

NOS. 2023-1509, 2023-1553 (XAP)

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**United States Court of Appeals  
for the Federal Circuit**

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ALIVECOR, INC.,

*Appellant,*

v.

INTERNATIONAL TRADE COMMISSION,

*Appellee,*

APPLE INC.,

*Intervenor.*

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APPLE INC.,

*Appellant,*

v.

INTERNATIONAL TRADE COMMISSION,

*Appellee,*

ALIVECOR, INC.,

*Intervenor.*

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

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**CORRECTED BRIEF OF DR. HUGH CALKINS AS *AMICUS CURIAE*  
IN SUPPORT OF APPLE INC. AND REVERSAL-IN-PART**

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

**CERTIFICATE OF INTEREST**

**Case Number** 23-1509, 23-1553

**Short Case Caption** Alivecor, Inc. v International Trade Commission, Apple, Inc.

**Filing Party/Entity** Dr. Hugh Calkins

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

Date: 08/14/2023

Signature: /s/ Abran J. Kean

Name: Abran J. Kean

<p><b>1. Represented Entities.</b> Fed. Cir. R. 47.4(a)(1).</p>	<p><b>2. Real Party in Interest.</b> Fed. Cir. R. 47.4(a)(2).</p>	<p><b>3. Parent Corporations and Stockholders.</b> 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>Dr. Hugh Calkins</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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Adam P. Seitz Erise IP, P.A.		

**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


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**STATEMENT OF INTEREST OF AMICUS CURIAE  
AND THE SOURCE OF AUTHORITY TO FILE**

Dr. Hugh Calkins respectfully submits this brief as an *amicus curiae* pursuant to Federal Rule of Appellate Procedure 29 and Federal Circuit Rule 29.<sup>1</sup> Dr. Calkins is a Professor of Cardiology and Director of the Electrophysiology Laboratory and Arrhythmia Service at Johns Hopkins Hospital. This case is of interest to Dr. Calkins because of his longstanding and ongoing work in the area of cardiology, especially work and research involving cardiac arrhythmias, and because of his concern for preserving public access to devices that include important health features. Dr. Calkins writes to emphasize public health considerations that the Court should be aware of when deciding the case.

Dr. Calkins is the Catherine Ellen Poindexter Professor of Cardiology and Director of the Electrophysiology Laboratory and Arrhythmia Service at the Johns Hopkins Hospital. He is an internationally recognized expert on catheter ablation, atrial fibrillation,

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<sup>1</sup> 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. Calkins 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). This statement of Dr. Calkins' background and professional involvement provides Dr. Calkins' interest in the case, and the source of Dr. Calkins' authority to file under Fed. R. App. P. 29(a)(4)(D).

syncope, arrhythmogenic right ventricular dysplasia (ARVD) and arrhythmia management.

Dr. Calkins attended Williams College and Harvard Medical School before training in medicine at Massachusetts General Hospital. He received his cardiology training at Johns Hopkins. His first faculty position was at the University of Michigan, where he directed the Pacemaker Service, and he returned to Johns Hopkins as director of the Arrhythmia Service in 1992.

Dr. Calkins is an Associate Editor of the *Journal of Cardiovascular Electrophysiology* and is on the editorial board of many other cardiology journals. He is a former member of the American Board of Internal Medicine Electrophysiology Boards Test Writing Committee. Dr. Calkins is a fellow of the American College of Cardiology, the American Heart Association and the Heart Rhythm Society. He led a 44-member international task force whose 2012 Expert Consensus Statement gave recommendations for treatment and research of atrial fibrillation. Dr. Calkins is a past president of the Heart Rhythm Society and was elected to be a member of the Miler Coulsen Academy of Clinical Excellence in 2014.

Dr. Calkins has published more than 500 articles and book chapters on a large variety of cardiac arrhythmias. His research has focused predominantly on catheter ablation, atrial fibrillation, syncope, and

arrhythmogenic right ventricular dysplasia. Dr. Calkins has also written extensively on most aspects of heart rhythm disorders and their treatment. As can be seen from the above, Dr. Calkins has devoted his professional career to understanding cardiovascular health and helping treat and cure patients that suffer from heart problems.

## ARGUMENT

Since its introduction to the market in 2015, the Apple Watch has become an important tool that serves the public health interests of United States citizens. In particular, the availability of heart monitoring software, including High Heart Rate Notifications, and cardiac arrhythmia focused software such as the electrocardiography (ECG) App and Irregular Rhythm Notifications on the Apple Watch help patients and doctors understand typical heart rates and potential issues with heart health.

First, these sensors and software in the Apple Watch provide significant benefit to patients by alerting them to possible arrhythmias such as atrial fibrillation, which is a common cardiac arrhythmia affecting millions of people in the United States and a common cause for stroke. Importantly, the risk for stroke can be mitigated through treatment if the atrial fibrillation is discovered in a patient. The Apple Watch significantly aids in diagnosis of conditions such as atrial fibrillation and positions patients to receive a diagnosis and to receive treatment earlier than they otherwise would without this information

from the Apple Watch. *See* Appx1408 (Dr. Calkins Letter).<sup>2</sup> This early warning of heart problems is critical in successful treatment and avoiding what could otherwise become emergency situations. If the Apple Watch and this functionality were to no longer be available, millions of people would no longer have advanced warning of atrial fibrillation. This could lead to countless numbers of citizens being placed at a heightened risk for severe health complications, including death.

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<sup>2</sup> *See also* Kadire, Siri R et al., *Anticoagulation after Ablation for Atrial Fibrillation*, THE NEW ENGLAND JOURNAL OF MEDICINE, July 29, 2021, at 468 (suggesting an Apple Watch equipped with electrocardiographic monitoring for patients suffering from atrial fibrillation); Camm, A. John et al., *The Year in Cardiology: Arrhythmias and Pacing: The Year in Cardiology 2019*, CARDIOLOGIA CROATICA, May/June 2020, at 134 (referencing an Apple Watch study investigating if a smartwatch based irregular pulse notification algorithm identified possible atrial fibrillation); Hugh Calkins, *New Supraventricular Tachycardia Initiative Seeks to Help Patients Find the Best Possible Care and Support*, 7(1) EUROPEAN J. OF ARRHYTHMIA & ELECTROPHYSIOLOGY 2 (2021) (explaining how use of mobile devices, such as Apple Watches, improved the diagnosis of SVT (an elevated heart rate condition) during the COVID-19 pandemic); David O. Arner, *Management of asymptomatic arrhythmias: a European Heart Rhythm Association (EHRA) consensus document, endorsed by the Heart Failure Association (HFA), Heart Rhythm Society (HRS), Asia Pacific Heart Rhythm Society (APHRS), Cardiac Arrhythmia Society of Southern Africa (CASSA), and Latin America Heart Rhythm Society (LAHRS)*, EUROPEAN SOCIETY OF CARDIOLOGY, March 18, 2019 at 845 (explaining how devices like the Apple Watch can measure pulse rates for patients with heart rhythm irregularities).

Second, the data generated by the Apple Watch and its sensors and software is also useful to doctors. Traditionally, lacking specialized equipment, patients were required to go to the hospital to undergo an ECG. Many patients were unable to make it to the hospital before their symptoms resolved, making it difficult for doctors to gather data that showed an arrhythmia and complicating further treatment. Other patients did not have access to a care provider that was able to quickly perform an ECG. Many other patients suffer from a fear of doctors and simply refuse to go to a care provider to have their symptoms examined. The Apple Watch has alleviated many of these problems by providing patients with a way to gather a more robust data set about their heart health without stepping foot into a provider's office. The data gathered and stored by the Apple Watch and its sensors and software can be useful to doctors in understanding a patient's heart health, can help doctors diagnose potential issues, and can lead to a more thorough treatment plan.. See Appx1408 (Dr. Calkins Letter).<sup>3</sup> The advanced atrial

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<sup>3</sup> See also Ritu Yadav et al., *Sex-Based Differences in Safety and Efficacy of Catheter Ablation for Atrial Fibrillation*, J. CARDIOVASCULAR ELECTROPHYSIOLOGY (2023) (describing how Apple Watches were used for arrhythmia recurrence monitoring to gather data related a medical procedure's effectiveness); Ben Freedman et al., *Screening for Atrial*

fibrillation warning systems of the Apple Watch also can provide the necessary “push” for patients to receive treatment who otherwise would not visit a doctor’s office.

Third, the Apple Watch and its sensors and software are currently being used in clinical arrhythmia research. Thus, not only does the availability of the Apple Watch help direct consumers and their doctors, but also the public at large stands to gain from this research. This clinical arrhythmia research using the Apple Watch will lead to advancements in science and heart health saving many more Americans from serious illness or death. Indeed, many clinically-impactful research studies in the United States depend on the use of the Apple Watch to make meaningful discoveries that will serve the health interests of the overall population. See Appx1408 (Dr. Calkins Letter).<sup>4</sup>

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*Fibrillation: A Report of the AF-SCREEN International Collaboration*, 135 CIRCULATION 1851–67 (2017) (explaining that ongoing monitoring detects atrial fibrillation more effectively than repeated patient-activated devices and that noninvasive devices can accomplish continuous monitoring).

<sup>4</sup> See also Agnieszka Kotalczyk, Gregory YH Lip, & Hugh Calkins, *The 2020 ESC Guidelines on the Diagnosis and Management of Atrial Fibrillation*, 10(2) ARRHYTHMIA & ELECTROPHYSIOLOGY REV. 65-67 (2021) (“[i]ncreasing data on the identification and monitoring of AF are available for the use of wearable technology or implantable loop recorders

I understand the International Trade Commission has recommended an injunction on sales of the Apple Watch in the United States. As a practicing physician who has devoted his career to studying cardiology and treating heart problems, it is my opinion that removing the Apple Watch and its heart health functionality from the marketplace has the potential to create a public health crisis. Millions of citizens would lose access to a device that includes functionality for detecting potential heart problems. Without this early detection, millions of citizens who are suffering from heart problems would then miss the crucial early treatment that helps doctors and emergency providers save lives. This injunction would compromise ongoing projects that will lead to further advancements in medical science, which has the potential to cause significant setbacks to future treatments. Any injunctive remedy that disrupts the availability of the Apple Watch and its heart health functionality would be detrimental to the public health interest of United

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to detect and record AF episodes . . . . [n]ovel tools and technologies for digital ECG analysis, in the form of wearables, machine learning and artificial intelligence, have brought potentially significant opportunities for the detection and diagnosis of [atrial fibrillation] and may be used for long-term [atrial fibrillation] screening, especially in high-risk cohorts.”).

States citizens and to the advancement of the science by medical professionals across the nation. *See* Appx1408 (Dr. Calkins Letter).

### CONCLUSION

The Court should consider the public health consequences of injunctive relief when deciding this appeal.

Dated: October 18, 2023

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**CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME  
LIMITATION, TYPEFACE AND TYPE STYLE REQUIREMENTS**

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) or Federal Rule of Appellate Procedure 28.1(e). The brief contains 1,656 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) or Federal Rule of Appellate Procedure 28.1(e) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft Word for Mac in Century Schoolbook, 14 point font.

Dated: October 18, 2023

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