The Public Interest Impact – Considerations from *AliveCor* and *Masimo*

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The year 2023 was marked by two landmark Commission determinations resulting in exclusion orders and cease and desist orders against a popular consumer wearable—the Apple Watch. Both investigations focused on health monitoring technologies offered by the device, and, as a consequence, public interest considerations pulsed through the parties' briefing and the Commission's decisions.

The main takeaway from these recent decisions is that the Commission continues to apply a high standard for the public interest inquiry and remains reluctant to withhold remedial orders on the basis of public interest, even if it means excluding highly popular consumer devices. Of particular note is the Commission's broad view of what qualifies as a reasonable substitute, as it found that reasonable substitutes existed even if it required a consumer to purchase multiple devices to achieve the same functionality and even if the substitute devices lacked the same regulatory approval as the Apple Watch for the asserted health-monitoring features.

I. AliveCor v. Apple[1]

On April 20, 2021, AliveCor, Inc. filed a complaint against Apple accusing the Apple Watches with electrocardiogram (ECG) functionality of infringing three U.S. patents pertaining to methods for arrhythmia tracking and discordance monitoring. The principal technology at issue involved the ability to take an ECG reading on a wearable device and perform a heartrate analysis to detect heart conditions such as episodes of atrial fibrillation (AFib). The ALJ ultimately issued a Corrected Initial Determination finding a violation of Section 337 and recommended issuance of a limited exclusion order and cease and desist order. The parties petitioned for review, and the Commission issued a standard notice requesting submissions on the public interest.

A. Public Interest Arguments

The parties and numerous non-parties submitted public interest comments in response to the Commission's notice. Thereafter, the Commission issued a notice of determination to review in part the ALJ's determination and expressed particular interest in (1) arguments responsive to already submitted public interest statements and (2) receiving more information regarding the availability and capacity of alternatives to replace the infringing products.

1. AliveCor's Public Interest Position

AliveCor argued the remedies would promote innovation, competition, and intellectual property rights. They would not adversely affect the public health or economic competition because other suppliers offered substitute wearable heart monitoring devices (*e.g.*, Samsung and Fitbit's FDA-cleared smartwatches). AliveCor noted that Apple could still sell its non-infringing Apple Watches, which could be combined with AliveCor's KardiaBand System. It further suggested that Apple could seek a license from AliveCor or design around the infringing feature. According to AliveCor, Apple's arguments pertaining to the lifesaving nature of the Apple Watches were overstated. AliveCor reiterated that not all health monitoring features of the Apple Watch were found to infringe—only those with both (1) PPG-based arrhythmia detection features (*i.e.*, the Irregular Rhythm Notification (IRN) feature and the High Heart Rate Notification (HHRN) feature) *and* (2) the ECG App, would be subject to the remedial orders. Apple Watch products with IRN and HHRN but no ECG functionality would not be excluded. Relatedly, it opposed Apple's definition of suitable alternatives as consisting of solely wearable devices with FDA-cleared IRN *and* ECG functionalities, arguing Apple divorced the scope of suitable substitutes from the full scope of available consumer products and pushing back on the notion that all functionalities had to be included within a single device. AliveCor further

1 *In the Matter of Certain Wearable Electronic Devices with ECG Functionality and Components Thereof*, Inv. No. 337-TA-1266.

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argued that an exclusion order would not impact existing users or interrupt any ongoing medical research involving existing Apple Watch users. Finally, it argued against delayed imposition of a remedy as well as any carve-outs or exemptions.

2. Apple's Public Interest Position

Apple argued the remedies would restrict the availability of FDA-authorized, lifesaving technology. It referenced testimonials of such incidents and cited data on the number of Apple Watch users activating the ECG application and who receive daily AFib warnings. It argued that limiting the availability of these features could increase healthcare costs. Moreover, exclusion would disrupt research efforts and ongoing clinical studies. It argued that reduced competition could lead to higher-priced wearables. Apple focused on the multi-faceted nature of its Apple Watches and its ability to allow millions of wearers to do many things unrelated to AliveCor's patented technology. For example, Apple noted that its Apple Watches have other health features that benefit the public, which could become unavailable. The remedial orders could also lead to increased unemployment in Apple Watch-reliant industries. And exclusion would result in a supply shock, particularly in view of potential manufacturing constraints. Apple further noted the FDA approval process could take years for new devices, and suggested a delayed remedy would allow for replacements to become more readily available. It defined suitable alternatives as devices that had a specific combination of health features and FDA approval, including the ECG technology at issue. Specifically, Apple argued that the only suitable alternatives would comprise wearable devices with both FDA-cleared ECG and IRN functions. According to Apple, only the Fitbit Charge 5 and Sense fell into that category as having HHRN and both FDA-cleared ECG and IRN features, which products Apple argued were markedly inferior, even assuming Fitbit could ramp up their production. Finally, Apple also sought an exemption for warranty, service, replacements, and repairs.

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B. The Commission's Determination on the Public Interest

On December 22, 2022, the Commission issued its notice of Final Determination finding a violation of Section 337, a limited exclusion order, and a cease and desist order. However, the Commission suspended enforcement of these orders pending final resolution of the PTAB's Final Written Decisions, which found the asserted claims unpatentable.

The Commission determined current users of the infringing Apple Watches would be unaffected by the remedial orders and would further maintain access to the non-accused features of those devices. By extension, ongoing research based on these existing devices would be unaffected. It noted that new research could utilize any of the numerous available alternatives. The Commission evaluated Apple's contention that suitable alternatives must (1) have ECG, IRN, and HHRN features; (2) be wearable; and (3) have FDA clearance. But it determined that wearable devices with IRN and HHRN functionalities in conjunction with portable ECG devices also constituted a reasonable alternative. The Commission did not credit Apple's argument that FDA-clearance was mandatory for alternatives to constitute suitable substitutes. Even still, the Commission noted that substitutes with FDA clearance existed. The Commission observed that its PTAB-related suspension would allow time for alternatives to become readily available. It expressed its opinion that competitive conditions would not be harmed, especially in view of the number of alternative products. Lastly, it included an exemption for Apple's service, repair, and replacement obligations.[2]

II. Masimo v. Apple[3]

On June 29, 2021, the Masimo Corporation filed a complaint against Apple, accusing the Apple Watch Series 6 (and later models) with light-based pulse oximetry functionality of infringing five U.S. patents. The technology at issue involved physiological measurement devices that rely on the transmission of light through body tissue to monitor and report physiological signals. Masimo's asserted patents were directed to devices used for non-invasive measurement of physiological parameters such as blood oxygen saturation (or pulse oximetry) and thermal mass technology. The ALJ ultimately issued a Final Initial Determination finding a violation of Section 337, upon which both parties petitioned for review. The ALJ further recommended the issuance of a limited exclusion order and cease and desist order. The Commission issued a standard notice requesting submissions on the public interest.

A. Public Interest Arguments

The Commission's request resulted in 31 non-party public interest comments, as well as Masimo and Apple's public interest statements. Seven (7) additional non-party submissions came after the Commission issued its notice of determination to review in part the ALJ's Final Initial Determination, wherein it requested written submissions, at least from the parties, regarding the public interest factors. In particular, the Commission set forth a list of public-interest-related questions on a variety of issues, including the effects of any remedial order on medical research, how the Commission should define a reasonable substitute, and the ease of design-around options.

2 ***PTAB Appeals***: As previously noted, enforcement of the Commission's remedial orders is currently suspended until final resolution of the PTAB's Final Written Decisions, which found the asserted claims to be unpatentable. *See Apple, Inc. v. AliveCor*, Inc., IPR2021-00971, U.S. Patent No. 10,595,731, Final Written Decision Determining All Challenged Claims Unpatentable (Dec. 6, 2022); *Apple, Inc. v. AliveCor, Inc.*, IPR2021-00972, U.S. Patent No. 10,638,941, Final Written Decision Determining All Challenged Claims Unpatentable (Dec. 6, 2022). AliveCor appealed both Final Written Decisions on February 7, 2023. Appeals from the PTAB decisions are pending before the Federal Circuit.

ITC Appeals: In addition, both AliveCor and Apple appealed the Commission's Final Determination to the Federal Circuit. *See AliveCor, Inc. v. ITC*, Appeal No. 23-1509 (Fed Cir.); *Apple Inc. v. ITC*, Appeal No. 23-1553 (Fed. Cir.). Those appeals are currently pending.

3 *In the Matter of Certain Light-Based Physiological Measurement Devices and Components Thereof*, Inv. No. 337-TA-1276.

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1. Masimo's Public Interest Position

Masimo argued the remedies would promote investment in life-saving technologies and discourage "efficient infringement." It argued Apple should be estopped from arguing public interest concerns because of the Commission's rejection of similar public interest arguments in *AliveCor*. It observed that the infringing Apple Watches did not contain FDA-cleared pulse oximetry, and the non-accused Apple Watch SE with its various features would remain on the market. Masimo identified a variety of companies that offered smartwatches with pulse oximetry, including the Masimo W1, as well as smartwatches capable of pairing with pulse oximetry sensors. In this regard, it referenced the Commission's determination in *AliveCor* in arguing that reasonable substitutes should be defined as watches with a range of health, safety, and wellness features. It also argued that reasonable substitutes should be defined by the protected interest in the features benefitting the public health and welfare, further arguing that consumers' health and welfare did not depend on watch capabilities such as making phone calls, sending emails and text messages, showing news and weather updates, and other such features. And it argued there was no evidence that other manufacturers lacked the capacity to meet increased demand. Massimo suggested that Apple could remove the infringing feature, and argued that U.S. consumers would benefit from the remedial orders because of the feature's poor performance. Masimo argued against any service, repair, or replacement exemption, indicating a refund as set forth in Apple's warranty terms would be sufficient. It also opposed Apple's request for a 12-month delay in implementation of the recommended remedial orders.

2. Apple's Public Interest Position

Apple countered that it was not collaterally estopped because different public interest concerns were at issue. It argued that Masimo was attempting to narrow the set of features relevant to the public interest inquiry solely to health, safety, and wellness features. It referenced numerous features it argued were pertinent to the reasonable substitute inquiry, including general smartwatch capabilities, fitness tracking features, as well as health and wellness features. It posited that customers buy Apple Watches to obtain combinations of desired features, which would affect a consumer's consideration of alternative products. Hence, there could be a broad range of reasonable substitutes, but the consumer would not be able to purchase alternatives with the same set of features and quality as the excluded Apple Watches. Relatedly, it argued the Masimo W1 was not a reasonable substitute because of (1) its overall unavailability to U.S. consumers in terms of material quantity, (2) it was not a smartwatch in the sense that it lacked the communications and numerous other features provided by the Apple Watches accused of infringement, (3) it had not been shown to take reliable measurements of physiological parameters, and (4) it was not sufficiently manufactured to meet the increased demand caused by an exclusion order. Apple also argued the remedial orders would not only limit future access to its blood oxygen feature, but would also limit future access to other health features and other more general functionalities. Apple argued again that the remedial orders would interfere with medical research. It emphasized that a multi-year shortage would occur without delayed implementation, and there was no evidence that other manufacturers could meet increased demand. It asked for a 12-month delay to allow others to scale up production. Exclusion would also reduce the number of choices available and lessen competition for new purchasers. Finally, Apple requested a warranty exemption for service, repair, and replacement.

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B. The Commission's Determination on the Public Interest

On October 26, 2023, the Commission issued a notice of its Final Determination finding a violation of Section 337, a limited exclusion order, and a cease and desist order. The Commission included a warranty exemption for service, repair, and replacement, but ultimately determined the public interest factors did not preclude issuance of these remedial orders. In its Opinion, the Commission concluded that Apple was not collaterally estopped. It further determined that any adverse effect on the public health could be mitigated by its service, repair, and replacement exemption. The Commission further determined there were numerous available substitutes, including the Masimo W1 and Masimo Freedom watches, and Apple failed to show that manufacturers could not ramp up their production.

With respect to the scope of reasonable alternatives, the Commission observed that such scope is assessed "from the perspective of public interest concerns raised in an investigation." It acknowledged Apple's argument that consideration of the public health and welfare should take into account the exclusion of the infringing Apple Watches' ECG feature because it too was present in all of the infringing products. The Commission defined "reasonable substitutes" to include those offering a range of health, safety, and wellness features (e.g., measuring blood oxygen levels or recording ECGs), but noted a single device did not need to be able to measure oxygen levels and record ECGs. The inconvenience of having to wear two wearable devices did not amount to a public interest concern. The Commission indicated that Apple had stretched the public health and welfare factor too far by including features with connections too far removed from the public health and welfare (e.g., telecommunications features) as part of the requirements for a reasonable substitute. The Commission referenced prior precedent in noting that the correct analysis for reasonable substitutes is not whether the exact device can be obtained by every consumer. In listing products within the scope of reasonable substitutes, the Commission noted that its list of products "alone or combined with each" included either "one or both of the blood oxygen features and the ECG features (as well as the IRN, HHRN, or other features), and thus are reasonable substitutes." Regarding medical research at various stages, the Commission found there would be no meaningful effect. For example, the remedial orders would not prevent current study

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participants from continued participation. They could fix or replace their watches if necessary because of the service, repair, and replacement exemption. In terms of competitive conditions and U.S. consumers, the Commission found there would be no adverse impact because of the numerous suitable alternatives. Moreover, there would be no public interest concern with respect to U.S. consumers in view of the service, repair, and replacement exemption. The Commission did not impose a 12-month delay.[4]

III. Considerations from *AliveCor* and *Masimo*

The Commission's determinations in *AliveCor* and *Masimo* maintain the high public interest threshold that is rarely overcome when seeking to avoid implementation of exclusionary relief at the ITC. The health-related features of the accused products in each of these investigations present one of the most compelling public interest cases since the Obama Administration's 2013 disapproval of the Commission's remedial orders in the *Samsung v. Apple* dispute involving the iPhone and iPad.[5] However, in the *AliveCor* and *Masimo* investigations, the U.S. Trade Representative, as delegated by the President, took no action with respect to the Commission's Final Determinations. Given the popularity of the Apple Watch, it is no surprise that the Commission appeared to give greater scrutiny to the public interest considerations raised by the parties and the public. Nevertheless, the Commission's reasoning in both investigations suggests that public interest concerns remain a difficult path for preventing the issuance of exclusion orders once a Section 337 violation has been established.

4 On October 30, 2023, Apple filed a motion to stay the limited exclusion order and cease and desist order pending appeal and/or in light of the potential government shutdown. In this motion, Apple made various public interest arguments. Masimo opposed Apple's motion on November 9, 2023, arguing in large measure that the Commission already considered and rejected Apple's public interest arguments. On November 20, 2023, Masimo also submitted a request for judicial notice of the FDA's regulatory determination on November 17, 2023, which made the Masimo W1 Watch the only FDA-cleared over-the-counter pulse oximeter. But on December 20, 2023, the Commission denied Apple's motion to stay (without reliance on the materials that Masimo submitted as part of its request for judicial notice). In its January 3, 2024 supporting opinion, the Commission found that the public interest counseled against a stay, noting (1) that it already considered and rejected Apple's public interest arguments in its final determination and (2) the exclusion of infringing products to protect intellectual property rights is favored by the public interest. Apple's appeal to the Federal Circuit was docketed on December 26, 2023—the day after the Presidential Review Period expired on December 25, 2023—and on that same day, Apple filed (1) a non-confidential emergency motion for an immediate interim stay pending disposition of motion for stay pending appeal, and (2) a non-confidential emergency motion to stay enforcement of the ITC's orders pending review. In the former motion, Apple sought an interim stay for the time required to resolve the second, concurrently filed stay motion, or at least until the Exclusion Order Enforcement Branch could issue a decision regarding Apple's redesign for the excluded products. Apple noted that the Exclusion Order Enforcement Branch was set to determine whether a redesigned version of the excluded Apple Watch products is within the scope of the remedial orders on January 12, 2024. Apple also incorporated its reasoning from the second stay motion, which raised various arguments, including an assertion that the public interest supported a stay. The Commission and Masimo submitted letters on December 26, 2023, opposing both stay motions. But on December 27, 2023, the Federal Circuit granted Apple's motion for an interim stay, temporarily staying the remedial orders and directing the government not to enforce them "until further notice while the court considers the motion for a stay pending appeal." *See Apple Inc. v. ITC*, Appeal No. 2024-1285, ECF No. 19, Order at 2 (Fed. Cir. Dec. 27, 2023).

5 *In the Matter of Certain Electronic Wireless Devices, including Wireless Communication Devices, Portable Music and Data Processing Devices, and Tablet Computers*, Inv. No. 337-TA-794, Letter from USTR (Aug. 3, 2013).