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.
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Tel. (650) 396-8650

Proposed Respondent

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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):

<table>
<thead>
<tr>
<th>Patent No.</th>
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<tr>
<td>10,595,731</td>
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<td>1, 2, 3, 4, 6, 7, 8, 9, 10, 11, 12, 13, 14, 16, 17, 18, 19, 20</td>
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</table>

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.


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.