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](image-url)

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, 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.

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

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

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

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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.