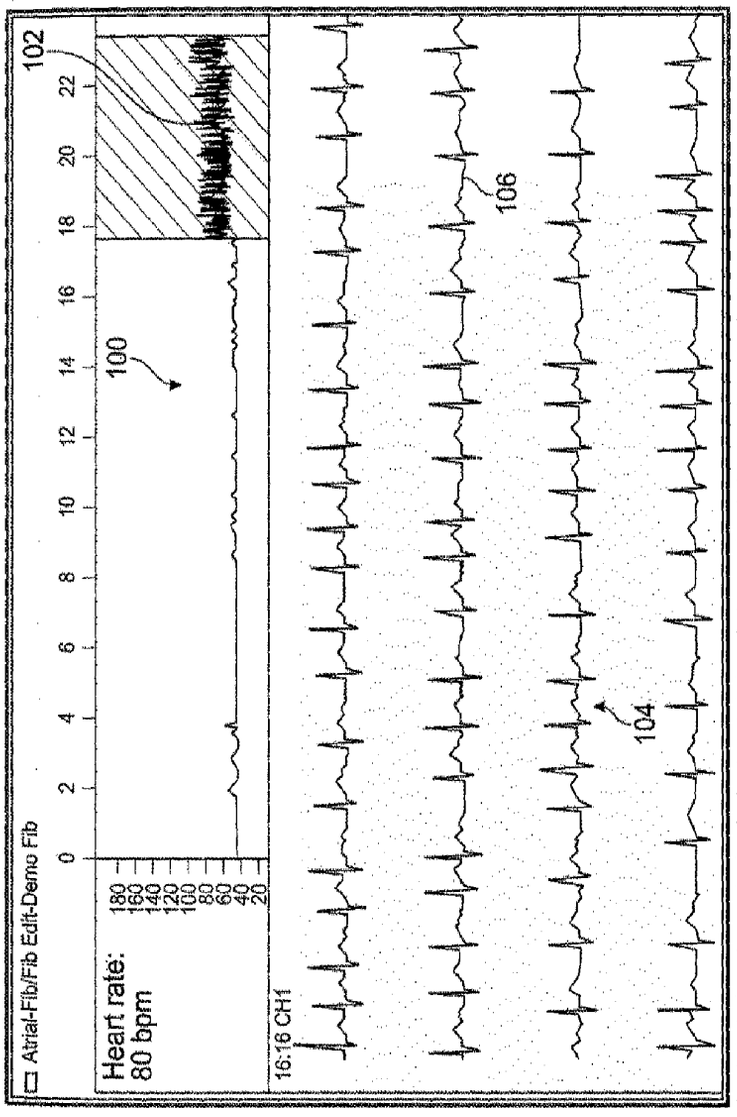

FIG. 1

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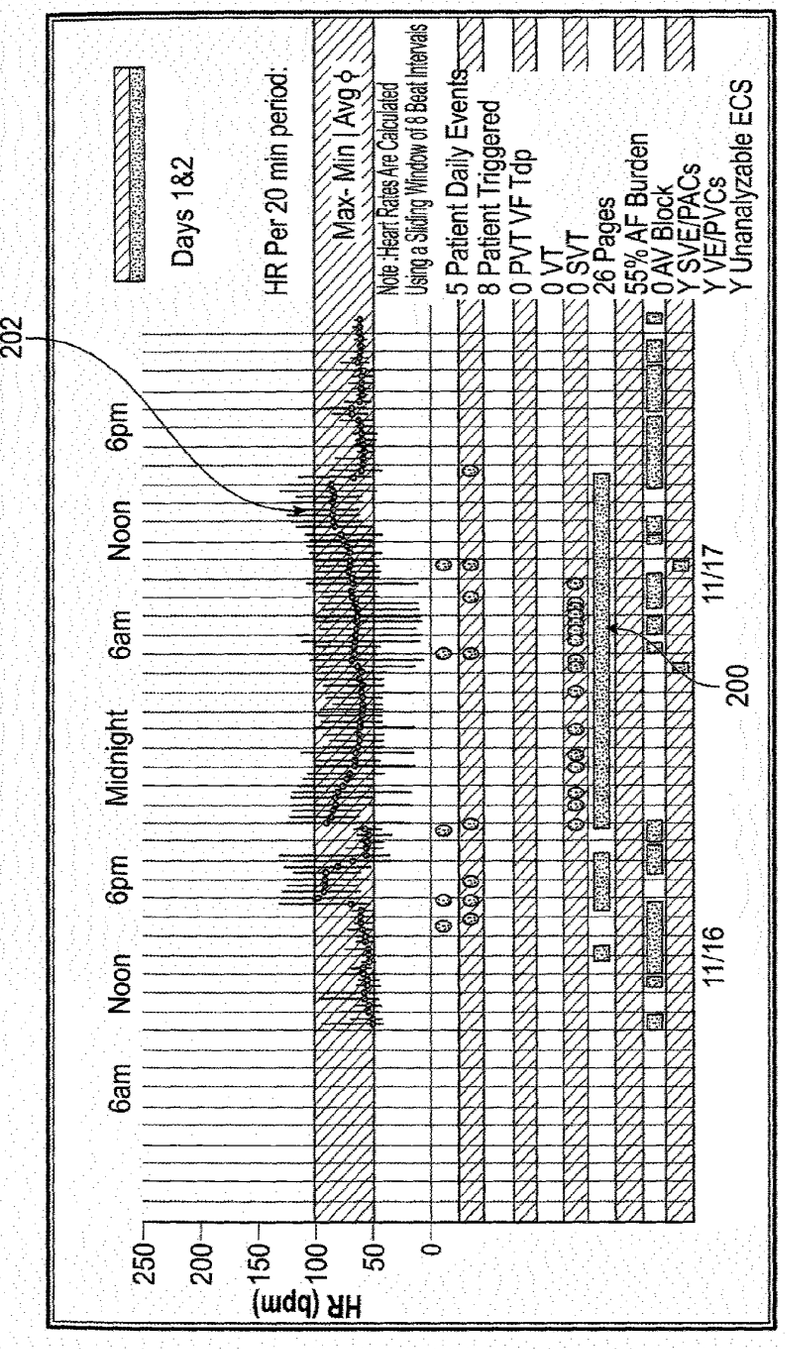

FIG. 2

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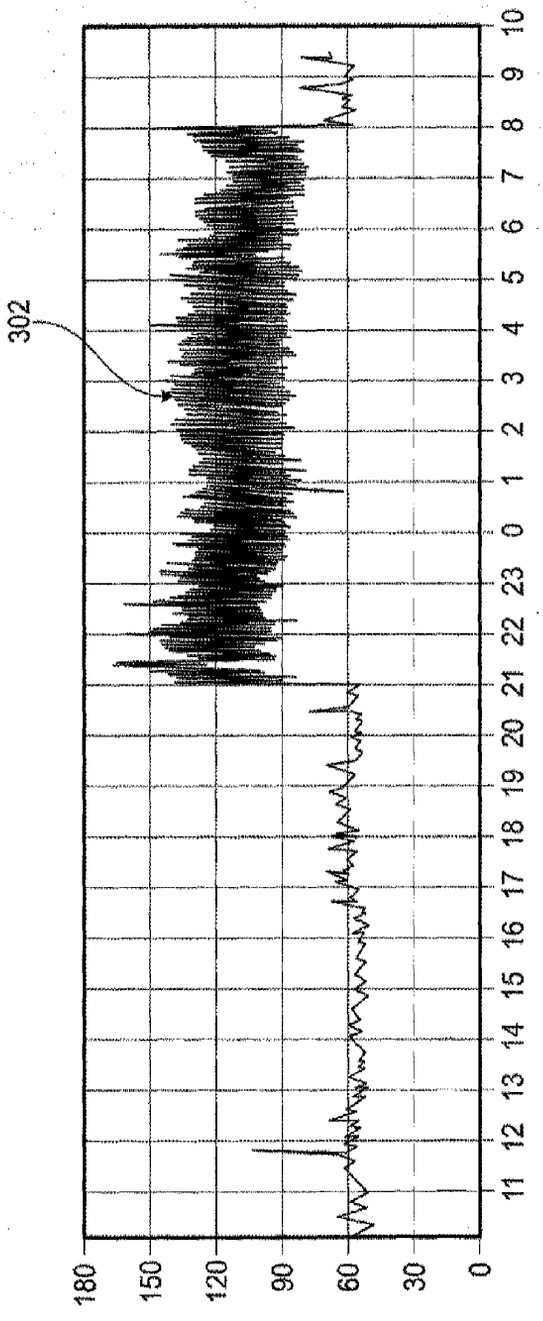

FIG. 3

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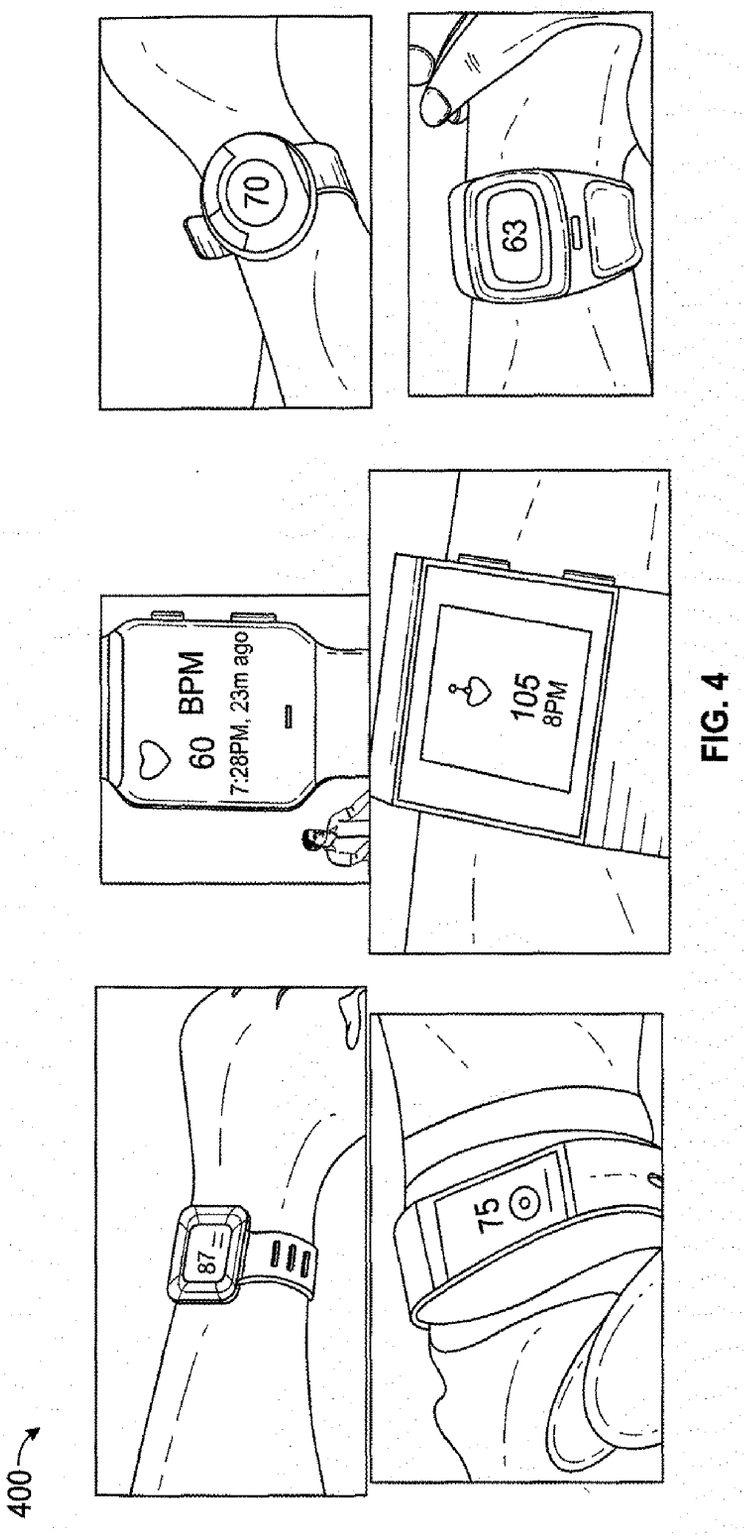

FIG. 4

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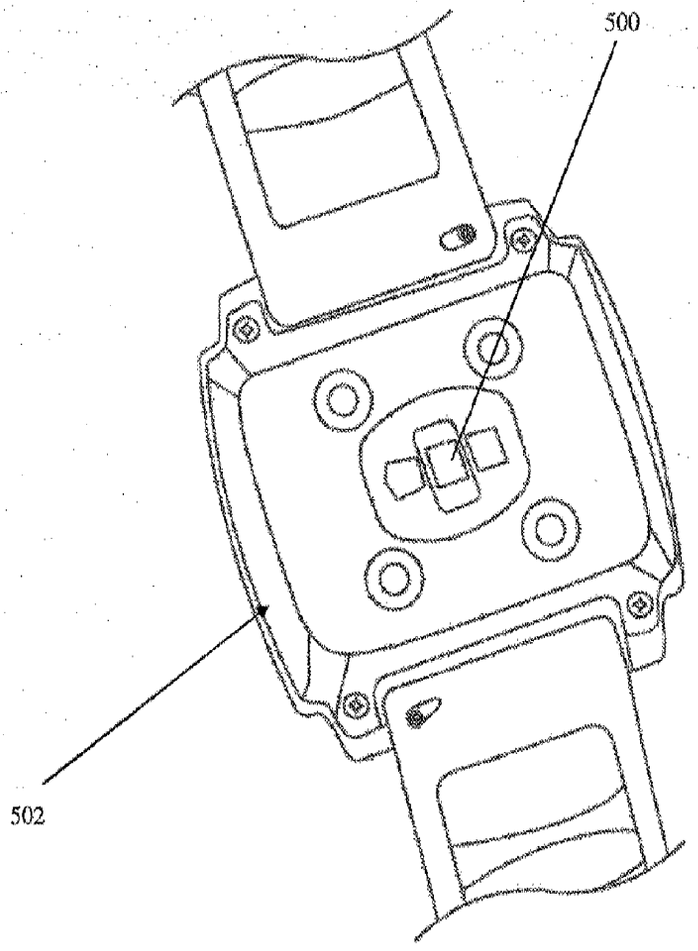

FIG. 5

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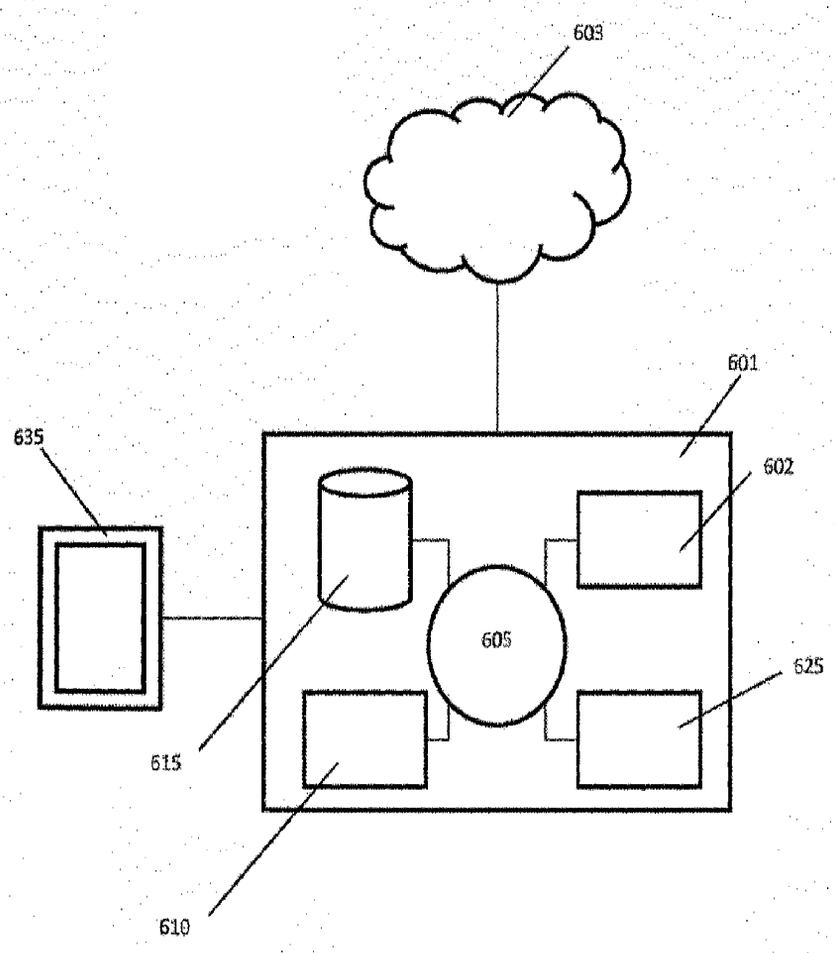

FIG. 6

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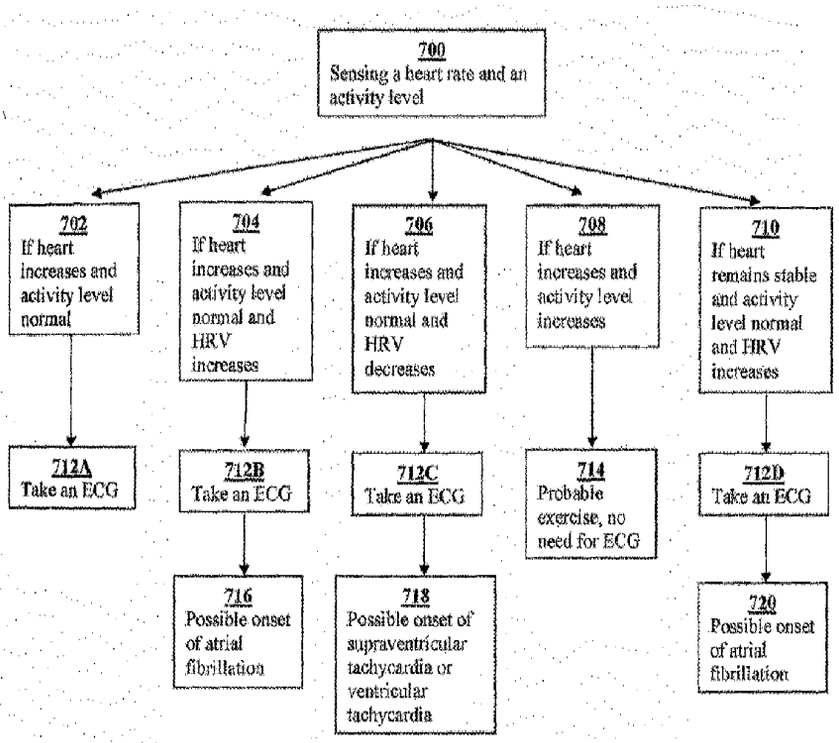

FIG. 7

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DISCORDANCE MONITORING

CROSS-REFERENCE

This application is a continuation of U.S. patent application Ser. No. 15/656,745, filed Jul. 21, 2017, entitled "DISCORDANCE MONITORING", which is a continuation of U.S. patent application Ser. No. 15/154,849, filed May 13, 2016, entitled "DISCORDANCE MONITORING", now issued as U.S. Pat. No. 9,839,363 on Dec. 12, 2017, which claims the benefit of U.S. Provisional Application No. 62/161,092, filed May 13, 2015, both of which are incorporated herein by reference in its entirety.

BACKGROUND

Irregular heartbeats and arrhythmias are associated with significant morbidity and mortality in patients. Arrhythmias may occur continuously or may occur intermittently. Types of arrhythmia include atrial fibrillation and supraventricular tachycardia. Non-invasive cardiac monitoring is useful in diagnosing cardiac arrhythmia.

SUMMARY

Described herein are systems, devices, and methods for cardiac monitoring. The systems, devices, and methods described herein for cardiac monitoring may comprise portable computing devices such as smartphones, smartwatches, laptops, and tablet computers. Cardiac monitoring using the systems, devices, and methods described herein may be used to predict or identify the occurrence of arrhythmias.

Arrhythmias may occur continuously or may occur intermittently. Continuously occurring arrhythmias may be diagnosed using a number of different techniques including, for example, palpating a radial pulse of an individual, auscultating heart sounds of an individual, recording a heart rate of an individual, and recording an electrocardiogram of an individual. Because a continuous or essentially continuous arrhythmia is always present or essentially always present in the patient, any of the aforementioned diagnosis techniques may be applied at any time in order to make a diagnosis. For intermittent arrhythmia diagnosis any of the aforementioned diagnosis techniques may also be used, however, because intermittent arrhythmias do not always present, the diagnostic technique cannot be applied at any time, but must be applied at the time when the individual is experiencing the arrhythmia. Thus, diagnosing, intermittent arrhythmias may be difficult, because, for example, it is not practical to be prepared to apply one of the aforementioned diagnostic modalities at the exact time that an individual experiences an intermittent arrhythmia. This particular difficulty may also be compounded when an individual is not aware that they are experiencing an intermittent arrhythmia so that they would not, for example, seek out a health care provider during the intermittent arrhythmia.

However, certain parameter values may be conveniently sensed continuously such as, for example, heart rate and activity level, and analyzed to predict or determine the presence of an arrhythmia. One or more conveniently continuously sensed parameter values such as, for example, heart rate and activity level may be analyzed to determine the future onset of or the presence of an arrhythmia by identifying discordance between these two parameter values. For example, discordance between two sensed values may indicate the future onset of or the presence of an arrhythmia. In response to the identification of the future onset of or presence of an arrhythmia an electrocardiogram may be caused to be sensed.

Additional sensed parameters may also be used in an analysis as part of the cardiac monitoring systems, devices, and methods described herein. For example, a determined heart rate variability may be compared to a sensed heart rate and activity level to determine the presence of, for example, atrial fibrillation or supraventricular tachycardia.

Described herein is a method for cardiac monitoring, comprising: sensing an activity level value of an individual with a first sensor of a wearable device worn by said individual; sensing a heart rate value of said individual with a second sensor of said wearable device; determining a heart rate variability value with a processor of said wearable device; determining if a discordance is present between two or more of said activity level value, said heart rate value, and said heart rate variability value with said processor; and indicating to said individual with said wearable device to record an electrocardiogram when said discordance is determined to be present. In some embodiments, said first sensor comprises an accelerometer. In some embodiments, said first sensor comprises a gyroscope. In some embodiments, said second sensor comprises a photosensor. In some embodiments, said discordance is determined to be present when said activity level value is normal and said heart rate value is elevated. In some embodiments, said discordance is determined to be present when said activity level value is normal, said heart rate value is elevated, and said heart rate variability value is increased. In some embodiments, said method comprises indicating a presence of atrial fibrillation. In some embodiments, said discordance is determined to be present when said activity level value is normal, said heart rate value is elevated, and said heart rate variability value is decreased. In some embodiments, said method comprises indicating a presence of a supraventricular tachycardia. In some embodiments, setting one or more threshold values based on said activity level value, said heart rate value, and said heart rate variability value. In some embodiments, said one or more threshold values is determined using a machine learning algorithm.

Described herein is wearable device for cardiac monitoring, comprising: a processor; a first sensor configured to sense an activity level value of an individual, wherein said first sensor is coupled to said processor; a second sensor configured to sense a heart rate value of an individual, wherein said second sensor is coupled to said processor; a first electrode and a second electrode configured to sense an electrocardiogram; a non-transitory computer readable storage medium encoded with a computer program including instructions executable by said processor to cause said processor to: determine if a discordance is present between said activity level value of said individual and said heart rate value of said individual; and indicate that said electrocardiogram be recorded when said discordance is determined to be present. In some embodiments, said first sensor comprises an accelerometer. In some embodiments, said first sensor comprises a gyroscope. In some embodiments, said second sensor comprises a photosensor. In some embodiments, said discordance is determined to be present when said activity level value is normal and said heart rate value is elevated. In some embodiments, said computer program includes instructions that cause said processor to determine a heart rate variability value. In some embodiments, said discordance is determined to be present when said activity level value is normal, said heart rate value is elevated, and said heart rate variability value is increased. In some

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embodiments, said computer program includes instructions that cause said processor to indicate a presence of atrial fibrillation. In some embodiments, said discordance is determined to be present when said activity level value is normal, said heart rate value is elevated, and said heart rate variability value is elevated. In some embodiments, said computer program includes instructions that cause said processor to indicate a presence of a supraventricular tachycardia. In some embodiments, said computer program includes instructions that cause said processor to set one or more threshold values based on said activity level value, and said heart rate value.

In some embodiments, said one or more threshold values is determined using a machine learning algorithm.

Described herein is a method for cardiac monitoring, comprising: sensing an activity level value of an individual with a first sensor of a wearable device worn by said individual; sensing a heart rate value of said individual with a second sensor of said wearable device; determining if a discordance is present between two or more of said activity level value and said heart rate value by using an activity level threshold and a heart rate threshold with a processor of said wearable device; and adjusting said activity level threshold and said heart rate level threshold using a machine learning algorithm executed by said processor.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the individual matter described herein are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present individual matter described herein will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the individual matter described herein are utilized, and the accompanying drawings of which:

FIG. **1** shows a heart rate tracing with a corresponding electrocardiogram (ECG) tracing both sensed from the same individual over the same period.

FIG. **2** shows a graphic showing both heart rate and rhythm analysis over a period of time in an individual who experienced different arrhythmias.

FIG. **3** shows a close up of a heart rate tracing sensed over a period of paroxysmal atrial fibrillation.

FIG. **4** shows available technologies for continuously sensing a heart rate or an activity level.

FIG. **5** shows a photosensor commonly used to measure heart rates integrated with a smartwatch.

FIG. **6** exemplifies a computer system that is programmed or otherwise configured to sense one or more physiologic parameters of an individual.

FIG. **7** shows a schematic of an algorithm for discordance monitoring.

DETAILED DESCRIPTION

Cardiac Monitoring

Described herein are systems, devices, and methods for use in cardiac monitoring. Cardiac monitoring typically comprises monitoring of the heart function of an individual for changes in, for example, heart rate or heart rhythm.

Heart rate may vary between, for example, bradycardia which typically is defined as a heart rate of less than 60 beats per minute, normal resting heart rate which typically is defined as a heart rate of between 60-100 beats per minute, and tachycardia which typically is defined as a heart rate of greater than 100 beats per minute. Variance of heart rate over a period of time may be referred to as Heart Rate Variability (HRV).

Heart function is also measured in terms of regularity of rhythm. A normal heart rhythm comprises of a systole (ejection phase) and diastole (filling phase). During the phases of systole and diastole, the ventricles of the heart act in concert in a regular manner that is repeated with every single heartbeat. When there is an abnormality of rhythm, the condition is typically referred to as an arrhythmia. Examples of arrhythmias include atrial fibrillation, WPW syndrome, prolonged QT syndrome, and premature ventricular contractions.

Many arrhythmias occur intermittently and relatively infrequently. Thus, in order to monitor and capture an intermittent arrhythmia, continuous monitoring is typically required. ECGs can be measured continuously in the ambulatory patient using holter monitoring, but this type of monitoring is cumbersome for the patient and is thus not widely used. A device or system configured to take an intermittent ECG is much more convenient for users. Such devices or systems comprise a mobile computing device that includes one or more electrodes that sense an ECG when contacted by a skin surface of the patient. Such devices are light and portable and don't necessarily require the user to be in continuous physical contact with one or more electrodes as they would with a holter type monitor. Intermittent arrhythmias can be recorded with these devices and systems when a user is given an indication that an intermittent arrhythmia is occurring. HRV sensing is used in combination with these devices or systems to indicate to a user when to contact one or more electrodes in order to sense an ECG.

FIG. **1** shows a heart rate tracing **100** with a corresponding electrocardiogram (ECG) tracing **104** both sensed from the same individual over the same period. As is shown in the ECG tracing **104**, the individual experienced a period of intermittent atrial fibrillation **106** during the time that the ECG was sensed. As is also shown in the heart rate tracing **100**, the heart rate of the individual rapidly increased **102** during the period of intermittent atrial fibrillation. As such, the HRV of the individual increased during the period of intermittent atrial fibrillation as the heart rate of the individual increased from a resting heart rate to an increased heart rate **102**. HRV changes are therefore associated with atrial fibrillation, wherein increased HRV is found during periods of intermittent atrial fibrillation.

FIG. **2** shows a graphic showing both heart rate **202** and rhythm analysis **200** over a period of time in an individual who experienced different arrhythmias. As shown, the measured heart rate **202** tended to increase above 100 beats per minute during the periods of sensed atrial fibrillation **200**. Thus, elevated heart rate above resting heart rate occurred in this individual during the period of arrhythmia.

FIG. **3** shows a close up of a heart rate tracing sensed over a period of paroxysmal atrial fibrillation. As shown, there was a substantial step increase from a normal heart of between 60-100 beats per minute to above 100 beats per minute **302** during the period of atrial fibrillation.

FIG. **4** shows available technologies **400** for continuously sensing a heart rate or an activity level. Shown are smartwatches made available by manufactures such as, for example, Apple. A wearer of one of the shown smartwatch technologies **400** may conveniently and continuously wear one or more sensors that are either coupled to or integrated with the watch throughout the day, thus, effectively continuously monitoring one or more parameter values via the one or more sensors that are either coupled to or integrated with

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the smartwatch. Thus, one of the smartwatch technologies **400** are an example of a type of device in the form of a wearable that conveniently provides continuous monitoring of one or more parameters of a user. Non-limiting examples of wearable devices that may have one or more sensors either coupled to them or integrated with them include watches (e.g. smartwatches), eyeglasses, wristbands, necklaces, and clothing. The one or more continuously sensed parameters of the user of such a technology as, for example, shown in FIG. **4**, are then used to indicate to the user to use a device or system to sense an ECG. For example, a user wearing a smartwatch having a heart rate sensor is alerted by the smartwatch to record an ECG when the HRV of the user increases.

FIG. **5** shows a photosensor **500** commonly used to measure heart rates integrated with a smartwatch **502**.

Activity level is correlated with arrhythmia in many individuals who have a predisposition to develop arrhythmia wherein increased activity level is associated with onset of arrhythmia. In other individuals an increased activity level that is detected by one or more activity sensors in the presence of increased HRV is likely normal and is not associated with arrhythmia. Thus, as described herein, the addition of continuous heart rate monitoring along with continuous activity level monitoring may achieve the same results, in terms of arrhythmia monitoring, as continuous electrocardiogram monitoring. Using one or more sensors associated with the devices or systems described herein two parameter values of heart rate and activity level may be conveniently and accurately continuously and simultaneously sensed.

Devices and Systems

FIG. **6** exemplifies a computer system **601** that is programmed or otherwise configured to sense one or more physiologic parameters of an individual. Non-limiting examples of physiologic parameters include heart rate, blood pressure, temperature, oxygen saturation, ECG, HRV, and activity level. The computer system **601** comprises an electronic device of a user **635**, or comprises a computer system that is remotely located with respect to the electronic device **635**. Electronic devices suitable for use with the system **601** include mobile electronic devices such as smartphones, smartwatches, tablets, and laptops. The electronic device **601** comprises one or more sensors configured to sense a physiologic parameter. Numerous sensors are known for measuring heart rate. Non-limiting examples of suitable sensors include light based sensors such as, for example, infrared sensor/emitter, ultrasound sensors, and tactile sensors. Sensors for measuring rhythm include electrodes for measuring electrocardiograms (ECG) and light based sensors for measuring photoplethysmograms.

The computer system **601** includes a central processing unit (CPU, also "processor" and "computer processor" herein) **605**, which can be a single core or multi core processor, or a plurality of processors for parallel processing. The computer system **601** also includes memory or memory location **610** (e.g., random-access memory, read-only memory, flash memory), electronic storage unit **615** (e.g., hard disk), communication interface **602** (e.g., network adapter) for communicating with one or more other systems, and peripheral devices **625**, such as cache, other memory, data storage and/or electronic display adapters. The memory **610**, storage unit **615**, interface **602** and peripheral devices **625** are in communication with the CPU **605** through a communication bus (solid lines), such as a motherboard. The storage unit **615** can be a data storage unit (or data repository) for storing data. The computer system **601** can be operatively coupled to a computer network ("network") **603** with the aid of the communication interface **602**. The network **603** can be the Internet, an internet and/or extranet, or an intranet and/or extranet that is in communication with the Internet. The network **603** in some cases is a telecommunication and/or data network. The network **603** can include one or more computer servers, which can enable distributed computing, such as cloud computing. The network **603**, in some cases with the aid of the computer system **601**, can implement a peer-to-peer network, which may enable devices coupled to the computer system **601** to behave as a client or a server.

The CPU **605** can execute a sequence of machine-readable instructions, which can be embodied in a program or software. The instructions may be stored in a memory location, such as the memory **610**. The instructions can be directed to the CPU **605**, which can subsequently program or otherwise configure the CPU **605** to implement methods of the present disclosure. Examples of operations performed by the CPU **605** can include fetch, decode, execute, and writeback.

The CPU **605** can be part of a circuit, such as an integrated circuit. One or more other components of the system **601** can be included in the circuit. In some cases, the circuit is an application specific integrated circuit (ASIC).

The storage unit **615** can store files, such as drivers, libraries and saved programs. The storage unit **615** can store user data, e.g., user preferences and user programs. The computer system **601** in some cases can include one or more additional data storage units that are external to the computer system **601**, such as located on a remote server that is in communication with the computer system **601** through an intranet or the Internet.

The computer system **601** can communicate with one or more remote computer systems through the network **603**. For instance, the computer system **601** can communicate with a remote computer system of a user (e.g., mobile device, server, etc.). Examples of remote computer systems include personal computers (e.g., portable PC), slate or tablet PC's (e.g., Apple® iPad, Samsung® Galaxy Tab), telephones, Smart phones (e.g., Apple® iPhone, Android-enabled device, Blackberry®), or personal digital assistants. The user can access the computer system **601** via the network **603**.

Methods as described herein can be implemented by way of machine (e.g., computer processor) executable code stored on an electronic storage location of the computer system **601**, such as, for example, on the memory **610** or electronic storage unit **615**. The machine executable or machine readable code can be provided in the form of software. During use, the code can be executed by the processor **605**. In some cases, the code can be retrieved from the storage unit **615** and stored on the memory **610** for ready access by the processor **605**. In some situations, the electronic storage unit **615** can be precluded, and machine-executable instructions are stored on memory **610**.

The code can be pre-compiled and configured for use with a machine have a processor adapted to execute the code, or can be compiled during runtime. The code can be supplied in a programming language that can be selected to enable the code to execute in a pre-compiled or as-compiled fashion.

Aspects of the systems and methods provided herein, such as the computer system **601**, can be embodied in programming. Various aspects of the technology may be thought of as "products" or "articles of manufacture" typically in the form of machine (or processor) executable code and/or associated data that is carried on or embodied in a type of

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machine readable medium. Machine-executable code can be stored on an electronic storage unit, such memory (e.g., read-only memory, random-access memory, flash memory) or a hard disk. "Storage" type media can include any or all of the tangible memory of the computers, processors or the like, or associated modules thereof, such as various semiconductor memories, tape drives, disk drives and the like, which may provide non-transitory storage at any time for the software programming. All or portions of the software may at times be communicated through the Internet or various other telecommunication networks. Such communications, for example, may enable loading of the software from one computer or processor into another, for example, from a management server or host computer into the computer platform of an application server. Thus, another type of media that may bear the software elements includes optical, electrical and electromagnetic waves, such as used across physical interfaces between local devices, through wired and optical landline networks and over various air-links. The physical elements that carry such waves, such as wired or wireless links, optical links or the like, also may be considered as media bearing the software. As used herein, unless restricted to non-transitory, tangible "storage" media, terms such as computer or machine "readable medium" refer to any medium that participates in providing instructions to a processor for execution.

Hence, a machine readable medium, such as computer-executable code, may take many forms, including but not limited to, a tangible storage medium, a carrier wave medium or physical transmission medium. Non-volatile storage media include, for example, optical or magnetic disks, such as any of the storage devices in any computer(s) or the like, such as may be used to implement the databases, etc. shown in the drawings. Volatile storage media include dynamic memory, such as main memory of such a computer platform. Tangible transmission media include coaxial cables; copper wire and fiber optics, including the wires that comprise a bus within a computer system. Carrier-wave transmission media may take the form of electric or electromagnetic signals, or acoustic or light waves such as those generated during radio frequency (RF) and infrared (IR) data communications. Common forms of computer-readable media therefore include for example: a floppy disk, a flexible disk, hard disk, magnetic tape, any other magnetic medium, a CD-ROM, DVD or DVD-ROM, any other optical medium, punch cards paper tape, any other physical storage medium with patterns of holes, a RAM, a ROM, a PROM and EPROM, a FLASH-EPROM, any other memory chip or cartridge, a carrier wave transporting data or instructions, cables or links transporting such a carrier wave, or any other medium from which a computer may read programming code and/or data. Many of these forms of computer readable media may be involved in carrying one or more sequences of one or more instructions to a processor for execution

The computer system **601** can include or be in communication with an electronic display **535** that comprises a user interface (UI) **640** for providing, for example, distributions of magnetic fields, distributions of electrical currents, distributions of local myocardial activities, etc. Examples of UI's include, without limitation, a graphical user interface (GUI) and web-based user interface.

Methods and systems of the present disclosure can be implemented by way of one or more algorithms. An algorithm can be implemented by way of software upon execution by the central processing unit **605**. The algorithm, for example, is used to analyze a sensed physiologic parameter.

A device as described herein is in some embodiments configured to sense two or more physiologic parameters. For example, a device configured to measure the heart rate of an individual as described herein is also in some embodiments configured to sense the electrocardiogram of said individual. In these embodiments, a device as described herein includes one or more electrodes configured to sense an electrocardiogram of an individual. In some embodiments, a device as described herein comprises two electrodes. In some embodiments, a device as described herein comprises three electrodes. In some embodiments, a device as described herein comprises four electrodes. In some embodiments, a device as described herein comprises five electrodes. In some embodiments, a device as described herein comprises six electrodes. In some embodiments, a device as described herein comprises seven electrodes. In some embodiments, a device as described herein comprises eight electrodes. In some embodiments, a device as described herein comprises nine electrodes. In some embodiments, a device as described herein comprises ten electrodes. Electrodes of the device described herein are configured to sense an electrocardiogram of an individual and transmit the sensed electrocardiogram data to a processor integrated with the device or part of the system described herein. In some embodiments, the processor is configured to display the electrocardiogram on a display of the device described herein. In some embodiments, the device is configured to sense and/or display a single lead electrocardiogram. In some embodiments, the single lead comprises any of Lead I, Lead II, Lead aVR, Lead aVL, Lead aVF, Lead V1, Lead V2, Lead V3, Lead V4, Lead V5, and Lead V6. In some embodiments, the device is configured to sense and/or display two leads comprising any two of Lead I, Lead II, Lead aVR, Lead aVL, Lead aVF, Lead V1, Lead V2, Lead V3, Lead V4, Lead V5, and Lead V6. In some embodiments, the device is configured to sense and/or display two leads comprising any three of Lead I, Lead II, Lead aVR, Lead aVL, Lead aVF, Lead V1, Lead V2, Lead V3, Lead V4, Lead V5, and Lead V6. In some embodiments, the device is configured to sense and/or display three leads comprising any three of Lead I, Lead II, Lead aVR, Lead aVL, Lead aVF, Lead V1, Lead V2, Lead V3, Lead V4, Lead V5, and Lead V6. In some embodiments, the device is configured to sense and/or display four leads comprising any four of Lead I, Lead II, Lead aVR, Lead aVL, Lead aVF, Lead V1, Lead V2, Lead V3, Lead V4, Lead V5, and Lead V6. In some embodiments, the device is configured to sense and/or display five leads comprising any five of Lead I, Lead II, Lead aVR, Lead aVL, Lead aVF, Lead V1, Lead V2, Lead V3, Lead V4, Lead V5, and Lead V6. In some embodiments, the device or system is configured to sense and/or display six leads comprising any six of Lead I, Lead II, Lead aVR, Lead aVL, Lead aVF, Lead V1, Lead V2, Lead V3, Lead V4, Lead V5, and Lead V6. In some embodiments, the device is configured to sense and/or display seven leads comprising any seven of Lead I, Lead II, Lead aVR, Lead aVL, Lead aVF, Lead V1, Lead V2, Lead V3, Lead V4, Lead V5, and Lead V6. In some embodiments, the device is configured to sense and/or display eight leads comprising any eight of Lead I, Lead II, Lead aVR, Lead aVL, Lead aVF, Lead V1, Lead V2, Lead V3, Lead V4, Lead V5, and Lead V6. In some embodiments, the device is configured to sense and/or display nine leads comprising any nine of Lead I, Lead II, Lead aVR, Lead aVL, Lead aVF, Lead V1, Lead V2, Lead V3, Lead V4, Lead V5, and Lead V6. In some embodiments, the device is configured to sense and/or display ten leads comprising any ten of Lead I, Lead II, Lead aVR, Lead aVL, Lead aVF, Lead V1, Lead V2,

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Lead V3, Lead V4, Lead V5, and Lead V6. In some embodiments, the device is configured to sense and/or display eleven leads comprising any eleven of Lead I, Lead II, Lead aVR, Lead aVL, Lead aVF, Lead V1, Lead V2, Lead V3, Lead V4, Lead V5, and Lead V6. In some embodiments, the device is configured to sense and/or display twelve leads comprising any twelve of Lead I, Lead II, Lead aVR, Lead aVL, Lead aVF, Lead V1, Lead V2, Lead V3, Lead V4, Lead V5, and Lead V6. In some embodiments, the device includes software configured to cause a processor of said device to analyze the sensed electrocardiogram. An analysis of a sensed electrocardiogram performed by the processor of the device identifies the presence of an abnormal heart condition. For example, an analysis performed by a processor of a device, in some embodiments, identifies arrhythmias by, for example, analysis of the PQRST waveform and/or comparing multiple PQRST waveforms within an electrocardiogram. In some embodiments, the processor carries out an analysis of an electrocardiogram by comparing one or more PQRST waveforms of an individual against a one or more PQRST waveforms of other individuals from a database containing electrocardiograms of other individuals. In some embodiments of the devices described herein, an individual is alerted to sense an electrocardiogram by, for example, engaging one or more electrodes when the device senses one or more physiologic parameters. For example, in some embodiments, a device as described herein is configured to sense a blood pressure of an individual, and in some of these embodiments, the device is configured to sense a second physiologic parameter of the individual such as for example a heart rate. An accelerated heart rate of an individual sensed by the device in addition to, for example, a low blood pressure of the individual concurrently sensed by the device, triggers the processor of the device to indicate to the individual to engage with the electrodes of the device in order to sense an electrocardiogram.

The combination of a sensed accelerated heart rate and low blood pressure typically indicate an abnormality, however, other physiologic conditions may also produce an elevated heart rate accompanied by low blood pressure including, for example, dehydration. Thus, in some embodiments, accuracy is enhanced when physiologic parameters such as, for example, heart rate, blood pressure, oxygen saturation, and temperature are compared to baseline values of the individual or to a data from a database containing the physiological parameters of other individuals. Some elite athletes, for example, have physiologic parameter values that would be abnormal in another individual such as, for example, very low heart rates or increased heart rate variability (e.g. during a period of exercise).

A device as described herein is in some embodiments configured to sense a photophletysmogram of an individual. A photopletysmogram, for example, provides cardiac cycle information and may, for example, be analyzed by a processor of a device described herein to determine a presence of a premature ventricular contraction.

In some embodiments, a device as described herein is configured to sense a pulse oxygenation of an individual. A device as described herein is configured to sense a pulse oxygenation of an individual in some embodiments.

Analysis

In some embodiments, a device as described herein is configured to sense and/or analyze a number of additional physiologic parameters. Non-limiting examples of parameter values sensed and/or analyzed by the devices and systems described herein include heart rate, activity level, blood pressure, temperature, pulse oxygen, and heart rate variability. Analysis includes in some embodiments the comparison of a first sensed physiologic parameter to a second sensed physiologic and determining if a discordance exists between the first and second sensed parameter values.

In some embodiments, a device as described herein is configured to monitor for arrhythmia in an individual, wherein monitoring may comprise the identification of onset of an arrhythmia. In some embodiments, cardiac monitoring carried out by the devices described herein comprises, for example, monitoring for the presence or onset of arrhythmia in an individual who has not previously been identified to have an arrhythmia. In some embodiments, cardiac monitoring carried out by the devices described herein comprises the identification of onset of a known or suspected intermittent arrhythmia. In some embodiments, the devices described herein are configured to predict an onset of an arrhythmia in an individual. The onset of an arrhythmia is, for example, predicted due to a sudden and significant shift in the value of a sensed physiologic parameter such as heart rate. A prediction of arrhythmia is more accurate when two or more physiologic parameters are concurrently sensed and analyzed with respect to one another. For example, sensing of heart rate changes with respect to a sensed activity level provides contextual information for the sensed heart rate.

A subset of arrhythmias are sometimes termed tachyarrhythmias. Tachyarrhythmias typically comprise a tachycardic heart rate which may comprise a heart rate above 100 beats per minute. Tachyarrhythmias may comprise, for example, certain types of atrial fibrillation and supraventricular tachycardia. In some embodiments, the devices as described herein are configured to identify the presence or onset of a tachyarrhythmia, such as, for example, atrial fibrillation or supraventricular tachycardia. In some embodiments, the devices as described herein are configured to identify the presence or onset of a tachyarrhythmia. In some embodiments, the devices as described herein are configured to predict the onset of a tachyarrhythmia.

In some embodiments, the devices as described herein are configured to provide continuous cardiac monitoring. In some embodiments, the devices as described herein are configured to provide continuous cardiac monitoring for a period of up to one year. In some embodiments, the devices as described herein are configured to provide continuous cardiac monitoring for a period of up to 12 months. In some embodiments, the devices described herein are configured to provide continuous cardiac monitoring for a period of up to 6 months. In some embodiments, the devices described herein are configured to provide continuous cardiac monitoring for a period of up to 3 months. In some embodiments, the devices described herein are configured to provide continuous cardiac monitoring for a period of up to 1 month. In some embodiments, the devices described herein are configured to provide continuous cardiac monitoring for a period of up to 2 weeks. In some embodiments, the devices described herein are configured to provide continuous cardiac monitoring for a period of up to 1 weak. In some embodiments, the devices described herein are configured to provide continuous cardiac monitoring for a period of up to 72 hours. In some embodiments, the devices described herein are configured to provide continuous cardiac monitoring for a period of up to 48 hours. In some embodiments, the devices described herein are configured to provide continuous cardiac monitoring for a period of up to 24 hours. In some embodiments, the devices described herein are configured to provide continuous cardiac monitoring for a period of up to 12 hours. In some embodiments, the devices

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described herein are configured to provide continuous cardiac monitoring for a period of up to 8 hours. In some embodiments, the devices described herein are configured to provide continuous cardiac monitoring for a period of up to 4 hours. In some embodiments, the devices described herein are configured to provide continuous cardiac monitoring for a period of up to 2 months.

In some embodiments, the devices described herein are configured to provide intermittent cardiac monitoring. In some embodiments, intermittent cardiac monitoring is initiated in response to one or more sensed parameter values. Non-limiting examples of the one or more sensed parameter value that may cause initiation of intermittent cardiac monitoring may comprise, for example, a heart rate of an individual, a blood pressure of an individual, an activity level an individual, a temperature of an individual, a pulse oximetry of an individual, or any other sensed biometric parameter of an individual. In some embodiments, an electrocardiogram of an individual may be sensed in response to one or more sensed parameters. For example, an electrocardiogram may be caused to be sensed in response to a heart rate value.

In some embodiments, one or more continuous sensors may sense one or more parameters that cause the initiation of intermittent cardiac monitoring by one or more sensors. In some embodiments, a heart rate of an individual is sensed continuously. In some embodiments, an activity level of an individual is sensed continuously. In some embodiments, a heart rate variability of an individual is sensed continuously. In some embodiments, an electrocardiogram of an individual is sensed intermittently. In some embodiments, an intermittently sensed electrocardiogram is caused to be sensed in response to a continuously measured heart rate of an individual. In some embodiments, an intermittently sensed electrocardiogram is caused to be sensed in response to an activity level of an individual. In some embodiments, an intermittently sensed electrocardiogram is caused to be sensed in response to both a continuously measured heart rate and a continuously measured activity level. In some embodiments, an intermittently sensed electrocardiogram is caused to be sensed in response to a continuously sensed heart rate, a continuously sensed activity level, and a continuously sensed heart rate variability.

In some embodiments, a device or system as described herein comprises one or more sensors configured for continuous cardiac monitoring. In some embodiments, a device or system as described herein comprises one or more sensors configured for intermittent cardiac monitoring. In some embodiments, a device or system as described herein comprises one or more heart rate sensors, which may, for example, comprise a photosensor. In some embodiments, a device or system as described herein comprises one or more activity level sensors, which may, for example, comprise an accelerometer or a gyroscope. In some embodiments, a device or system as described herein comprises one or more electrocardiogram sensors, which may, for example, comprise one or more electrodes. Non-limiting examples of other sensors suitable for use with the devices, systems, and methods described herein further comprise blood pressure sensors, temperature sensors, and pulse oximetry sensors.

In some embodiments, a device or system as described herein comprises a processor. In some embodiments, a process is coupled with one or more sensors that are configured to sense continuously and one or more sensors that are configured to sense intermittently. In some embodiments, a processor is configured to receive parameter values from one or more sensors. In some embodiments, a processor is configured to activate one or more sensors or to initiate the sensing of a parameter value. In some embodiments, a processor is configured to analyze a parameter value. In some embodiments, a processor is configured to compare a first parameter value with a second parameter value. In some embodiments, a first and a second parameter value to be compared are simultaneously or essentially simultaneously sensed.

In some embodiments, a device or system as described herein further comprises software in the form of a program or application. In some embodiments, the program or application may be configured to cause a processor to carry out one or more functions. In some embodiments, the program or application may be configured to cause a processor to receive parameter values from one or more sensors. In some embodiments, the program or application may be configured to cause a processor to activate one or more sensors or to initiate the sensing of a parameter value. In some embodiments, the program or application may be configured to cause a processor to analyze a parameter value. In some embodiments, the program or application may be configured to cause a processor to compare a first parameter value with a second parameter value. In some embodiments, a first and a second parameter value to be compared are simultaneously or essentially simultaneously sensed.

In some embodiments, the devices described herein are configured to carry out an analysis, wherein the analysis is performed by a processor. In some embodiments, an analysis of one or more parameter values carried out by the devices described herein comprises a comparison of a sensed parameter value to a threshold or range. For example, an analysis may comprise determining whether a sensed heart rate value falls within one or more ranges. For example, in some embodiments, a sensed heart rate may be determined to be within a heart rate range comprising a range between 60-100 beats per minute. For example, in some embodiments, a sensed heart rate may be determined to be in a heart rate range comprising a range of values less than 60 beats per minute. For example, in some embodiments, a sensed heart rate may be determined to be within a heart rate range comprising a range of values above 100 beats for minute.

In some embodiments, an analysis of one or more parameter values carried out by the devices described herein comprises a comparison of a first sensed parameter to a second sensed parameter. For example, in some embodiments, a heart rate value is compared to a sensed activity level of an individual.

In some embodiments, a first sensed value is compared to a second sensed value, and it is determine whether a discordance exists between the two values. For example, in some embodiments, an elevated heart rate value would be expected to be present during a period of elevated activity, thus an elevated heart rate and an elevated activity level that are simultaneously sensed would not be found to be in discordance with one another.

A discordance may be identified when a first sensed parameter value would not be expected to coincide with a second sensed parameter value. For example, an elevated heart rate value would not be expected to be present with a normal or resting activity level and thus the two values are in discordance with one another. For example, in some embodiments, when a heart rate sensor senses a heart rate above 100 beats per minute and a simultaneously sensed activity level is determined to be a resting activity level, an analysis of the two sensed values determines that they are in discordance with one another.

In some embodiments, an analysis carried out by the devices and systems described herein comprises the deter-

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mination of an increase in a heart rate variability. In some embodiments, an analysis carried out by the devices and systems described herein comprises comparing a heart rate variability with one or more sensed parameter values. For example, in some embodiments, a heart rate variability is compared to concurrently or essentially concurrently sensed heart rate and activity level values.

In some embodiments, an analysis carried out by the devices and systems described herein comprises the prediction of or the identification of the initiation of an arrhythmia using an identified discordance as described herein. In some embodiments, a discordance comprising a simultaneously or essentially simultaneously sensed elevated heart rate and resting or normal activity level is determined to indicate the imminent initiation of an arrhythmia or the presence of an arrhythmia. In particular, because the heart rate is elevated, the arrhythmia with this type of discordance typically comprises a tachyarrhythmia.

In some embodiments, a simultaneously sensed increase in heart rate variability, an elevated heart rate, and a resting or normal activity rate is determined to indicate the future onset or presence of atrial fibrillation. In some embodiments, a sensed increased heart rate variability, normal resting heart rate, and resting or normal activity rate may also be determined to indicate the future onset of or the presence of atrial fibrillation. In some embodiments, a simultaneously sensed decrease in heart rate variability, an elevated heart rate, and a resting or normal activity rate is determined to indicate the future onset or presence of supraventricular tachycardia. In some embodiments, when an arrhythmia is determined to be imminent or present, an electrocardiogram is recorded. In some embodiments, an individual is instructed or signaled by a cardiac monitoring device or system described herein to engage one or more electrodes in order to sense in electrocardiogram. In some embodiments, one or more electrodes may be positioned on a surface of a cardiac monitoring device so that the individual may, for example, comfortably engage a first electrode with a skin surface of a first extremity while simultaneously engaging a second electrode with a skin surface of a second extremity. In some embodiments, one or more electrodes may be affixed to an individual's body and are automatically engaged to sense an electrocardiogram by a cardiac monitoring device or system when an arrhythmia is determined to be imminent or present in the individual. For example, a first electrode may be positioned on smartwatch worn by the individual on a first extremity and a second electrode may be positioned on a wristlet worn by the individual on a second extremity. In this example, the first electrode on the smartwatch and the second electrode on the wristlet are both in communication with and controlled by the cardiac monitoring device.

In some embodiments, the devices described herein are configured to carry out machine learning. In some embodiments, the devices, systems, and methods described herein comprise machine learning algorithms which analyze parameter values sensed from an individual over period of time. In some embodiments, the devices, systems, and methods described herein comprise machine learning algorithms which analyze parameter values sensed from a plurality of individuals. In some embodiments, a machine learning algorithm causes the devices, systems, and methods described herein to more accurately identify or predict the presence of an arrhythmia in a given individual. For example, in some embodiments, sensed electrocardiogram data may be compared back to parameter values such as, for example, sensed heart rates and activity levels that triggered the sensing of said electrocardiograms. When, for example, sensed electrocardiograms confirm the presence of an arrhythmia, the presence of which was indicated by, for example, a discordance between other parameter values, the machine algorithm causes the device or system described herein to learn from that data. Similarly, when, for example, sensed electrocardiograms do not confirm the presence of an arrhythmia, the presence of which was indicated by, for example, a discordance between other parameter values, the machine algorithm causes the device or system described herein to learn from that data as well. That is, in some embodiments, the machine learning algorithm correlates the sensed electrocardiogram with the discordance between parameter values that caused it (i.e. the electrocardiogram) to be sensed. The presence or absence of an arrhythmia on the electrocardiogram either respectively reinforces the correlation of an arrhythmia with the discordance that caused the electrocardiogram to be sensed or contradicts the presence of a correlation of an arrhythmia with the discordance. For example, when a heart rate of 110 is sensed and simultaneously a resting activity is sensed, an electrocardiogram is caused to be sensed, and when the sensed electrocardiogram does not indicate a presence of an arrhythmia the machine learning algorithm causes the device or system as described herein to learn that for that individual a heart rate of 110 at rest does not necessarily indicate a presence of an arrhythmia. In some embodiments, the machine learning algorithm continues to cause the storing of parameter value data, such as, for example, heart rate, activity level, and heart rate variability, and compare the parameter values to the associated electrocardiogram data over time. Thus, in some embodiments, with multiple parameter values sensed over time and compared to associated electrocardiogram data, a cardiac monitoring device or system improves its ability to predict or identify the onset of arrhythmia based on a discordance between parameter values for a specific individual. In some embodiments, a machine learning algorithm may obviate the need to sense an electrocardiogram when a particular discordance is present between parameter values of a specific individual, because of an extremely high likelihood of a presence or absence of an arrhythmia based on the parameter values as determined by the machine learning algorithm.

Any of the devices, systems, and methods for cardiac monitoring described herein may comprise one or more of a smartphone, a laptop or desktop computer, a smartwatch, or a tablet computer.

Discordance Monitoring

FIG. **7** shows a schematic of an algorithm for discordance monitoring. In a step **700**, a heart rate and an activity level are sensed by, for example, a device or system as described herein. In some embodiments, an activity level is sensed with a gyroscope or an accelerometer that is. Heart rate is sensed with a light based or other commonly used heart rate sensors. The device that measures the heart rate and the activity level may be the same device or more than one device. For example, a smartwatch or other wearable device may be configured to include a heart rate sensor as well as an activity level sensor.

If, as shown in a step **702**, an increased heart rate is sensed together with a normal or resting activity level, the two values are determined to be in discordance by the device or system processor. That is, the elevated heart rate does no match the sensed stable activity level. Determination of the presence of the discordance is done by a processor of either the device or system as described herein. The identified discordance may indicate the presence of an arrhythmia. As such, an ECG is caused to be sensed in a step **712**A. The step

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712A, may, for example, comprise indicating to the user through the device or system that sensed the heart rate and activity level to contact one or more electrodes of an ECG sensing device and thus sense the ECG. The ECG sensing device may be the device or part of the system used to sense the heart rate and activity level or may be a separate device. For example, a user wearing a smartwatch with heart rate and activity level monitoring receives an audible and/or visual indication from the smartwatch to sense an ECG when a discordance is present between a sensed heart rate value and a sensed activity level value. In some embodiments, the smartwatch comprises one or more electrodes and a user contacts one electrode with the left side of their body and one electrode with the right side of their body when an indication is received to do so from the smartwatch because a discordance is present thus sensing an ECG. In some embodiments, a smartphone comprises one or more electrodes and a user contacts one electrode with the left side of their body and one electrode with the right side of their body when an indication is received to do so from the smartwatch because a discordance is present thus sensing an ECG.

If, as shown in step **704**, an increased heart rate is sensed together with an increased heart rate variability, and a normal or resting activity level is sensed. The increased heart rate and HRV are in discordance with the normal or resting activity level, and a presence of a discordance is determined by the device or system processor. Once the discordance is determined, an ECG is caused to be sensed in a step **712**B as, for example, described herein with respect to step **712**A. As shown, in step **716**, this particular discordance may be indicative of the presence of atrial fibrillation and it should be confirmed with the ECG **712**B.

If, as shown in step **706**, an increased heart rate is sensed together with a decreased heart rate variability and a normal or resting activity level is sensed. The increased heart rate, decreased heart rate variability, and normal or resting activity level are in discordance with each other, and a presence of a discordance is determined by the device or system processor. Once the discordance is determined, an ECG is caused to be sensed in a step **712**C as, for example, described herein with respected to step **712**A. As shown, in a step **718**, supraventricular tachycardia may be present and it should be confirmed with the ECG of **712**C.

If, as shown in a step **708**, an increased heart rate is sensed together with an increased activity level, the device or system processor determines that no discordance is present, and an ECG is not recorded as the individual is probably exercising **714**.

If, as shown in a step **710**, a regular heart rate is sensed (e.g. 60-100 beats per minute) and an increased heart rate variability is sensed together with a normal or resting activity level. The normal heart rate, increased heart rate variability, and normal or resting activity level are in discordance with each other, and a presence of a discordance is determined by the device or system processor. Once the discordance is determined, an ECG is caused to be sensed in a step **712**D as, for example, described herein with respect to step **712**A. As shown, in a step **720**, atrial fibrillation may be present and it should be confirmed with the ECG of **712**D.

In some embodiments, a determination of the presence of a discordance is based on a comparison of two or more sensed physiologic parameters with each other. That is, for example, an elevated heart rate of 110 is compared to a resting activity level as sensed by an accelerometer which measures that the individual is traveling at 0 miles/hr. The 110 heart rate is elevated whereas the activity level of 0 miles/hr is a resting level, which indicates a discordance between the sensed heart rate and activity level. In some embodiments, a processor determines that the value of a sensed physiologic parameter is either above or below a threshold value or range of values. In some embodiments, the threshold value or range of values are deemed to be normal or resting values in the population. In some embodiments, the thresholds are specific to the biometric data of the user so that the user is, for example, age-matched or gender matched to the appropriate threshold from the general population. For example, an activity level is determined to be increased in a 70 year old user but would not be increased in a 7 year old user. Thus, a discordance is determined by qualifying if a sensed physiologic parameter is elevated, decreased, or normal (or resting) and then comparing that qualified value to a qualified value of another sensed physiologic parameter. That is, for example, a value that is qualified as either increased, decreased, or normal (or resting) is compared to a value that is also qualified as increased, decreased, or normal (or resting).

In some embodiments, there is the added step (not shown in FIG. **7**) of the devices and systems described herein running machine learning algorithms so that the threshold values and ranges used to determine whether a sensed physiologic parameter is increased, decreased, normal (or resting) are adjusted to more accurately fit the user. That is, for example, a user who was determined, through ECG, to have an arrhythmia at a heart rate of 80 will have their heart rate threshold lowered so that a heart of 85 (which is normal in some) would be determined to be an increased rate. The machine learning algorithm more accurately sets the thresholds over time so that discordances are more accurately determined resulting in more accurate (and efficient) recording of ECGs in response to the determination of the presence of the discordance.

Table 1 below presents some of the information found in FIG. **7** in table form.

TABLE 1

HR Data	Activity Level Data	HRV Data	Action
HR increases	Activity level stable		Take an ECG, possible arrhythmia
HR increases	Activity level stable	HRV increases	Take an ECG, possible atrial fibrillation
HR increases	Activity level stable	HRV decreases	Take an ECG, possible supraventricular tachycardia or ventricular tachycardia
HR increases	Activity level increases		Don't take an ECG, probable exercise
HR stable	Activity level stable	HRV increases	Take an ECG, possible atrial fibrillation

While preferred embodiments of the present individual matter described herein have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the individual matter described herein. It should be understood that various alternatives to the embodiments of the individual matter described herein described herein may be employed in practicing the individual matter described herein. It is intended that the following claims define the scope of the individual matter described herein and that methods and structures within the scope of these claims and their equivalents be covered thereby.

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What is claimed is:

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.

2. The method according to claim 1, wherein the heart rate parameter comprises an indication of a heart rate variability, and wherein the arrhythmia is atrial fibrillation.

3. The method according to claim 1, wherein the heart rate parameter comprises an indication of a heart rate variability and a heart rate value, and wherein the arrhythmia is atrial fibrillation.

4. The method according to claim 1, wherein the heart rate parameter comprises an indication a heart rate value, and wherein the arrhythmia is atrial fibrillation.

5. The method according to claim 1, wherein indicating to the user further comprises: instructing the user to record an ECG using the smartwatch.

6. The method according to claim 1, wherein the arrhythmia is selected from a group consisting of atrial fibrillation, supraventricular tachycardia, and ventricular tachycardia.

7. The method according to claim 1, wherein the heartrate parameter is a PPG signal.

8. The method according to claim 7, wherein the heart rate parameter is a heartrate variability ("HRV") value, wherein the HRV value is derived from the PPG signal.

9. The method according to claim 7, wherein the heart rate parameter is a heartrate, wherein the heartrate is derived from the PPG signal.

10. The method according to claim 1 further comprising:

displaying an ECG rhythm strip from the electric signals on the smartwatch.

11. The method according to claim 1, wherein the first electrode is located on the smartwatch in a location where the first electrode contacts a first side of the user's body while the user wears the smartwatch, and the second electrode is located on the smartwatch in a location where the user must actively contact the second electrode with a second side of the user's body opposite from the first side.

12. A smartwatch, comprising:

a processor;

a first sensor configured to sense an activity level value of a user, wherein the first sensor is coupled to the processor;

a photoplethysmogram ("PPG") sensor configured to sense a heart rate parameter of the user when the activity level value is resting, wherein the PPG sensor is coupled to the processor;

an electrocardiogram ("ECG") sensor configured to sense electrical signals of a heart, wherein the ECG sensor comprises a first electrode and a second electrode, and wherein the ECG sensor is coupled to the processor; and

a non-transitory computer readable storage medium encoded with a computer program including instructions executable by the processor to cause the processor to:

determine if a discordance is present between the activity level value of the user and the heart rate parameter of the user;

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

receive electric signals of the user from the ECG sensor to confirm the presence of the arrhythmia.

13. The smartwatch or wristlet according to claim 12, wherein the heart rate parameter comprises an indication of a heart rate variability, and wherein the arrhythmia is atrial fibrillation.

14. The smartwatch or wristlet according to claim 12, wherein the heart rate parameter comprises an indication of a heart rate variability and a heart rate value, and wherein the arrhythmia is atrial fibrillation.

15. The smartwatch or wristlet according to claim 12, wherein the heart rate parameter comprises an indication of a heart rate value, and wherein the arrhythmia is atrial fibrillation.

16. The smartwatch or wristlet according to claim 12, wherein indicating to the user further comprises: instructing the user to record an ECG using the ECG sensor.

17. The smartwatch or wristlet according to claim 12, wherein the arrhythmia is selected from a group consisting of atrial fibrillation, supraentricular tachycardia, and ventricular tachycardia.

18. The smartwatch according to claim 12, wherein the heart rate parameter is a PPG signal.

19. The smartwatch according to claim 18, wherein the heart rate parameter is a heartrate variability ("HRV") value, wherein the HRV value is derived from the PPG signal.

20. The smartwatch according to claim 18, wherein the heart rate parameter is a heartrate, wherein the heartrate is derived from the PPG signal.

21. The smartwatch according to claim 12, the processor further to: display an ECG rhythm strip from the electric signals.

22. The smartwatch according to claim 12, wherein the PPG sensor is located on a back of the smartwatch.

23. The smartwatch according to claim 12, wherein the first electrode is located on the smartwatch where the first electrode contacts a first side of the user's body while the user wears the smartwatch, and the second electrode is located on the smartwatch where the user must actively contact the second electrode with a second side of the user's body opposite from the first side.

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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 13,976 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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