Nos. 23-1509, -1553

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,
Investigation No. 337-TA-1266

NONCONFIDENTIAL RESPONSE BRIEF OF APPELLEE INTERNATIONAL TRADE COMMISSION

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REPRESENTATIVE PATENT CLAIMS

Claim 12 of U.S. Patent No. 10,638,941 (Appx10092)

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.

Claim 1 of U.S. Patent No. 10,595,731 (Appx10072)

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.

Claims 16 and 17 (depending from claim 11) of U.S. Patent No. 9,572,499 (Appx10039)

11. A system for determining the presence of an arrhythmia of a first user, comprising a heart rate sensor coupled to said first user;

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

a motion sensor

a non-transitory computer readable medium encoded with a computer program including instructions executable by said processor to cause said processor to receive a heart rate of said first user from said heart rate sensor, sense an activity level of said first user from said motion sensor, determine a heart rate variability of said first user based on said heart rate of said first user, compare and activity level of said first user to said heart rate variability of said first user, and alert said first user to record an electrocardiogram using said mobile computing device.

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

17. The system of claim **11**, wherein said computer program further causes said processor to determine a presence of said arrhythmia using a machine learning algorithm.

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CONFIDENTIAL MATERIAL OMITTED

Pursuant to Federal Circuit Rule 25.1(e) and the Protective Order issued in the underlying investigation, Appellee, International Trade Commission, is filing a confidential version of this brief that highlights the material marked confidential, and a non-confidential version that includes appropriate redactions. In the nonconfidential version of this brief, confidential material has been deleted on pages i, ii, 4, 7, 8, 9, 10, 18, 22, 23, 24, 25, 26, 27, 28, 29, 30, and 31. The general nature of the deleted material is confidential business information of AliveCor, Inc. regarding its finances and product information.

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STATEMENT OF RELATED CASES

Other than the cases identified in the Statement of Related Cases by Appellant AliveCor, Inc. ("AliveCor" or "ALC") and Cross-Appellant Apple Inc. ("Apple") in their principal briefs, Appellee International Trade Commission ("Commission") is unaware of any other cases pending in this or any other court or agency that will directly affect or be directly affected by this Court's decision in the pending appeal.

STATEMENT OF THE ISSUES

The issues in the present appeal are properly framed as follows:

1. Whether substantial evidence supports the Commission's determination that AliveCor established a domestic industry under 19 U.S.C. § 1337(a)(3)(C) through R&D investments in AliveCor's KardiaBand.

2. Whether the Commission correctly construed the limitation "confirm the presence of the arrhythmia" in the claims of U.S. Patent No. 10,595,731 ("the '731 patent") and U.S. Patent No. 10,638,941 ("the '941 patent") and Apple does not dispute that its products infringe under the Commission's construction.

3. Whether substantial evidence supports the Commission's finding that Apple's products do not meet the "alert" limitation in the claims of U.S. Patent No. 9,572,499 ("the '499 patent").

4. Whether the Commission correctly determined that Apple failed to demonstrate that the asserted claims are obvious in view of the record evidence, including evidence of copying by Apple and industry praise for the KardiaBand System.

5. Whether the Commission correctly determined that the asserted claims of the '499 patent were directed to patent-ineligible abstract idea and otherwise lacked an inventive concept.

6. Whether the Commission abused its discretion in issuing relief with an exemption that would mitigate any harm to the public interest and in suspending its orders pending final resolution of the validity of the claims.

STATEMENT OF THE CASE

The Commission instituted the underlying investigation, based on a complaint filed by AliveCor, alleging a violation of section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337, by Apple in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain wearable electronic devices with ECG[1] functionality and components thereof by reason of patent infringement. Appx40005. Claims 1, 3, 5, 8-10, 12, 15, and 16 of the '731 patent; claims 12, 13, and 19-23 of the '941 patent; and claims 16 and 17 of the '499 patent are relevant on appeal.

[1] ECG stands for electrocardiogram.

I. TECHNOLOGY, PATENTS, AND PRODUCTS AT ISSUE

A. Technology at Issue

The technology at issue relates to wearable electronic devices for monitoring cardiac health and managing cardiac disease. Appx109. AliveCor, a California-based company, designs and develops wearable electronic devices to help diagnose serious heart conditions, such as atrial fibrillation. Appx108; Appx15; Appx371; Appx30044 (44:2-8); Appx30053-30054 (53:22-54:20).

In 2017, AliveCor released KardiaBand, the first FDA-cleared medical wristband for monitoring cardiac health with the Apple Watch. Appx11632-11643; Appx371. Development for this technology began in the late 2000s when AliveCor's founders prototyped an iPhone case that integrated ECG. Appx30054-30057 (54:24-57:20). AliveCor designed and developed KardiaBand specifically for use with the Apple Watch. Appx30101-30102 (101:13-102:1); Appx30083-30084 (83:20-84:9). KardiaBand allowed Apple Watch users to quickly and easily record an ECG on demand and obtain results using AliveCor's proprietary software, KardiaApp. KardiaApp includes two components: (1) KardiaAI, an ECG classification algorithm that determines whether a particular ECG reading showed signs of a serious heart condition such as atrial fibrillation ("AFib"); and (2) SmartRhythm, a machine learning algorithm that monitors a user's heart rate for irregular rhythms and notifies the user to record an ECG when the user is

experiencing an episode of arrhythmia such as AFib. Appx111; Appx30385-30386; Appx30132-30135; Appx30070-30071; Appx30101-30102. KardiaBand and an Apple Watch series 1-3 with Watch OS 5.0 or earlier running KardiaApp comprise the KardiaBand System ("KBS"). Appx111; Appx30064-30066.

When AliveCor released the KBS, it received praise from researchers, clinicians, and others in the industry as "a paradigm shift for cardiac care." Appx15925-15926; Appx11629-11651; Appx11999-12004; Appx12007-12015; Appx13667. Apple itself was excited about KardiaBand: one Apple employee noted KardiaBand was "a high quality accessory and works really well with the Watch." Appx16279-16280.

Apple had attempted to incorporate ECG sensors into the Apple Watch around 2013 but was unsuccessful and shelved the project. Appx40001 (45:14-20); Appx40003 (47:13-24); Appx31210-31213 (1210:17-1213:12). Not until 2017, after obtaining information about the KBS, did Apple succeed. Appx31202-31203 (1202:23-1203:5). In 2018, Apple changed its Apple Watch software, ending compatibility with AliveCor's KardiaBand and forcing AliveCor to discontinue sales of the KBS in 2019. Appx30083-30085; Appx30198-30200.

Despite discontinuing sales of the KBS, AliveCor continued to improve and develop KardiaBand for existing KBS users and for two new products, product 1 [redacted] and product 2 [redacted] that do not depend on the

Apple Watch but would continue to use AliveCor's patented technology. Appx30085-30086 (85:20-86:22); Appx12257-12263. AliveCor also continued to provide updates, enhancements, and customer support to existing KBS users. Appx30201-30202.

B. Patents and Claims at Issue

The '499 and '731 patents are directed to managing cardiac health and describe "a dashboard centered around arrhythmia or atrial fibrillation"[2] which includes a "cardiac health score" calculated in response to user data such as their ECG, other personal information, and "cardiac health influencing factors." Appx10002.

Claim 1 of the '731 patent recites a "smart watch" comprising "a photoplethysmography ("PPG")[3] sensor" and "an ECG sensor, comprising two or more ECG electrodes." Appx10072 (26:27-28). The claim further requires "a processing device" (1) to "receive PPG data from the PPG sensor" to "detect, based on the PPG data, the presence of an arrhythmia" and (2) to "receive ECG data from the ECG sensor" to "confirm the presence of the arrhythmia based on the ECG data." Appx10072 (26:40-46).

[2] The '499 and '731 patents are related and share essentially the same specification.

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

By contrast, claim 11[4] of the '499 patent recites generic sensors and conventional computing components to carry out a method commonly known to medical professionals. Specifically, claim 11 recites "[a] system for determining the presence of an arrhythmia" comprising "a heart sensor," "a motion sensor," and "a mobile computing device" having "a processor." Appx10039 (27:5-13). Claim 16 requires "a smartwatch" and claim 17 requires the processor to "determine a presence of said arrhythmia using a machine learning algorithm." Appx10039 (28:9-13).

The '941 patent relates to determining if a discordance is present between a user's activity level and a heart rate parameter, which may indicate the future onset of or the presence of an arrhythmia. Appx10084 (2:10-21). Claim 12 recites a "smartwatch" comprising a PPG sensor for discordance monitoring and an ECG sensor with at least two electrodes to confirm the presence of the arrhythmia. Appx10092 (17:52-18:18).

C. Products at Issue

AliveCor accused the Apple Watch series 4-7 of infringement. The accused products include an accelerometer, a PPG sensor, an ECG sensor, a display screen, a processor, and memory. Appx111-112.

[4] While independent claim 11 itself was not asserted, asserted claims 16 and 17 depend from claim 11.

To establish the existence of a domestic industry under section 337(a)(3), AliveCor presented wearable electronic devices that were being developed, manufactured, and/or sold under the tradenames KardiaBand System [KBS], product 1, and product 2. Appx110-111 (citing Appx30385-30386 (385:16-386:15)). AliveCor relied on the KBS for a domestic industry that "exists," and relied on prod 1 and prod 2 for a domestic industry "in the process of being established." 19 U.S.C. § 1337(a)(2); Appx151; Appx214-215; Appx245. Each product includes, "among other things, a smartwatch, activity sensor, PPG sensor, and ECG sensor." Appx111.

II. THE COMMISSION PROCEEDINGS

The ALJ found a violation of section 337 as to the '941 and '731 patents but no violation as to the '499 patent. Appx301. The Commission affirmed the ALJ's findings with certain modifications. Appx3.

A. Domestic Industry in the Process of Being Established for prod 1 and prod 2

The Commission affirmed the ALJ's finding that AliveCor had shown that prod 1 and prod 2 would practice each of the Asserted Patents but failed to show significant or substantial qualifying investments in prod 1 and prod 2 to establish a domestic industry "in the process of being established." Appx11; Appx161-166; Appx218-219; Appx245-246; Appx289-292. These findings are not at issue on appeal; however, the ALJ's factual findings that prod 1 and prod 2 would practice the

Asserted Patents show a link between AliveCor's domestic R&D expenditures and the Asserted Patents. *See infra*, Argument, Part II(B).

The ALJ pointed to testimony by AliveCor's expert, Dr. Jafari, that "prod 2 and prod 1 as planned will practice each element of the claims," which the ALJ found supported by descriptions of the planned products. Appx162-163 (citing *e.g.*, Appx30393-30399 (393:11-399:13)). The ALJ noted that AliveCor's "previous product, KBS, has been shown to practice all of these claims" and that "the SmartRhythm (PPG analysis) and KardiaApp (ECG collection and analysis) features—primary software features behind the KBS' practice of the claims—[can be transferred] to other portable heart monitors in development." Appx163-164 (citing, *e.g.*, Appx30388-30389 (388:25-389:7); Appx30389 (389:21-25); Appx30390 (390:6-15); Appx30392-30393 (392:3-393:10); Appx30198 (198:13-19); Appx30202 (202:11-21); Appx30203-30205 (203:19-204:1)); Appx30565 (565:4-22)).

B. Existence of a Domestic Industry for the KBS

The Commission affirmed the ALJ's finding that AliveCor established the existence of a domestic industry for the KBS under section 337(a)(3)(C).[5]

[5] The Commission also affirmed the ALJ's findings that AliveCor did not establish a domestic industry under subparagraphs (A) and (B), which has not been appealed. However, Apple argues that the Commission's treatment of subparagraphs (B) and (C) are inconsistent. As discussed *infra*, Argument, Part

[*Footnote continued on next page*]

Appx11; Appx289. The Commission agreed with the ALJ that AliveCor's R&D expenditures for KardiaBand and its continued support for the KBS establish a domestic industry under subparagraph (C). Appx16.

First, the Commission noted that the ALJ found the "record certainly evidences a qualitative effort on the part of ALC to refine and improve features like SmartRhythm and KardiaAI—which have a clear nexus to the heart rate and ECG analysis limitations recited in the Asserted Claims of the 941, 731, and 499 patents." Appx19 (quoting Appx276-277).

Second, the Commission agreed with the ALJ that although AliveCor ceased manufacturing and sales of the KBS in 2019, from 2017 through 2020, it continued to exploit the Asserted Patents through R&D payments to its contractor, iQor, to address KardiaBand customer concerns and these continuing investments benefited current KBS users. Appx16-17; Appx16261-16263; Appx275-276. Those relevant R&D payments total about [redacted]:

2016	2017	2018	2019	2020	2021	Total
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

II(B), the Commission affirmed the ALJ's finding that AliveCor failed to show the existence of a domestic industry under subparagraph (B) because AliveCor's labor investments from 2016-2021, which amounted to [redacted] of its total labor and capital investments, were not significant. Appx23-24.

Appx282; Appx11655. The ALJ observed that the [redacted] dollars R&D payments, which were summed by Dr. Akemann (Appx16291-16314), "provides at least some description of the activity behind each cost that *suggests* a nexus to sensors, circuitry, and housing structure." Appx281-282 (citing Appx16291-16314; Appx11654-11655; Appx16301-16302 (Tab "2017 QB"); Appx16304-16305 (Tab "NS 2018-2020"); Appx30176-30177 (176:22-177:3); Appx111; Appx31028-31029 (1028:20-1029:3); Appx30210-30211 (210:19-211:2); Appx30227 (227:5-20); Appx30567-30569 (567:10-569:12); Appx30198 (198:13-19), Appx30202 (202:3-21)); Appx288.

The Commission agreed with the ALJ that the evidence was reliable and sufficient to show a substantial investment under subparagraph (C) because AliveCor's "R&D labor expenses overall, including for the DI Products, are mostly domestic." Appx15-21; Appx281-282; Appx286-288.

C. Infringement of the '731 and '941 Patents

During Commission proceedings, the parties disputed the plain meaning of the limitation "confirm the presence of the arrhythmia" based on ECG data in claim 1 of the '731 patent and claim 12 of the '941 patent. AliveCor argued it means "to confirm the 'condition' of arrhythmia," but Apple argued that the claims require an ECG confirmation that related to the "particular arrhythmic event detected by the PPG sensor," which "requires the ECG sensor to record and

analyze data significantly overlapping in time with the data collected by the PPG sensor." Appx128-129.

The ALJ found "scant intrinsic evidence to support Apple's simultaneous-measurement theory." Appx130. By contrast, the ALJ found AliveCor's purported meaning "encompass[es] later-in-time ECG measurements," and "enjoys plentiful support" as "[t]he patent repeatedly describes a process where ECG is initiated or sensed in response to (*i.e.*, later in time than) other physiological measured parameters." Appx131-136. For support, the ALJ cited Figure 7 (Appx10083) and the following exemplary disclosures from the '941 patent:[6]

- "[D]iscordance between two sensed values may indicate the future onset of or the presence of an arrhythmia. In response to the identification of the future onset of or presence of an arrhythmia an electrocardiogram may be caused to be sensed." Appx10084 (1:67-2:3).

- "Many arrhythmias occur intermittently and relatively infrequently. … A device or system configured to take an intermittent ECG is much more convenient for users. … Intermittent arrhythmias can be recorded with these devices and systems *when a user is given an indication that an intermittent arrhythmia is occurring*." Appx10085 (4:14-30) (emphasis added).

- "Once the discordance is determined, an ECG is caused to be sensed in a step 712B … in step 716, this particular discordance may be indicative of the presence of atrial fibrillation and it should be confirmed with the ECG 712B." Appx10091 (15:27-32).

[6] The parties did not make a separate argument for the '731 patent but relied on the arguments they made for the '941 patent. Appx208-209.

Appx131-135; Appx149; Appx10090 (13:63-14:10). The Commission adopted the ALJ's determination to accord the limitation "its full plain and ordinary meaning, which covers simultaneous or sequential data readings." Appx135-136; Appx327-328; Appx332.

The ALJ found that Apple's accused products infringe the asserted claims of the '731 and '941 patents as construed. Appx147-148.

D. Noninfringement of the '499 Patent

The Commission adopted the ALJ's finding that the accused Apple products do not satisfy the limitation: "alert said first user to record an electrocardiogram using said mobile computing device" in claim 11 of the '499 patent. Appx244. The ALJ accorded this limitation its plain meaning, adding that "the 'alert' is not limited to a message." Appx323. The ALJ found that Apple's Irregular Rhythm Notification ("IRN"), which expressly directs a user to "talk to your doctor," does not meet the limitation because it does not alert the user to take an ECG. Appx11897; Appx243 (citing Appx30380 (380:2-13)).

The ALJ also found AliveCor's doctrine of equivalents argument unpersuasive because "[t]he intended result of 'alert said first user to record an electrocardiogram using said mobile computing device' is for an ECG to be taken using the mobile device's sensors"; but that "[t]he intended result of 'you should

talk to you doctor' is a doctor's office visit where any number of procedures could occur." Appx244.

E. Nonobviousness

1. The '941 Patent

For claim 21 of the '941 patent, the Commission affirmed the ALJ's finding that AMON[7] alone or combined with Almen[8] fails to disclose the limitation that the processor "display an ECG rhythm strip from the electric signals." Appx197-198.

For the remaining asserted claims, the Commission affirmed the ALJ's finding that, upon consideration of the evidence as a whole, including the objective evidence of copying and industry praise for the KBS, Apple failed to establish obviousness.[9] Appx196-202. Specifically, the ALJ found that the evidence of copying "includes the fact that Apple had access to [AliveCor's] technology," "had multiple meetings with [AliveCor's] personnel about KBS prior to KBS receiving FDA approval, and obtained KBS-related FDA submissions via Freedom of Information Act requests." Appx201-202. The ALJ noted that "[i]n September

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[7] Urs Anlike, et.al. *AMON: A Wearable Multiparameter Medical Monitoring and Alert System*, IEEE Transactions on Information Technology in Biomedicine, Vol. 8, No. 4, December 2004 (Appx11966-11978).

[8] U.S. Patent No. 7,460,899 (Appx11930-11965).

[9] The Commission did not adopt the ALJ's findings as to commercial success. Appx43-44.

2017, shortly before KBS received FDA clearance, an Apple presentation described its method of mitigating problems with the Apple Watch as 'similar to AliveCor'" and compared Apple Watch's ECG features to the KBS' ECG features. Appx202. The ALJ further noted that "in Apple's own FDA submissions, it described the 'AliveCor KardiaBand' as '[t]he most similar product on the market, different only in that the AliveCor offers a 'physician in the loop option.'" Appx202. The ALJ also found that industry praise for the KBS included praise from Apple, "a positive technical analysis published in the Journal of the American College of Cardiology," and "a peer-reviewed journal which Dr. Efimov views as the 'topmost, high, impactful journal' in cardiology." Appx200 (citing Appx11644-11651; Appx31198-31199 (1198:21-1199:14)).

2. The '731 Patent

The Commission reversed the ALJ's finding that claims 1, 8, 12, and 16 of the '731 patent are obvious in view of AMON and/or Almen because the ALJ did not consider the evidence of secondary considerations. Appx45-47. As with the '941 patent, the Commission found that, upon consideration of the industry praise and copying evidence, the evidence as a whole did not support a conclusion of obviousness. Appx47.

The Commission affirmed the ALJ's finding that claims 3, 5, 9, 10, and 15 of the '731 patent are not obvious in view of AMON and Almen because they do not disclose certain limitations in the claims. Appx221-232.

3. The '499 Patent

The Commission affirmed the ALJ's finding that, upon consideration of the evidence as a whole, including evidence of copying and industry praise, Apple's *prima facie* case was insufficient to establish the obviousness of claim 16. Appx40; Appx252-257. For claim 17, the Commission affirmed the ALJ's finding that AMON and other prior art fail to disclose the recited "machine learning algorithm." Appx257.

F. Patent-Ineligibility of the '499 Patent Claims

The Commission affirmed the ALJ's finding that under *Alice* step one independent claim 11, as well as dependent claims 16 and 17, are directed to the abstract idea of "taking in heart rate data (of any kind), taking in activity level data (of any kind), calculating heart rate variability, comparing that variability with the activity (by any means), and then alerting the user to 'record an electrocardiogram using said mobile computing device.'" Appx249-250. In making that determination, the ALJ observed that the "bulk of the claim is directed to the data analysis algorithms taking place within the 'processor' and according to the 'instructions' saved in memory (*i.e.*, ineligible subject matter)." Appx249. The

ALJ further found that the "bit of apparatus recited (*i.e.*, potentially eligible subject matter) is devoid of specificity, such that it can only be considered generic computer hardware—'a heart rate sensor,' 'mobile computing device,' 'a processor,' 'a motion sensor,' and 'non-transitory computer readable medium.'" Appx249. The ALJ further pointed to the testimony of Dr. Stultz, who testified that "carrying out these steps is common in medical practice." Appx249.

Turning to *Alice* step two, the Commission affirmed the ALJ's conclusion that claims 11 and 17 in essence cover "the addition of generic sensors to an existing ECG machine, and for no particular purpose" and that "[a]lone or as an ordered combination, all this is equivalent to the basic idea of using such sensors." Appx250. The Commission, however, disagreed with the ALJ's finding that claim 16's recitation of a "smartwatch" imbues the recited abstract idea with patentable subject matter. Appx37. The Commission noted that the only difference between claims 16 and 17 is the environment in which the abstract idea is carried out and that under this Court's precedent, this is insufficient to confer patentability on claim 16. Appx39.

G. Issuance and Suspension of Remedial Orders

The Commission sought and obtained briefing from the parties and the public on the effect of remedial orders on the public interest prior to its final determination. 19 U.S.C. §§ 1337(d), (f); Appx40008-40010; Appx40006-40007;

Appx52-54. After finding a violation of section 337 by Apple and considering all the public interest submissions received, the Commission determined that any adverse effect from the remedial orders would be mitigated by the provided service, repair, and replacement exemption. Appx80-81. In view of this exemption, the Commission determined that the public interest factors do not counsel against providing AliveCor a remedy. The Commission suspended enforcement of its remedial orders, however, pending final resolution of the Patent Trial and Appeal Board's Final Written Decisions finding all the asserted claims unpatentable (companion appeals). Appx85-87.

SUMMARY OF THE ARGUMENT

The Commission correctly found a violation of section 337 with respect to the '941 and '731 patents. Apple argues the Commission erred in finding that a domestic industry existed for the KBS. Yet, Apple does not dispute the following: AliveCor developed the KBS in the United States, the KBS is an "article[]" protected by the Asserted Patents, and the majority of AliveCor's R&D occurs in the United States. Apple contends the Commission erred in crediting over [redacted] dollars in R&D expenditures from 2018-2020 for the development of prod 1, a product that Apple believes is unrelated to the KBS. Record evidence, however, shows that the design and development of prod 1 involved improving the same patented technology used in the KBS and claimed in the Asserted Patents. And those improvements directly benefit users of the KBS. Thus, the Commission correctly found that AliveCor established the existence of a domestic industry under section 337(a)(3)(C).

Apple's other challenges on appeal do not warrant reversal. First, the Commission properly construed the limitation "confirm the presence of the arrhythmia" in the claims of the '731 and '941 patents to encompass simultaneous as well as sequential PPG and ECG data readings in view of the intrinsic evidence. Under that construction, Apple does not dispute that its accused products infringe. Second, the Commission correctly determined that Apple failed to prove the

asserted claims are invalid for obviousness. Substantial evidence supports the Commission's finding that the prior art fails to disclose limitations in claim 21 of the '941 patent, claims 3, 5, 9, 10, and 15 of the '731 patent, and claim 17 of the '499 patent. For the remaining claims, the Commission correctly found that the evidence as a whole, including evidence of copying and industry praise for the KBS, shows nonobviousness. Finally, the Commission did not abuse its discretion in issuing remedial orders. The Commission explained across thirty pages of its opinion why the public interest factors do not counsel against excluding Apple's infringing products. Appx52-82.

AliveCor challenges the Commission's finding of no violation of section 337 with respect to the '499 patent. Two alternative bases support the Commission's finding. First, the Commission properly accorded the limitation "alert said first user to record an electrocardiogram using said mobile computing device" in claim 11 of the '499 patent its plain and ordinary meaning. Substantial evidence supports the Commission's finding that Apple's accused products do not infringe because they direct a user to "talk to your doctor," not "alert" a user to record an ECG. Second, the Commission correctly determined that claims 16 and 17 of the '499 patent are directed to a patent-ineligible abstract idea and merely recite activities that physicians routinely conduct, using conventional and generic sensors in their ordinary manner to measure cardiac activity.

ARGUMENT

I. STANDARD OF REVIEW

The Commission agrees with AliveCor's and Apple's statements of the applicable standard of review for the issues on appeal. Although Apple is correct that the "question [of] whether a complainant has satisfied the domestic industry requirement typically presents issues of both law and fact," Apple's appeal raises only factual issues relating to the link between certain domestic expenditures and the asserted patents and whether those expenditures were substantial. *See John Mezzalingua Assocs. v. Int'l Trade Comm'n,* 660 F.3d 1322, 1327 (Fed. Cir. 2011). This Court applies the "substantial evidence" test in reviewing these factual findings by the Commission. *Id.*; *Motorola Mobility, LLC v. Int'l Trade Comm'n*, 737 F.3d 1345, 1351 (Fed. Cir. 2013).

II. THE COMMISSION CORRECTLY DETERMINED THAT ALIVECOR ESTABLISHED THE EXISTENCE OF A DOMESTIC INDUSTRY UNDER SECTION 337(a)(3)(C) (APPLE CROSS-APPEAL)

A. The Domestic Industry Requirement Under Subparagraph (C)

Section 337 declares unlawful "[t]he importation into the United States, the sale for importation, or the sale within the United States after importation" of "articles" that "infringe a valid and enforceable United States patent." 19 U.S.C. § 1337(a)(1)(B). Section 337 further requires "an industry in the United States,

relating to the articles protected by the patent … exists or is in the process of being established." 19 U.S.C. § 1337(a)(2).

A domestic industry will be found to exist under subparagraph (C) if, "with respect to the articles protected by the patent," a complainant can show "substantial investment in its exploitation,[10] including engineering, research and development, or licensing." 19 U.S.C. § 1337(a)(3)(C). In addition to a showing that those investments relate to the protected domestic industry articles, there must be a nexus between the domestic investments and the exploitation of the asserted patents. *InterDigital Commc'ns, LLC v. Int'l Trade Comm'n*, 707 F.3d 1295, 1304 (Fed. Cir. 2013). As the Court explained in *InterDigital*,

> As long as the patent covers the article that is the subject of the exclusion proceeding, and as long as the party seeking relief can show that it has a sufficiently substantial investment in the exploitation of the intellectual property to satisfy the domestic industry requirement of the statute, that party is entitled to seek relief under section 337.

Id. This Court has also recognized that past expenditures may be considered to support a domestic industry claim by virtue of their connection to ongoing qualifying expenditures exploiting the patented technology. *Hyosung TNS Inc. v. Int'l Trade Comm'n*, 926 F.3d 1353, 1361-62 (Fed. Cir. 2019).

[10] For purposes of this appeal, this Court has interpreted "its exploitation" to mean exploitation of "the patent." *InterDigital*, 707 F.3d at 1298.

As discussed below, Apple does not dispute that AliveCor's KBS is an "article[] protected by the patent[s]." AppleBr.35-36; 19 U.S.C. § 1337(a)(3)(C). Thus, the only dispute on appeal is whether substantial evidence supports the Commission's finding that AliveCor made substantial investments in the exploitation of the Asserted Patents with respect to the KBS.

B. Substantial Evidence Supports the Commission's Finding That AliveCor Made Substantial Investments in the Exploitation of the Asserted Patents with Respect to the KBS

There is no dispute that AliveCor developed the inventions claimed in the Asserted Patents and introduced the patented technology to consumers through the KBS, a system that included KardiaBand and an Apple Watch (series 1-3) with Watch OS 5.0 (or earlier) running AliveCor's proprietary software, KardiaApp. Appx10; Appx30385 (385:16-386:15); Appx30083 (83:4-7).

Between 2013 and 2018, AliveCor invested heavily in creating the KBS. AliveCor discontinued the KBS in 2019 after Apple altered the software in its Apple Watch to no longer work with the KBS. Appx30073-30074 (73:2-74:10); Appx30083-30085 (83:8-85:19). Yet, as the record evidence discussed below shows, AliveCor continued to exploit the Asserted Patents through substantial investments in improving KardiaBand, which is undisputedly covered by the Asserted Patents, for new products, prod 1 and prod 2, and for current users of the KBS. Appx30085-30086 (85:20-86:22). Accordingly, the Commission correctly

determined that AliveCor's dollars in payments to contractors for the design and development of KardiaBand from 2017-2020 adequately support its claim of a domestic industry under subparagraph (C).

1. AliveCor's R&D Investments in Improving KardiaBand for KBS Users and for New Products Demonstrate Exploitation of the Asserted Patents

Prior to 2019, AliveCor invested heavily in the design and development of the KBS, which is undisputedly an article protected by the Asserted Patents. AppleBr.35-36; Appx30072-30085 (72:6-85:20). After AliveCor discontinued the KBS in 2019, AliveCor shifted its focus to incorporating the patented components, KardiaBand and KardiaApp, in new products, prod 1 and prod 2, that do not depend on Apple Watch. Appx111 (finding that "[u]nlike KBS, prod 1 will collect its own PPG data rather than taking heart rate data from the Apple Watch."); Appx30085-30086 (85:20-86:22); Appx12257-12263. AliveCor also continued to provide updates, enhancements, and customer support to existing KBS users. Appx30201-30202.

Apple argues that the Commission should not have credited dollars of AliveCor's dollars payments to contractors because they pertain to KardiaBand for AliveCor's new product prod 1, and not for the domestic industry product KBS. AppleBr.36-38. However, the ALJ found that the prod 1 would practice the Asserted Patents because of the overlapping technology in prod 1 and

the KBS. Appx161-166; Appx218-219; Appx245-246. As discussed below, substantial evidence supports the Commission's finding that AliveCor's ongoing R&D investments in KardiaBand demonstrate continued exploitation of the Asserted Patents and directly benefit current users of the KBS. Appx11; Appx110-111.

Specifically, the ALJ found that prod 1 and prod 2 are designed to include a smartwatch, activity sensor, PPG sensor, and ECG sensor—the same components that exist in the KBS. Appx110-111. The ALJ also found prod 1 and prod 2 are designed to use the same KardiaApp software used in the KBS, which includes AliveCor's SmartRhythm and KardiaAI. Appx30198 (198:13-19 (AliveCor explaining "there is no difference" in functionality between the SmartRhythm on product 1 and SmartRhythm on KardiaBand system, clarifying that "to the user, it's exactly the same way as it used to work on the KardiaBand system.")); Appx30202 (202:3-21); Appx30565-30566 (565:4-566:12). As the evidence shows, "the core part of the invention" claimed in the Asserted Patents is embodied in SmartRhythm and KardiaAI—"technology that measures heart rate and heart rate parameters in the background," that "use[s] … AI [artificial intelligence] and machine learning algorithms to mine that data and" when it "identif[ies] irregularities that are suggestive of atrial fibrillation, provide[s] a trigger to the user

to take an ECG" and allows "the user [to] take on-demand ECG on the wrist." Appx30292-30293 (292:17-293:2).

In addition, AliveCor's witness, Dr. Albert, explained the KBS and prod 1 include overlapping technology that are covered by the Asserted Patents: the "AliveCor software team … is developing the software that runs on the product 1 Smart Watch, … [a]nd it is also working on the KardiaApp for the product [which] is, again, the same app that we have running for all the other shipping devices, and KardiaApp also uses the KardiaAI model." Appx30210-30211 (210:19-211:2). He also testified: "We didn't just stop KardiaBand. [W]e have hundreds of millions of datapoints from SmartRhythm and KardiaBand—ECGs, steps, and PPG heart rate with time stamps—and that data has all gone into the continuing efforts." Appx30176-30177 (176:22-177:3); *see* Appx30567-30569 (567:10-569:12).

Dr. Albert further described how development of KardiaBand for new products such as prod 1 benefit current users of the KBS:

> Q. I understand AliveCor no longer offers the KardiaBand system. So is it fair for me to conclude, then, that there is no further development work on the KardiaBand system?
>
> A. That would not be a right characterization, because … there are people using not the KardiaBand today but the old Apple watches collecting their ECGs, and we know this because we collect the data in our background systems. And then there are a very small set of users on which SmartRhythm alerts are still happening. And then when we do the app updates, they roll out

> to everyone, all of our customers, including all our products, and one of those is KardiaBand system, KardiaBand system customers.

Appx30227 (227:5-20). Given the overlapping technology in the KBS and prod 1 and evidence that development of the patented technologies for prod 1 also benefit current users of the KBS, the Commission appropriately credited the dollars in contractor payments associated with KardiaBand as evidence of exploitation of the Asserted Patents. Appx16-17.

In addition to showing that the technology from the KBS is used in prod 1, AliveCor also showed continuing exploitations of the patented technology in other ways. For instance, in 2020, AliveCor received FDA clearance for an updated version of the KardiaAI using data from the KBS that showed that the updated version can be used on wrist-worn ECG devices. Appx30568-30569 (568:16-569:12). Current KBS users continue to rely on KardiaAI and KardiaApp to take ECGs, and AliveCor continues to update the KardiaAI software for current users. Appx30201-30202 (201:22-202:2); Appx30227 (227:5-20); Appx30210-30211 (210:24-211:14). Further, through at least 2021, AliveCor has continued to provide technical support for current users of the KBS. Appx16261-16263; Appx31028 (1028:20-24). Accordingly, the Commission properly credited AliveCor's dollars in domestic investments from 2017-2020 as continued exploitation of the Asserted Patents.

Apple also argues that the Commission should not have credited the contractor expenses because "[n]o witness testified about the contents of these spreadsheets tabs" in Appx16291-16314. AppleBr.33-34. Apple, however, cites no law for the proposition that a factfinder cannot rely on a self-explanatory document without a witness. As the Commission found, the physical exhibit recording these contractor expenditures "on its face provides at least some description of the activity behind each cost that *suggests* a nexus to sensors, circuitry, and housing structure" relating to AliveCor's KardiaBand. Appx18; Appx282; Appx16301-16302 (Tab "2017 QB"); Appx16304-16305 (Tab "NS 2018-2020"); Appx11654-11655; Appx11717-11718; Appx16340. The Commission, as factfinder, was within its province to credit that substantial evidence. *See Nutrinova Nutrition Specialties & Food Ingredients GmbH v. Int'l Trade Comm'n*, 224 F.3d 1356, 1359 (Fed. Cir. 2000).

Apple further argues that the Commission excluded the contractor expenses under subparagraph (B) because they related to prod 1, but erroneously credited those expenses under subparagraph (C). AppleBr.38-39. This is a red herring. While the ALJ excluded a portion of the contractor expenses for purposes of subparagraph (B) (employment of labor or capital), the ALJ did not err in finding those same expenses qualify under subparagraph (C) (investment in exploitation of the patents) given the substantial evidence discussed above showing that the KBS

and prod 1 include overlapping technology that exploit the Asserted Patents. *See Motorola Mobility*, 737 F.3d at 1351 ("[N]othing in § 337 precludes a complainant from relying on investments or employment directed to significant components, specifically tailored for use in an article protected by the patent. The investments or employment must only be 'with respect to the articles protected by the patent.'") (quoting 19 U.S.C. § 1337(a)(3)).

Moreover, the Commission did not pass judgment on the propriety of the contractor expenses the ALJ excluded under subparagraph (B). Rather, the Commission affirmed the ALJ's finding that AliveCor failed to establish a domestic industry under subparagraph (B) because it failed to explain why the contextual analysis it relied on, a comparison of its domestic labor expenses in the DI product to its overall company-wide labor and capital expenditure, showed that its domestic investment was significant. Appx24; Appx285. Thus, the excluded contractor expenses played no role in the Commission affirming the ALJ's finding under subparagraph (B).

Contrary to Apple's assertion (at 37-38), *Marine Sonar* and *Hyosung* are consistent with the Commission's determination here. *Certain Marine Sonar Imaging Devices, Including Downscan and Sidescan Devices, Prods. Containing the Same, and Components Thereof*, Inv. No. 337-TA-921, Comm'n Op., 2016 WL 10987364, at *37 (Jan. 6, 2016); *Hyosung*, 926 F.3d at 1362. Like the situation in

Marine Sonar and *Hyosung*, the Commission appropriately credited continuing investments in improving patented components such as KardiaBand and KardiaApp that benefit current KBS users. Appx30198 (198:13-19); Appx30202 (202:3-21); Appx30565-30566 (565:4-566:12). Thus, the Commission correctly found that early and ongoing investments in KardiaBand can be relied on to show a domestic industry even though AliveCor discontinued the KBS. Appx17-19. Against this evidentiary backdrop, Apple's assertion that the Commission overreached the statute in finding a violation of section 337 absent a domestic industry rings hollow.[11] AppleBr.35-36.

2. Substantial Evidence Supports the Commission's Finding That AliveCor's dollars R&D Investment Is Substantial

Substantial evidence supports the Commission's finding that AliveCor's dollars domestic R&D investment is substantial because most of AliveCor's R&D activities, including for the KBS, take place in the United States.

[11] Apple's argument that the Commission violated the Constitution is not sufficiently developed for the Commission to adequately respond. AppleBr.34-35. Apple merely states that "the Commission's resolution of patent-infringement disputes without a jury would likely be in violation of the Seventh Amendment." *Id.* In any event, the argument has no merit. In accordance with the statute, section 337, the Commission properly found that AliveCor established the existence of a domestic industry and infringement of valid patent claims before issuing remedial orders against Apple. *See generally Ninestar Tech. Co. v. Int'l Trade Comm'n*, 667 F.3d 1373, 1384 (Fed. Cir. 2012) (holding that the Seventh Amendment does not bar the Commission from imposing civil penalties under section 337).

Appx40011; Appx21; *see Certain High-Density Fiber Optic Equipment and Components Thereof* ("*Fiber Optic Equipment*"), Inv. No. 337-TA-1194, Comm'n Op., 2021 WL 3809088, at *39-40, 42 (Aug. 23, 2021) (finding complainant's domestic investments substantial based on a comparison of complainant's domestic R&D labor relative to its global R&D labor for the domestic industry products), *aff'd on other grounds*, *FS.com Inc. v. Int'l Trade Comm'n*, 65 F.4th 1373 (Fed. Cir. 2023). The Commission properly credited AliveCor's economic expert, Dr. Akemann's headcount comparison showing that AliveCor's R&D labor expenses for the KBS were substantially domestic. Appx40011.

The Commission also found that a comparison of the domestic contractor expenses to the foreign contractor expenses—dollar comparison—shows that AliveCor's domestic R&D labor expenses were substantial. Appx20-21; Appx287-288; Appx11716-11718. Apple argues that the Commission erred in its domestic-to-foreign comparison, but it does not explain why such a comparison cannot shed light on the substantiality of a complainant's investment.[12]

[12] As the Commission explained, the appropriate context for evaluating whether domestic investments are significant or substantial may vary depending upon the facts of a particular investigation. While a domestic-to-foreign comparison is one way to show significance, it may also be shown, for example, by demonstrating the value added by domestic activities, comparing domestic investments to costs of goods sold or revenues for DI products, or considering other contextual evidence of significance specific to the company's operations, the marketplace, or the industry in question. *See Certain Carburetors & Prods. Containing Such*

[*Footnote continued on next page*]

AppleBr.43. Here, the Commission found AliveCor's domestic R&D investments substantial because they represent the majority of AliveCor's R&D expense. That is, the evidence showed that the bulk of AliveCor's R&D takes place in the United States. *See Fiber Optic Equipment*, 2021 WL 3809088, at *40 ("[A] complainant may compare its domestic investments with its foreign investments to inform the contextual analysis for determining whether the claimed domestic investments are significant or substantial.").

Apple also argues that the dollars investment is not substantial because it "represent[s] roughly % of AliveCor's revenues for the same time period." AppleBr.43. Apple did not present a revenue comparison in its petition for Commission review, and thus this argument is waived. 19 C.F.R. § 210.43(b)(2); *Finnigan Corp. v. Int'l Trade Comm'n*, 180 F.3d 1354, 1362 (Fed. Cir. 1999) ("A party seeking review in this court of a determination by the Commission must 'specifically assert' the error made by the ALJ in its petition for review to the Commission.").

Carburetors, Inv. No. 337-TA-1123, Comm'n Op. at 15-16, 2019 WL 5622443, at *6-7, 10-11 (Oct. 28, 2019).

III. THE COMMISSION CORRECTLY DETERMINED THAT APPLE'S ACCUSED PRODUCTS INFRINGE THE ASSERTED CLAIMS OF THE '731 AND '941 PATENTS (APPLE CROSS-APPEAL)

Claim 1 of the '731 patent recites: "receive PPG data from the PPG sensor; detect the presence of an arrhythmia based on the PPG data; receive ECG data from the ECG sensor; and *confirm the presence of the arrhythmia* based on the ECG data." Appx10072 (26:41-46); Appx327 (emphasis added). Claim 12 of the '941 patent recites: "receive electric signals of the user from the ECG sensor to *confirm the presence of the arrhythmia*." Appx10092 (18:18-19); Appx331 (emphasis added).

Apple argues the Commission erred in finding that the "confirm the presence of the arrhythmia" limitation does not require the ECG to confirm the particular arrhythmia episode detected by the PPG sensor.[13] AppleBr.45; Appx10092 (18:19); Appx10072 (26:45). In essence, Apple argues that the ECG sensor must record and "analyze data significantly overlapping in time with the data collected by the PPG sensor" to confirm the same episode of arrhythmia. Appx129.

As discussed below, the intrinsic evidence supports the Commission's finding that the plain meaning of "confirm the presence of the arrhythmia" covers

[13] We note that Apple did not present any meaningful differences between the construction of these limitations for the two patents. Appx209 ("Apple does not provide an independent discussion of this construction issue, but similarly to ALC, 'incorporates by reference the testimony, evidence, and analysis from [the '941 patent discussion].'").

both simultaneous and sequential data comparisons, *i.e.*, ECG measurements made after a PPG reading or later-in-time ECG measurements. Appx135-136. Apple does not dispute that its products infringe under the Commission's construction.

A. The Intrinsic Evidence Supports the Commission's Construction of the Limitation "Confirm the Presence of the Arrhythmia"

The Commission accorded the limitation "confirm the presence of the arrhythmia" its plain and ordinary meaning to "encompass later-in-time ECG measurements," Appx135-136, and not, as Apple contends, limited to ECG measurements "significantly overlapping in time with the data collected by the PPG sensor," Appx129. The claim language and patent specifications support the Commission's claim construction.

During the proceedings below, the parties focused on two disputes with respect to this limitation: (1) what was being detected and confirmed (a particular episode or an arrythmia); and (2) when the confirmation needed to happen in relation to the detection. Appx128-130. Apple argued that the limitation required a simultaneous PPG/ECG measurement sequence to enable the ECG to confirm the "truth or accuracy" of a detectable "episode" of arrhythmia. Appx128-130. AliveCor argued that the cardiac condition of arrhythmia was being detected by PPG and then confirmed by ECG, which could occur later in time. Appx128-130. The Commission found the intrinsic evidence supported AliveCor's interpretation and contradicted Apple's interpretation.

The language of the claims and the patent specifications do not support Apple's argument as to the timing of the confirmation by the ECG. The Commission found the portion of the specification that Apple relies on (AppleBr.48-49) does not limit the claims to simultaneous detection and confirmation. The specification teaches that "[a] prediction of arrhythmia is more accurate when two or more physiologic parameters are concurrently sensed and analyzed with respect to one another." Appx10088 (10:21-22). The specification, however, does not mention ECG as one of those parameters "concurrently sensed." Rather, it appears related to predicting the *onset* of arrhythmia (*i.e.*, future—before it happens), and not to detecting current arrythmias. Appx10088 (10:16-18) ("In some embodiments, the devices described herein are configured to predict an onset of an arrhythmia in an individual.").

While the patents disclose an "intermittent" ECG and a "continuous" sensed heart rate, Appx10089 (11:22-42), which may result in occasional overlap between ECG and heart rate measurements, the Commission found those disclosures do not limit the invention as Apple argues, Appx135, because "[t]he patent repeatedly describes a process where ECG is initiated or sensed in response to (*i.e.*, later in time than) other physiological measured parameters." Appx132-133; Appx10084 (1:67-2:3) ("For example, discordance between two sensed values may indicate the future onset of or the presence of an arrhythmia. In response to the identification of

the future onset of or presence of an arrhythmia an electrocardiogram may be caused to be sensed."). Figure 7, which depicts disclosed embodiments of the invention, instructs a user to "[t]ake an ECG" at steps 712A-D *after* "[s]ensing a heart rate and an activity level" at step 700." Appx10050 (Fig. 7). Indeed, the specifications of both the '941 and '731 patents describe numerous embodiments in which an ECG is taken *after* an indication of arrhythmia from the PPG data, and the ECG sensor "confirms" the underlying condition of arrhythmia previously detected. *See, e.g.*, Appx130-136; Appx10060 (1:40-54), Appx10061 (4:20-32), Appx10062 (6:3-5), Appx10071 (23:20-34), Appx10069-10070 (20:62-21:9), Appx10050 (Fig. 7), Appx10053 (Fig. 10); Appx10084 (1:42-57), Appx10085 (3:63-4:15), Appx10085-10086 (4:65-5:16), Appx10091 (15:27-43; 15:52-59), Appx10083 (Fig. 7). Consistent with the claim language and the specifications, the Commission correctly determined that the plain meaning of "confirm the presence of the arrhythmia" includes simultaneous as well as sequential data readings. Appx135-136.[14]

[14] Apple's argument that the confirmed "arrhythmia" can only be the previously detected "arrhythmia" is also not supported by the claim language. AppleBr.46. The parties do not dispute that arrhythmia is a cardiac condition that includes different species such as Afib and supraventricular tachycardia. Appx10084 (1:19-20), which is consistent with their agreed-upon construction of "arrhythmia" to mean "a cardiac condition in which the electrical activity of the heart is irregular or is faster or slower than normal." Appx145. As the Commission explained, "[e]ven assuming as a matter of construction that the two arrhythmias must be the same

[*Footnote continued on next page*]

B. Apple Does Not Dispute That Its Accused Products Infringe the Asserted Claims of the '731 and the '941 Patents Under the Commission's Claim Construction

Apple's infringement challenge depends on the Court adopting its proposed construction. AppleBr.51. As discussed above, Apple's proposed construction finds no support in the intrinsic evidence.

Apple does not dispute that its accused products meet the "confirm the presence of the arrhythmia" limitation under the Commission's construction. Substantial evidence shows that Apple's ECG App is programmed with instructions that, when executed, cause the ECG to confirm the arrhythmia condition previously detected by IRN (*i.e.*, Afib) or by HHRN (High Heart Rate Notification) (*e.g.*, abnormal tachycardia). Appx148-150.

Apple does not challenge any other limitation on appeal and, thus, the Commission correctly found Apple's products infringe the asserted claims of the '731 and the '941 patents.

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condition," Apple "offers no intrinsic evidence that the only way to confirm that fact is by comparing ECG sensor data to PPG sensor data." Appx327. The specifications say nothing about such a comparison. Indeed, the portion of the specification that Apple relies on discloses future arrhythmias or later-in-time ECG measurements and supports the Commission's interpretation. AppleBr.50 (citing Appx10084 (1:58-2:3)). Contrary to Apple's argument, nothing in this disclosure limits the arrhythmia confirmed by the ECG to any particular arrhythmia.

IV. THE COMMISSION CORRECTLY DETERMINED THAT APPLE'S ACCUSED PRODUCTS DO NOT INFRINGE THE ASSERTED CLAIMS OF THE '499 PATENT (ALIVECOR APPEAL)

Claim 11, from which asserted claims 16 and 17 depend, recites: "a non-transitory computer readable medium encoded with a computer program including instructions executable by said processor to … *alert said first user to record an electrocardiogram* using said mobile computing device." Appx10039 (27:14-24) (emphasis added). The Commission properly construed this limitation according to its plain and ordinary meaning and faithfully applied that construction to find that Apple's accused products do not infringe claims 16 and 17 of the '499 patent. Unsatisfied with the substantial evidence supporting the Commission's non-infringement finding, AliveCor attempts to concoct a claim construction dispute where none exists.

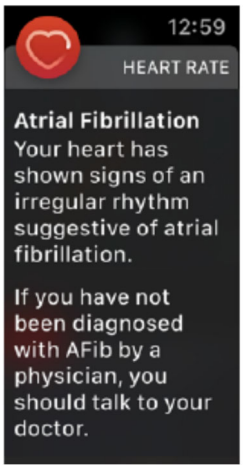
A. The Commission Did Not Change Its Construction of "Alert"

The plain language of claim 11 requires "alert[ing] said first user to record an electrocardiogram using said mobile computing device." Appx10039 (12:22-24). AliveCor, however, argues that "the plain language of the 'alert' limitation does not require that users be explicitly told or instructed to take an ECG, but merely that they be triggered to take that action by way of the claimed 'alert.'" AliveCorBr.56. This is contrary to law. As the Court has made clear, "[i]n construing claims, the analytical focus must begin and remain centered on the

language of the claims themselves, for it is that language that the patentee chose to use to 'particularly point [ ] out and distinctly claim [ ] the subject matter which the patentee regards as his invention.'" *Interactive Gift Exp., Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) (quoting 35 U.S.C. § 112, ¶ 2). Here, the plain language of the claim requires "alert said first user to record an electrocardiogram using said mobile computing device." Appx10039 (12:22-24). AliveCor's argument that the Commission narrowed the claim limitation to avoid covering the accused products is unsupported. AliveCorBr.55.

B. Apple's Accused Products Do Not "Alert" a User "to Record an Electrocardiogram" Either Literally or Under the Doctrine of Equivalents

Substantial evidence supports the Commission's finding that AliveCor failed to show that Apple's IRN alert meets the "alert" limitation. AliveCor contends "the IRN alert serves as a call to action directed to users, alerting or triggering them to an opportune time to take an ECG. …" AliveCorBr.56-57 (emphasis omitted). Apple's IRN (relevant part reproduced below), however, expressly directs a user to "talk to your doctor," not to record an ECG.



Appx11897.

AliveCor also contends that "Apple [allegedly] publicly endors[ed] and encourage[d] users to take an ECG upon receiving the IRN alert message" and that "Apple is both aware of and derives benefit from users using IRN and ECG sequentially." AliveCorBr.57-59. This, even if true, fails to show infringement. AliveCor chose to word its claim to require an alert that causes a user to take an ECG. Appx10039 (27:14-24). Public endorsement by Apple outside of an alert from its accused products and any benefit to Apple is entirely irrelevant to direct infringement.

Substantial evidence also supports the Commission's finding that AliveCor failed to show infringement under the doctrine of equivalents. The Commission found "[t]he intended result of [the claimed] 'alert said first user to record an electrocardiogram using said mobile computing device' is for an ECG to be taken using the mobile device's sensors"; but that "[t]he intended result of [of the actual

alert of] 'you should talk to your doctor' is a doctor's office visit where any number of procedures could occur." Appx244. AliveCor argues that:

> [T]he Commission improperly assumed that the user will only follow the literal written suggestion of the IRN alert message, rather than taking other appropriate or logical action considering the context of the sudden delivery of the alert, including taking an ECG on the only voluntary, on-demand Afib-sensing app on the Apple Watch: Apple's ECG App.

AliveCorBr.63. The Commission did not make any assumptions. The alert tells the users exactly what to do—"talk to your doctor." Appx11897. AliveCor's own expert, Dr. Jafari, "acknowledged that this message would send a user to the doctor, and that the desire to take an ECG would need to come from the user asking themselves what else could be done and consulting additional resources." Appx243-244 (citing Appx30380 (380:2-13)).

Accordingly, substantial evidence supports the Commission's finding that Apple's accused products do not infringe claims 16 and 17 of the '499 patent.

V. THE COMMISSION CORRECTLY DETERMINED THAT APPLE FAILED TO PROVE THE ASSERTED CLAIMS ARE OBVIOUS (APPLE CROSS-APPEAL)

A. The Commission Correctly Found Evidence of Industry Praise and Copying to be Probative of Nonobviousness

This Court has held the objective indicia analysis of the section 103 inquiry is not only a cumulative or confirmatory part of the obviousness calculus but also constitutes independent evidence of nonobviousness. *Liqwd, Inc. v. L'Oreal USA,*

Inc., 941 F.3d 1133, 1136-37 (Fed. Cir. 2019); *Ortho–McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1365 (Fed. Cir. 2008). Such evidence "may often be the most probative and cogent evidence" of nonobviousness. *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1285 (Fed. Cir. 2000).

Here, the Commission found that Apple, the infringer, copied AliveCor's KBS, which undisputedly embodies the claimed inventions, rather than separately derive that which they now claim is obvious. *Brown & Williamson Tobacco Corp. v. Philip Morris, Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000) (holding that a patentee is entitled to a presumption of nexus when it shows that the asserted objective evidence is tied to a specific product that "embodies the claimed features, and is coextensive with them."); *Immunex Corp. v. Sandoz, Inc*., 964 F.3d 1049, 1067 (Fed. Cir. 2020)). Such evidence of copying along with evidence of industry praise supports the Commission's finding of nonobviousness.

1. Substantial Evidence Supports the Commission's Finding That Apple Copied AliveCor's KBS

"[A]lthough copying is not alone dispositive of nonobviousness," this Court has explained that a determination of copying can be "strong evidence of nonobviousness." *Volvo Penta of the Americas, LLC v. Brunswick Corp.*, 81 F.4th 1202, 1212-13 (Fed. Cir. 2023); *Advanced Display Sys.*, 212 F.3d at 1285 ("Objective considerations such as failure by others to solve the problem and

copying may often be the most probative and cogent evidence of nonobviousness.") (quotation omitted).

Apple argues that it "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." AppleBr.73. But the Commission found that Apple's attempts to incorporate ECG functionality in 2013 were unsuccessful, so Apple copied AliveCor's KBS, and ultimately forced the KBS off the market. Appx16-20. Indeed, substantial evidence shows that Apple obtained *confidential* information about the KBS from AliveCor and the FDA before it was able to successfully develop the infringing Series 4 Apple Watch in 2017. *See* Appx31210-31213; Appx40001-40002. That evidence shows:

(1) Apple shelved the ECG functionality for the Apple Watch in 2013, and it "remained a back burner technology development" until 2017, Appx40001 (45:14-20) (Dr. Klaassen, Director of Apple Health Technologies); Appx40003 (47:13-24); Appx31210 (1210:17-1213:12);

(2) from 2013 to 2015, Apple obtained confidential information from the FDA about AliveCor's KardiaBand,[15] Appx31202-31213 (1202:23-1213:12);

[15] Apple argues that "the bulk of the evidence" that the Commission relied on is "irrelevant" because it "predates the public release of KBS" and "none of the documents … indicates that Apple had access to a version of KardiaBand with SmartRhythm." AppleBr.71. Not so. The Commission found that, after the public

[*Footnote continued on next page*]

Appx15354-15722; Appx14796-15164; Appx13991-14339; Appx14340-14601; Appx14602-14795; Appx13695-13700; Appx15723-15911; Appx201-202;

(3) Apple researched and compared its software with software in the KBS (Appx13989-13990); and

(4) from 2015 through at least 2017, Apple executives and engineers met numerous times with AliveCor's executives and inventors to learn about the patented technology and to receive live demonstrations of KardiaBand, Appx30057-30059 (57:21-59:20); Appx30073-30076 (73:13-76:15); Appx30082-30083 (82:9-83:7); Appx10282 (135:3-13); Appx10282-10283 (135:23-136:1); Appx10283-10284 (136:24-137:8); Appx10284; Appx10290-10291; Appx10292-10293; Appx30783-30784 (783:16-784:11) (Dr. Waydo, Apple's Director of Health Algorithms, discussing meetings with AliveCor).

Apple admits that it obtained confidential information about the KBS from AliveCor and the FDA in developing its infringing Series 4 Apple Watch but it argues that "it is common practice." Appx1297. Such evidence, however, can later be used as evidence of copying, especially when the copied information and

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release of the KBS, Apple met with AliveCor's executives and inventors to learn about KardiaBand and Apple's engineers used AliveCor's SmartRhythm as a guide in developing its own product. Appx201-202; Appx16285 (an Apple employee, in a November 30, 2017 email, comparing SmartRhythm in the KBS with Antimony (Apple's codename for IRN)). Moreover, the fact that Apple used information that predates the KBS's public release shows the lengths that Apple went to obtain information about and ultimately copy AliveCor's KBS.

technology is used in an infringing device. Accordingly, substantial evidence supports the Commission's finding that Apple's copying of the KBS is strong evidence of nonobviousness.

2. Substantial Evidence Supports the Commission's Finding That Industry Praise for the KBS Is Probative of Nonobviousness

Substantial evidence showing industry praise for the KBS's contribution to health and wellness further supports a finding of nonobviousness. This evidence includes:

- Dr. Ronald Karlsbert, a Board Certified Cardiologist and Clinical Professor at Cedars Sinai Heart Institute and UCLA's medical school, called the KBS "a paradigm shift for cardiac care as well as an important advance in healthcare" and "a giant leap in personalized healthcare." Appx15925-15926.

- A paper published in the peer-reviewed Journal of the American College of Cardiology praised Kardiaband's ECG functionality as it was implemented with the Apple Watch. Appx11644-11651.

- An article called the KBS "one of the most impressive examples of an Apple Watch accessory we've seen, health-related or not." Appx11999-12002. That article further stated that "[w]e know from experience the resolution and amount of data required to record an ECG, and we're blown away with how everything performs quickly and seamlessly" and that "if you own an Apple Watch and are concerned at all about the health of your ticker [heart], consider placing a KardiaBand around your wrist." Appx12002.

- A leading cardiologist, Dr. Topol, in praising the KBS stated that the "prompting function" offered by SmartRhythm "is important to doctors taking care of heart patients at risk of atrial fibrillation," adding that "[a] lot of my patients already use the credit card sensor (AliveCor's earlier smartphone-connected Kardia Mobile EKG

> reader), but they don't know when to take an EKG; so they just do it when they feel light headed or dizzy."). Appx11635-11636; Appx31197-31202 (1197:13-1202:22).

Notably, Apple itself also praised the KBS. Praise from a competitor is especially probative evidence of nonobviousness because "[i]ndustry participants, especially competitors, are not likely to praise an obvious advance over the prior art." *Apple Inc. v. Samsung Elecs. Co., Ltd.*, 839 F.3d 1034, 1053 (Fed. Cir. 2016); *see In re Cree, Inc.*, 818 F.3d 694, 702 (Fed. Cir. 2016) ("[P]raise in the industry for a patented invention, and specifically praise from a competitor tends to indicate that the invention was not obvious."). Dr. Waydo, Apple's Director of Health Algorithms, testified that he and others at Apple "tried out" the KardiaBand because they "had some excitement about these products, because [Apple] like[s] it when people build innovative things on our platform. …" Appx30784 (784:12-18). He further testified that users of the Apple Watch could benefit from combining ECG and PPG technologies in the context of the KardiaBand. Appx13667 (316:7-17). Another Apple employee, Rich Taggart, wrote that the KardiaBand was "a high quality accessory and works really well with the Watch" and that "[w]ith a few small tweaks this could be a great experience for Apple Watch customers." Appx16279-16280.

Apple faults the Commission for giving weight to industry praise from the Journal of the American College of Cardiology (Appx11644-11651) because the

"lead author was on the advisory board of AliveCor." AppleBr.69. The article, however, appears in a *peer-reviewed* medical journal and, thus, was vetted through the normal processes of the American College of Cardiology. Similarly, Apple invites the Court to discount the testimony of a doctor because he "helped test the KardiaBand." AppleBr.69-70. Apple, however, fails to explain why testing a product disqualifies a doctor from praising it. Indeed, praise from one who has actually used the product is more probative. Apple also argues that "AliveCor failed to connect the evidence of industry praise to the novel elements of the claims" because examples of industry praise focus on the ECG function. AppleBr.70, 71. But the ECG functionality is an element of the claimed invention. Moreover, the industry praise is not for ECG in a vacuum, but for how ECG is used in the KBS. Accordingly, substantial evidence supports the Commission's finding that industry praise for the KBS is probative of nonobviousness.

3. The Commission Correctly Weighed All the Evidence, Including Evidence of Apple's Copying and Industry Praise for the KBS, to Find Nonobviousness

Evidence that Apple copied AliveCor's KBS in developing its infringing Series 4 Apple Watch along with significant praise in the industry for the KBS, and specifically praise from Apple, is probative that the claimed inventions are not obvious. *Volvo Penta*, 81 F.4th at 1213. In view of the record evidence, the Commission correctly concluded the prior art teachings considered in light of the

evidence of secondary considerations was not sufficient to show that claims 12, 13, 16, 19, 20, 22, and 23 of the '941 patent; claims 1, 8, 12, and 16 of the '731 patent; and claim 16 of the '499 patent would have been obvious to one of ordinary skill at the time of the inventions.

The cases that Apple rely on are not persuasive. None of those courts found the patentee had established strong evidence of copying and industry praise like the Commission did here. *See Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010) (rejecting the patentee's attempt to establish a nexus for commercial success based solely on the success of the alleged infringer's product)*; ZUP, LLC v. Nash Mfg., Inc.*, 896 F.3d 1365, 1373-75 (Fed. Cir. 2018) (holding the patentee's "minimal evidence of secondary considerations" does not "overcome the strong showing of obviousness" "where the differences between the claimed invention and the prior art are minimal")*; Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007) (finding "no basis to disagree with the district court's conclusion" that the "evidence on secondary considerations was inadequate").

B. The Commission Correctly Found the Prior Art Does Not Render Obvious Certain Asserted Claims

1. Substantial Evidence Supports the Commission's Finding That AMON Does Not Disclose the Limitation in Claim 21 of the '941 Patent and Claim 15 of the '731 Patent

Substantial evidence supports the Commission's finding that AMON[16] fails to disclose the claimed processor "display[ing] an ECG rhythm strip from the electric signals," as recited in claim 21 of the '941 patent and claim 15 of the '731 patent. Appx199. Apple asks this Court to reweigh the evidence as to what AMON discloses and to disregard the Commission's credibility determinations.

Apple points to disclosures from AMON allegedly showing that the device included a display that gave "real time feedback" to the user. AppleBr.62. Apple's expert, Dr. Stultz, testified that AMON "specifically mentions a display" and that Figure 4 in AMON was "a representative ECG measurement." Appx31129 (1129:7-14). However, the Commission credited the testimony of AliveCor's expert, Dr. Efimov, who testified that he did not find any disclosure in AMON of that feature. Appx197-199; Appx31269 (1269:11-20). Dr. Efimov explained that Figure 4 "is a plot for publication purposes" and that "there is really no evidence of [a display showing ECG rhythm strip from the electric signals] in the paper." Appx31269 (1269:11-20). Indeed, the only time AMON even

[16] Apple relies on AMON as disclosing this limitation.

mentions Figure 4 in the body of the paper is as a citation for the proposition that "a reasonable signal quality can be obtained" from the ECG sensor, not that it can be displayed on the device. Appx11969. The Commission found Dr. Stultz's testimony, without more, is insufficient to show that AMON taught displaying the ECG rhythm strip created from the electric signals on the device's display or that it would have been obvious for a person of ordinary skill in the art to modify AMON to do so. Appx199.

Apple argues that AMON describes Figure 4 as the output of the device. AppleBr.63. That is incorrect. AMON discloses displaying averages of the RR, QRS, and QT distances in seconds to the user. Appx197-198 (citing Appx11969) ("The distances RR, QRS, and QT are stored for every discovered QRS wave. For an overall result—as displayed to the user—averages are taken over all the valid QRS."). This disclosure does not teach that the processor of the smartwatch [is] configured to "display an ECG rhythm strip from the electrical signals" as required by claim 21. Other than attorney argument, Apple presents no evidence that the representative ECG measurement disclosed in Figure 4 can be displayed to a user, or that such a display would have been obvious to an ordinarily skilled artisan. As the ALJ found, "AMON's Figure 4 is 'a rhythm strip created for publication to demonstrate the efficacy of the single lead ECG sensor'" but that "[t]here is no

disclosure in AMON that the rhythm strip illustrated was ever on a device driven by AMON's processor." Appx198.

2. Substantial Evidence Supports the Commission's Finding That AMON Does Not Disclose the Limitations in Claims 3 and 5 of the '731 Patent and Claim 17 of the '499 Patent

Claim 3 of the '731 patent and claim 17 of the '499 patent require using a "machine learning" algorithm to "detect" arrhythmias. Apple does not dispute that only ECG inputs are fed into AMON's algorithm and that the algorithm is trained to determine characteristics of the ECG signal, not detect arrhythmias. Appx224-225. Apple contends that an "artisan would have been 'well-aware'" of these allegedly "fundamental" concepts. AppleBr.66. The Commission, however, credited the testimony of AliveCor's expert, who testified that the cited references fail to disclose the use of machine learning algorithms to detect arrhythmias. Appx31266-31268 (1266:1-1268:24). Substantial evidence supports the Commission's finding that AMON does not disclose the use of a machine learning algorithm to detect arrhythmias.

Claim 5 of the '731 patent requires "the processing device is configured to input HRV [heart rate variability] data into a machine learning algorithm trained to detect arrhythmias." In the proceeding below, Apple did not argue claim 5 is obvious for reasons different from claim 3. *See* Appx227 ("Apple contends that 'AMON discloses or renders obvious all the additional limitations of claim 5 of the

'731 patent' . . . it offers no discussion of obviousness [as to that claim] in either of its briefs."); Appx1300 (Apple petitioned for Commission review of claims 3 and 5 together). This Court should find that Apple has waived any such argument on appeal. *See Broadcom Corp. v. Int'l Trade Comm'n*, 542 F.3d 894, 901 (Fed. Cir. 2008) (citing *Hazani v. Int'l Trade Comm'n*, 126 F.3d 1473, 1476-77 (Fed. Cir. 1997)); *Kinik Co v. Int'l Trade Comm'n*, 362 F.3d 1359, 1367 (Fed. Cir. 2004).

3. Substantial Evidence Supports the Commission's Finding That AMON in View of Almen Does Not Disclose the Limitations of Claims 9 and 10 of the '731 Patent

Claim 7, from which claims 9 and 10 depend, requires "the processing device … to extract one or more features from the PPG data." These features include "a nonlinear transform of R-R ratio or R-R ratio statistics with an adaptive weighting factor" (claim 9) or "an HRV signal analyzed geometrically" (claim 10). Appx10073 (27:6-10, 14-19).

Apple asserts that "[t]he Commission acknowledged that AMON in view of Almen 'discloses measurement of HRV' from PPG data." AppleBr.67. This is incorrect. Rather, the Commission found that while Almen discloses HRV, it does not disclose extracting "nonlinear transform of R-R ratio or R-R ratio statistics with an adaptive weighting factor" from PPG data. Appx229; Appx10073 (27:14-16). The Commission also found that "[e]ven accepting Dr. Stultz's opinion that the claimed technique was well-known, the one reference Apple cites as disclosing

the [nonlinear] transform discusses it as applying to ECG data, not PPG data, as the claim requires." Appx229.

Apple also asserts the '731 patent discloses this limitation. AppleBr.66 (citing Appx10063-10064 (8:64-9:2)). But that disclosure is also directed to ECG data, not PPG data. Accordingly, the Commission correctly found that AMON in view of Almen do not render obvious claims 9 and 10 of the '731 patent.

VI. THE COMMISSION CORRECTLY DETERMINED THAT CLAIMS 16 AND 17 OF THE '499 PATENT ARE PATENT-INELIGBLE UNDER SECTION 101 (ALIVECOR APPEAL)

If the Court agrees that claims 16 and 17 of the '499 are not infringed, then it need not reach this issue. *See supra*, Part IV. The Commission correctly found that claims 16 and 17 of the '499 patent recite patent-ineligible subject matter. At *Alice* step one, the Commission affirmed the ALJ's finding that the claims are directed to an abstract idea. Appx37-38; Appx248-250. At *Alice* step two, the Commission found the claims recite activities that physicians routinely conduct, using generic and conventional sensors in their ordinary manner to perform the claimed functions. Under well-established precedent, such claims are invalid for claiming patent-ineligible subject matter under section 101. Appx37-38; Appx248-250; *see Alice Corp. Pty. v. CLS Bank Int'l*, 573 U.S. 208, 217-18, 221 (2014); *Intell. Ventures I LLC v. Symantec Corp.*, 838 F.3d 1307, 1314 (Fed. Cir. 2016).

A. Under *Alice* Step One, Claims 16 and 17 Are Drawn to An Abstract Idea

AliveCor asserts that claims 16 and 17 are drawn to specific improvements in cardiac monitoring technology akin to the asserted claims in the '941 and '731 patents that the Commission found recite patentable subject matter. AliveCorBr.38-39; Appx31-34.

The Commission found the '499 patent claims are written at a high level of generality. Unlike the claims in the '941 and '731 patents, the claims of the '499 patent do not recite any specific improvement in any sensors (be it heart rate, ECG, or motion sensors) or a new way a sensor or a combination of sensors operate. Rather, independent claim 11, from which claims 16 and 17 depend, recites the abstract idea of "taking in heart rate data (of any kind), taking in activity level data (of any kind), calculating heart rate variability, comparing that variability with the activity (by any means), and then alerting the user to 'record an electrocardiogram using said mobile computing device.'" Appx249. As the Commission observed, the "bulk of the claim is directed to the data analysis algorithms taking place within the 'processor' and according to the 'instructions' saved in memory," all of which are commonly carried out by medical professionals. Appx249. Moreover, the claims simply recite generic and conventional sensors to measure cardiac activity; the apparatus included "is devoid of specificity, such that it can only be considered generic computer hardware—'a heart rate sensor,' 'mobile computing

device,' 'a processor,' 'a motion sensor,' and 'non-transitory computer readable medium.'" Appx249; Appx37-38; Appx31058-31059 (1058:13-1059:19), Appx31077-31078 (1077:21-1078:15); Appx31085 (1085:15-22).

AliveCor relies heavily on C*ardioNet, LLC v. InfoBionic, Inc.*, 955 F.3d 1358 (Fed. Cir. 2020). AliveCorBr.40-43. The Commission found *CardioNet* provides support for patentability of the asserted claims of the '941 and '731 patents, but not for the claims of the '499 patent. In *CardioNet*, the patent "describe[d] cardiac monitoring systems and techniques for detecting and distinguishing atrial fibrillation and atrial flutter from other various forms of cardiac arrhythmia." 955 F.3d at 1362. This Court found that claim 1 was "directed to a device that detects beat-to-beat timing of cardiac activity, detects premature ventricular beats, and determines the relevance of the beat-to-beat timing to atrial fibrillation or atrial flutter, taking into account the variability in the beat-to-beat-timing caused by premature ventricular beats identified by the device's ventricular beat detector." *Id*. at 1368. The Court pointed to the specification's disclosure that the claimed device "more accurately detects the occurrence of atrial fibrillation and atrial flutter—as distinct from [ventricular tachycardia] and other arrhythmias—and allows for more reliable and immediate treatment of these two medical conditions" and "achieves multiple technological improvements." *Id*. at 1368-69. The claim in *CardioNet* is thus akin to the

specific ECG and PPG sensors recited in the asserted claims of the '941 and '731 patents.

CardioNet, however, provides no support for patentability of claims 16 and 17 of the '499 patent. Rather, claims 16 and 17 are like the claims found patent-ineligible in another *CardioNet* case. *See CardioNet, LLC v. InfoBionic, Inc.*, 816 F. App'x 471, 475 (Fed. Cir. 2020) (unreported). At *Alice* step one, this Court stated that "[w]hile some of the claims are couched as systems or articles, they essentially recite and are directed to collecting, analyzing, and displaying data by conventional means." *Id.* at 475. The Court observed that the claims "begin by collecting physiological data" and that "[t]he specifications explain that a monitoring system 'monitors and reports physiological data,' which can be analyzed and 'arrhythmia events can be identified based on predetermined criteria.'" *Id.* (citation omitted). "The identified events are 'correlated' with events identified by a parallel human assessment to determine whether the events are valid." *Id*. (citation omitted). As the Court further observed, "the claims are not directed to specific methods for identifying cardiac events or determining correlation between machine- and human-identified events, nor do the specifications disclose specific methods for doing so." *Id.* "Instead, the claims and specifications treat those steps as conventional processes, and therefore the claims cannot be said to require anything more than generic data analysis." *Id.*

Here too, claims 16 and 17 are not directed to a specific improvement in any sensor (be it heart rate, ECG, motion sensors) or the way a sensor operates. The claimed sensors function in their ordinary manner to capture data generally. Appx249-250.

The details set forth in the '499 patent specification do not change the conclusion under *Alice* step one. AliveCor contends that "continuous monitoring may allow a subject to be alerted immediately upon an indication of [a] potential [cardiac] problem" and that "the claimed heart rate monitor informs the user when they are most likely experiencing an arrhythmia and therefore when it is most beneficial to record an ECG." AliveCorBr.42. This alleged continuous monitoring, however, is wholly absent from the claims. The Court has made clear that the focus of a section 101 inquiry is "on the language of the Asserted Claims themselves, considered in light of the specification." *See TecSec, Inc. v. Adobe Inc.*, 978 F.3d 1278, 1292 (Fed. Cir. 2020).

AliveCor further points to the specification's disclosure that "[b]y comparing measured heart rate changes with measured activity changes, the presently disclosed software or 'app' minimizes false alarms." AliveCorBr.43 (citing Appx10038 (25:22-25)). Claims 16 and 17, however, are not directed to a specific software app that minimizes "false alarms." Rather, as the Commission found, the "bulk of the claim is directed to the data analysis algorithms taking

place within the 'processor' and according to the 'instructions' saved in memory." Appx249. The claims do not recite any specific and special software routines to aid in minimizing "false alarms" and the "bit of apparatus recited … is devoid of specificity, such that it can only be considered generic computer hardware—'a heart rate sensor,' 'mobile computing device,' 'a processor,' 'a motion sensor,' and 'non-transitory computer readable medium.'" Appx249.

The additional limitations in claims 16 and 17 also do not alter the *Alice* step one analysis. Dependent claim 16 adds the limitation "said mobile computing device comprises a smartwatch." Appx10039. AliveCor asserts that one of ordinary skill "would have understood that incorporating an ECG sensor into a wrist-worn smartwatch would require using a specific type of ECG sensor: a single-lead ECG." AliveCorBr.45. AliveCor, however, did not make this argument to the Commission and thus has waived it. *See Broadcom*, 542 F.3d at 901; *Hazani*, 126 F.3d at 1476-77. Notwithstanding waiver, claim 16 is not limited to a single lead ECG and the expert testimonies cited in AliveCor's brief do not support its argument. AliveCorBr.45 (citing Appx31236; Appx31094-31095). Unclaimed features "cannot function to remove [the claims] from the realm of ineligible subject matter." *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 967 F.3d 1285, 1295 (Fed. Cir. 2020) (citing *ChargePoint, Inc. v. SemaConnect, Inc.*, 920 F.3d 759, 766 (Fed. Cir. 2019)).

Dependent claim 17 adds the limitation of "said computer program further causes said processor to determine a presence of said arrhythmia using a machine learning algorithm." Appx10039 (28:11-13). AliveCor asserts that the machine learning algorithm allows the claimed devices to "more accurately detect arrhythmias in real time." AliveCorBr.46. But as the ALJ found, merely adding a machine learning algorithm is "literally just another algorithm" that "only deepens the connection between the claim and ineligible subject matter." Appx37-38; Appx250. At bottom, a machine learning algorithm is simply an extension of a mental process or mathematical algorithm that is not patent-eligible subject matter under longstanding precedent. *See, e.g.*, *Parker v. Flook*, 437 U.S. 584, 594-95 (1978). Thus, the use of a machine learning algorithm in claim 17, even if "[g]roundbreaking," is still directed to an abstract idea. *SAP Am., Inc. v. InvestPic, LLC*, 898 F.3d 1161, 1163 (Fed. Cir. 2018) (citing *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 591 (2013)).

B. Under *Alice* Step Two, Generic Sensors Operating in Their Ordinary Manner Fail to Transform the Claims Into Patentable Inventions

Under *Alice* step two, a tribunal must "determine whether [any] additional elements 'transform the nature of the claim' into a patent-eligible application," requiring an "inventive concept" or "additional features." *Alice*, 573 U.S. at 221. This is to ensure that the patent does not seek simply to "monopolize the abstract idea." *Id.*

The Commission correctly found that "claim 11's non-ineligible elements, either individually or as an ordered combination, do not transform the nature of the claim into something more than a patent on the abstract concept." Appx36-38; Appx250 (citing *Alice*, 573 U.S. at 217-18). As the Commission explained, "there are sensors recited ('heart rate,' 'electrocardiogram,' 'motion'), but they are unrestricted as to structure, arrangement, or data output so long as they relate to 'heart rate,' electrical activity of the heart, or 'activity level,' respectively." Appx36-38; Appx250. Contrary to AliveCor's assertion (at 48), the other recited features "mobile computing device," "processor," and "computer readable medium" are generic, and perform their ordinary functions. As the Commission found, "there is nothing recited that could be viewed as improving the operation of any of these computing elements (*e.g.*, faster, fewer errors, less power consumption, etc.)." Appx39. In other words, the "physical components behave exactly as expected according to their ordinary use," so there is no inventive concept. *In re TLI Commc'ns LLC Pat. Litig.*, 823 F.3d 607, 615 (Fed. Cir. 2016).

"[U]nlike claim 12 of the '941 patent, claim 11 of the '499 patent does not recite the number of leads to further specify the type of ECG sensor, nor does it expressly recite any use for the ECG data—it simply exists within the 'mobile computing device.'" Appx38; Appx250. AliveCor contends that "the ECG sensor's presence … is important to the technological innovation" because it "can

alert the user to record an ECG when doing so is most likely to capture the cardiac information most helpful for a doctor to render a diagnosis or order further testing." AliveCorBr.47-48. But physicians have been using ECGs to record heart activity for decades, and the claims here do not prescribe any use for the ECG data that would substantiate AliveCor's contention. As Dr. Stultz testified, he learned in medical school over 30 years ago that "[i]f an irregularity is suspected, an ECG is obtained" and that this is routine in medical practice. Appx30177-78 (1077:4-1078:15). "In essence the claim covers the addition of generic sensors to an existing ECG machine, and for no particular purpose." Appx250. "Alone or as an ordered combination, all this is equivalent to the basic idea of using such sensors." Appx38.

As to claim 16, merely limiting the abstract idea to a particular technological environment such as a "smartwatch" having generic sensors and processor is insufficient to pass muster under *Alice* step two. To qualify as a patent-eligible improvement, the invention must be directed to a specific improvement in the smartwatch, not simply to using the generic processor in the smartwatch to carry out the abstract idea. Here, claim 16 falls into the latter category. It simply incorporates generic sensors used in their ordinary manner in a "smartwatch." This is insufficient to confer patentability on claim 16. *See Intell. Ventures I LLC v. Capital One Bank (USA)*, 792 F.3d 1363, 1366 (Fed. Cir. 2015) ("An abstract idea

does not become nonabstract by limiting the invention to a particular field of use or technological environment, such as the Internet or [a] computer."); *Affinity Labs of Tex., LLC v. DIRECTV, LLC*, 838 F.3d 1253, 1259 (Fed. Cir. 2016).

Regarding claim 17, the recited "machine learning algorithm" is an unspecified "algorithmic step" and "only deepens the connection between the claim and ineligible subject matter." Appx37-38; Appx250. Even accepting AliveCor's argument that use of a machine learning algorithm is inventive, "[a] claim for a new abstract idea," here, a machine learning algorithm, "is still an abstract idea." *SAP*, 898 F.3d at 1163 (quoting *Synopsys, Inc. v. Mentor Graphics Corp.*, 839 F.3d 1138, 1151 (Fed. Cir. 2016)).

Accordingly, the Commission properly found that claims 16 and 17 of the '499 patent are patent-ineligible under section 101.

VII. THE COMMISSION DID NOT ABUSE ITS DISCRETION IN ITS CHOICE OF REMEDY (APPLE CROSS-APPEAL)

Section 337 requires that the Commission, upon finding a violation of section 337, issue an exclusion order "unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry." 19 U.S.C. § 1337(d). Prior to issuing its remedial orders in this case, the Commission thoroughly considered each of the statutory public

interest factors in view of the public interest comments received from the parties and from interested non-parties. In over 30 pages of its opinion, the Commission discussed the public interest factors and set forth its reasoning for concluding that remedial orders with an exemption for service, repair, and replacement would not adversely affect the public interest. Appx52-82.

Apple alleges two errors with the Commission's entry of remedial orders.[17] First, Apple argues the Commission's finding that "other available products can remedy the serious health harms" is "contrary to all record evidence." AppleBr.88. But Apple admits that there are alternative wearable devices such as Fitbit's Charge 5 and Sense 2 that include ECG, HHRN and IRN features. AppleBr.92. Apple stretches the public health and welfare factors too far by seeking to require that substitutes "offer[] many features available on Apple Watches," even features that have nothing to do with the asserted claims. AppleBr.92. Apple further

[17] Apple submits that the Commission rarely declines to issue remedial orders and cites a law review article discussing exclusion orders since the Supreme Court's *eBay* decision. AppleBr.88. Section 337 mandates the Commission to issue an exclusion order upon finding a violation unless it finds that the public interest factors warrant against such relief. Thus, it is not surprising that the Commission declines to issue an exclusion order only in rare circumstances where the evidence shows that public interest concerns warrant denying relief. Moreover, the Commission's remedial orders are subject to review by the President, who may disapprove of the orders for broader policy reasons. 19 U.S.C. § 1337(j); Memorandum for the United States Trade Representative, 70 Fed. Reg. 43,251 (July 26, 2005). As to *eBay*, this Court has made clear that it does not apply to the Commission. *Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1359 (Fed. Cir. 2010).

argues, with no supporting evidence, that there are "supply chain issues and other logistical constraints," that would affect competitors' abilities to produce these alternate products. AppleBr.93. Such attorney argument does not show that the Commission abused its discretion in finding there are reasonable substitutes for Apple's infringing products.

Second, Apple argues that "numerous ongoing and planned research studies involving Apple Watches" will be jeopardized by exclusion. AppleBr.88. As the Commission found, Apple failed to "identify any new studies that would be impacted by the remedial orders here, but rather the issue pertains solely to studies already underway." Appx71-72. The remedial orders will not prevent current participants using infringing Apple Watches from continuing to participate in research studies or new participants that have already purchased Apple Watches or reasonable substitutes from joining the studies. Furthermore, the Commission determined that any adverse effect on the public health and welfare from the remedial orders can be mitigated by allowing Apple Watches that have already been imported and sold to be repaired, and if under warranty, replaced. Appx80-81. In view of this exemption, the Commission did not abuse its discretion in determining that the public interest factors do not counsel against providing AliveCor a remedy.

CONCLUSION

For the foregoing reasons, the Commission respectfully requests that the Court affirm the Commission's determination.

Respectfully submitted,

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Date: November 17, 2023

CERTIFICATE OF SERVICE

I, Panyin A. Hughes, hereby certify that, on this November 17, 2023, I caused a copy of the foregoing **RESPONSE BRIEF OF APPELLEE INTERNATIONAL TRADE COMMISSION**, to be served on counsel of record via the Court's CM/ECF system. In addition, pursuant to an agreement among the parties, the confidential version of the Commission's brief was served by email attachment.

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CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(g)(1) of the Federal Rules of Appellate Procedure and Federal Circuit Rule 32(b)(3), I hereby certify that the attached brief complies with the type-volume limitation and typeface requirements Federal Rule of Appellate Procedure 32(a)(7) and Federal Circuit Rules 32(b)(1) and 32(b)(2). The brief has been prepared in a proportionally spaced typeface using Microsoft Office 365, in Times New Roman 14-point font. The brief contains a total of 13,715 words including 13,679 words obtained from the word-count function of the word-processing system, including all footnotes, annotations, and claim language, and a manual count of 36 words appearing in the graphics and figures.

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CERTIFICATE OF COMPLIANCE WITH CONFIDENTIALITY REQUIREMENTS

Pursuant to Fed. Cir. R. 25.1(e)(2), I hereby certify that the attached brief, which contains material marked as confidential under Fed. Cir. R. 25.1(d)(1), complies with the limitations and requirements related to confidential information set forth in Fed. Cir. R. 25.1(d) and 28(d). This brief contains 5 unique words marked as confidential, not including words or images marked as confidential in Appellant's or Cross-Appellants' principal briefs. All such confidential material has been properly identified with required bracketing, page headers, and labeled redactions (in the non-confidential version of the brief).

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