Nos. 23-1509, -1553

IN THE

United States Court of Appeals for the Federal Circuit

ALIVECOR, INC.

Appellant,

v.

INTERNATIONAL TRADE COMMISSION

Appellee,

APPLE INC.,

Intervenor.

APPLE INC.,

Appellant,

v.

INTERNATIONAL TRADE COMMISSION

Appellee,

ALIVECOR, INC.

Intervenor.

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

NON-CONFIDENTIAL OPENING AND RESPONSE BRIEF OF INTERVENOR–CROSS-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 Claims 16 and 17

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.

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.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 23-1509, -1553

Short Case Caption AliveCor, Inc. v. International Trade Commission

Filing Party/Entity Apple Inc.

Instructions:

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

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

Date: 08/07/2023

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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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, 20-21, 25, 32-34, and 36-43. 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.

TABLE OF AUTHORITIES

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Cases

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Other Authorities

STATEMENT OF RELATED CASES

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 three asserted patents unpatentable. *See AliveCor, Inc. v. Apple Inc.*, No. 23-1512. This Court has designated that appeal as a companion case to this appeal. *See* Order, No. 23-1509, Dkt. 25 (Apr. 25, 2023).

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, 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 the Commission's finding of a violation and issuance of remedial orders.

STATEMENT OF JURISDICTION

The Commission had jurisdiction 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. Dkt. 1-2. 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. No. 23-1553, Dkt. 1-2. 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 substantial evidence supports the Commission's finding that Apple Watch does not infringe patent claims requiring the device to "alert [the] user to record an electrocardiogram," when Apple Watch instead alerts users to "talk to [their] doctor."

4. 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.

5. Whether the Commission properly held claims patent-ineligible when they were directed to a known diagnostic process, implemented on generic technology.

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

This case involves 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. 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 heart rate and heart-rate variability. Appx497-498.

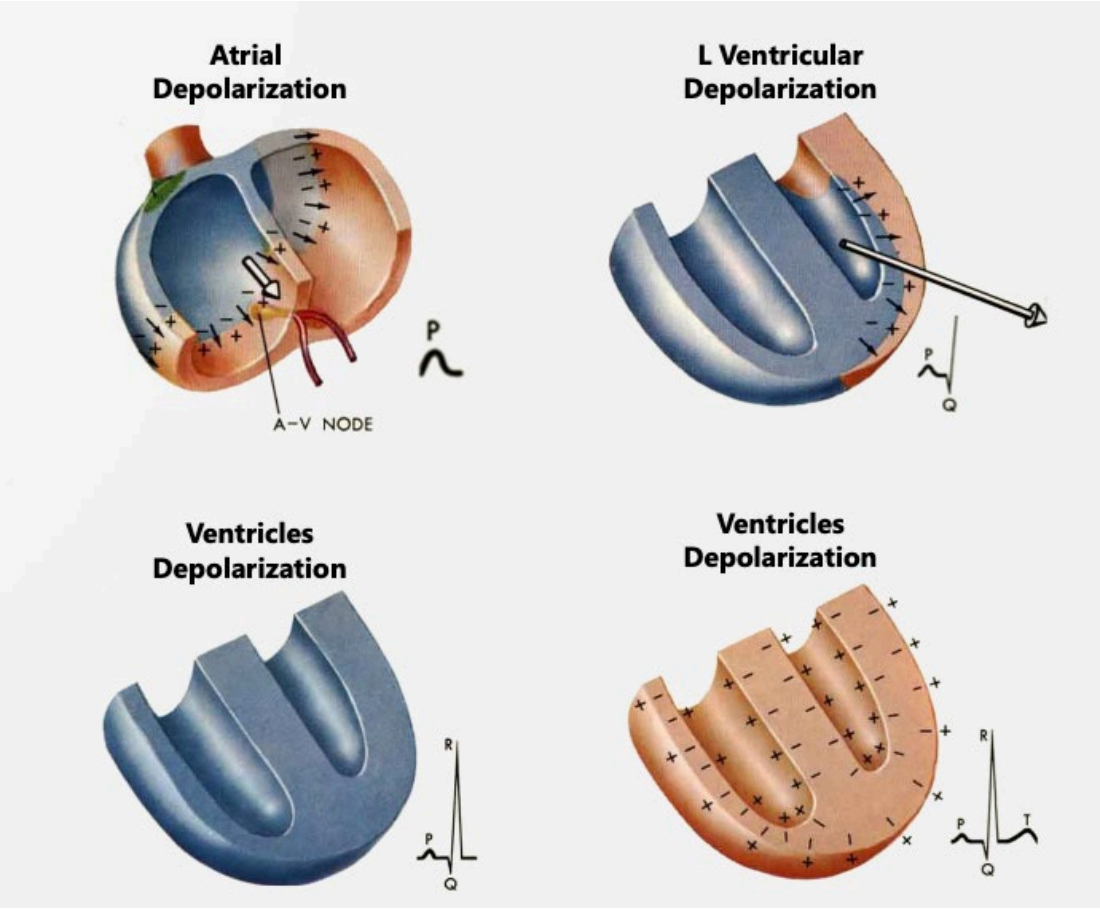
Beginning with the Series 3 model released in 2017, Apple Watch has also included the "High Heart Rate Notification" feature, or "HHRN." Appx12206; Appx30744-30745. If the Background Heart Rate measurement exceeds a user-set threshold while the user seems inactive (as measured by the Watch's accelerometer), 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. Electrocardiograms use 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 (called "depolarization") occurs—and the corresponding ECG measurement—is depicted below:

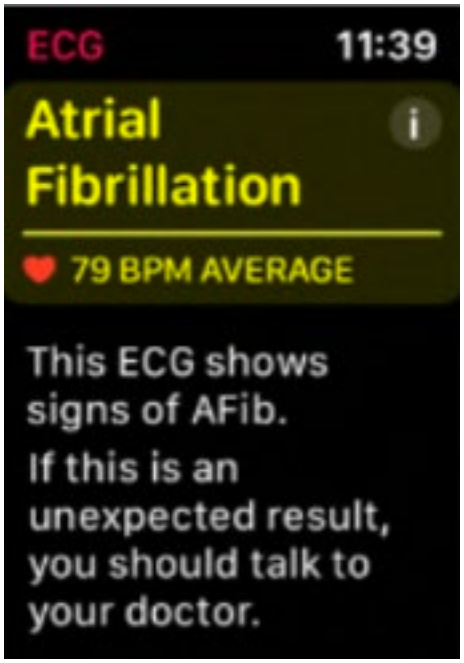


Appx12114. The P wave (top left) corresponds to current flow that depolarizes the atria (causing contraction), while the "QRS complex"—reflected in the spike shown in the bottom graphics—corresponds to current flow that depolarizes the ventricles (again causing contraction). Appx31065-31068. An ECG can reveal abnormal electrical activity (or "arrhythmias") in the heart, which can manifest 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:

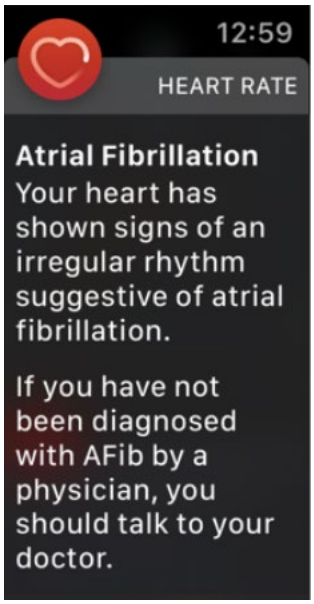
Appx11750. The electrical sensors then acquire ECG signals, which are visually represented on the Watch face. Appx725. The ECG app analyzes the acquired data and tells the user whether it shows a sinus rhythm (normal), a low or high heart rate, atrial fibrillation, atrial fibrillation with high heart 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":

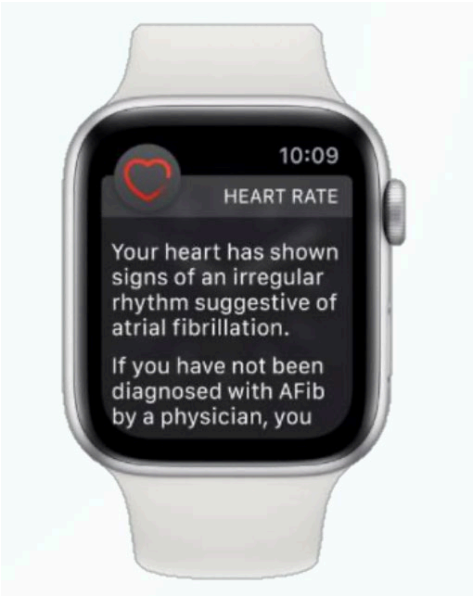


Appx11421.

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 a 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 sensor. 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 results, 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.

Based on data from users that opt in to sharing data, Apple estimates that more than 10 million Americans have IRN activated on their Apple Watch, and a similar number have enabled the ECG app on their Apple Watch. 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.

AliveCor Develops But Then Abandons 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 KardiaMobile, which received FDA clearance in 2012. Appx30062. KardiaMobile, pictured below, is a standalone ECG sensor 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 version the shape and size of a credit card, are AliveCor's current commercial products. Appx30100. But KardiaMobile is not at issue here. 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 a KardiaBand, which contained a built-in ECG sensor:

Appx11676 (annotations added). Using the sensor 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 Watch to continually 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 in December 2018. Appx1375. Apple had updated the algorithms that process PPG signals and output heart-rate data for exercise sessions, resulting in "substantially better accuracy." Appx30748-30749. Contrary to AliveCor's conjecture, this change was not made to "kill[]" KardiaBand (or other third-party apps), Opening Br. ("OB") 1, 17-18, but to "improve [Watch's] workout app." Appx30748-30749; *see* Appx30863. 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 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 "[Confidential product information]" to be a [Confidential product information] by [Confidential product information] for [Confidential product information]. Appx30093. At the time AliveCor filed its complaint, [Confidential product information] "did not exist in any hardware-sense." Appx245. By the time of expert discovery, "[Confidential product information]

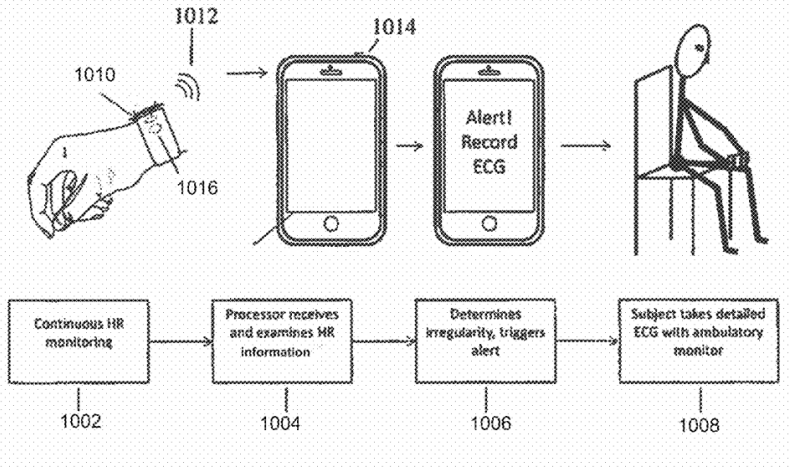
Confidential product information [redacted]" Appx153-154; *see* Appx1241-1242. Even today, Confidential product information [redacted] is not on the market. Nor is AliveCor's other supposedly forthcoming product, as discussed below (at 20-21). OB19.

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 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 U.S. Patent No. 9,572,499, issued in February 2017, and U.S. Patent No. 10,595,731, 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, 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 heart rate. Appx10060 2:30-41 (mentioning Google Glass and 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, but it specifies that the watch includes a PPG sensor, an "ECG sensor, comprising two or more ECG electrodes," a display, and a processor with instructions to first "detect, based on the PPG data, the presence of an arrhythmia," and then "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 similar to that claimed by the '731 patent. 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.). Unlike the usual case, this Commission investigation did not begin contemporaneously with that filing. Instead, three months later, AliveCor contracted with Description of third party Third party [redacted] to Confidential product information [redacted] a product consisting of an Confidential product information [redacted] smartwatch with PPG, motion, and ECG sensors. Appx30384-30385; Appx30672; Appx10106; Appx10120-10125; Appx11982-11983. Third party [redacted] provided a "reference design" (which it later updated) for other manufacturers to produce under their own labels. Appx30091; Appx10108-10119; Appx30482-30486; Appx154-157; *compare* Appx11795 *with* Appx11796. Shortly thereafter,

in April 2021, AliveCor filed the complaint that led the Commission to begin this proceeding, making the same infringement assertions as it had in district court and seeking to exclude Apple Watch from importation into the United States. Appx363-395. The district court litigation is stayed pending resolution of the Commission proceeding. *See* Appx1220. Meanwhile, despite a promised ship date of "late 2021 or early 2022," Appx10122, neither AliveCor nor [Third party] has [Confidential product information] any [Confidential product information] to [Confidential product information] the [Confidential product information], nor have they begun discussions with [Third party] related to the product. Appx756; Appx31013; Appx30156; Appx10508; Appx10519.

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 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. Contrary to AliveCor's suggestion (OB30), the ALJ rejected the assertion that a domestic industry in [Confidential product information] or the [Third party] design was "in

the process of being established." While the ALJ found that those products would meet the "technical prong" of the domestic-industry requirement, Appx161-166, Appx218-219, Appx245-246, it concluded that AliveCor "has not shown a domestic industry is 'in the process of being established'" for those products. Appx259; Appx290. Given AliveCor's "uncertain" plans for those products and the unreliable financial evidence it submitted, the ALJ rejected AliveCor's attempt to rely on them to show a domestic industry. Appx290-293.

The ALJ found the domestic-industry requirement satisfied for KardiaBand, however, despite acknowledging that its analysis was "troubling." Appx288-289. Although AliveCor discontinued KardiaBand in 2019, the ALJ in 2022 found an "exist[ing]" domestic industry related to that product. Appx259. The ALJ rejected most of AliveCor's evidence as "not reliable," Appx264, but seized on two tabs of a single spreadsheet showing "payments made to R&D contractors," which the ALJ "accepted" despite AliveCor's failure to link those payments to KardiaBand. Appx281-282.

The ALJ reached a split outcome on infringement. As to the '499 patent, the ALJ found no infringement because Apple Watch does not

"alert" a user to record an ECG. Appx243-244. AliveCor accused IRN of performing this function when it notifies a user showing signs of atrial fibrillation to "talk to [their] doctor." As found by the ALJ and shown in the image above (at 11), "[t]his is not an alert for the user to take an ECG; it is an alert for the user to see their doctor." Appx243-244.

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. *See* Appx30891-30894; Appx12065. Yet the ALJ found that the accused Apple Watches meet the claim limitations requiring executable instructions that "detect" "an arrhythmia" and then "confirm" "the arrhythmia" using ECG data. The ALJ found infringement simply because an Apple Watch user can both receive a PPG-based notification (from HHRN or IRN) and take an ECG reading, and that each operation may detect an arrhythmia. Appx148-150; Appx213-214.

The ALJ's application of § 101 was similarly split. At *Alice* Step One, the ALJ found all asserted claims directed to ineligible subject matter. Appx167-177; Appx219-221; Appx250-252. And it held that a generic machine-learning algorithm did not provide an inventive

concept at Step Two for '499 patent claim 17. Appx250-252. For the remaining asserted claims, however, the ALJ concluded that reciting a "smartwatch" or a particular arrangement of sensors on a smartwatch was enough to confer patent-eligibility. Appx167-177; Appx219-221; Appx250-252.

As to validity, the ALJ found a "strong" prima facie case of obviousness for most asserted claims (including all independent claims). Appx177-203; Appx221-233; Appx252-256. But the ALJ found this showing overcome by indicia of: KardiaBand's commercial success (though it acknowledged its "profitability is not clear"); industry praise "focus[ed] on" KardiaBand's ECG functionality that was "[a]dmittedly … not … unqualified"; and "not especially impressive" "circumstantial[]" evidence of purported copying. Appx200-203.

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 agreed with the ALJ's overall finding of a violation of Section 337 with respect to the '941 and '731 patents but not with respect to the '499 patent, but it modified some of the underlying reasoning. Appx3. The Commission held both asserted claims of the '499 patent (not just claim 17) ineligible under § 101, though it concluded that the '941 and '731 patent claims would survive at either *Alice* step. Appx31-40. Over the Chairman's dissent, the Commission affirmed the ruling that secondary considerations overcome the prima facie case of obviousness, though it excluded commercial success from the analysis. Appx44-45.

The Commission agreed with the ALJ that "AliveCor failed to establish the economic prong of the domestic industry requirement as to a domestic industry in the process of being established." Appx11. But it also agreed that AliveCor had shown an existing domestic industry based on the lone spreadsheet of contractor payments. Appx18-19. While the Commission elsewhere recognized that any expenses needed to be tied to KardiaBand—the only domestic-industry product—it inexplicably considered all $[redacted] (Dollar amount) in payments despite most of that amount 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 issued a limited exclusion order and a cease and desist order directed to the accused Apple Watches. Appx49-52. The Commission acknowledged the "numerous ongoing studies related to heart diseases using the Apple Watch," but suggested that the studies, which are still enrolling participants, would not need any additional Apple Watches. Appx71. The Commission also noted the "health, wellness, and safety features" Apple Watches provide to consumers but 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. Appx70-73.

The Commission did agree to suspend its remedial orders, however. While this Investigation was proceeding, Apple sought inter partes review of AliveCor's patents before the Patent Trial and Appeal

Board. Shortly 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 as to the '941 and '731 patents and its entry of remedial orders. The Court should affirm the Commission's finding of no violation as to the '499 patent.

I. 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 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.

II.A. The Commission erred in finding infringement of the '941 and '731 patents 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.

II.B. Substantial evidence supports the Commission's conclusion that Apple Watches do not infringe the '499 patent claims, which require a device programmed to "alert" the user "to record an electrocardiogram." As the Commission found, Apple Watch's IRN notification is an alert for the user to speak to their doctor, which is

neither the same as nor equivalent to an alert to "record an electrocardiogram." This is not, as AliveCor suggests, a question of construing the claim term "alert," but a factual question about the content of the alert. And the Commission properly rejected AliveCor's evidence as "irrelevant" because none of it suggests that Apple Watch itself alerts the user to take an ECG, as the claims demand.

II.C. The Commission erroneously held that AliveCor's patent claims are not obvious. It upheld a handful of dependent 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 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."

II.D. The Commission correctly determined that the asserted claims of the '499 patent are not patent-eligible. The claims are directed to the abstract concept of performing a well-known diagnostic

process, and they implement this abstract idea using generic hardware to collect and analyze "heart rate data (of any kind)" and "activity level data (of any kind)." Appx37-38. The claims contain nothing to transform this abstract idea into a patent-eligible application. AliveCor's argument to the contrary ignores both the claim language and the record evidence demonstrating that the components and combination of the '499 patent claims were conventional.

III. 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 and patent eligibility are both questions of law with underlying factual issues. *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1368 (Fed. Cir. 2018). 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 the "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 Confidential product information [redacted] or the Confidential product information [redacted], given AliveCor's lack of progress and "unclear" future intent for developing them. Appx11; Appx289-293.[1] 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 Confidential product information [redacted] Confidential product information [redacted] or [redacted] products. Appx264-265. And the numbers AliveCor offered were compiled by its founder, Dr. Albert, "solely from memory."

[1] AliveCor has not appealed that finding and cannot now dispute the Commission's finding of a domestic industry based on KardiaBand alone. *See, e.g.*, Appx19 n.17.

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.

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.[2] The Commission plucked two tabs of data from a spreadsheet to find that $[redacted] (Dollar amount) 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

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

tabs. Appx281-282; Appx16-17. And the $[redacted] (Dollar amount) of payments drawn from these tabs includes more than $[redacted] (Dollar amount) that plainly relates to [redacted] (Confidential product information), 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] (Dollar amount), over five years, amounts to a "substantial" investment for a company whose revenues across the same five-year period totaled $[redacted] (Dollar amount). Appx11929 (Total Revenue, 2016 through 2020). *Infra* Part I.C.

If that is enough to constitute a domestic industry, then the 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. That outcome would not only be contrary to Section 337, it would threaten the constitutionality of the Commission's proceedings. Without the critical role of protecting "an industry in the United States," 19 U.S.C. § 1337(a)(2), the Commission's resolution of patent-infringement disputes without a jury would likely be in violation of the

Seventh Amendment. *See Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1379 (2018) (reserving ruling on "whether other patent matters, such as infringement actions, can be heard in a non-Article III forum").[3] This Court should not permit the 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."[4] *See,*

[3] Apple reserves the right to raise this and other constitutional challenges directly at a future point in this litigation.

[4] The Commission used this "system" terminology because AliveCor's KardiaBand accessory and associated software do not, by themselves,

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 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. It simply stated, without citation, that AliveCor's "continuing R&D investments" in potential

practice the asserted patent claims; they require Apple Watch to do so. Appx111; Appx152-157; Appx214-215; Appx245.

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

The Commission did not explain how research into [redacted] (Confidential product information), a potential product that still does not exist, could benefit any remaining users of 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).[5]

But the issue here is not simply that AliveCor's spending happened before the complaint was filed. It is that most of AliveCor's spending related to something other than the domestic-industry product. And qualifying investments must be made "with respect to the articles protected by the patent." 19 U.S.C. § 1337(a)(3). The Commission's seeming attempt to analogize this case to *Marine Sonar* by citing AliveCor's ongoing customer-service expenditures is therefore irrelevant. *See* Appx17. Even if that limited spending could justify counting pre-complaint spending on KardiaBand,[6] it does not justify counting pre-complaint spending on other products.

The Commission adhered to this statutory requirement—and properly excluded the $[redacted] (Dollar amount) linked to [redacted] (Confidential product information)—when it analyzed whether AliveCor had shown "significant employment of labor

[5] *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).

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

Confidential product information

or capital" under § 1337(a)(3)(B). The ALJ found that "removing [redacted] investment is proper" and so limited AliveCor's spend on "contractor R&D amounts" to $[redacted] (Dollar amount) for 2017 and $[redacted] (Dollar amount) for 2018. Appx271-272; Appx23. But it took the opposite approach under subsection (C), *including* the exact same $[redacted] (Dollar amount) in [redacted] (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 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 domestic-industry "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.

To establish a domestic industry under subsection (C), a complainant 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 establish this nexus for the Dollar amount $[redacted] of expenses that supported the Commission's domestic-industry finding. Indeed, as the ALJ observed, AliveCor's expert "made clear he conducted no analysis 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," "Confidential product information," or "Confidential product information." Appx11717-11718. Some descriptions suggest the absence of any link, indicating expenses related to Confidential product information, for example, or Confidential product information. 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"). But here, the ALJ found a

nexus simply 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 "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 $[redacted] (Dollar amount) 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 this amount would qualify as a "substantial investment" in exploiting the asserted patents. If the Court believes that $[redacted] (Dollar amount) is the correct number, therefore, a remand is required at a minimum for the Commission to address that question.

But no remand is necessary. Even if the Commission's $[redacted] (Dollar amount) 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 $[redacted] (Dollar amount) that AliveCor spent on domestic contractor payments from 2016 through 2020 to the $[redacted] (Dollar amount) 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. The question is whether AliveCor's qualifying domestic expenditures are themselves substantial.

The Commission offered no other basis for finding $[redacted] (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 [redacted] (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 the '941 and '731 patents.

Every asserted claim of the '941 and '731 patents 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. Appx30780. The accused Apple Watch features relying on the PPG sensor run in the background, while the ECG app uses the ECG sensor only when the user affirmatively requests it. Appx30768-30769; Appx30891-30892; Appx30894-30896; Appx30463-30464; Appx1106-1110. But the Commission found infringement by construing the claims 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. 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. When something is "confirmed," in other words, it is verified. *See* Appx436-439; Appx441-443. That plain meaning is also 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.").[7]

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

[7] Indeed, AliveCor agreed before the Patent Trial and Appeal Board (and the Board found) that "confirm" and "detect" are "discrete requirements." No. 23-1512, Appx85.

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."

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. 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; Appx10088 9:23-37; Appx10083 (Fig. 7). 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 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 sensors 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 this as "the core part of the invention"). 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 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, Apple Watch cannot infringe the asserted claims. The Commission found otherwise on the basis that Apple's PPG-based 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 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 Watch's 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 the ECG sensor's detection of cardiac electrical activity 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. No substantial evidence supports a finding of infringement under the correct claim construction.

B. The Commission correctly found no infringement of the '499 patent because Apple Watch alerts users to see their doctor, not to record an ECG.

Substantial evidence supports the Commission's finding that Apple Watch does not infringe the '499 patent. Appx243-244; Appx94-95. The asserted '499 patent claims recite executable instructions that cause a mobile computing device's processor to "alert" the user "to record an electrocardiogram using" the device. Appx10039 27:22-24, 28:9-14. But Apple Watch never alerts a user to record an ECG. Instead, as the Commission found, Apple Watch's accused IRN alert "is an alert for the user to see their doctor." Appx243. Far from being equivalent to the '499 patent claims, the IRN alert achieves a "very different" result: "a doctor's office visit where any number of procedures could occur," instead of an ECG taken with the user's mobile device. Appx244. AliveCor offers no basis to disturb these findings.

AliveCor first argues that the Commission improperly "reconstru[ed]" the term "alert" in its infringement analysis to require a "literal message" instructing the user to take an ECG, and that this "unexpected" construction prejudiced AliveCor. OB53-56.

There is no claim construction issue here. At the *Markman* stage, the Commission agreed with AliveCor that the term "alert" carried its plain and ordinary meaning and was "not limited to a message." Appx321-323. And the Commission applied that construction in its infringement analysis, assessing whether the accused devices contain any form of "alert" to the user "to take an electrocardiogram." Appx239-244. In finding that they do not, the Commission specifically rejected AliveCor's argument that claim construction was relevant to the parties' dispute. Indeed, the Commission found that the accused IRN alert is in fact a "message." Appx244. Therefore the "determination that an 'alert' is not limited to a message [was] not implicated." Appx244.

The decisive fact was instead the content of that "alert." And substantial evidence—indeed, undisputed evidence—supports the Commission's non-infringement finding because Apple Watches "alert" a user to "see their doctor," not to "record an electrocardiogram" as the

claims require. Appx243; *see* Appx94-95. As the Commission found, AliveCor's own expert "acknowledged … 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." Appx243; *see* Appx30380.

AliveCor argues that the Commission erroneously "disregarded" evidence that an IRN notification "serves as a call to action" to take an ECG. OB57. But the Commission correctly found all this evidence "irrelevant," Appx243, because none of it shows that Apple Watch includes the claimed "instructions" that cause the "processor" to "alert" the user to "record an electrocardiogram," Appx10039 27:14:24.

AliveCor cites a statement on Apple's website advising consumers they "can take an ECG at any time," including "when you receive an irregular rhythm notification." Appx13903-13904. But AliveCor's patent claims recite "instructions executable" by the mobile device's processor; statements on Apple's website are not instructions on Apple Watch. *See also* Appx30906-30907; Appx30974. Likewise, that third-party websites purportedly "encourage" users to take an ECG after receiving an IRN message, OB58-59, has nothing to do with whether Apple Watch contains the claimed instructions. And the same response

disposes of AliveCor's reliance on any information users learn when activating the IRN feature "about the deadly and elusive nature of" atrial fibrillation. OB60-61. Whether or not a user might remember this information when they receive an IRN alert and be more likely to decide to take an ECG, that does not change the nature of the IRN alert that Apple Watch's processor is programmed to provide.

Equally misplaced is AliveCor's assertion that "Apple is both aware of and derives benefit from users using IRN and ECG sequentially." OB59. AliveCor is not alleging indirect infringement, such that Apple's awareness might be relevant. *See also* Appx30467-30468 (AliveCor's expert admitting that the tracking metrics AliveCor cites "ha[ve] nothing to with the operation" of the accused device). And again, Apple's FDA clearances mandate separation between the IRN and ECG features. *See supra* 53.

AliveCor misstates the record in suggesting that "Apple intentionally designed the IRN to provide a 'trigger' for the Apple Watch's ECG functionality." OB59-60. Apple did not implement that "trigger" design. Appx30859-30863 (detailing why "[Apple] chose not to

tie [IRN and ECG app] together"); *see* OB60 n.4. Instead, as noted above (at 52-53), Apple designed the features to function independently.

AliveCor's final refuge is the doctrine of equivalents. OB62-64. But here too, substantial evidence supports the Commission's rejection of AliveCor's arguments.

The Commission found no substantial similarity because "the results" of the IRN notification and the '499 alert "are very different." Appx244. Apple's expert, Dr. Picard, testified that "the differences are substantial" because "the user who receives the notification that the arrhythmia is irregular is simply not instructed to record an ECG." Appx30907-30908. As Dr. Picard explained, a user who received an IRN notification "would read what it says, and if they have not been diagnosed with AFib, they would hopefully talk to their doctor," not take an ECG. Appx30973-30974; *see also* Appx30859-30860 (explaining that Apple "chose not to tie" IRN together with ECG app in part because of the risk that a user would rely on technology alone instead of "seek[ing] medical care").

AliveCor nonetheless argues that the "IRN alert serves a substantially equivalent purpose" of alerting a user to record an ECG,

and faults the Commission for "improperly assum[ing] that the user will only follow the literal written suggestion." OB63. But the claims say nothing about a user's actions. They recite a specific functionality of the mobile device (or smartwatch) itself. While "[t]he doctrine of equivalents does not require a one-to-one correspondence between components of the accused device and the claimed invention, … [t]he accused device must nevertheless contain *every* limitation or its equivalent." *Dolly, Inc. v. Spalding & Evenflo Cos.*, 16 F.3d 394, 398 (Fed. Cir. 1994). And AliveCor has identified nothing in Apple Watch that functions in substantially the same way and achieves substantially the same result as programming "instructions" that "cause [the] processor to … alert [the] user to record an electrocardiogram." Appx10039 27:14:24.

C. 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 AliveCor's 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 nonobviousness 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 certain 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 device recited by all the independent claims. Appx11966-11978; *see* Appx178-188; Appx232; Appx256.

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 and '499

claim 17); 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 only on the literal disclosure of the prior art.

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:

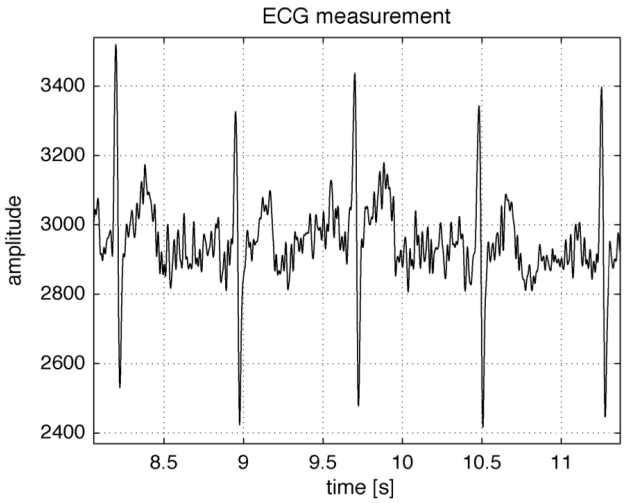


Fig. 4. AMON one lead ECG sample measurement: A digital bandpass filter [0.015 40]Hz has been applied to reduce noise. Heart rate, QT interval and QRS duration can be detected.

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; *see also* Appx30114-30115. AMON is no exception.

The Commission's reasoning focused narrowly on AMON's Figure 4, which the Commission inexplicably labeled a mere "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 both 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 goal of ensuring that high-risk cardiac patients' heart "problems will be detected in time," Appx11966, would at 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. Claim 17 of the '499 patent recites "determin[ing] a presence of said arrhythmia using a machine learning algorithm." Appx10039 28:11-14. 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; Appx257.

In both respects, the Commission improperly focused solely on what AMON literally states. 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 AMON's algorithm and provided his opinion that it rendered obvious the machine-learning claim limitations. Appx31136-31138; Appx31143-31144; *see also* Appx12184-12188; Appx12204. And AliveCor's expert, Dr. Efimov, agreed that machine-learning techniques that classify arrhythmias from heart-rate variability data (which can be derived from PPG data, *see* Appx31126) had long been known. Appx31299-31300; *see* Appx11985-11998 (2008 paper disclosing machine-learning algorithms using heart-rate variability data to identify atrial fibrillation).

The Commission faulted Apple for supposedly "not argu[ing]" that the machine-learning claims 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, and

"all of the '499 patent's Asserted Claims," Appx826-827; *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 heart-rate variability data to detect arrhythmias. Appx772-773; Appx1153; Appx1161; *see also* Appx31084-31086; Appx31081.

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 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 nonobvious because the prior-art references Apple cited—AMON as well as the Almen reference, a patent published in 2005—do not expressly

disclose these 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 skilled artisan 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.

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 nonobviousness 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 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 medical journal article 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, 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 it); 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 v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010). But the bulk of the evidence—all of which the Commission deemed circumstantial, Appx202—is irrelevant because it predates the public release of KardiaBand in November 2017. That is the earliest date Apple had access to any product found to practice the asserted claims. Although AliveCor publicly disclosed a prototype of 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 indicates that Apple had access to a version of KardiaBand with SmartRhythm before its public release. Some of those documents

plainly refer to AliveCor's earlier products—not KardiaBand. Appx11653; Appx11524. And none provides 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 already in-development 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"—"i.e., compar[ing]" one's product to others—"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 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, 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 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 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. *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 nonobviousness. *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 nonobviousness, "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 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 nonobviousness cannot stand.

D. The Commission properly held the '499 patent claims ineligible under Section 101.

In contrast to its treatment of the '941 and '731 patents, the Commission correctly determined that the asserted claims of the '499 patent, claims 16 and 17, are patent-ineligible.

As both the ALJ and the Commission recognized, the claims are "directed to" an abstract concept at *Alice* Step One: namely, performing the same diagnostic process doctors have done for decades using generic hardware. Appx249; Appx37-38; *see Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 217 (2014). And, as the Commission further concluded, the claims contain nothing to "'transform' the claimed abstract idea into a patent-eligible application" at Step Two. *Alice*, 573 U.S. at 221; *see* Appx38-40. One claim limits the abstract idea to a particular environment (a smartwatch), and the other adds a generic "machine learning algorithm" to the equation. Appx37-40. AliveCor's arguments ignore the claim language and offer no basis to disturb the Commission's ruling.

1. The claims are directed to a known diagnostic process using generic technology.

Independent claim 11, from which the asserted claims depend, recites a "system" that includes "a mobile computing device" capable of "sens[ing] an electrocardiogram," a "heart rate sensor," a "motion sensor," and programming "instructions" to calculate heart-rate variability, compare it to activity level, and "alert" the user to take an ECG. Appx10039 27:5-24. Nothing about this system reflects a

technological improvement to cardiac monitoring. Instead, the focus of the claim is the "data analysis algorithms" telling the processor to do what doctors have done for decades. Appx35; Appx37-38; Appx249. AliveCor does not dispute, and both experts agreed, that the claimed "instructions" recite a process "common in medical practice." Appx249; Appx37-38; *see* Appx31076-31079; Appx12125; Appx31295-31296. The remaining claim limitations recite "conventional components" performing their "basic functions," confirming that "[w]hat is claimed is simply a generic environment in which to carry out the abstract idea." *Yu v. Apple Inc.*, 1 F.4th 1040, 1043 (Fed. Cir. 2021).

The additional limitations of claims 16 and 17 do not change this fact. Claim 16 specifies that the "mobile computing device" is "a smartwatch." Appx10039 28:9-11. But, as the ALJ explained, "no other limitation … benefits or is affected by the computing device being in this form factor," so "this does not materially transform the claim." Appx250. And claim 17 recites a generic machine-learning algorithm, which "only deepens the connection between the claim and ineligible subject matter." Appx36-38 (quoting Appx250); *see RecogniCorp, LLC v.*

Nintendo Co., 855 F.3d 1322, 1327 (Fed. Cir. 2017) ("Adding one abstract idea … to another … does not render the claim non-abstract.").

AliveCor's arguments ignore the claim language. Unlike the '731 and '941 patents, the '499 patent claims are not limited to a "particular choice of sensors." OB42.[8] Rather than requiring a PPG sensor, for example, they provide for any "heart rate" sensor. *Compare* Appx10039 27:7 *with* Appx10072 26:30-31. The specification explains that "heart rate may be measured" in various ways, including by "electrodes," a "motion sensor," or "by imaging and lighting sources." Appx10026 2:44-48. Similarly, while the other patents require "an ECG sensor, comprising two or more ECG electrodes," Appx10072 26:32-34, the '499 patent encompasses any device "configured to sense an electrocardiogram," which may include "single-lead," "multiple lead," or even "leadless" sensors. Appx10039 27:8-11; Appx10032 13:37-41.

AliveCor now argues that claim 16 "require[s] … a single-lead ECG" because it recites a smartwatch. OB45. But AliveCor did not

[8] To streamline the issues for appeal, Apple has not challenged the Commission's eligibility ruling on the '941 and '731 patents. Apple continues to believe that all three patents claim ineligible subject matter but agrees with the Commission that the '499 patent claims are "more abstract" than the others. Appx37.

argue that to the Commission or seek a construction of claim 16 to that effect. Regardless, limiting the nature of one claimed sensor would not meaningfully change the focus of the claim.

As to claim 17, that machine-learning algorithms can improve the accuracy of arrhythmia detection, OB46, is not enough to confer patentability. *See, e.g.*, *Parker v. Flook*, 437 U.S. 584, 594-95 (1978) (claims not patentable even though use of algorithm provided a "presumably better method for calculating alarm limit values"). The '499 patent allows for "[a]ny number of machine learning algorithms or methods" analyzing a long list of variables "known in the art." Appx10030 9:1-67. And the fact that these algorithms "can be trained" (OB43) is just a statement of the concept of machine learning. *See* Appx31137.

AliveCor argues that this case is just like *CardioNet, LLC v. InfoBionic, Inc.*, 955 F.3d 1358 (Fed. Cir. 2020), which upheld the eligibility of patent claims to cardiac-monitoring devices. *See* OB40-43. But the key to subject-matter eligibility in *CardioNet* was not, as AliveCor claims, recitation of "a *specific combination* of sensors." OB42. Rather, the *CardioNet* claims recited a different form of data analysis

than a human doctor would use. 955 F.3d at 1368-71. Because the claims did not "computerize pre-existing techniques," but instead recited a "specific technological improvement," they were upheld at Step One. *Id.* at 1370.

AliveCor cannot identify any similar "specific technological improvement" in its patent claims, no matter how many times it invokes some variation of that phrase. OB2, 34, 38, 39, 40, 41, 42, 43. Nor does it articulate what "specific combination of sensors" the claims supposedly require. OB39. The claims require some form of ECG sensor on the mobile computing device (or smartwatch) but do not limit the other sensor types or locations.

The '499 patent specification makes clear that portable sensor devices were known in the art—undermining AliveCor's protestation that this conclusion was unsupported. *See* OB44. AliveCor told the Patent Office that heart-rate and motion sensors were "readily available" in portable devices, including "smart phones," "smart watches" and "wearable accessory devices" from companies like Garmin, Fitbit, Polar, New Balance, and Nike. Appx10029 7:10-17; Appx10038 25:5-16. It likewise acknowledged the existence of "ambulatory

electrocardiography devices." Appx10026 1:57; *accord* Appx10032 13:16-25. And Dr. Albert, AliveCor's founder, admitted that "we have had ECG watches since the early 1990s." Appx10235.

None of the supposed advantages identified by AliveCor changes that conclusion. *See* OB42-43, 45-46. Some are not relevant because they are not required by "the claims themselves." *Hawk Tech. Sys., LLC v. Castle Retail, LLC*, 60 F.4th 1349, 1357 (Fed. Cir. 2023). The claims do not provide for "continuous monitoring" or an "immediate[]" alert. OB42. They do not provide for any particular comparison of heart-rate variability and activity level, Appx249-250, and they do not require that any ECG data is used, let alone for a particular purpose. *Contra* OB43. They are not limited to a single-lead ECG. *Supra* 78; *contra* OB45. Furthermore, while claim 17 does invoke machine learning, it does not recite a device capable of diagnosing arrythmia "without any need for a medical professional." OB46.

Other advantages AliveCor identifies flow from the abstract diagnostic process itself, not any technological advance. Doctors already understood the value of continuous monitoring and knew to initiate ECG measurement as soon as heart-rate data indicated a

potential problem. Appx31077-31079; Appx31097. Doctors also knew that comparing "heart rate changes with" activity changes "minimizes false alarms." OB43 (quoting Appx10038); Appx31240-31241; Appx31073-31080. Even if running the diagnostic process on a smartwatch could "result in life altering consequences," that fact would "not render [the claims] any less abstract." *Univ. of Fla. Rsch. Found., Inc. v. Gen. Elec. Co.*, 916 F.3d 1363, 1367 (Fed. Cir. 2019).

2. Using standard sensors to perform routine functions is not inventive.

The claims fare no better under *Alice* Step Two. The recited sensors are standard, conventional components. *See* Appx30114-30115; Appx38-39; Appx250-251. And both parties' experts agreed that the sensor data is used by a conventional processor to perform the same analyses that doctors have long performed. Appx31076-31083; Appx31296.

Using known components for known purposes cannot render an abstract idea patent-eligible at Step Two. If "physical components behave exactly as expected according to their ordinary use," there is no inventive concept. *In re TLI Commc'ns LLC Pat. Litig.*, 823 F.3d 607, 615 (Fed. Cir. 2016); *see, e.g., CardioNet, LLC v. InfoBionic, Inc.*, No. 20-

2123, 2021 WL 5024388, at *6 (Fed. Cir. Oct. 29, 2021) (no inventive concept where conventional components perform abstract cardiac-monitoring idea).

None of the supposed inventive concepts offered by AliveCor changes this result. AliveCor does not actually identify any "unconventional arrangement of sensors and algorithmic steps." OB48. And while comparing heart-rate variability to activity level "can reduce false positives … caused by motion," OB48, that principle is a foundation of the known diagnostic process that the Commission identified as "the abstract idea itself" and therefore "cannot supply the inventive concept at step two." *ChargePoint, Inc. v. SemaConnect, Inc.*, 920 F.3d 759, 775 (Fed. Cir. 2019); *see* Appx31240-31241; Appx31073-31080.

"[A]lert[ing] the user to record an ECG when doing so is most likely to capture [useful] cardiac information," OB47-48, is also part of the previously known diagnostic approach. Appx31077; Appx31079. Moreover, as noted above (at 81), the '499 patent claims say nothing about the timing of the alert or the ECG recording. *See, e.g.*, *Two-Way Media Ltd. v. Comcast Cable Commc'ns, LLC*, 874 F.3d 1329, 1338 (Fed.

Cir. 2017) ("[T]he main problem … is that the *claim*—as opposed to something purportedly described in the specification—is missing an inventive concept."). The claims likewise do not require any particular "comparison of HRV to activity level," or recite detecting arrhythmias "without a physician present." OB48; *see* Appx37 (noting that claims allow comparison "by any means"); Appx238 (reasoning that "even … a binary comparison qualifies as comparison"); Appx10032 13:28-30 (allowing for "[c]linical or hospital based ECG recording devices").

AliveCor next argues that claim 16's "recitation of a smartwatch form factor … renders it patent-eligible" because smartwatches were not well-known devices. OB48. But the specification contradicts that argument, specifically citing "presently available smart watches" like the "Samsung Galaxy Gear Smart Watch." Appx10026 2:21-26; Appx10038 25:5-6. And the record reflects that ECG watches were known since the 1990s. Appx10235. The '499 patent says nothing new about smartwatch design, and it makes clear that the invention implements the same abstract idea whether the "mobile computing device" is the smartwatch of claim 16 or, for example, the "smartphone" recited in dependent claim 15. Appx10028 6:39-47; Appx10039 28:7-8.

Thus, the Commission correctly recognized that claim 16's smartwatch form factor is simply "the environment in which the abstract idea is carried out." Appx39. And AliveCor is wrong (OB51) that the Commission needed expert testimony to recognize the preemption risk that would flow from a contrary holding. *See, e.g.*, *ChargePoint*, 920 F.3d at 769 (addressing preemption without such evidence).

Finally, AliveCor's arguments specific to claims 16 and 17 are no more persuasive at Step Two than at Step One. The claims do not recite a "single-lead ECG sensor." OB50; *supra* 78. Regardless, AliveCor's founder conceded that single-lead ECG patches were already "popular and effective." Appx30053. AliveCor's suggestion of industry skepticism (OB51) is belied by record evidence that machine learning was used to classify arrhythmias years before the '499 patent's 2013 priority date. *See, e.g.*, Appx11985; Appx31084-31086. And, as the Patent Trial and Appeal Board observed, the skepticism AliveCor invokes related only to one machine-learning method called "deep learning," not all machine-learning methods. Appeal No. 23-1512, Appx49; *see* Appx31137; Appx15972; Appx30923.

III. Because Exclusion Of Apple Watches 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* 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: 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 concluded—contrary to all record evidence—that other available products can remedy the serious health harms that will be caused by exclusion. And second, the Commission decided—again without any record basis—that the numerous ongoing and planned research studies involving Apple Watches will not be jeopardized by exclusion. The Commission's entry of remedial orders was an abuse of discretion because the agency arbitrarily and capriciously "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. Apple estimates that 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."); Appx1586 ("Apple Watch literally saved my life."); Appx1612-1613 ("[T]hank 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 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 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 on, for example, over-the-counter "[ECG] software device[s]." 21 C.F.R. § 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 may be "inaccurate" and "may lead to ill-advised decisions about medications and treatment." Appx1391 (StopAfib.org); *see also* Appx1562. The Commission offered no basis to question the importance of FDA clearance, apart from characterizing StopAfib.org's comments on the topic 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—could address the harms caused by exclusion. 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, and neither offers many features available on Apple Watches. 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.

Regardless, ongoing supply chain issues and other logistical constraints—combined with the tremendous volume of Apple Watches subject to exclusion—would make it impossible under current conditions 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. Even Apple would currently 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. There is not a shred of support for concluding that most or all of the 2.5 million Americans who do not know they have atrial fibrillation, Appx1394—or those who will develop it—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 Apple Watch's widespread availability helps researchers collect data cost-effectively from a "large and representative" population, facilitating research that "might not otherwise be attempted, or only attempted less frequently or with smaller sample sizes." Appx1401-1404. 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 2023. This trial is designed to determine if Apple Watch's heart-monitoring features can help cardiac patients minimize the 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* would 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 as to the '941 and '731 patents as well as its issuance of remedial orders. The Court should affirm the Commission's finding of no Section 337 violation as to the '499 patent.

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