

Nos. 23-1509, -1553

**IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

ALIVECOR, INC.
Appellant

v.

INTERNATIONAL TRADE COMMISSION
Appellee

APPLE INC.
Intervenor

(Caption Continued on Inside Cover)

**BRIEF OF *AMICUS CURIAE* LESLIE A. SAXON, M.D. IN SUPPORT OF
INTERVENOR-CROSS-APPELLANT APPLE INC. IN SUPPORT OF
REVERSAL OF THE COMMISSION'S EXCLUSION ORDER**

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

HAYNES AND BOONE, LLP

Debra J. McComas
2323 Victory Avenue, Suite 500
Dallas, TX 75201
Phone: (214) 651-5375

Adam L. Erickson
6000 Headquarters Drive, Suite 200
Plano, TX 75024
Phone: (972) 739-8661

Attorneys for Amicus Curiae Leslie A. Saxon, M.D.

APPLE, INC.
Appellant

v.

INTERNATIONAL TRADE COMMISSION
Appellee

ALIVECOR, INC.
Intervenor

CERTIFICATE OF INTEREST

Case Number 23-1509, -1553
Short Case Caption AliveCor, Inc. v. ITC
Filing Party/Entity Leslie A. Saxon, M.D. / Amicus Curiae

Instructions:

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

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

Date: August 14, 2023

Signature: /s/ Debra J. McComas

Name: Debra J. McComas

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	2. Real Party in Interest. Fed. Cir. R. 47.4(a)(2).	3. Parent Corporations and Stockholders. Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. <input checked="" type="checkbox"/> None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. <input checked="" type="checkbox"/> None/Not Applicable
Leslie A. Saxon, M.D. (Amicus Curiae)		

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4). <input checked="" type="checkbox"/> None/Not Applicable <input type="checkbox"/> Additional pages attached		

5. Related Cases. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

Yes (file separate notice; see below) No N/A (amicus/movant)

If yes, concurrently file a separate Notice of Related Case Information that complies with Fed. Cir. R. 47.5(b). Please do not duplicate information. This separate Notice must only be filed with the first Certificate of Interest or, subsequently, if information changes during the pendency of the appeal. Fed. Cir. R. 47.5(b).

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

None/Not Applicable Additional pages attached

TABLE OF CONTENTS

CERTIFICATE OF INTEREST	i
TABLE OF CONTENTS	iv
TABLE OF AUTHORITIES	v
INTEREST OF <i>AMICUS CURIAE</i>	1
INTRODUCTION.....	2
ARGUMENT.....	4
I. Apple Watch’s ECG feature provides substantial benefits to public health and welfare.	4
A. Stroke is a debilitating and unpredictable issue in the United States and is linked to atrial fibrillation.	4
B. Evaluating atrial fibrillation before and after the Apple Watch.	5
1. Symptomatic atrial fibrillation.	5
2. Asymptomatic atrial fibrillation	7
II. The Apple Watch’s uniquely high adoption rate is the key to its positive impact on public health and welfare.	10
A. Apple Watch’s adoption rate is unparalleled.....	10
B. AliveCor’s products do not fill the void left by the Apple Watch.	11
III. The Apple Watch addresses unanswered obstacles that have plagued medical research for years.	13
CONCLUSION.....	15
CERTIFICATE OF COMPLIANCE.....	17

TABLE OF AUTHORITIES

	Page(s)
Statutes	
19 U.S.C. § 1337	1, 4, 13
Other Authorities	
Apple Research & Care, Explore published projects (last accessed Aug. 10, 2023), https://www.researchandcare.org/publications/	15
Atrial Fibrillation Institute, <i>Atrial Fibrillation: A Guide to Wearable ECG Smart Watches</i> , https://afibinstitute.com.au/atrial-fibrillation-a-guide-to-wearable-ecg-smart-watches/ (last visited Aug. 10, 2023)	6, 7
Connie W. Tsao et al., <i>Heart Disease and Stroke Statistics—2022 Update: A Report From the American Heart Association</i> , 145 <i>Circulation</i> 153 (2022)	4
Conor Hale, ACC: Massive Chinese smartwatch study screens millions for signs of afib (April 3, 2022, 12:15 pm), https://www.fiercebiotech.com/medtech/acc-massive-chinese-smartwatch-study-screens-millions-signs-afib	15
Erik Fung et al., <i>Electrocardiographic patch devices and contemporary wireless cardiac monitoring</i> , <i>Frontiers in Physiology</i> 1 (2015)	8
Ewa Majos et al., <i>Significance and Management Strategies for Patients with Asymptomatic Atrial Fibrillation</i> , <i>J Atr Fibrillation</i> 51 (2015).....	4, 8, 10
Felix Richter, <i>Apple Beats Swiss Watch Industry At Its Own Game</i> (Sep. 14, 2020), https://www.statista.com/chart/12878/apple-watch-vs-swisswatches/#:~:text=According%20to%20estimates%20from%20Strategy,watches%20over%20the%20same%20period	10
Gregory Y. H. Lip et al, <i>Stroke Prevention in Atrial Fibrillation</i> , <i>J. Am. Med. Ass’n</i> . 1950 (2015)	5

John Koetsier, *Apple Heart Study: What Stanford Medicine Learned From 400,000 Apple Watch Owners* (Mar. 18, 2019, 12:17 pm), <<https://www.forbes.com/sites/johnkoetsier/2019/03/18/apple-heart-study-what-stanford-medicine-learned-from-400000-apple-watch-owners/?sh=604653aa2d2>..... 9

Kardia, *Shop our products* (last accessed Aug. 10, 2023), <https://store.kardia.com/> 12

Maggie Fox, *The new Apple Watch has a heart monitor and the FDA approves* (Sept. 12, 2018, 3:20 PM), <https://www.nbcnews.com/health/health-news/new-apple-watch-has-heart-monitor-fda-approves-n908976>..... 7

Marco V. Perez et al., *Large-Scale Assessment of a Smartwatch to Identify Atrial Fibrillation*, *N. Engl. J. Med.* 1909 (2019).....9, 10

Michael Potuck, *Apple Watch praised for saving UK man’s life after wild 48 hours when heart stopped 138 times* (Sep. 2, 2022, 9:13 AM), <https://9to5mac.com/2022/09/02/apple-watch-saves-life-heart-stopped-138-times/> 9

National Heart, Lung, and Blood Institute, <https://www.nhlbi.nih.gov/health/atrial-fibrillation/diagnosis> (last visited Aug. 9, 2023) 5

Rebecca A. English et al., *TRANSFORMING CLINICAL RESEARCH IN THE UNITED STATES: CHALLENGES AND OPPORTUNITIES ix-x* (Nat’l Acad. Press, 2010) 13, 14

Sara Salinas et al., *Apple adds heart monitoring to Apple Watch* (Sep. 12, 2018, 1:13 pm), <https://www.cnbc.com/2018/09/12/apple-watch-series-4.html> 13

Statista, *Smartwatches – United States* (last accessed Aug. 10, 2023), <https://www.statista.com/outlook/dmo/digital-health/digital-fitness-well-being/digital-fitness-well-being-devices/smartwatches/united-states> 10

Statista, *Subscriber share held by smartphone operating systems in the United States from 2012 to 2023* (last accessed Aug. 10, 2023), <https://www.statista.com/statistics/266572/market-share-held-by-smartphone-platforms-in-the-united-states/> 11

Stroke Awareness Foundation, <https://www.strokeinfo.org/stroke-facts-statistics/> (last visited Aug. 9, 2023) 5

U.S. Patent Application No. 16/153,446 13

U.S. Patent Application No. 16/158,112 13

Zac Hall, *Apple Watch detects British dad’s heart condition, requiring surgery to avoid stroke or heart attack* (Sep. 30, 2019, 7:30 AM), <https://9to5mac.com/2019/09/30/apple-watch-ecg-heart-condition/> 9

Zbibniew Kalarus et al., *Searching for atrial fibrillation: looking harder, looking longer, and in increasingly sophisticated ways*, *Eurospace* 185 (2023) 6, 8

Zeid Nesheiwat et al., *Atrial Fibrillation*, 1 (StatPearls 2023), <https://www.ncbi.nlm.nih.gov/books/NBK52607>..... 5

INTEREST OF *AMICUS CURIAE*

Amicus, Dr. Leslie A. Saxon, is a professor of clinical medicine at the Keck School of Medicine of the University of Southern California specializing in the diagnosis and treatment of cardiac arrhythmias and wearable technology used in the medical discipline. Amicus presents this brief to inform the Court of the impact of the exclusion of the Apple Watch with ECG feature on public health and welfare as a factor outlined in 19 U.S.C. § 1337(d)(1).

Pursuant to Federal Rule of Appellate Procedure 29(a)(4)(E), Amicus states that no party's counsel authored this brief in whole or in part; no party or party's counsel contributed money that was intended to fund preparing or submitting the brief; and no person other than amicus curiae contributed money that was intended to fund preparing or submitting the brief.

Pursuant to Federal Rule of Appellate Procedure 29(a)(2), *Amicus* submits this brief along with an accompanying motion for leave to file.

INTRODUCTION

Medical innovation has produced an endless supply of devices for diagnosing and treating an endless list of medical conditions. While some of these devices perform extraordinary feats, they typically share two limitations: (1) they are typically underutilized due to inconvenience and discomfort and (2) they are only purchased by people who are already aware of a symptom or condition. The Apple Watch addresses both of these limitations and, therefore, serves an important public interest that cannot be easily replaced by competitor products.

Apple prides itself on the interoperability and ease-of-use of its products, as illustrated by its unparalleled adoption rate over competitors. As a result, symptomatic patients, doctors, and medical researchers are far more likely to prefer using an Apple Watch for monitoring various medical conditions over purchasing multiple single-feature medical devices. The Apple Watch is more comfortable, more convenient, and more widely distributed than both traditional health monitoring devices and competing smartwatches.

From a clinical perspective, the real medical benefit of the Apple Watch lies in the fact that it is not per se a medical device. The general, asymptomatic population purchases the Apple Watch for entirely different reasons. It is purchased as a fitness tracker, a sleep tracker, an efficient extension to the iPhone, or even a

status symbol. But what starts as a non-medical device for the user ultimately serves a vital medical role—continuous monitoring of the user’s health and catching asymptomatic conditions that were previously undetected in a way no medical device ever could. The Apple Watch unassumingly provides lifesaving features to tens of millions of Americans.

The ITC’s decision to exclude the Apple Watch from importation leaves an unfillable void. The Apple Watch’s health features combined with its unique market position allow medical professionals to monitor for symptomatic and asymptomatic heart conditions on a scale unmatched by any other product. Removal of that product from the smartwatch industry is potentially detrimental to both the individual health of millions of Americans and medical research nationally.

This amicus brief is filed to emphasize the significance of the public interests impacted by exclusion of the Apple Watch, a factor the ITC failed generally to take into account in its decision to exclude the Apple Watch.

ARGUMENT

19 U.S.C. § 1337(d)(1) states that, before excluding an article from entry into the United States, the ITC must “consider[] 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.” Dr. Saxon does not take a position on questions of whether the Apple Watch actually infringes AliveCor’s patents. Instead, this brief is intended to provide information to the Court on the positive impact the Apple Watch has on millions of patients and to encourage the Court to seek a remedy that preserves that impact, while fulfilling any obligation to the administration of justice.

I. Apple Watch’s ECG feature provides substantial benefits to public health and welfare.

A. Stroke is a debilitating and unpredictable issue in the United States and is linked to atrial fibrillation.

In the United States, stroke is a leading cause of serious long-term disability and someone has a stroke every 40 seconds. Connie W. Tsao et al., *Heart Disease and Stroke Statistics—2022 Update: A Report From the American Heart Association*, 145 *Circulation* 153, 405, 412 (2022). Approximately one-third of stroke victims die and another third are left “permanently disabled.” Ewa Majos et al., *Significance and Management Strategies for Patients with Asymptomatic Atrial Fibrillation*, 7(5) *J Atr Fibrillation* 51, 51 (2015). The Stroke Awareness Foundation estimates that 80% of

strokes are preventable but identifying early warning signs is an important part of prevention. Stroke Awareness Foundation, <https://www.strokeinfo.org/stroke-facts-statistics/> (last visited Aug. 9, 2023). Atrial fibrillation (“AF”) is the leading cause of stroke. Zeid Nesheiwat et al., Atrial Fibrillation, 1 (StatPearls 2023), <https://www.ncbi.nlm.nih.gov/books/NBK526072/>. If AF can be identified, a patient’s chance of a stroke decreases substantially. Gregory Y. H. Lip et al, *Stroke Prevention in Atrial Fibrillation*, 313(19) J. Am. Med. Ass’n. 1950 (2015).

B. Evaluating atrial fibrillation before and after the Apple Watch.

Catching both symptomatic and asymptomatic AF is extremely challenging. Symptomatic patients typically exhibit symptoms so infrequently that the symptoms are not observed during a typical doctor’s visit, or even during multi-day monitoring. And asymptomatic patients simply never see a doctor for AF because they are unaware of the condition in the first place. The Apple Watch is uniquely positioned to solve both of these challenges, which are largely unaddressed at this time by the medical industry.

1. Symptomatic atrial fibrillation.

AF is identified with an electrocardiogram (ECG). National Heart, Lung, and Blood Institute, <https://www.nhlbi.nih.gov/health/atrial-fibrillation/diagnosis> (last visited Aug. 9, 2023). A 12-lead ECG is performed in a doctor’s office and monitors the heart for 10–15 minutes. To monitor for a longer period of time, a Holter monitor

can be worn around a patient's neck for one to three days. But even this extended test is often not enough to catch AF.

Until about five years ago people couldn't record their own ECG at home. Traditionally people used to come to a cardiologist due to symptoms like palpitations, with a general idea of when they occurred. We would then arrange for [a] monitoring study [to be] done[,] for example, a Holter study, and hope that we [would] catch that same rhythm if it occurred again during the period that they are wearing the monitor. [But] in some cases, people have gone for years without a diagnosis – they know they've got a symptom, but no one can ever capture it at the right time, particularly as AFib can come and go.

Atrial Fibrillation Institute, *Atrial Fibrillation: A Guide to Wearable ECG Smart Watches*, <https://afbinstitute.com.au/atrial-fibrillation-a-guide-to-wearable-ecg-smart-watches/> (last visited Aug. 10, 2023) (quoting Dr. Robert Perel, Cardiac Electrophysiologist, Cardiologist and Director of Queensland Cardiovascular Group) (cleaned up).

A recent study revealed that a one-day ECG identified AF in just 3.2% of patients, while a 30-day ECG identified AF in 16.1% of patients, ultimately concluding that “[e]ven exceptionally long monitoring may be insufficient to detect all cases.” See Zbibniew Kalarus et al., *Searching for atrial fibrillation: looking harder, looking longer, and in increasingly sophisticated ways*, 25(1) *Eurospace* 185 (2023).

The Apple Watch continuously monitors the heart and allows users to

perform an ECG immediately when they experience symptoms. After the Apple Watch Series 4 announcement, the president of the American Heart Association, Ivor Benjamin, described it as “game-changing.” Maggie Fox, *The new Apple Watch has a heart monitor and the FDA approves*, (Sept. 12, 2018, 3:20 PM), <https://www.nbcnews.com/health/health-news/new-apple-watch-has-heart-monitor-fda-approves-n908976>. He continued, “[i]n my experience, people often report symptoms that are absent during their medical visits.” *Id.* Dr. Michael Valentine, president of the American College of Cardiology agreed. “There are many patients we see that have palpitations or rapid heart rates and we put a monitor on them [but don’t] capture their symptoms when the monitor was on.” *Id.* Dr. Perel explained that “[n]ow patients can visit their cardiologist and say ‘this is what I felt, and here is what the ECG from my watch showed at the time that I felt it.’ This means that together we can look at your rhythm and correlate it with your symptoms. And that’s so much more efficient to get to an AFib diagnosis, and then begin management.” Atrial Fibrillation Institute *supra*.

2. Asymptomatic atrial fibrillation

Putting aside the challenges of diagnosing symptomatic AF, detecting asymptomatic AF, sometimes called “silent atrial fibrillation,” is practically

impossible. Alarming, asymptomatic patients are just as susceptible to “morbidity and mortality for disabling stroke, disabling anoxic encephalopathy, major central nervous system hemorrhage, and cardiac arrest” as symptomatic patients, but remain completely unaware of the risk. The difficulty and urgency of identifying asymptomatic AF is well documented. *See Majos supra* at 53 (“[T]he search for a proper monitoring method [for silent AF] remains a significant clinical challenge” and “[t]he question of screening for silent AF in the general population is extremely important.”).

The medical industry has produced several devices designed to make ECG testing more available to the general population, including AliveCor’s products, a 14-day ECG patch, implantable ECG monitoring devices, belts, and vests. Erik Fung et al., *Electrocardiographic patch devices and contemporary wireless cardiac monitoring*, 6(149) *Frontiers in Physiology* 1 (2015); Kalarus *supra* at 188. But these devices do nothing to detect asymptomatic AF because they appeal solely to symptomatic patients. A patient with asymptomatic AF has no reason to purchase them, leaving their condition undiscovered.

In that regard, the revolutionary nature of the Apple Watch stems not just from providing continuous heart monitoring and on-the-spot ECG tests but packaging it in a product that appeals to people who aren’t concerned with heart

monitoring at all. Numerous anecdotal accounts describe individuals who purchased an Apple Watch with the ECG feature for reasons unrelated to heart health, received a notification for AF, and saw a doctor where they received life-saving care.¹

The Apple Watch's unique ability to detect asymptomatic AF is also shown in its own study in partnership with Stanford University, "the Apple Heart Study." Apple Watch owners without any history of AF were invited to participate in the study, resulting in nearly 420,000 participants, the largest AF screening study ever conducted. Marco V. Perez et al., *Large-Scale Assessment of a Smartwatch to Identify Atrial Fibrillation*, 381(20) N. Engl. J. Med. 1909, 1910 (2019); John Koetsier, *Apple Heart Study: What Stanford Medicine Learned From 400,000 Apple Watch Owners* (Mar. 18, 2019, 12:17 pm), <https://www.forbes.com/sites/johnkoetsier/2019/03/18/apple-heart-study-what-stanford-medicine-learned-from-400000-apple-watch-owners/?sh=604653aa2d20>. Over the course of 117 days, 2,161 participants

¹ An Apple Watch warned a 30-year-old fitness enthusiast of potential asymptomatic AF. Cardiologists discovered two leaking valves. Zac Hall, *Apple Watch detects British dad's heart condition, requiring surgery to avoid stroke or heart attack* (Sep. 30, 2019, 7:30 AM), <https://9to5mac.com/2019/09/30/apple-watch-ecg-heart-condition/>. A 54-year-old man was alerted to an abnormally low heart rate. During a subsequent ECG, his heart stopped 138 times for periods of 10 seconds. He ultimately received a pacemaker that healthcare professionals say saved his life. Michael Potuck, *Apple Watch praised for saving UK man's life after wild 48 hours when heart stopped 138 times* (Sep. 2, 2022, 9:13 AM), <https://9to5mac.com/2022/09/02/apple-watch-saves-life-heart-stopped-138-times/>.

received notifications of potential AF, 76% of whom sought medical attention from a health care provider, 28% were prescribed a new medication and 33% were recommended to see a cardiologist. Perez *supra* at 1913–1914.

II. The Apple Watch’s uniquely high adoption rate is the key to its positive impact on public health and welfare.

Addressing “[t]he question of screening for silent AF in the general population” requires convincing the general population, who largely do not exhibit any symptoms, to consent to monitoring in the first place, purchase, and actually wear a monitoring device. Majos *supra* at 53. ECG devices produced by the medical industry are not purchased by the asymptomatic population and competing watches are not nearly as widely adopted. The Apple Watch’s extraordinary adoption rate makes it uniquely positioned to address the problem of screening for silent AF and no competing product on the market or in development fills that void.

A. Apple Watch’s adoption rate is unparalleled.

Apple currently occupies 47% of the smartwatch industry in the US, an \$11B industry estimated to grow to \$15B by 2027. Statista, *Smartwatches – United States* (last accessed Aug. 10, 2023), <https://www.statista.com/outlook/dmo/digital-health/digital-fitness-well-being/digital-fitness-well-being-devices/smartwatches/united-states>. In 2019, Apple sold 30.7 million watches, surpassing the entire Swiss watch industry combined. Felix Richter, *Apple Beats Swiss Watch Industry At Its Own*

Game (Sep. 14, 2020), <https://www.statista.com/chart/12878/apple-watch-vs-swisswatches/#:~:text=According%20to%20estimates%20from%20Strategy,watches%20over%20the%20same%20period>. Known for its seamless integration across Apple devices, iPhone users are far more likely to buy an Apple Watch over any other brand of smartwatch and there are more iPhones in the United States than all other brands of smartphone combined. Statista, *Subscriber share held by smartphone operating systems in the United States from 2012 to 2023* (last accessed Aug. 10, 2023), <https://www.statista.com/statistics/266572/market-share-held-by-smartphone-platforms-in-the-united-states/>.

As useful as the Apple Watch's ECG feature is on its own (*see supra* Section I), it is its combination with the Apple ecosystem as a vehicle for providing that feature to the general population that makes it an unprecedented tool addressing the difficulties of assessing symptomatic and asymptomatic AF.

B. AliveCor's products do not fill the void left by the Apple Watch.

In asserting its smartwatch patents, AliveCor asserts itself as the sole provider of a smartwatch with ECG functionality in the United States. Dr. Saxon has no preference for which manufacturer provides a smartwatch with continuous cardiac monitoring and ECG functionality. She simply urges that the product actually be provided and done in a way that encourages as many people as possible to adopt it.

AliveCor has never, does not currently, and, based on the facts before this Court, does not plan to ever release a product that provides the benefits of the Apple Watch. AliveCor's discontinued KardiaBand was only ever an accessory to the Apple Watch, and like other ECG-specific devices, appeals only to already diagnosed AF patients. AliveCor's current products, shown in Figure 1 below, similarly do not appeal to the general population to solve the problem of detecting asymptomatic AF. See Kardia, *Shop our products* (last accessed Aug. 10, 2023), <https://store.kardia.com/>.

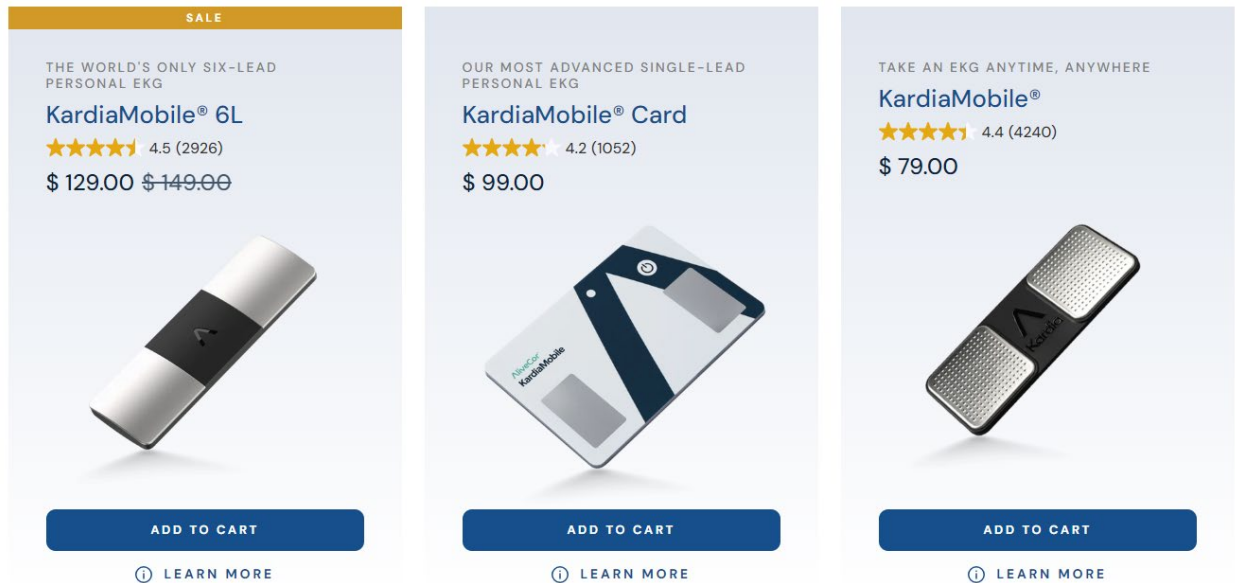


Figure 1

AliveCor's lack of a device providing the same benefits of the Apple Watch is even more concerning given the timeline of events in this case. Apple announced its Apple Watch Series 4, its first smartwatch with ECG capabilities, in September

2018. Sara Salinas et al., *Apple adds heart monitoring to Apple Watch* (Sep. 12, 2018, 1:13 pm), <https://www.cnbc.com/2018/09/12/apple-watch-series-4.html>. Just one month after Apple’s announcement, still with no plans to produce a smartwatch of its own, AliveCor filed continuation applications in its years-long patent families claiming, for the first time, a “smartwatch” with stand-alone ECG capabilities. *See* U.S. Patent Application No. 16/158,112 (application of U.S. Patent No. 10,638,941, filed October 11, 2018); U.S. Patent Application No. 16/153,446 (parent application of U.S. Patent No. 10,595,731, filed October 5, 2018). As soon as the ’941 and ’731 patents issued in 2020, still with no plans to produce any product, AliveCor sued Apple. The exclusion of the Apple Watch monitoring features is detrimental to public health and welfare and is precisely what 19 U.S.C. § 1337(d)(1) was intended to prevent.

III. The Apple Watch addresses unanswered obstacles that have plagued medical research for years.

The Institute of Medicine of the National Academies evaluated and summarized the challenges of planning and conducting clinical trials in the United States. *See* Rebecca A. English et al., *TRANSFORMING CLINICAL RESEARCH IN THE UNITED STATES: CHALLENGES AND OPPORTUNITIES* ix–x (Nat’l Acad. Press, 2010). Clinical trials typically involve “a diverse group of stakeholders—including research sponsors . . . , clinical investigators, patients, payers, physicians, and regulators.”

Organizing all of these stakeholders requires “significant time, energy, and money” and lacks efficiency due to a lack of standardized systems. *Id.* at 19. In addition, disparate administrative and regulatory requirements for the stakeholders, and the difficulty of patient recruitment further complicate a clinical study. *Id.* at 30, 35–36.

The Apple Watch was, and remains, a pioneer in revolutionizing medical research practices and overcomes several of these problems. The variety of health-related features of the Apple Watch provide researchers with several low- to no-cost monitoring devices already present within a customer’s purchased device. The Apple Watch is also significantly more cost-effective compared to typical medical research equipment and does not require physical presence of patients at any particular site. *See id.* at 26 (predicting a cost of \$90M for monitoring 14,000 patients across 300 sites). The interface of the Apple Watch and its companion Apple products also provide a standardized system for informing patients of a clinical trial, acquiring proper consent documents, and patient instruction, as well as data review for researchers, solving many of the inefficiencies of traditional clinical trials. All of these features, in combination with the ubiquity of the Apple Watch, also solve the problem of patient recruitment, as illustrated by the record-breaking 420,000 participants of the Apple Health Study. *See supra* Section I.B.2.

The numerous past and active studies that currently use the Apple Watch for

any and all of these functions also illustrates the powerful research capabilities the Apple Watch provides. *See* Apple Research & Care, Explore published projects (last accessed Aug. 10, 2023), <https://www.researchandcare.org/publications/> (listing 44 studies in which medical researchers partnered with Apple to perform clinical trials).

Even other countries, including China, have caught onto the power of smartwatches to streamline clinical studies. Following the Apple Heart Study, Huawei, China’s flagship tech giant and global competitor, conducted its own four-year AF study with “more than 2.8 million participants” and its own smartwatch, smashing Apple’s previous 420,000 participant record. Conor Hale, ACC: Massive Chinese smartwatch study screens millions for signs of afib (April 3, 2022, 12:15 pm), <https://www.fiercebiotech.com/medtech/acc-massive-chinese-smartwatch-study-screens-millions-signs-afib>. The exclusion of the Apple Watch would significantly hamper US medical research efforts.

CONCLUSION

For the reasons above, Dr. Saxon urges this Court to reverse the International Trade Commission’s exclusion order of the Apple Watch with ECG functionality in favor of a less drastic remedy that preserves the substantial benefits to public health and welfare.

Respectfully Submitted,

HAYNES AND BOONE, LLP

/s/ Debra J. McComas

Debra J. McComas
2323 Victory Avenue, Suite 500
Dallas, TX 75201
Phone: (214) 651-5375
Debbie.McComas@haynesboone.com

Adam L. Erickson
6000 Headquarters Drive, Suite 200
Plano, TX 75024
Phone: (972) 739-8661
Adam.Erickson@haynesboone.com

Attorneys for *Amicus Curiae*
Leslie A. Saxon, M.D.

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Fed. Cir. R. 29(b) and 32(b)(1) because:

■ this brief contains **3,015** words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f) and Fed. Cir. R. 32(b)(2).

2. This brief complies with the typeface and type style requirements of Fed. R. App. P. 32(a)(5) and 32(a)(6) because:

■ this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point Equity A font.

/s/ Debra J. McComas

Debra J. McComas