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April 20, 2021

FILED VIA EDIS

The Honorable Lisa R. Barton
Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112A
Washington, DC 20436

Re: ***Certain Wearable Electronic Devices With ECG Capability and Components Thereof***

Dear Secretary Barton:

Enclosed for filing, please find documents in support of a request by AliveCor, Inc. ("Complainant") that the U.S. International Trade Commission institute an investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, concerning certain wearable electronic devices with electrocardiogram ("ECG") capability and components thereof. There is no confidential business information contained in the complaint itself, but we have included a separate letter requesting confidential treatment for five exhibits included with this filing.

On March 16, 2020, the Commission provided "notice that it is temporarily waiving and amending certain of the Commission's rules that required the filing of paper copies, CD-ROMS, and other physical media in section 337 investigations to address concerns about COVID-19." International Trade Commission, Temporary Changes to Filing Procedures, Federal Register Vol. 85, No. 54 (March 19, 2020). Specifically, the Commission approved the temporary amendment of various rules "to permit parties to file section 337 complaints, exhibits, attachments, and appendices, electronically." *Id.* Accordingly, Complainant's filing only contains electronic documents.

Complainant's submission via EDIS includes the following:

1. One (1) electronic copy of Complainant's Verified Complaint, pursuant to Commission Rule 210.8(a)(1)(i).

2. One (1) electronic copy of the public exhibits to the Verified Complaint pursuant to Commission Rules 210.8(a)(1)(1) and 210.12(a)(9), including:

a. one (1) electronic certified copy of each of United States Patent Nos. 10,595,731 ("the '731 patent"), 10,638,941 ("the '941 patent"), and 9,572,499 ("the '499 patent"), copies of which are respectively included as Exhibits 1, 2, and 3, to the Verified Complaint pursuant to Commission Rule 210.12(a)(9)(1); and

b. one (1) electronic copy of the certified assignment records for each of the '731 patent, '941 patent, and '499 patent, copies of which are respectively included as Exhibits 4, 5, and 6 to the Verified Complaint, pursuant to Commission Rule 210.12(a)(9)(ii).

3. One (1) electronic copy of the confidential exhibits to the Verified Complaint, pursuant to Commission Rules 201.6(c) and 210.8(a)(1)(ii).

4. Four (4) electronic copies of the certified prosecution history of the '941 patent which is identified as Appendix C to the Verified Complaint, pursuant to Commission Rule 210.12(c)(1). Four (4) electronic copies of the prosecution history of the '731 patent and '499 patent, which are respectively identified as Appendices A and E to the Verified Complaint.[1]

5. Four (4) electronic copies each of each patent and applicable pages of each technical reference mentioned in the prosecution history of '731 patent, '941 patent, and '499 patent, which are respectively identified as Appendices B, D, and F to the Verified Complaint, pursuant to Commission Rule 210.12(c)(2).

6. A letter and certification requesting confidential treatment for the information contained in confidential exhibits 8 and 16-22 to the Verified Complaint, pursuant to Commission Rules 201.6(b) and 210.5(d).

7. A Statement on the Public Interest regarding the remedial orders sought by Complainants in the Verified Complaint, pursuant to Commission Rule 210.8(b).

Complainant confirms that it will serve copies of the non-confidential versions of the Complaint and all associated exhibits and appendices upon the institution of this investigation on the Respondent consistent with 19 C.F.R. part 201 (including 19 C.F.R. § 201.16) and the Temporary Procedures.

Please contact me with any questions regarding this filing.

[1] Certified copies of the prosecution history for the '499 and '731 patents have been ordered and will be provided once they are received from the U.S.P.T.O.

Respectfully submitted

/s/ S. Alex Lasher

S. Alex Lasher
Counsel for Complainant AliveCor, Inc.

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REQUEST FOR CONFIDENTIAL TREATMENT

April 20, 2021

FILED VIA EDIS

The Honorable Lisa R. Barton
Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112A
Washington, DC 20436

Re: ***Certain Wearable Electronic Devices With ECG Capability and Components Thereof***

Dear Secretary Barton:

Pursuant to Commission Rule 201.6, Complainant AliveCor, Inc. ("Complainant" or "AliveCor") respectfully requests confidential treatment of certain confidential business information contained in confidential exhibits 8 and 16-22 to the Verified Complaint.

The information in the exhibits for which Complainant seeks confidential treatment consists of proprietary commercial information, including confidential and proprietary licensing information, technical information related to domestic articles protected by Complainant's asserted patents, technical information related to accused products articles obtained from nonpublic teardowns, and financial data regarding Complainant's domestic investments in plant and equipment and labor and capital related to domestic articles protected by Complainant's asserted patents.

The proprietary information described herein qualifies as confidential business information under Commission Rule 201.6 because substantially-identical information is not available to the public, because the disclosure of this information would cause substantial competitive harm to Complainant, and because the disclosure of this information would likely impede the Commission's efforts and ability to obtain similar information in the future.

Thank you for your attention. Please contact me with any questions regarding this request for confidential treatment.

Respectfully submitted

/s/ S. Alex Lasher
S. Alex Lasher
Counsel for Complainant AliveCor, Inc.

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

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

CERTIFICATION

I, S. Alex Lasher, counsel for Complainant AliveCor, Inc., declare as follows:

1. I am duly authorized by Complainant to execute this certification.

2. I have reviewed confidential exhibits 8 and 16-22 to Complainant's Verified Complaint, for which Complainant seeks confidential treatment.

3. Confidential Exhibit 8 is a list of private agreements between AliveCor and its licensees. Disclosure of this information to the public would cause substantial harm to AliveCor, their respective competitive positions, and their ability to negotiate future agreements. Disclosure of this information would also impair the Commission's ability to obtain information necessary to perform its statutory function.

4. Confidential Exhibit 16 contains confidential commercial and technical information concerning the development of domestic industry products, which is not available for public dissemination. Disclosure of this information to the public would cause substantial harm to AliveCor and its competitive position. Disclosure of this information also would impair the Commission's ability to obtain information necessary to perform its statutory function.

5. Confidential Exhibit 17 contains confidential commercial and technical information concerning the development of domestic industry products, which is not available for public dissemination. Disclosure of this information to the public would cause substantial harm to AliveCor and its competitive position. Disclosure of this information also would impair the Commission's ability to obtain information necessary to perform its statutory function.

6. Confidential Exhibit 18 contains confidential commercial and technical information concerning the development of domestic industry products, which is not available for public dissemination. Disclosure of this information to the public would cause substantial harm to AliveCor and its competitive position. Disclosure

of this information also wouldimpair the Commission's ability to obtain information necessary to perform its statutory function.

7. Confidential Exhibit 19 contains confidential commercial and technical information concerning the development of domestic industry products, which is not available for public dissemination. Disclosure of this information to the public would cause substantial harm to AliveCor and its competitive position. Disclosure of this information also would impair the Commission's ability to obtain information necessary to perform its statutory function.

8. Confidential Exhibit 20 contains confidential commercial and financial information concerning AliveCor's investments in its domestic industry, which is not available for public dissemination. Disclosure of this information to the public would cause substantial harm to LG and its competitive position. Disclosure of this information also would impair the Commission's ability to obtain information necessary to perform its statutory function.

9. Confidential Exhibit 21 contains confidential commercial and technical information concerning the development of domestic industry products, which is not available for public dissemination. Disclosure of this information to the public would cause substantial harm to AliveCor and its competitive position. Disclosure of this information also would impair the Commission's ability to obtain information necessary to perform its statutory function.

10. Confidential Exhibit 22 is a private license agreement to AliveCor's patents that contains confidential information regarding the terms of the agreement and the circumstances that led to the agreement, which is not available for public dissemination. Disclosure of this information to the public would cause substantial harm to AliveCor and its licensee, their respective competitive positions, and their ability to negotiate future agreements. Disclosure of this information would also impair the Commission's ability to obtain information necessary to perform its statutory function.

3. To the best of my knowledge, information, and belief, founded after a reasonable inquiry, substantially-identical information to that contained in the exhibits is not available to the public.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 20th day of April, 2021 in Washington, DC.

/s/ S. Alex Lasher
S. Alex Lasher

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

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

COMPLAINANT'S STATEMENT ON THE PUBLIC INTEREST

Pursuant to Commission Rule 210.8(b), Complainant AliveCor, Inc. ("AliveCor") submits this Statement on the Public Interest regarding the remedial orders it seeks against Proposed Respondent Apple Inc. ("Apple"). AliveCor seeks a permanent limited exclusion order barring from entry into the United States certain wearable electronic devices with electrocardiogram ("ECG") capability and components thereof that infringe one or more claims of United States Patent Nos. 10,595,731, 10,638,941, and 9,572,499 (collectively, the "Asserted Patents"). AliveCor also seeks a permanent cease and desist order prohibiting Apple, its subsidiaries, related companies, and agents from engaging in the importation, sale for importation, marketing and/or advertising, distribution, offering for sale, sale, use after importation, sale after importation, or other transfer within the United States of the accused products.

I. Introduction

AliveCor is headquartered in Mountain View, California, and is a leader in the design and development of products that provide intelligent, highly-personalized heart data to help diagnose heart conditions. In 2017, capitalizing on development work performed by its founders and its team of California-based engineers, AliveCor was first company to bring to market an FDA-cleared wearable consumer device capable of monitoring the owner's heart rate, detecting episodes of atrial

fibrillation ("AFib"), and then allowing the owner to perform an ECG. This revolutionary wearable device—the KardiaBand—embodies inventions protected by the patents AliveCor is asserting in its Complaint. After Apple anti-competitively and unfairly excluded KardiaBand from the market, AliveCor developed additional products that practice those patents. The remedies requested in AliveCor's complaint will enforce its intellectual property rights, protecting AliveCor's innovations and products. As the Commission has recognized, protecting such intellectual property rights is in the public interest. *See, e.g.*, *Certain Baseband Processor Chips and Chipsets, Transmitter and Receiver (Radio) Chips, Power Control Chips, and Products Containing Same, Including Cellular Telephone Handsets*, Inv. No. 337-TA-543, Comm'n Op. at 136-37 (June 19, 2007).

AliveCor's requested remedies will not adversely affect "the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, [or] United States consumers." 19 U.S.C. § 1337(d)(1). Any demand for the products that would be subject to the requested remedial orders could be filled by the diverse field of suppliers offering smartwatches or wearable ECG devices to United States consumers. The availability of those products would prevent adverse effects on the public health and welfare. And because Apple engaged in anticompetitive conduct to aid sales of the accused products, the requested remedies are likely to increase competition, benefiting consumers and competitive conditions.

The Commission has previously instituted an investigation involving wearable health and activity monitoring devices without directing the ALJ to make a recommended determination on the public interest. *See Certain Wearable Monitoring Devices, Systems, and Components Thereof*, Inv. No. 337-TA-1190, Notice of Institution of Investigation, 85 Fed. Reg. 2440 (Jan. 15, 2020). The requested remedies here likewise raise no public interest concerns. By protecting AliveCor's

innovative intellectual property, consumers, and the competitive conditions, the requested remedies will serve—rather than harm—the public interest.

II. Use of the Accused Products in the United States

The Respondents' products potentially subject to remedial orders in the proposed investigation are wearable electronic devices and components thereof. As described in the Complaint, the Accused Products are used by consumers to look for heart arrhythmias and confirm the presence of arrhythmias by taking and analyzing ECGs on the wearable electronic device.

III. The Requested Remedies Do Not Pose Any Public Health, Safety, or Welfare Concerns

AliveCor's requested remedial orders, if issued, will not raise any public health, safety, or welfare concerns. As explained below, there are numerous suppliers fully capable of providing consumers with wearable monitoring devices that can record ECGs and identify episodes of AFib. The availability of these substitute ECG monitors and AFib detection devices obviates any impact on the public health from exclusion of the accused Apple products.

IV. Like or Directly-Competitive Articles Could Replace the Accused Products

AliveCor's requested remedies would exclude certain versions of Apple smartwatches. The market for smartwatches in the United States has a diverse field of participants that directly compete with Apple's accused products and functionalities. Numerous suppliers sell competitive smartwatches, wearable electronic ECG devices, and other personal electronic devices capable of detecting AFib to United States consumers. Third parties such as Samsung and FitBit sell smartwatches with ECG functionality in the United States and could easily ramp up production to

replace any excluded Apple products. For example, the Samsung Galaxy Watch 3 and the Samsung Watch Active 2,[1] and the Fitbit Sense[2] are all FDA-approved smartwatches with ECG functionality.

Even if non-accused FDA-approved Smartwatches with ECG functionality, standing alone, cannot replace the products subject to an exclusion order, other products, including Apple's own non-infringing products, can be combined to replace all accused products subject to an exclusion order. Apple and other suppliers sell smartwatches that do not have the infringing functionality and would not therefore be subject to an exclusion order. For example, the Apple Watch SE[3]; the Apple Watch Series 3[4]; the Fitbit Versa 3, Versa 2, and Versa Lite[5]; and the Fossil Hybrid, Hybrid HR, Gen 4, Sport, and Gen 5[6] would still be available to consumers if an exclusion order issues in this investigation. Consumers would also be able to acquire portable ECG readers, like AliveCor's KardiaMobile product.[7] Alone or in combination, these substitute products are competitive with every aspect of Apple's accused products. And more substitute products are likely coming soon.

Exclusion of infringing products does not harm the public interest when substitute products are available and the accused products are manufactured overseas. *See Certain Digital Televisions & Certain Prods. Containing Same & Methods of Using Same*, Inv. No. 337-TA-617, Comm'n Op. at 15 (Apr. 23, 2009). That is the case here.

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[1] https://news.samsung.com/global/fda-cleared-electrocardiogram-monitor-app-is-available-in-the-us-starting-today-on-galaxy-watch3-and-galaxy-watch-active2

[2] https://www.theverge.com/2020/9/14/21436090/fitbit-sense-ekg-heart-fda-clearance-apple-samsung-withings

[3] https://www.apple.com/apple-watch-se/

[4] https://www.apple.com/shop/buy-watch/apple-watch-series-3

[5] https://help.fitbit.com/articles/en_US/Help_article/2457.htm

[6] https://www.fossil.com/en-us/shopbr/watch-comparison-chart

[7] https://www.alivecor.com/kardiamobile

V. Alternative Suppliers Have the Capacity to Replace the Accused Products

No public interest concerns exist when the market contains an adequate supply of competitive or substitute products for those subject to a remedial order. *See, e.g.*, *Certain Elec. Digital Media Devices & Components Thereof*, Inv. No. 337-TA-796, Comm'n Op. at 114-15 (Sept. 6, 2013). The numerous suppliers listed above include major companies with established supply chains, like Samsung, Fitbit, and even Apple itself. They have the capacity to replace Apple's infringing products without delay.

VI. The Requested Remedial Orders Will Not Harm U.S. Consumers

Consumers will not likely experience any negative impact from the requested remedial orders. Because numerous suppliers of smartwatches and wearable ECG devices have the capacity to immediately fill any void left by the exclusion of Apple's infringing products, consumers will continue to have a wide variety of both type of products available to them. Apple's past sales of its infringing products were, moreover, propped up by anticompetitive and unfair business practices. Apple introduced an infringing version of the Apple Watch after seeing the utility of—and copying—AliveCor's KardiaBand and SmartRhythm technology. Apple then decided to eliminate AliveCor as a competitor and took the steps necessary to exclude AliveCor products from the market. Excluding Apple's infringing products, as requested in AliveCor's complaint, will promote the competition Apple unfairly eliminated. Through its protection of intellectual property rights, and against Apple's anticompetitive conduct, the requested remedies will benefit consumers.

VII. Conclusion

The requested remedies raise no public interest concerns, and the strong public interest in protecting intellectual property rights outweighs any hypothetical harm. The Commission should decline to delegate consideration of the public interest to the ALJ, and it should issue a limited exclusion order and cease and desist orders if it determines that Apple violated Section 337.

Dated: April 20, 2021

Respectfully submitted,

/s/S. Alex Lasher

S. Alex Lasher
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Counsel for AliveCor, Inc.

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

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

COMPLAINT UNDER SECTION 337 OF THE TARIFF ACT OF 1930, AS AMENDED

Complainant

AliveCor, Inc.
444 Castro St, Suite 600,
Mountain View, CA 94041
Tel. (650) 396-8650

Proposed Respondent

Apple Inc.
One Apple Park Way,
Cupertino, California 95014
Tel. (408) 996–1010

TABLE OF CONTENTS

EXHIBIT LIST

Exhibits	Description
1	U.S. Patent No. 10,595,731
2	U.S. Patent No. 10,638,941
3	U.S. Patent No. 9,572,499
4	Assignment Records for U.S. Patent No. 10,595,731
5	Assignment Records for U.S. Patent No. 10,638,941
6	Assignment Records for U.S. Patent No. 9,572,499
7	List of Foreign Counterparts
8	Confidential List of Licensees
9	’731 Infringement Claim Charts
10	’941 Infringement Claim Charts
11	’499 Infringement Claim Charts
12	Photographs and proof of purchase of the Apple Watch
13	’731 Domestic Industry Claim Chart KardiaBand
14	’941 Domestic Industry Claim Chart KardiaBand
15	’499 Domestic Industry Claim Chart KardiaBand
16	Confidential ’731 Domestic Industry Claim Chart Reference
17	Confidential ’941 Domestic Industry Claim Chart Reference
18	Confidential ’499 Domestic Industry Claim Chart Reference
19	Confidential Declaration of Siva Somayajula
20	Confidential Declaration of Clyde Hosein
21	Confidential Domestic Industry Product Reference
22	Confidential License to the Asserted Patents

APPENDIX LIST

Appendices	Description
A	Prosecution History of U.S. Patent No. 10,595,731
B	Patents and Applicable Pages of Technical References Mentioned in the Prosecution History of U.S. Patent No. 10,595,731
C	Prosecution History of U.S. Patent No. 10,638,941
D	Patents and Applicable Pages of Technical References Mentioned in the Prosecution History of U.S. Patent No. 10,638,941
E	Prosecution History of U.S. Patent No. 9,572,499
F	Patents and Applicable Pages of Technical References Mentioned in the Prosecution History of U.S. Patent No. 9,572,499

I. INTRODUCTION

1. AliveCor, Inc. (hereinafter "AliveCor" or "Complainant") files this complaint under Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, based on the Proposed Respondent Apple Inc.'s ("Apple" or "Respondent") unlawful importation into the United States, sale for importation into the United States, and/or sale within the United States after importation of certain wearable electronic devices with electrocardiogram ("ECG") capability and components thereof ("the Accused Devices").

2. These products infringe one or more claims of United States Patent Nos. 10,595,731 ("the '731 patent"), 10,638,941 ("the '941 patent"), and 9,572,499 ("the '499 patent") (collectively, the "Asserted Patents"), either literally or under the doctrine of equivalents. AliveCor owns full rights, title, and interest in and to the Asserted Patents.

3. Exemplary models of Apple's wearable electronic devices at issue in this complaint include the Apple Watch Series 4, Apple Watch Series 5, and Apple Watch Series 6.

4. The following table provides a summary of the asserted claims of the Asserted Patents (independent claims in bold):

Patent No.	Asserted Claims
10,595,731	**1**, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, **17,** 18, 19, 20, 21, 22, 23, 24, **25**, 26, 27, 28, 29, 30
10,638,941	**1**, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, **12**, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23
9,572,499	**1**, 2, 3, 4, 6, 7, 8, 9, 10, **11**, 12, 13, 14, 16, 17, 18, 19, 20

5. A domestic industry as required by 19 U.S.C. § 1337(a)(2) and (3) exists and/or is in the process of being established in the United States relating to articles protected by AliveCor's Asserted Patents. AliveCor's domestic industry includes significant investment in plant and equipment, significant employment of labor and capital, and substantial investment in the

exploitation of the inventions claimed in AliveCor's Asserted Patents, including through engineering, research, and development.

6. Apple's unlicensed and unauthorized use of AliveCor's technology—including the technology disclosed in the Asserted Patents—to import and sell wearable electronic devices with ECG functionality in the United States constitutes an unfair act within the meaning of Section 337.

7. On information and belief, the Accused Devices are manufactured and/or sold for importation into the United States, imported into the United States, and/or sold after importation into the United States by or on behalf of Apple.

8. AliveCor seeks as relief a permanent limited exclusion order under 19 U.S.C. § 1337(d) barring from entry into the United States infringing wearable electronic devices with ECG capability and components thereof that are manufactured, sold for importation, and/or imported by or on behalf of Apple.

9. AliveCor further seeks as relief permanent cease and desist orders under 19 U.S.C. § 1337(f) prohibiting Apple from marketing, distributing, selling, offering for sale, warehousing inventory for distribution, and otherwise transferring or bringing into the United States wearable electronic devices with ECG functionality and components thereof that violate Section 337.

10. AliveCor further seeks as relief a bond, for the 60-day Presidential review period pursuant to 19 U.S.C. § 1337(j), for the importation of Respondent's wearable electronic devices with ECG functionality and components thereof that infringe one or more claims of the Asserted Patents.

II. PARTIES

A. AliveCor

11. AliveCor is a corporation organized and existing pursuant to the laws of the State of Delaware, and has its principal place of business at 444 Castro St, Suite 600, Mountain View, CA 94041. AliveCor is a leader in the design and development of products that provide intelligent, highly-personalized heart data to help diagnose heart conditions.

12. In 2017, AliveCor was first to bring to market an FDA cleared wearable consumer device, the KardiaBand, capable of monitoring the owner's heart, detecting heart rate irregularities, and then allowing the owner to perform an ECG to diagnose potential atrial fibrillation ("AFib"). In doing so, it became the first to ever receive FDA clearance for a non-prescription wearable medical device that allowed the consumer to record an ECG reading.

13. Since introducing KardiaBand, AliveCor has devoted significant resources to bringing additional wearable electronic ECG devices to market.

14. AliveCor currently employs approximately 95 individuals in the United States and has made a substantial investment in domestic activities in the United States including, engineering, design, data collection and analysis, customer service, research, and development to bring products to market that make diagnosing AFib, and other irregular heart beat illnesses, more accessible, more accurate, and more convenient.

15. AliveCor's patent-protected breakthroughs were acknowledged, and subsequently duplicated, without license or permission, by Apple. This Complaint is one step, among others, AliveCor is taking to obtain relief for Apple's intentional copying of AliveCor's patented technology—including the ability to take an ECG reading on the Apple Watch, and to perform

heartrate analysis—as well as Apple's efforts to eliminate AliveCor as competition in the heartrate analysis market for the Apple Watch.

B. Apple

16. Apple is a California corporation with a principal place of business at One Apple Park Way, Cupertino, California 95014.

17. On information and belief, Apple designs, develops, tests, imports into the United States, offers for sale, and sells in the United States after importation infringing wearable electronic devices, including those sold under the tradenames Apple Watch Series 4, Apple Watch Series 5, and Apple Watch Series 6.

III. BACKGROUND

A. Heart Disease in the United States

18. According to the Centers for Disease Control and Prevention (the "CDC"), heart disease is the leading cause of death for men, women, and people of most racial and ethnic groups in the United States. One person dies every 36 seconds in the United States from cardiovascular disease.

19. AFib is one type of heart disease. AFib is a quivering or irregular heartbeat (arrhythmia) that can lead to blood clots, stroke, heart failure and other heart-related complications. Normally, the heart contracts and relaxes to a regular beat. When a person has AFib, however, the normal beating in the upper chambers of the heart (the two atria) is irregular, and blood does not flow as well as it should from the atria to the lower chambers of the heart (the two ventricles). AFib may happen in brief episodes, or it may be a permanent condition.

20. Millions of Americans live with AFib. Untreated atrial fibrillation doubles the risk of heart-related deaths and is associated with a 5-fold increased risk for stroke. Despite this, many patients are unaware that they have AFib—or that it is a serious condition at all.

21. There are different types of atrial fibrillation, but the most difficult type of AFib to diagnose is paroxysmal atrial fibrillation. This type of atrial fibrillation is episodic—it comes and goes in paroxysms, or sudden attacks. A principal feature of this type of atrial fibrillation is its unpredictability.[1] For a patient, that unpredictability makes diagnosis difficult--the episodes may occur when no doctor is monitoring the heart. When a patient does go to a doctor, the doctor may find that the heart is operating in perfect order.

B. AliveCor's Wearable ECG Technology

22. In 2010, David Albert, Bruce Satchwell, and Kim Barnett began working together to address the leading cause of death in the United States: heart disease. Their idea was to give patients the ability to monitor their heart health with an accurate and easy to use device that allowed individuals to take their own ECG.

23. In late December 2010, Dr. Albert uploaded a video demo of an ECG device that could work with an iPhone to YouTube. The video went viral with more than 100,000 views in the first few days, and it made AliveCor's ECG device one of the most talked about technologies at the 2011 Consumer Electronics Show.

24. Shortly after the 2011 Consumer Electronics Show, Dr. Albert, Mr. Satchwell, and Mr. Barnett officially formed AliveCor in order to bring their novel ECG device to market.

[1] "Sometimes the symptoms last for minutes, sometimes they can last for days; a principle feature of this type of AFib is that it's unpredictable." *See, e.g.*, https://www.alivecor.com/blog/articles/the_3_forms_of_AFib/

C. AliveCor's First Heart Monitor

25. Just two years later, in 2013, AliveCor introduced the first FDA approved portable ECG product. That product—the AliveCor Heart Monitor—incorporated two electrodes into an iPhone case. Those electrodes allowed the user to take real-time ECG readings by either holding the monitor in their hands or by pressing it against their chest. Before reaching the market, AliveCor demonstrated the effectiveness and accuracy of its revolutionary heart monitor through clinical trials.

26. AliveCor participated in two clinical trials to field test both the hardware and the accompanying iPhone application for the AliveCor Heart Monitor. One study investigated how AliveCor's single-lead ECG compared to a traditional 12-lead device. Another examined if 54 participants could figure out how to use the case properly, with no previous medical training. The latter study not only showed the device could be used without specialized training, but also led to the diagnosis of two serious heart problems.

27. The AliveCor Heart Monitor system consisted of the heart monitor itself, which could be mounted onto the back of most smartphones, or embedded into a special case for the iPhone, and the AliveECG app, which showed the user's ECG reading. To check heart activity, the user placed the detector against their fingers or chest. The detector then recorded an ECG and sent that data to the app on a smartphone, using an ultrasonic signal that is sent to the phone's microphone.

28. The data was also sent to AliveCor's servers so that the AFib Detector algorithms could analyze the data and interpret it. Once the ECG reading was obtained, it could be sent to a doctor or a heart specialist for more information.

Figure 1: AliveCor Heart Monitor

D. AliveCor's KardiaBand and SmartRhythm Application

29. In late 2014 or early 2015, AliveCor began working on what ultimately became the AliveCor KardiaBand. The KardiaBand was a replacement watch band for a user's Apple Watch. The KardiaBand was the first FDA cleared medical accessory for the Apple Watch. KardiaBand, in conjunction with the Kardia watch app, enabled a user to record an ECG on their wrist anywhere in the world. KardiaBand entered the U.S. market at the end of 2017.

30. Like the AliveCor Heart Monitor,[2] the KardiaBand was also easy to use and activate. Recording an ECG took just three steps: (i) open the Kardia watch app; (ii) open the in-app instructions; and (iii) put your right thumb on the KardiaBand outer electrode while ensuring the inner electrode was in contact with the skin of the left wrist.

[2] The current AliveCor Heart Monitor is marketed under the KardiaMobile brand name.

Figure 2: AliveCor KardiaBand

31. Along with the KardiaBand for Apple Watch, AliveCor also introduced a new software feature in its Kardia App called SmartRhythm. SmartRhythm used artificial intelligence to continuously evaluate the correlation between heart activity and physical activity using heart rate data and activity data sensors in the Apple watch. SmartRhythm was developed to work in coordination with the KardiaBand and the Kardia App to detect and notify users of heart rate irregularities. Users were then asked to record an ECG which could confirm the occurrence of AFib.

32. Dr. Ronald Karlsberg of Cedars Sinai Heart Institute and UCLA's School of Medicine described the combination of KardiaBand and SmartRhythm as "a paradigm shift for cardiac care as well as an important advance in healthcare." See https://www.alivecor.com/press/press_release/fda-clears-first-medical-device-for-apple-watch/. Dr. Karlsberg further explained the significance of AliveCor's innovation: "Today, [ECGs] are available only in offices and hospitals, using complex equipment, and usually only after a life threatening event, for example a stroke. With an EKG device on the wrist, AFib can be detected wherever the patient is, 24 hours a day. In randomized research trials, KardiaMobile, the first AliveCor [ECG] device, proved to be superior to routine care provided by physicians. Today, KardiaBand is a giant leap in personalized health care." *Id.*

33. The SmartRhythm algorithm was trained, via user data, to monitor a user in real time and provide alerts to users when they were experiencing unexpected heart rates. These unexpected heart rates were potential occurrences of AFib. Users could then record an ECG which would confirm possible AFib. Initially, SmartRhythm was trained to recognize discordant heart rates by looking at a user's heart rate as provided by the Apple Watch. Over time, AliveCor developed a neural network architecture that could project what a patient's future heart rate should be such that when the projected heart rate did not match the actual heart rate, the user would receive a notification and be instructed to record an ECG.

34. SmartRhythm used heart rate data generated by the Apple Watch to identify heart rate irregularities and suggest recording an ECG. An algorithm in the Apple Watch uses a photoplethysmogram ("PPG") sensor to report a heart rate. PPG data was converted to heart rate data at certain times based on proprietary Apple code.

E. Apple Copies AliveCor's Technology and Eliminates Competition

35. After AliveCor presented KardiaBand publicly, its founder Dr. Albert was invited to Apple's campus by Dr. Michael O'Reilly, Apple's Vice President of Medical Technology, to present to Apple on KardiaBand. Dr. Albert demonstrated KardiaBand's operation to Apple engineers and Apple's COO, Jeff Williams. Mr. Williams told Dr. Albert that Apple wanted to figure out how to work with AliveCor.

36. A few months later, Dr. Albert and AliveCor's then-CEO met with Phil Schiller, Apple's SVP of Worldwide Marketing, in order to further demonstrate the KardiaBand product. Unbeknownst to AliveCor, however, Apple was using these meetings to gather information on the operation of KardiaBand. Apple recognized the value in the combination of AliveCor's

KardiaBand and SmartRhythm products and wanted to take those ideas as their own and eliminate AliveCor and everyone else as competition.

37. In fact, after seeing the utility of KardiaBand and SmartRhythm, Apple decided to copy these features and introduce a version of an Apple Watch with its own ECG and AFib analysis and reporting functionality. In late 2018, Apple announced that it was introducing its own ECG app and irregular heart rhythm notification feature as part of an update to the Operating System for the Apple Watch Series 4.

38. After Apple introduced its KardiaBand and SmartRhythm competitor products, it decided to eliminate AliveCor as a competitor. Specifically, with the Apple Watch series 4, Apple updated the watch operating systems from OS4 to OS5. This operating system update included changes to the algorithm the Watch OS used to report heart rates in specific ways that made it impossible for KardiaBand and SmartRhythm (as well as all other third party heartrate analysis app providers) to identify and predict unexpected heartrates and arrhythmias and suggest users record an ECG for confirming potentially occurrences of AFib.

39. Ultimately, the changes Apple made to its operating system in OS5 and the introduction of Apple's copycat ECG watches compelled AliveCor to pull the KardiaBand product and SmartRhythm from the market in 2018. Despite the fact that KardiaBand is no longer sold, AliveCor continues to collect and analyze information from KardiaBand customers as well as support customers who had previously purchased the products and continue to use it.

F. AliveCor's Continuing Investment in KardiaBand and SmartRhythm Technology

40. AliveCor spent millions of dollars and thousands of man hours developing KardiaBand and SmartRhythm, including time and money to engineer the product and clinical studies to verify it worked.

41. After Apple changed its heart rate reporting algorithm, but before KardiaBand and SmartRhythm were pulled from the market in 2018, AliveCor began development of its own hardware platform for detecting AFib that builds on the technology introduced in the KardiaBand product and SmartRhythm app. As described in more detail in Confidential Exhibits 19 and 20, since Apple's actions caused AliveCor to remove KardiaBand and SmartRhythm from the market, AliveCor has continued to invest significant resources into developing alternative wearable electronic ECG devices that incorporate the inventions of the Asserted Patents.

IV. THE TECHNOLOGY AND PRODUCTS AT ISSUE

42. Pursuant to Commission Rules 210.10(b)(1) and 210.12(a)(12), the accused products are Apple Watches with ECG functionality, including the Apple Watch Series 4, 5, and 6, including both hardware and software.[3]

43. The technology at issue relates to wearable electronic devices with ECG functionality.

44. Given the unpredictable nature of AFib, it is difficult to diagnose. Before AliveCor, the state-of-the-art for monitoring the heart for episodes of AFib was expensive and either (1) short-term and unwieldy or (2) or long-term. The first kind of device required wearing sensors with wires strapped across the body, like those for a sleep study. The second kind of device required a sensor to be implanted underneath the skin and cost tens of thousands of dollars.

45. AliveCor solved the difficulty in diagnosis and the problems with prior AFib monitors by integrating sensors into a wearable device, such as a smartwatch that allowed for comfortable, long-term monitoring of the heartbeat for a few hundred dollars, instead of thousands or tens of thousands of dollars.

[3] Representative samples of the products at issue are available upon request.

46. In bringing this new technology to market, AliveCor had to win consumer trust. The margin of error for the technology was small. If the heart rate discordance technology was too sensitive, it risked sending too many false positives, leading consumers to ignore the request to record an ECG when a potential real episode of AFib was occurring. On the other hand, if the heart rate discordance technology was not sensitive enough it would fail to notify the owner when the heartbeat really was erratic thereby failing to perform its designed function.

47. To reduce the risk of these kinds of errors, AliveCor developed a method for marshaling data from other sensors in the smartwatch in order to compare the activity level, the heart rate, and the heart rate variability of the wearer. The method looks for discordance between those values to determine when to notify the wearer of a possible heart issue and to suggest an ECG.

48. Apple intentionally replicated AliveCor's patented technology into its Apple Watch, and took other steps to eliminate AliveCor as a competitor. This Investigation is one avenue, among others, AliveCor is taking to seek redress for Apple's duplicitous conduct.

V. THE ASSERTED PATENTS AND NONTECHNICAL DESCRIPTIONS OF THE INVENTIONS[4]

49. The claims of the '731, the '941, and the '499 Patents are novel, unconventional and focus on specific means and methods of using specialized sensors in a wearable device to improve upon existing cardiac monitoring technology. The Asserted Patents explain the state of the art in arrhythmia diagnosis, the limitations in known diagnostic techniques and diagnostic

[4] All non-technical descriptions of the patents herein are presented to give a general background of those patents. These descriptions are not intended to be used nor should they be used for purposes of patent claim construction. Complainant presents these statements subject to and without waiver of its right to argue that claim terms should be construed in a particular way under claim interpretation jurisprudence and the relevant evidence.

equipment, and the need for the inventors' improvement in diagnostic techniques and equipment. '941 Patent at 1:26-3:26; '499 Patent at 1:20-2:4. The claims then recite specific and novel implementations of apparatus and methods used for diagnosing intermittent arrhythmias that address the limitations in the prior art including the requirement that the users be made aware of the potential arrhythmia and have ready access to specialized diagnostic equipment in a clinical setting.

50. In the Asserted Patents, a unique and novel combination of sensors are used to sense certain parameter values such as, for example, heart rate and activity level, which are then analyzed to predict or determine the presence of an arrhythmia. *See, e.g.*, '731 Patent at 26:27-52. These novel wearable devices differ from the disclosed and known prior art for several reasons including the incorporation and coordinated use of photoplethysmography ("PPG"), electrocardiography ("ECG"), and movement sensors in order to collect accurate, real-time cardiac data of the user and compare such data to the expected cardiac data based on the activity level of the user. *Id.* at 4:46-5:29. The collected data also allows device makers to train machine learning algorithms that can more quickly predict and notify users of potential arrhythmias using heart rate data along with information and signals from the other sensors in the watch. *Id*. at 4:2-10, 5:15-19. The claimed inventions thus offer a uniquely convenient heart monitoring apparatus and methods that leverages wearability, specialized sensors, and machine learning to generate more accessible and effective diagnosis of potentially dangerous arrhythmia conditions.

A. The '731 Patent

1. Identification and Ownership of the '731 Patent

51. AliveCor owns by assignment the right, title and interest in United States Patent No. 10,595,731, titled "Methods and systems for arrhythmia tracking and scoring," which issued

on May 5, 2020, naming David E. Albert, Omar Dawood, Lev Korzinov, Iman Abuzeid, Nupur Srivastava, Fei Wang, Euan Thomson, and Ravi Gopalakrishnan as co-inventors. The '731 patent issued from U.S. Patent Application Serial No. 16/158,112, filed on October 28, 2018, and expires on December 12, 2034. A copy of the '731 patent is attached as Exhibit 1. A copy of the assignment from the named inventors to AliveCor is attached as Exhibit 4. A copy of the prosecution history of the '731 patent is attached as Appendix A.[5] Copies of each patent and applicable pages of each technical reference mentioned in the prosecution history of the '731 patent are attached as Appendix B.

2. Foreign Counterparts to the '731 Patent

52. Exhibit 7 lists each foreign patent and each pending foreign patent application (not already issued as a patent), and each foreign patent application that has been denied, abandoned or withdrawn, corresponding to the '731 patent, with an indication of the prosecution status of each such patent application. No other foreign patents or patent applications corresponding to the '731 patent have been filed, abandoned, withdrawn, or rejected.

3. Non-Technical Description of the '731 Patent

53. The '731 patent generally relates to the method and device AliveCor invented that enabled a user to wear a smartwatch that would continuously monitor the heart and allow the user to record an ECG. It describes how to take data from an ECG sensor, a PPG sensor, and a motion sensor and run it through machine learning algorithms to determine whether the user may be experiencing an episode of atrial fibrillation and recommending an ECG. Compared to the prior art, the '731 patent dramatically increased the convenience of such heart monitoring.

[5] A certified copy of the patent prosecution history has been ordered and will be provided once they are received from the U.S.P.T.O.

B. The ’941 Patent

1. Identification and Ownership of the ’941 Patent

54. AliveCor owns by assignment the right, title and interest in United States Patent No. 10,638,941, titled “Discordance monitoring,” which issued on May 5, 2020, naming David E. Albert, Omar Dawood, Ravi Gopalakrishan, Fei Wang, Euan Thomson, and Iman Abuzeid as co-inventors. The ’941 patent issued from U.S. Patent Application Serial No. 16/158,112, filed on October 11, 2018, and expires on May 13, 2036. A copy of the ’941 patent is attached as Exhibit 2. A copy of the assignment from the named inventors to AliveCor is attached as Exhibit 5. A copy of the prosecution history of the ’941 patent is attached as Appendix C. Copies of each patent and applicable pages of each technical reference mentioned in the prosecution history of the ’941 patent are attached as Appendix D.

2. Foreign Counterparts to the ’941 Patent

55. Exhibit 7 lists each foreign patent and each pending foreign patent application (not already issued as a patent), and each foreign patent application that has been denied, abandoned or withdrawn, corresponding to the ’941 patent, with an indication of the prosecution status of each such patent application. No other foreign patents or patent applications corresponding to the ’941 patent have been filed, abandoned, withdrawn, or rejected.

3. Non-Technical Description of the ’941 Patent

56. The ’941 patent generally relates to the method of refining the accuracy of an potential arrhythmia diagnosis by comparing the data coming in from different sensors with each other. By determining whether each value falls within an expected range as the other values change, the ’941 patent explains how discordance can be used to reduce the rate of false positive and false negative errors in a cardiac monitor.

C. The ’499 Patent

1. Identification and Ownership of the ’499 Patent

57. AliveCor owns by assignment the right, title and interest in United States Patent No. 9,572,499, titled “Methods and systems for arrhythmia tracking and scoring,” which issued on February 21 2017, naming David E. Albert, Omar Dawood, Lev Korzinov, Iman Abuzeid, Nupur Srivastava, Fei Wang, Euan Thomson, and Ravi Gopalakrishnan as co-inventors. The ’941 patent issued from U.S. Patent Application Serial No. 14/730,122, filed on June 3, 2015, and expires on December 12, 2034. A copy of the ’499 patent is attached as Exhibit 3. A copy of the assignment from the named inventors to AliveCor is attached as Exhibit 6. A copy of the prosecution history of the ’941 patent is attached as Appendix E.[6] Copies of each patent and applicable pages of each technical reference mentioned in the prosecution history of the ’499 patent are attached as Appendix F.

2. Foreign Counterparts to the ’499 Patent

58. Exhibit 7 lists each foreign patent and each pending foreign patent application (not already issued as a patent), and each foreign patent application that has been denied, abandoned or withdrawn, corresponding to the ’499 patent, with an indication of the prosecution status of each such patent application. No other foreign patents or patent applications corresponding to the ’499 patent have been filed, abandoned, withdrawn, or rejected.

3. Non-Technical Description of the ’499 Patent

59. Like the ’941 patent, the ’499 patent generally relates to the method and devices AliveCor invented that enabled a user to wear sensors that would continuously monitor the heart

[6] A certified copy of the patent prosecution history has been ordered and will be provided once they are received from the U.S.P.T.O.

and allow the user to record an ECG. The ’499 patent envisioned sending the sensor data to a smartphone or a smartwatch in order to determine whether a heart arrhythmia was occurring. Like the ’941 patent, the ’499 patent increased the convenience of heart monitoring for conditions like atrial fibrillation.

D. Apple’s Infringement Of The Asserted Patents[7]

1. Infringement of the ’731 Patent

60. 71. Apple infringes, literally and/or under the doctrine of equivalents, at least claims 1-15 of the ’731 patent. Apple infringes at least these claims by importing, selling for importation, and/or selling after importation into the United States certain of the Accused Devices, including at least the Apple Watch Series 4, Apple Watch Series 5, and Apple Watch Series 6 (the “Accused ‘731 Devices”). The Accused ’731 Devices satisfy all claim limitations of claims 1-15 of the ’731 Patent at the time of importation into the United States.

61. On information and belief, Apple also knowingly induces and/or contributes to the infringement of at least claims 1-15 of the ’731 patent by others. On information and belief, Apple has had knowledge of the ’731 patent, and its infringement of the ’731 patent, since at least December 7, 2020, when AliveCor filed a parallel action in the Western District of Texas.

62. Apple also contributes to infringement of the ’731 patent by selling for importation into the United States, importing into the United States, and/or selling within the United States after importation the Accused ’731 Devices and the non-staple constituent parts of those devices, which are not suitable for substantial non-infringing use and which embody a material part of the invention described in the ’731 patent. These wearable electronic devices with

[7] Complainant’s investigation of Respondent’s infringement is ongoing. Complainant may provide additional theories concerning Respondent’s infringement of the Asserted Patents as Complainant receives discovery.

ECG functionality are known by Apple to be especially made or especially adapted for use in the infringement of the ’731 patent. Apple also contributes to the infringement of the ’731 patent by selling for importation into the United States, importing into the United States, and/or selling within the United States after importation components, such as the chipsets or software containing the infringing functionality, of the Accused ’731 Devices, which are not suitable for substantial non-infringing use and which embody a material part of the invention described in the ’731 patent. These mobile devices are known by Apple to be especially made or especially adapted for use in the infringement of the ’731 patent. Specifically, on information and belief, Apple sells the Accused ’731 Devices to resellers, retailers, and end users with knowledge that the devices are used for infringement.

63. Attached as Exhibit 9 are representative claim charts for the Accused ’731 Devices showing infringement of the ’731 patent by exemplary Accused ‘731 Devices.

2. Infringement of the ’941 Patent

64. Apple infringes, literally and/or under the doctrine of equivalents, at least claims 12-23 of the ’941 patent. Apple infringes at least these claims by importing, selling for importation, and/or selling after importation into the United States certain of the Accused Devices, including at least the Apple Watch Series 4, Apple Watch Series 5, and Apple Watch Series 6 (the “Accused ’941 Devices”). The Accused ’941 Devices satisfy all claim limitations of claims 12-23 at the time of importation into the United States.

65. On information and belief, Apple also knowingly induces and/or contributes to the infringement of at least claims 12-23 of the ’941 patent by others. On information and belief, Apple has had knowledge of the ’941 patent, and its infringement of the ’941 patent, since at least December 7, 2020, when AliveCor filed a parallel action in the Western District of Texas.

66. Apple also contributes to infringement of the ’941 patent by selling for importation into the United States, importing into the United States, and/or selling within the United States after importation the Accused ’941 Devices and the non-staple constituent parts of those devices, which are not suitable for substantial non-infringing use and which embody a material part of the invention described in the ’941 patent. These mobile electronic devices are known by Apple to be especially made or especially adapted for use in the infringement of the ’941 patent. Apple also contributes to the infringement of the ’941 patent by selling for importation into the United States, importing into the United States, and/or selling within the United States after importation components, such as the chipsets or software containing the infringing functionality, of the Accused ’941 Devices, which are not suitable for substantial non-infringing use and which embody a material part of the invention described in the ’941 patent. These mobile devices are known by Apple to be especially made or especially adapted for use in the infringement of the ’941 patent. Specifically, on information and belief, Apple sells the Accused ’941 Devices to resellers, retailers, and end users with knowledge that the devices are used for infringement.

67. Attached as Exhibit 10 are representative claim charts for the Accused ’941 Devices showing infringement of the ’941 patent by exemplary Accused ‘9419 Devices.

3. Infringement of the ’499 Patent

68. Apple infringes, literally and/or under the doctrine of equivalents, at least claims 11-14, and 16-20 of the ’499 patent. Apple infringes at least these claims by importing, selling for importation, and/or selling after importation into the United States certain of the Accused Devices, including at least the Apple Watch Series 4, Apple Watch Series 5, and Apple Watch

Series 6 (the "Accused '499 Devices"). The Accused '499 Devices satisfy all claim limitations of claims 11-14, and 16-20 at the time of importation into the United States.

69. On information and belief, Apple also knowingly induces and/or contributes to the infringement of at least claims 11-14, and 16-20 of the '499 patent by others. On information and belief, Apple has had knowledge of the '499 patent, and its infringement of the '499 patent, since at least December 7, 2020, when AliveCor filed a parallel action in the Western District of Texas.

70. Apple also contributes to infringement of the '499 patent by selling for importation into the United States, importing into the United States, and/or selling within the United States after importation the Accused '499 Devices and the non-staple constituent parts of those devices, which are not suitable for substantial non-infringing use and which embody a material part of the invention described in the '499 patent. These mobile electronic devices are known by Apple to be especially made or especially adapted for use in the infringement of the '499 patent. Apple also contributes to the infringement of the '499 patent by selling for importation into the United States, importing into the United States, and/or selling within the United States after importation components, such as the chipsets or software containing the infringing functionality, of the Accused '499 Devices, which are not suitable for substantial non-infringing use and which embody a material part of the invention described in the '499 patent. These mobile devices are known by Apple to be especially made or especially adapted for use in the infringement of the '499 patent. Specifically, on information and belief, Apple sells the Accused '499 Devices to resellers, retailers, and end users with knowledge that the devices are used for infringement.

71. Attached as Exhibit 11 are representative claim charts for the Accused '499 Devices showing infringement of the '499 patent by exemplary Accused '499 Devices.

VI. SPECIFIC INSTANCES OF UNFAIR IMPORTATION AND SALE

72. Apple sells for importation into the United States, imports into the United States, and/or sells after importation into the United States the Accused Products. These Accused Products include, but are not limited to the Apple Watch Series 4, Apple Watch Series 5, and Apple Watch Series 6.

73. A sample of the Apple Watch Series 6 was purchased from bestbuy.com on March 19, 2021. *See* Ex. 12. The packaging states that the Apple Watch Series 6 was "assembled in Vietnam." *See id.*

74. A sample of the Apple Watch Series 5 was purchased from bestbuy.com on March 19, 2021. *See* Ex. 12. The packaging states that the Apple Watch Series 5 was "assembled in China." *See id.*

75. A sample of the Apple Watch Series 4 was purchased on March 24, 2021. *See* Ex. 12. The packaging states that the Apple Watch Series 4 was "assembled in China." *See id.*

76. Upon information and belief, substantially all of the Accused Products in the United States are manufactured by Apple's suppliers, which are located primarily in Asia, and sold for importation into the United States by or on behalf of Apple. *See* Ex. 12.

A. Harmonized Tariff Schedule Numbers

77. The Accused Products are classified under at least the following subheading of the Harmonized Tariff Schedule of the United States: 8517.62.00 (Telephone sets, including telephones for cellular networks or for other wireless networks; other apparatus for the transmission or reception of voice, images or other data, including apparatus for communication in a wired or wireless network (such as a local or wide area network), other than transmission or reception apparatus of heading 8443, 8525, 8527 or 8528; parts thereof: Other apparatus for

transmission or reception of voice, images or other data, including apparatus for communication in a wired or wireless network (such as a local or wide area network): Machines for the reception, conversion and transmission or regeneration of voice, images or other data, including switching and routing apparatus). This classification is exemplary in nature and not intended to restrict the scope of any exclusion order or other remedy ordered by the Commission.

VII. RELATED LITIGATION

78. AliveCor filed a complaint in the Western District of Texas on December 07, 2020, asserting the same patents asserted here. *See AliveCor, Inc. v. Apple, Inc.*, 6:20-cv-1112 (WDTX).

79. Aside from the above-mentioned parallel district court matter, AliveCor has not previously litigated the asserted patents before any other court or agency.

VIII. LICENSEES TO THE ASSERTED PATENTS

80. Confidential Exhibit 8 is a list of licensees that includes within that list all licenses to one or more of the Asserted Patents. Confidential Exhibit 22 is a copy of a license to the Asserted Patents.

IX. THE DOMESTIC INDUSTRY RELATING TO THE ASSERTED PATENTS

81. An industry as required by Section 337(a)(2) and defined by Section 337(a)(3)(A)-(C) exists and/or is in the process of being established in the United States relating to the Asserted Patents and AliveCor's products and components thereof protected by the Asserted Patents.

82. As described below and in the accompanying declaration at Confidential Exhibits 19 and 20, AliveCor researches, designs, and develops wearable electronic devices and components in the United States that practice the claims of each of the Asserted Patents ("Domestic Industry Products").

83. As further described in Confidential Exhibits 19 and 20, AliveCor is currently developing new wearable devices, that practice the claims of each of the Asserted Patents.

A. Technical Prong

84. The Domestic Industry Products include AliveCor's KardiaBand and new wearable devices under development. Claim charts demonstrating that representative Domestic Industry Products practice at least one claim of each Asserted Patent are attached as Exhibits 13-15 and Confidential Exhibits 16-18.[8]

B. Economic Prong

85. There is a domestic industry as defined under 19 U.S.C. § 1337(a)(3)(A), (B), and/or (C), comprising continuing significant investments made in the United States by AliveCor in plant and equipment and employment of labor and capital, and continuing substantial investment in exploitation of the Asserted Patents.

86. AliveCor has made and continues to make significant investments in plant and equipment directed to the Domestic Industry Products in the United States. Those investments in plant and equipment are dedicated to research, design, development, engineering, product support, manufacturing support, testing, and various customer support activities focused on the Domestic Industry Products.

87. AliveCor also has made and continues to make significant investments in labor and capital directed to the Domestic Industry Products in the United States. Those investments in labor and capital are dedicated to research, design, development, engineering, product support,

[8] The Domestic Industry Products practice additional claims of the Asserted Patents, and AliveCor may establish the technical prong of the domestic industry requirement through claims other than those used in these exhibits.

manufacturing support, testing, and various customer support activities focused on the Domestic Industry Products.

88. AliveCor further engages in exploitation of the Asserted Patents through its substantial domestic investments in research and development and engineering activities in the United States. These activities include, among other things, research and development and engineering and design tied to the claimed technology implemented in the Asserted Patents. These activities have occurred in the past and are ongoing with respect to prior and current versions of the Domestic Industry Products as well as future products under development.

89. In addition to the existing domestic industry, a domestic industry in new products that practice the Asserted Patents in the United States is in the process of being established under 19 U.S.C. § 1337(a)(3)(A), (B), and/or (C). AliveCor has taken necessary tangible steps to establish of this new domestic industry in the United States. As a result of these steps, there is a significant likelihood that this new domestic industry will be established in the future.

90. Specific, non-limiting examples of the foregoing investments are set forth in Confidential Exhibits 19 and 20.

X. RELIEF REQUESTED

91. Complainant respectfully requests that the Commission:

(a) Institute an investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, with respect to Apple's violations of that section arising from the importation into the United States, sale for importation, and/or the sale within the United States after importation of certain wearable electronic devices with ECG functionality and components thereof that infringe one or more claims of the Asserted Patents;

(b) Schedule and conduct a hearing pursuant to Section 337(c) for the purposes of (i) receiving evidence and hearing argument concerning whether there has been a violation of Section 337, and (ii) following the hearing, determining that there has been a violation of Section 337;

(c) Issue a permanent limited exclusion order pursuant to 19 U.S.C. § 1337(d) excluding entry into the United States of Respondent's wearable electronic devices with ECG functionality and components thereof that infringe one or more claims of the Asserted Patents;

(d) Issue a permanent cease and desist order pursuant to 19 U.S.C. § 1337(f) prohibiting Apple, its subsidiaries, related companies and agents from engaging in the importation, sale for importation, marketing and/or advertising, distribution, offering for sale, sale, use after importation, sale after importation, and other transfer within the United States of wearable electronic devices with ECG functionality and components thereof that infringe one or more claims of the Asserted Patents;

(e) Impose a bond upon importation of Respondent's wearable electronic devices with ECG functionality and components thereof that infringe one or more claims of the Asserted Patents during the 60-day Presidential review period pursuant to 19 U.S.C. § 1337(j); and

(f) Issue such other and further relief as the Commission deems just and proper under the law, based on the facts determined by the investigation and the authority of the Commission.

Dated: April 20, 2021

Respectfully submitted,

/s/ S. Alex Lasher
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UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

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

VERIFICATION OF COMPLAINT

I, Brian Clarke, am General Counsel at AliveCor, Inc., and I am authorized to execute this verification on behalf of Complainant. I have read the Complaint and am aware of its contents. To the best of my knowledge, information, and belief, and based upon a reasonable inquiry under the circumstances, I hereby certify that:

1. The allegations contained in the Complaint are well grounded in fact and have evidentiary support, or are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery;

2. The claims and other legal contentions set forth in the Complaint are warranted by existing laws or by a good faith, non-frivolous argument for extension, modification, or reversal of existing law, or by the establishment of new law; and

3. The Complaint is not being filed for any improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of litigation.

Dated: 4/19/2021 | 1:33 PM PDT

DocuSigned by:
Brian Clarke
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Brian Clarke