

Docket 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.

APPLE, INC.

Appellant,

v.

INTERNATIONAL TRADE COMMISSION

Appellee,

ALIVECOR, INC.

Intervenor.

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

**CORRECTED BRIEF OF ROBERT M. WACHTER, MD,
AS AMICUS CURIAE IN SUPPORT OF APPELLANT
APPLE INC. URGING REVERSAL**

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

CERTIFICATE OF INTEREST

Case Number 23-1509, -1553

Short Case Caption AliveCor, Inc. v. International Trade Commission

Filing Party/Entity Robert M. Wachter, MD

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Date: 10/02/2023

Signature: /s/ Michael Pieja

Name: Michael Pieja

<p>1. Represented Entities. Fed. Cir. R. 47.4(a)(1).</p>	<p>2. Real Party in Interest. Fed. Cir. R. 47.4(a)(2).</p>	<p>3. Parent Corporations and Stockholders. Fed. Cir. R. 47.4(a)(3).</p>
<p>Provide the full names of all entities represented by undersigned counsel in this case.</p>	<p>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.</p> <p><input checked="" type="checkbox"/> None/Not Applicable</p>	<p>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.</p> <p><input checked="" type="checkbox"/> None/Not Applicable</p>
<p>Robert M. Wachter, MD</p>		

Additional pages attached

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).

None/Not Applicable Additional pages attached

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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)?

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INTRODUCTION

Robert M. Wachter, MD, submits this brief as an *amicus curiae* pursuant to Federal Rule of Appellate Procedure 29, Federal Circuit Rule 29, and the pending motion requesting leave to file this brief. Dr. Wachter submits this brief in support of Appellant Apple Inc. on the grounds that excluding the Apple Watch from the United States will harm the public interest. Dr. Wachter’s decades spent treating patients and his experience as a department chair of a leading research and teaching hospital give him a unique perspective into uses of the Apple Watch to improve health outcomes nationwide and the potential impact of the Watch’s exclusion on our healthcare system.¹

INTEREST OF *AMICUS CURIAE*

Dr. Wachter is one of the nation’s leading clinicians, professors, and public health proponents. He chairs the Department of Medicine at the University of California San Francisco (“UCSF”), which is rated one of the top medical departments in the country. He is an expert in the digital transformation of healthcare and author of the bestselling book, *The Digital Doctor: Hope, Hype and Harm at the*

¹ Counsel for Apple and the ITC have consented to the filing of this brief; counsel for AliveCor has refused consent. Pursuant to Federal Rule of Appellate Procedure 29(a)(2), Dr. Wachter submits this brief along with an accompanying motion for leave to file. No counsel of record for any party authored this brief in whole or in part, or contributed money that was intended to fund the preparation or submission of this brief. *See* Fed. R. App. P. 29(a)(4).

Dawn of Medicine's Computer Age. Dr. Wachter wrote the world's leading patient-safety primer and received the John M. Eisenberg Award, the nation's top honor in patient safety. He also is a Master of the American College of Physicians and an elected member of the National Academy of Medicine.²

As a practicing physician, Dr. Wachter has an interest in identifying, researching, and pursuing new courses of treatment to assist his patients in achieving the best possible health outcomes. And as a department chair of a national research hospital, Dr. Wachter and his team at UCSF dedicate significant resources to investigating how emerging technologies can provide patients with safer, more effective treatment plans. Through this work, Dr. Wachter has gained a unique understanding of the gaps that exist in patient care and how the Apple Watch can play a role in bridging those gaps. Dr. Wachter submits this brief as an *amicus curiae* to offer his perspective as a clinician and chair of a research and teaching hospital on the benefits that health-related features of the Apple Watch provide in both clinical and research settings.

SUMMARY OF THE ARGUMENT

The Apple Watch and its health features give physicians and patients access to a unique healthcare tool. Features like the electrocardiogram (“ECG”) in the

² Dr. Wachter's full credentials are provided in Addendum A of the accompanying motion for leave.

Apple Watch allow for passive, long-term, at-home monitoring of cardiac rhythm. This feature offers an accessible and non-invasive way to detect conditions like atrial fibrillation that may otherwise go undetected and untreated. The Watch also provides its users with a dashboard summarizing their health data, which can be used to monitor their overall health and share relevant medical information with their healthcare providers.

In light of these capabilities, the Apple Watch provides at least three important benefits to public health. First, the Apple Watch is a valuable early-detection tool and long-term monitoring solution for patients with atrial fibrillation, improving physicians' ability to make appropriate decisions about prescribing medicine to decrease stroke risk associated with atrial fibrillation. Second, patients can use the Apple Watch to accurately monitor their own vitals, including to identify when medical intervention may be necessary, as many patients did during the COVID-19 pandemic when access to clinical care was limited. Third, the Apple Watch and the data it collects are currently being used to support numerous ongoing clinical studies directed to a variety of health applications. Excluding the Apple Watch from the United States as contemplated by the International Trade Commission's remedial orders at issue in this case would undermine each of these benefits.

ARGUMENT

The Apple Watch contributes meaningfully to healthcare practitioners' ongoing efforts to improve health outcomes nationwide by accurately detecting cardiac arrhythmias, monitoring vitals, and collecting data to support clinical studies.

I. The Apple Watch Is an Important, Emerging Tool for Diagnosing and Monitoring Atrial Fibrillation.

Despite being a relatively new technology, studies conducted at UCSF and elsewhere have shown that the Apple Watch and similar wearable devices can reliably detect atrial fibrillation. With time and continued studies, tools like the Apple Watch could increasingly serve as early-detection tools for atrial fibrillation, potentially leading to decreased mortality and fewer instances of other complications of atrial fibrillation, particularly stroke.

Increasing early detection of atrial fibrillation through tools like the Apple Watch is no small matter. Atrial fibrillation, a chronic cardiac rhythm disorder, affects approximately 34 million people worldwide, with cases increasing by about 5% per year and 12.1 million cases expected in the United States alone by 2030. Eric Y. Ding et al., *Emerging Technologies for Identifying Atrial Fibrillation*, 127 *Circulation Research* 128, 128 (2020); Geoffrey H. Tison et al., *Passive Detection of Atrial Fibrillation Using a Commercially Available Smartwatch*, 3(5) *JAMA Cardiol.* 409, 410 (2018); Connie W. Tsao et al., *Heart Disease and Stroke*

Statistics—2023 Update: A Report from the American Heart Association, 147 Circulation e93, e433 (2023). It is a leading cause of stroke, and it is associated with increased mortality in individuals with cardiovascular procedures, heart failure, and diabetes, among other conditions. Tison, *supra* 4, at 413; Tsao, *supra* 4, at e442. But this pervasive condition often goes undetected and undiagnosed because patients may be asymptomatic until a severe stroke or other life-threatening event occurs. Tison, *supra* 4, at 410; Ding, *supra* 4, at 128. An estimated one million people in the United States have undiagnosed atrial fibrillation. Ding, *supra* 4, at 128. Accordingly, researchers at UCSF and throughout the medical field have been calling for accessible, noninvasive, and user-friendly ways to screen for this “silent” condition. Tison, *supra* 4, at 413.

In just the few years since its release, the ECG functionality on the Apple Watch has been shown to be an accurate, noninvasive way to detect atrial fibrillation early—before a patient suffers from a stroke or other medical complication. Tison, *supra* 4, at 415; Marco V. Perez et al., *Large-Scale Assessment of a Smartwatch to Identify Atrial Fibrillation*, 381(20) N. Engl. J. Med. 1909, 1917 (2019). Studies have also found that, when notified of an irregular pulse, most users will follow up with their healthcare providers. Perez, *supra* 5, at 1916. Once the diagnosis of atrial fibrillation is confirmed, physicians can provide anticoagulation therapy in appropriate patients, which will lower the risk of stroke. Tison, *supra* 4, at 410.

Not only can the Apple Watch serve as an early-detection tool for unknowing atrial-fibrillation patients, but it also can serve as a long-term monitoring device for post-stroke patients. Before the Apple Watch, physicians' options for identifying intermittent or "paroxysmal" atrial fibrillation included Holter monitors, external loop recorders, or implantable loop recorders. Ding, *supra* 4, at 129. But each of those devices have drawbacks. Some are bulky external devices that restrict a patient's physical movement and can cause skin irritation, and others are implantable devices that are costly and carry potential complications. Ding, *supra* 4, at 129; Eko Sakti Pramukantoro & Akio Gofuku, *A Heartbeat Classifier for Continuous Prediction Using a Wearable Device*, 22 *Sensors* 5080, 1 (2022). In contrast, the Apple Watch and similar wearable devices allow for a less restrictive, less invasive, and longer-term monitoring solution. Ding, *supra* 4, at 133. Further, these wearable solutions have shown "great promise" in the identification of atrial fibrillation before it results in stroke, and in certain circumstances may be superior to Holter monitoring. Yun Gi Kim et al., *A Watch-Type Electrocardiography Is a Reliable Tool for Detecting Paroxysmal Cardiac Arrhythmias*, 11 *J. Clin. Med.* 3333, 10 (2022); Ding, *supra* 4, at 138.

Post-stroke patients can especially benefit from the Apple Watch's cardiac monitoring capabilities. Without detected instances of arrhythmia, physicians are reluctant to prescribe anticoagulants because they increase the risk of bleeding in an

already high-risk patient population of recovering stroke patients. Tsao, *supra* 4, at e441; Jonathan C. Hsu et al., *Oral Anticoagulant Therapy Prescription in Patients With Atrial Fibrillation Across the Spectrum of Stroke Risk*, 1(1) JAMA Cardiol. 55, 60 (2016). But a significant number of post-stroke patients will be found on prolonged monitoring to have episodic atrial fibrillation, and those patients could benefit from anticoagulation to reduce the associated risks. Accordingly, the Apple Watch offers the promise to improve the ability for clinicians to monitor post-stroke patients on a long-term basis to determine which are experiencing arrhythmias and so are good candidates for anticoagulation therapy.

II. The Apple Watch Provides an Accessible Option for Patients to Monitor Their Vitals Outside of a Hospital Setting, as Demonstrated During the COVID-19 Pandemic.

The Apple Watch serves as a beneficial health tool in contexts beyond atrial fibrillation, particularly because it allows a wearer to continuously monitor vitals. For example, the Apple Watch proved its worth as an at-home health monitoring tool during the COVID-19 pandemic. Concerns about the spread of a highly contagious virus led to reductions in on-site care and routine visits to providers during the pandemic. Pramukantoro, *supra* 6, at 1. Thus, the pandemic heightened the need to monitor patient vitals outside of a clinical environment. Patients did so with the help of devices like the Apple Watch. Physicians at UCSF became aware of many patients who used the Apple Watch to monitor their own vitals, including

blood-oxygen levels. These patients were able to contact their clinicians when there was early evidence of deterioration in a patient's vitals, such as blood-oxygen levels. Consistent with this observation, studies have confirmed that the Apple Watch can be used to assess blood oxygen levels in both healthy patients and those with cardiovascular or lung diseases. Carmen Spaccarotella et al., *Assessment of Non-Invasive Measurements of Oxygen Saturation and Heart Rate with an Apple Smartwatch: Comparison with a Standard Pulse Oximeter*, 11 J. Clin. Med. 1467, 6 (2022).

Similarly, a 2021 study found that patients' heart-rate metrics collected by the Apple Watch can predict COVID-19 infections and identify COVID-19-related symptoms. Robert P. Hirten et al., *Use of Physiological Data From a Wearable Device to Identify SARS-CoV2 Infection and Symptoms and Predict COVID-19 Diagnosis: Observational Study*, 23(2) J. Med. Internet Res. e26107, 11 (2021). That study, which evaluated nearly 300 healthcare workers at Mount Sinai in New York, concluded that heart-rate variability detected by the Apple Watch may enable detection of a COVID-19 infection before the onset of symptoms and before diagnosis by a nasal swab. *Id.* at 4, 11. The Mount Sinai study recognized that this approach may be useful to track and identify not only COVID-19 infections, but "possibly other types of infection" as well. *Id.* at 11.

The advances gained during the pandemic regarding remote health monitoring, including using the Apple Watch, can be applied to other settings as well. Given the Watch's ability to monitor a wearer's vitals continuously and outside of a clinical environment, it would be an important health tool in the event of a similar health crisis in the future. It is also a valuable way for patients who live in remote areas to monitor their health when access to healthcare facilities is limited.

III. The Apple Watch, and the Data It Collects, Is Being Used to Support over One Hundred Clinical Studies.

The Apple Watch also plays an important role in advancing healthcare through its use in numerous clinical studies directed to a variety of health applications. Clinical trials are research studies of humans designed to measure the safety and effectiveness of biomedical or behavioral treatments. *See, e.g.,* U.S. FDA, *Basics About Clinical Trials*.³ As of this filing, the National Institute of Health lists 115 ongoing, planned, or completed clinical trials that concern the Apple Watch or use data collected from it. *See* Nat'l Libr. Med., CLINICALTRIALS.GOV.⁴ Twenty-three of those studies relate to atrial fibrillation. *Id.* Clinical trials, including those

³ <https://www.fda.gov/patients/clinical-trials-what-patients-need-know/basics-about-clinical-trials> (May 8, 2023).

⁴ <https://www.clinicaltrials.gov/> (search "Apple Watch") (last visited Aug. 14, 2023).

involving the Apple Watch, are the cornerstone of medical progress because they test the effectiveness of various interventions in controlled circumstances.

In many of these clinical trials, researchers are using the Apple Watch to collect necessary patient data in a way that may be impossible or impracticable without it. For example, Johns Hopkins University is collaborating with the National Heart, Lung, and Blood Institute (NHLBI) to sponsor REACT-AF, a randomized controlled trial that will use data collected from the Apple Watch's heart-monitoring capabilities to assess effective dosages of anticoagulation therapy for atrial-fibrillation patients. *See*, Nat'l Libr. Med., *The Rhythm Evaluation for AntiCoagulaTion with Continuous Monitoring of Atrial Fibrillation (REACT-AF)*, CLINICALTRIALS.GOV.⁵ In other clinical trials, the capabilities of the Apple Watch are themselves the subject of the studies, which seek to expand and improve the healthcare community's understanding of the Apple Watch as a healthcare tool. For example, the Mayo Clinic has sponsored and continues to sponsor multiple clinical trials measuring the Apple Watch's ability to detect various conditions. *See, e.g.*, Nat'l Libr. Med., *Evaluation of ECG Transmission and AI Models Using Apple Watch ECGs and Symptoms Data Collected Using a Mayo iPhone App*, CLINICALTRIALS.GOV.⁶

⁵ <https://classic.clinicaltrials.gov/ct2/show/NCT05836987> (Aug. 14, 2023).

⁶ <https://clinicaltrials.gov/ct2/show/NCT05324566> (Aug. 8, 2023).

Given the Watch's use in a multitude of clinical trials and the wide interest across the medical community concerning the Watch's health-related features, removing public access to the Apple Watch would disrupt a myriad of efforts to advance healthcare in the United States.

CONCLUSION

The health features of the Apple Watch are gaining traction as beneficial clinical and research tools that can accurately detect cardiac arrhythmias in unknowing patients, monitor vitals in patients outside of clinical settings, and collect data to advance groundbreaking clinical studies. Excluding the Apple Watch would negatively impact each of these outcomes, ultimately harming the public by impeding the advancement of patient health in the United States. Dr. Wachter respectfully urges this Court to take into consideration these public health impacts when reviewing the International Trade Commission's issuance of remedial orders relating to the Apple Watch.

October 2, 2023

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify as follows:

1. The foregoing brief complies with the type-volume limitations of Fed. R. App. P. 32(b)(1). The brief has 2,391 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 requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this motion has been prepared in a proportionally spaced typeface using Microsoft Word for Microsoft 365 in Times New Roman 14-point font.

October 2, 2023

GOLDMAN ISMAIL TOMASELLI BRENNAN &
BAUM LLP

/s/ Michael T. Pieja

Michael T. Pieja
Counsel for Amicus Curiae,
Robert M. Wachter, MD

CERTIFICATE OF SERVICE

I hereby certify that on October 2, 2023, I electronically filed the foregoing Brief of Robert M. Wachter, MD, as Amicus Curiae in Support of Appellant Apple Inc. Urging Reversal with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the appellate CM/ECF system, which will serve as e-mail notice of such filing to all counsel registered as CM/ECF users, including the principal counsel for the parties.

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