No. 24-1392

In the

United States Court of Appeals

For the

Ninth Circuit

ALIVECOR, INC.,
Plaintiff-Appellant

v.

APPLE, INC.
Defendant-Appellee

On Appeal From the United States District Court
for the Northern District of California
Hon. Jeffrey S. White, District Judge
Case No. 4:21-cv-03958-JSW

BRIEF OF *AMICI CURIAE* PHYSICIANS IN SUPPORT OF APPELLANT ALIVECOR, INC.

Filed Unopposed by All Parties Pursuant to Ninth Circuit Rule 29-2(a)

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DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, *amici curiae* state that the physicians identified are individuals, and therefore do not issue stock or have a parent corporation.

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IDENTITIES AND INTEREST OF *AMICI CURIAE*

Amici curiae are leading physicians who specialize in cardiology and/or cardiac surgery. They conduct research on and treat patients with heart disease, including patients suffering from atrial fibrillation ("Afib")—a condition that causes an irregular heart rhythm. Afib is the most common type of cardiac arrhythmia, but it is a complex condition that is difficult to manage and varies with each individual. It is often asymptomatic until a major health event occurs, such as a stroke. Indeed, approximately one out of every seven strokes in the United States can be traced to Afib.

The physician signatories to this brief have spent years helping to treat patients with Afib and they have a deep and abiding interest in preserving patient access to cutting edge and life-saving treatments. Thus, *amici curiae* believe that this case raises critically important issues involving access to potentially life-saving technology. Appellant AliveCor, Inc. ("AliveCor") developed a heart rhythm analysis application—Kardia—which included a feature called SmartRhythm that patients could use with Appellee Apple, Inc.'s ("Apple") Apple Watch. SmartRhythm allowed patients to continuously monitor their own heart rhythms and receive notifications of irregularities in real time (every five seconds). Patients could then immediately utilize AliveCor's band to conduct an electrocardiogram ("ECG") if they were alerted to an irregular heart rhythm. This

was a major breakthrough in technology and many of the undersigned recommended SmartRhythm for their own patients suffering from Afib. Unfortunately, Apple introduced a new version of its Apple Watch ("watchOS 5") that cut off access to the raw heart data needed to continuously monitor heart rhythm and provide patients with real-time information. As a result, AliveCor had to pull SmartRhythm from the market.

Amici curiae understand that Apple, in an attempt to defend its actions, points to the introduction of Irregular Rhythm Notification ("IRN") with watchOS 5 as a supposed product improvement. From a medical point of view, IRN is inferior when it comes to medical monitoring. IRN only sporadically measures a user's heart rhythm; and critically, unlike the AliveCor product, Apple's feature is not FDA cleared for users with Afib. Indeed, Apple itself advises Afib patients not to use its replacement product for heart rhythm monitoring.

The district court's decision granting summary judgment in favor of Apple undermines the ability of patients to access the information they need to continuously monitor their heart rhythm. This is a very serious medical issue that has resulted in a loss of access to a potentially life-saving product.

The *amici curiae* physicians submit this brief in their individual capacities and do not purport to represent the views of their respective universities, hospitals, or research institutions.

Dr. Toby Cosgrove[1]

Dr. Daniel Frisch[2]

Dr. Ronald Karlsberg

Dr. Eric Topol

STATEMENT OF AUTHORSHIP AND CONSENT

The brief was written entirely by counsel for *Amici Curiae* and not by counsel for any party. No party has contributed money to prepare or submit this brief.

AliveCor, Inc. and Apple, Inc. both consent to *Amici Curiae* filing this brief.

BACKGROUND

The *amici curiae* physicians filing this brief believe that patient care will suffer if this Court does not reverse the district court's decision. AliveCor's product provided patients suffering from heart rhythm irregularities, especially patients with Afib, with the ability to continuously monitor heart rhythms via an application that worked with the AppleWatch. This groundbreaking application

[1] In the interests of full disclosure, Dr. Cosgrove hereby advises the Court that he serves on the Board of Directors for AliveCor, Inc. Dr. Cosgrove was not a director for AliveCor, Inc. when its Board of Directors voted to initiate this action. As noted, this submission is in Dr. Cosgrove's individual capacity based upon his own medical experience.

[2] Dr. Frisch hereby advises the Court that he serves on the Clinical Advisory Board for AliveCor, Inc. However, as noted, this submission is in his individual capacity based upon his own medical experience.

used inputs from the Apple Watch to continuously monitor heart rhythms and notify patients of irregularities in real time. From *amici* physicians' perspective, the availability of this technology could potentially help save lives until the events giving rise to this lawsuit.

A. Factual Background

When Apple introduced the Apple Watch it provided third-party developers, including AliveCor, with access to continuous heart rhythms of Apple Watch users. This was accomplished using a key algorithm—the Heart Rate Path Optimizer ("HRPO")—in Apple's Workout Mode application program interface ("API").[3] Utilizing this HRPO algorithm, AliveCor's SmartRhythm feature within its Kardia application ("SmartRhythm") was able to detect heart rhythm irregularities and offered continuous real-time monitoring and analysis of a patient's heart rhythms. Importantly, the patient could be at rest or in motion and AliveCor's app would still monitor and provide alerts regarding irregular heart rhythms. This continuous monitoring was extremely valuable to patients suffering from Afib because a patient is at greater risk of a stroke with each Afib event. SmartRhythm also allowed patients to track the number of heart rhythm irregularities after a cariologist recommended certain medications or lifestyle

[3] An API is essentially a set of programming codes that allow different software programs to interface and share data and functionality.

changes, which can assist doctors in making adjustments and providing better individualized care. For these reasons, there was significant patient demand for AliveCor's product[4], and it was an important tool in the cardiologist's tool belt. 5-ER-935–43 (2019 medical study explaining that SmartRhythm offered inexpensive and non-invasive approach to long-term Afib surveillance and management).

When Apple introduced watchOS 5, it introduced a new algorithm to the Workout Mode API called the Heart Rate Neural Network ("HRNN") algorithm. Apple then launched its own Irregular Rhythm Notification ("IRN") feature in watchOS 5. Apple's IRN feature only analyzes a patient's heart rhythms when they are at rest. After introducing watchOS 5, Apple stopped making HRPO-generated heart data available to third-party developers, like AliveCor. While AliveCor had been able to offer continuous analysis through HRPO, it could no longer do so after Apple introduced watchOS 5.

The problem with intermittent monitoring, as opposed to continuous monitoring, is that it misses irregular heart rhythm episodes and underreports their

[4] In the experience of *amici physicians*, patients strongly prefer monitoring their heart rhythms using a wrist wearable like an Apple Watch over chest straps and ambulatory cardio monitors. From a medical point of view, AliveCor's real-time monitoring cannot be achieved even with ambulatory cardio monitors which do not provide immediate feedback to the patient and require remote review of the data by a trained technician.

frequency. This is especially detrimental for Afib patients because each Afib occurrence increases the risk of stroke. The result is that Afib patients can no longer use their AliveCor's SmartRhythm (or any other application) to continuously monitor their heart rhythms. 4-ER-841, n.32 (quoting Apple executive acknowledging IRN does not run continuously). Indeed, Apple specifically warns consumers, as it should, that IRN does not provide continuous monitoring and should not be used by Afib patients. 5-ER-948 (Apple warning: "Since the irregular rhythm notifications feature is not intended for people with AFib, it is turned off automatically when you set up AFib History."); 3-ER-350 (Apple waring: "These notifications are not designed for people who have been diagnosed with AFib.").

Research studies show that AliveCor's electrocardiogram recording and heart rhythm analysis software is more comprehensive and accurate than what Apple offers consumers.[5] *See* Christopher Ford et al., *Comparison of 2 Smart Watch Algorithms for Detection of Atrial Fibrillation and the Benefit of Clinician Interpretation*, JACC: CLINICAL ELECTROPHIOLOGY 8(6), 782–91 (2022). However, Apple's decision to stop supporting the HRPO algorithm forced

[5] It should be noted that the FDA's approval of AliveCor's Kardia System, including the Kardia Band and Kardia App (https://www.accessdata.fda.gov/cdrh_docs/pdf17/K171816.pdf) was more robust as compared to the approval for Apple's IRN (https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN180042.pdf).

AliveCor to remove SmarthRhytm from the market.[6] Patients, including those with Afib, no longer have access to SmarthRhythm as a means of monitoring their heart rhythms. And because of Apple's decision to exclude third-party access to the HRPO data, no other competitor is able to provide a continuous-monitoring application to these patients.

B. Procedural Background

Apple moved for summary judgment on AliveCor's Section 2 claims. The district court found triable issues of fact on the issues of relevant markets and antitrust injury, but granted summary judgment in favor of Apple based on its finding that Apple's decision to replace HRPO with HRNN was a product improvement and there was no evidence of associated conduct establishing an abuse of monopoly power. 1-ER-23–24.

SUMMARY OF ARGUMENT

The district court's ruling is based upon a fundamental misreading and misapplication of this Court's decision in *Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp. LP*, 592 F.3d 991 (9th Cir. 2010). In *Allied Orthopedic*, this Court held only that a *bona fide* design change that improves a product by

[6] A key reason for AliveCor's decision to pull SmartRhythm from the market was that Apple's HRNN algorithm artificially modified ("smoothed") reported patient heart rate data. 3-ER-340–43. For understandable reasons of patient safety, AliveCore could not rely on heart rate data that Apple had elected to modify.

providing a new benefit to consumers *may* provide a safe harbor against antitrust liability under Section 2 of the Sherman Act. *See id*. at 998–1000, 1002. Importantly, however, this Court made clear that such antitrust immunity is limited to situations: (1) where there is an actual product improvement; and (2) even where there may be a product improvement, the defendant does not engage in "associated" anticompetitive conduct to maintain its monopoly. *See id*. Here, the district court erred when it granted summary judgment to Apple.

First, the district court erred by failing to consider whether cutting off third-party access to the HRPO data should be addressed at the threshold as an independent antitrust violation—separate and apart from whether Apple engaged in any alleged product improvement. *See Allied Orthopedic*, 592 F.3d at 1002. The district court also erred in finding, as a matter of law, that Apple improved its product. The district court's finding is contrary to the record. It is also contrary to what *amici* physicians have experienced in evaluating monitoring options for patients. Indeed, from the perspective of *amici* physicians, it is difficult to see how ending access to continuous heart rhythm data for medical monitoring could be viewed as an actual product improvement. Further, and contrary to the district court's holding, *Allied Orthopedic* did not state that a defendant is immune from antitrust liability if it implements a product change that is detrimental for some purposes so long as it is an improvement for consumers in some other way.

Moreover, antitrust precedent is clear that the purported benefits of Apple's product change still must be evaluated against its clear anticompetitive effects. *See United States v. Microsoft Corp*., 253 F.3d 34, 58–59, 65–67 (2001); *Epic Games, Inc. v. Apple, Inc*., 67 F.4th 946, 985–86, 993–94, 998 (9th Cir. 2023), *cert. denied*, 144 S. Ct. 681 (2024), *cert. denied*, 144 S. Ct. 682 (2024). Thus, to determine whether Apple's claimed product improvement was justified as procompetitive or, instead, pretext for anticompetitive or exclusionary conduct, requires a jury to address the issue on a fully developed factual record.

Second, the district court erred in ruling that Apple's supposed product improvement was not accompanied by associated anticompetitive conduct. As the district court acknowledged, even where there is a product improvement, "[a] monopolist's discontinuation of old technology may violate Section 2 if it effectively forces consumers to adopt its new technology" and that such action may be "associated conduct." *Allied Orthopedic*, 592 F.3d at 1002. Moreover, courts have specifically held that it is an "abuse of leverage" for a monopolist to create a new version of its app incompatible with a competitor's and end support for prior versions of its app. *See Teradata Corp. v. SAP SE*, 2018 WL 6528009, at *13 (N.D. Cal. Dec. 12, 2018). Here, Apple leveraged its monopoly power to deny patients from having access to SmartRhythm (or any other third-party application), thereby foreclosing all competition and depriving patients of a critically important,

potentially life-saving product. Yet, the district court made its own factual determinations in finding, as a matter of law, that Apple's foreclosure of all competitive apps did not constitute associated anticompetitive conduct. The district court's ruling was erroneous.

Under a proper application of *Allied Orthopedic*, the district court should have found that Apple's conduct raised quintessential fact issues for a jury to decide—*i.e.*, whether a monopolist used its monopoly power to foreclose all competition and eliminate patient choice. *Amici* physicians respectfully request that the Court reverse the district court's grant of summary judgment and remand for proper findings by a jury.

ARGUMENT

A. The District Court Erred in Concluding That Apple Implemented a Product Improvement.

Under *Allied Orthopedic*, the threshold question is whether Apple's decision to replace the HRPO algorithm with the HRNN algorithm—which denies third-party access to continuous heart rhythm data—should even be analyzed as a genuine product improvement. 1 HERBERT HOVENKAMP ET AL., IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 12.03[E][1] (3d ed. 2021 Supp.). The district court concluded, as a matter of law, that Apple's HRNN algorithm was an improvement over the HRPO algorithm ***for exercise purposes***. 1-ER-23 (lines 12–16). According to the

district court, record evidence supported that Apple believed it needed alternative ways to generate more accurate heart rates for exercise. *Id*. (lines 20–23). But this inquiry is too narrow. It fails to consider whether cutting off third-party access to the HRPO data should be addressed as an independent antitrust violation—separate and apart from whether Apple engaged in any alleged product improvement. *See Allied Orthopedic*, 592 F.3d at 1002 (no immunity from antitrust law where "[a] monopolist's discontinuation of its old technology . . . effectively forces consumers to adopt its new technology"). The district court's failure to address cutting-off access as an independent threshold issue constitutes reversible error.

However, even under the district court's framework, it is undisputed that the HRNN algorithm is not an improvement ***for medical monitoring purposes***. *See* AliveCor's Combined Reply in Further Support of its Mtn for Partial Summary Judgment and Opposition to Apple Inc.'s Cross-Motion for Summary Judgment, dated 8/24/23 at 15.[7] The district court dismissed any concern that Apple's actions harmed medical monitoring by stating that, "Apple has the right to implement a product change that is detrimental for some purposes so long as it is an improvement for consumers in some other way." 1-ER-24. The district court's

[7] *Amici curiae* are unable to provide the Court with the specific ER cite because while the referenced motion is part of the appellate record it was filed under seal in this Court. However, the public redacted version of the motion is available in the district court files and that contains the page cited.

assertion—which would effectively provide blanket antitrust immunity anytime a monopolist engaged in a supposed product improvement for any purpose—is not supported by longstanding antitrust precedents. Instead, courts consistently hold that they must assess the full competitive effects of a monopolist's conduct, even where the monopolist cites product innovations to justify its conduct. *See, e.g.*, *Microsoft*, 253 F.3d at 58–59, 65–67 (D.C. Cir. 2001) (en banc) (analyzing competitive effects of Microsoft's claimed product improvement justifications); *In re Apple iPod iTunes Antitrust Litig.*, 796 F. Supp. 2d 1137, 1146–47 (N.D. Cal. 2011) (claim of product improvement raises triable issue of fact for jury); *see also Eastman Kodak Co. v. Image Tech Serv., Inc.*, 504 U.S. 451, 485 (1992) (triable issues exist to determine if monopolist's change in policy cutting off access to parts was pretextual).

The district court's apparent reliance on *Allied Orthopedic* to conclude that *any* improvement satisfies the product improvement safe harbor is a misreading of the decision. 1-ER-24 (quoting *Allied Orthopedic*, 592 F.3d at 1000). In *Allied Orthopedic*, this Court first addressed (and affirmed) that the defendant had introduced a product improvement. Then, and only then, did the Court address a second question: whether *associated conduct accompanied the product change* such that a plaintiff could still assert an antitrust violation. Addressing only that second question, *Allied Orthopedic* observed that in determining "associated

conduct" there "is no room in this analysis for balancing the benefits or worth of a product improvement against its anticompetitive effects." 592 F.3d at 1000. In other words, for the second question, the key inquiry is whether the defendant used the product improvement as a means of foreclosing competition in a relevant market. Yet, the district court here conflated the analysis. It determined that no evaluation of the competitive benefits of a supposed product improvement was relevant. The district court's misapplication of the legal standard for "associated conduct" to the initial product improvement question constitutes reversible error. Indeed, the district court's decision, carried to its logical conclusion, would allow any defendant to avoid antitrust liability by claiming a product improvement when engaging in anticompetitive conduct. Because courts must analyze the competitive effects of specific restraints—in this case Apple's purported product improvement—the district court's decision must be reversed. *See Microsoft*, 253 F.3d at 58–59, 65–67 (analyzing competitive effects of claimed product innovation); *Epic*, 67 F.4th at 985–86, 993–94, 998; *see also NCAA v. Alston*, 594 U.S. 69, 101 (2021) (A party cannot "relabel a restraint as a product feature and declare it 'immune from'" antitrust law.).

Further, while *Allied Orthopedic* did conclude that there was a genuine product improvement, it did so on very different facts. There, the defendant Tyco made product improvements, including new types of sensors with added

capabilities that only worked with new monitors. 592 F.3d at 994. While it is true that Tyco discontinued its older sensor technology after its sensor patent expired, that did not restrict purchasers from using generic sensors with Tyco's legacy monitors. Customers had the choice to either purchase new monitors and new sensors from Tyco or use Tyco's legacy monitors with generic sensors. *Id*. at 994–96, 1002. In fact, after Tyco discontinued selling its old sensors, its market share went down from approximately 62–64% to 35%. *Id*. at 995. And Tyco's largest competitor's market share rose to approximately 40–45%. *Id*. Thus, competition remained robust.

Here, the facts could not be more different. Apple's new HRNN algorithm (and related APIs connected to its IRN offering) did not just allegedly improve the ability to measure heart rhythm during exercise—***it also removed the ability to continually monitor those heart rhythms***. As stated above, continuous monitoring is necessary for Afib patients because each Afib event increases a patient's risk of stroke. Continuous monitoring also allows cardiologists and patients to modify treatment plans that may not be working. Removing the option to continually monitor heart rhythms hampers a patient's ability to self-manage their Afib and work in tandem with their doctor on an individualized management plan.

In sum, Apple's alleged product improvement left patients without access to potential life-saving technology that was available prior to the product change.

The district court, in failing to apply the proper legal standard, erred in granting summary judgment on the basis that Apple's HRNN algorithm was a product improvement.

B. The District Court Erred in Determining That Apple's Alleged Product Improvement Was Not Accompanied by Associated Anticompetitive Conduct.

Even if Apple can be credited for its claim of improving its product for exercise, that does not end the inquiry. Apple can still be found to have violated Section 2 if the product change is accompanied by "associated anticompetitive conduct" that "constitutes an anticompetitive abuse or leverage of monopoly power, or a predatory or exclusionary means of attempting to monopolize the relevant market." *Allied Orthopedic*, 592 F.3d at 1000 (citing *Foremost Pro Color, Inc. v. Eastman Kodak Co*., 703 F.2d 534, 545–46 (9th Cir. 1983)). Indeed, the district court acknowledged that under *Allied Orthopedic*, "[a] monopolist's discontinuation of its old technology may violate Section 2 if it effectively forces consumers to adopt its new technology" and that such action may be "associated conduct." 1-ER-21, 24; *Allied Orthopedic,* 592 F.3d at 1002. Here, a proper application of *Allied Orthopedic's* associated conduct test raises a triable issue of fact that Apple's conduct was anticompetitive. Apple forced all Apple Watch users to adopt Apple's own heart rhythm analysis feature (IRN), which does not continuously monitor heart rhythm and thereby deprived its most vulnerable users

of the information needed to ensure proper medical care. Afib patients can no longer track every Afib event to fully understand their risk for stroke. And Afib patients can no longer use continuous monitoring to assist doctors in making adjustments to medication. Thus, those who are most likely to want continuous heart rhythm analysis due to their diagnosed condition are today completely unable to utilize SmartRhythm (or any other third-party app) because Apple eliminated a competitor's ability to access the HRPO data.

Once again, the district court's reliance on the facts in *Allied Orthopedic* is misplaced. There, Tyco introduced new technology for measuring patient blood oxygen levels. *Allied Orthopedic*, 592 F.3d at 994. The Court explained that Tyco "did nothing to force [its new] OxiMax monitors on its customers." *Id*. at 996. Customers were free to use other monitors and other sensors. *Id*. at 995, 1002. Here, with the HRNN algorithm, Apple has ***forced*** all Apple Watch users to use its IRN feature, which does not continuously monitor patient heart rhythms. Patients have no other choice or option. By using its claimed product improvement to eliminate all competition, including from AliveCor, Apple engaged in quintessential "associated conduct" under *Allied Orthopedic*.

It is an "abuse of leverage" for a monopolist to create a new version of its application incompatible with a competitor's and to end support for prior versions of an application. *See Teradata Corp. v. SAP SE,* 2018 WL 6528009, at *13 (N.D.

Cal. Dec. 12, 2018) ("[P]reventing customers from using other databases" is an "abuse of leverage"); *see also Staley v. Gilead Sciences, Inc.,* 446 F. Supp. 3d 578, 615 (N.D. Cal. 2020) (holding that degrading a product to move customers to a newer product has no procompetitive justification and constitutes associated conduct because it was a misuse of monopoly power rather than "letting the superiority of the products drive that change"); 1 HERBERT HOVENKAMP ET AL., IP AND ANTITRUST §12.03[E][2] (3d ed. 2021 Supp.) (stating that where an interface change could actually degrade system performance and give consumers a less powerful product, "it is difficult to imagine a plausible procompetitive reason for such a change, and the inference that the manufacturer changed its product in order to exclude competition in the peripheral market is rather stronger"). This is exactly the case here. Apple created the HRNN algorithm (used in its IRN feature) and removed third party access to the HRPO data that third parties relied on to provide continuous monitoring for medical reasons. By virtue of this conduct, Apple degraded the Apple Watch's health monitoring capabilities, even informing Apple Watch users that IRN should not be used by Afib patients, and at the same time, increased its market share to 100%.

Most important, from the point of view *amici* physicians, Apple's conduct has put patient safety at risk. This could have been avoided if Apple had not prevented third parties, like AliveCor, from continuing to access the HRPO data.

CONCLUSION

Apple's roll out of the HRNN algorithm and IRN feature is not a product improvement with respect to medical monitoring. Patients have been harmed because they can no longer continually monitor their heart rhythms. They have lost the choice to use a superior product that can save their lives. For all of the foregoing reasons, *amici curiae* physicians respectfully request that the Court reverse the district court's order granting summary judgment in favor of Apple and remand the case for trial.

DATED: June 24, 2024

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing brief contains 3393 words, excluding the items exempted by Fed. R. App. P. 32(f). The brief's type size and typeface comply with Fed. R. App. P. 32(a)(5) and (6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 14-point Times New Roman. I certify that this brief is an amicus brief and complies with the word limit of Fed. R. App. P. 29(a)(5).

DATED: June 24, 2024

s/ David W. Kesselman
David W. Kesselman