UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

In the Matter of	
CERTAIN WEARABLE ELECTRONIC DEVICES WITH ECG FUNCTIONALITY AND COMPONENTS THEREOF	**Investigation No. 337-TA-1266**

STATEMENT OF THIRD PARTIES COMPUTER & COMMUNICATIONS INDUSTRY ASSOCIATION AND NETCHOICE IN RESPONSE TO THE COMMISSION'S JULY 15, 2022, NOTICE OF REQUEST FOR STATEMENTS ON THE PUBLIC INTEREST

The Computer & Communications Industry Association ("CCIA") and NetChoice submit the following response to the Commission's Federal Register Notice of July 15, 2022,[1] inviting comments on the public interest in the above-referenced investigation. CCIA represents over two dozen companies of all sizes providing high technology products and services.[2] NetChoice LLC is a national trade association of online businesses that share the goal of promoting free speech and free enterprise on the Internet.[3] *Amici* believe that the proposed exclusion should be denied as it would harm U.S. consumers and the U.S. economy and have negative impacts on the public health and welfare.

Amici note that a public version of the ID was not available until Tuesday, July 26th, just one day prior to the public interest comment deadline. This occurs frequently at the ITC and creates significant difficulties in adequately commenting on the public interest. We suggest that future public interest comment periods not start until such time as a public version of the ID becomes available in order to provide third parties with a full opportunity for comment.

I. USE OF POTENTIALLY EXCLUDED ARTICLES IN THE UNITED STATES

The articles for which exclusion is sought are used for health and fitness purposes, as well as for communication, entertainment, and informational purposes. While these articles also have other uses, they focus significantly on health and fitness and the impacts of exclusion on consumer health and fitness in the United States might be significant.

II. PUBLIC HEALTH, SAFETY, AND WELFARE CONCERNS

The proposed exclusion order raises significant public health, safety, and welfare concerns. As even AliveCor's expert noted during the hearings before the ALJ, requiring a user

[1] Notice of Request for Submissions on the Public Interest, 87 Fed. Reg. 42500 (July 15, 2022).
[2] A list of CCIA's members is available online at https://www.ccianet.org/members. Respondent Apple is a CCIA member, but took no part in the preparation of this comment.
[3] A list of NetChoice's members is available online at https://netchoice.org/about/#association-members.

to obtain and utilize a separate EKG device is often an inadequate substitute.[4] Early detection of atrial fibrillation ("afib") significantly increases treatment success rates, but afib is typically paroxysmal in its early progression. As a result, even a brief delay to retrieve a user's separate EKG device, open the EKG app on the user's phone, and take an EKG might result in a failure to confirm the diagnosis, much less an obligation on the user to obtain an EKG device which is likely to take multiple days. Separate devices are thus insufficient to replace the subject devices.

It is undisputed that afib, which the articles can help to identify, is a significant health problem in the United States, affecting 2% of the U.S. population.[5] Forty percent of those cases are asymptomatic, meaning that approximately 2.5 million people in the U.S. may have afib and be unaware of that fact.[6] And afib creates a significant increase in the risk of suffering a serious stroke, likely causing up to one third of all such strokes.[7] Given the seriousness of afib, improved techniques for detecting and diagnosing afib, including those contained within the subject articles, are of significant use in managing this serious health risk. Exclusion of the subject articles would thus harm the health and welfare of a significant subset of the U.S. public.

III. SUBSTITUTE ARTICLES MADE BY COMPLAINANT OR ITS LICENSEES IN THE UNITED STATES

The Commission's notice requests comment on like or competitive articles made in the United States which could replace the subject articles if excluded. While AliveCor has identified a number of products that allegedly could replace the subject articles, those products do not appear to be made in the United States, as required by this factor. For example, AliveCor's

[4] ITC 337-TA-1266 Hearing Transcript at 292-293.
[5] ITC 337-TA-1266 Hearing Transcript at 50.
[6] *Id.*
[7] *Id.*

KardiaMobile and KardiaBand Instructions For Use (IFUs)[8] explicitly note that these products are "Made in China." Similarly, other products AliveCor identifies appear to be made in China.

A denial of exclusion on public health and welfare grounds would not impact the production of competitive articles within the United States, as required by the relevant statutory provision, and this factor weighs against exclusion.[9]

IV. ABILITY TO REPLACE EXCLUDED ARTICLES IN A COMMERCIALLY REASONABLE AMOUNT OF TIME

AliveCor does not itself make devices that could replace the subject articles. The asserted patents recite a smartwatch, a product AliveCor does not and has never manufactured.[10]

Further, even if there are products that could be substituted, it is not at all clear that the volume could be replaced in a commercially reasonable amount of time. Supply chain constraints, particularly with respect to electronics, continue to impact even global manufacturers such as automakers. Manufacturing timeslots and semiconductor orders are significantly delayed, with new orders often delayed by a year or more before product can be obtained. Further, given that (as AliveCor admits[11]) Apple's PPG and EKG functionality do not themselves infringe, it is likely that an alternate non-infringing design would maintain that functionality and that other manufacturers would lack any additional supply of those components.

Given the well-known chip supply issues—issues of such importance that Congress is considering legislation to correct them—and the lack of a true substitute product on market or

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[8] *See, e.g.*, AliveCor, *KardiaMobile System by AliveCor Instructions for Use* (Aug. 2021), https://www.kardia.com/assets/old/ifus/kardiamobile/02LB49.6-en.pdf.
[9] 19 U.S.C. § 1337(d)(1) ("production of like or directly competitive articles **in the United States**", emphasis added).
[10] Review of the public information on domestic industry appears to show that AliveCor relies in part on Apple's smartwatch products for its domestic industry. It is unclear how this would meet the domestic industry requirement, as an exclusion order would presumably exclude the domestic industry product.
[11] ITC 337-TA-1266 Hearing Transcript at 119-120, 125.

available within a commercially reasonable period, this factor also weighs against exclusion.

V. EXCLUSION OF THE REQUESTED ARTICLES WOULD HARM CONSUMERS

Consumers would experience a negative impact from exclusion. Consumers would likely be faced with an inability to obtain a replacement device, due to lack of substitute supply. As an alternative, they might obtain a separate EKG device, but such a combination is inferior to an integrated device as discussed above.

A consumer who does not already know they have a cardiac issue is unlikely to obtain a separate EKG device. Given the paroxysmal nature of early afib, even if they did obtain an EKG device, the afib would likely have stopped before they could perform an EKG test. This could lead to a lack of confidence in the arrythmia detection algorithm and in the EKG, potentially leading the user to ignore future notifications and thus negatively impacting the consumer's health. And even if a user did obtain a separate EKG device, paroxysmal afib may not recur frequently, leading to additional delay in diagnosis.

The negative impact on consumers, and particularly on their health and welfare, is an additional factor weighing against exclusion on public interest grounds.

VI. THE COMMISSION WOULD BENEFIT FROM FULFILLING THE STATUTORY CONSULTATION REQUIREMENT OF 19 U.S.C. § 1337(b)(2)

Section 337(b)(2) requires that "the Commission shall consult with, and seek advice and information from, the Department of Health and Human Services, …, and such other departments and agencies as it considers appropriate."[12] Here, both the domestic industry product and the articles sought to be excluded are FDA-regulated devices. The FDA, as a component of HHS, should be consulted in order to obtain additional information about the availability of substitutes and the impact on consumer health and welfare.

[12] 19 U.S.C. § 1337(b)(2).

Furthermore, the Commission should consider whether consultation with the USPTO would be appropriate in this case. The USPTO is currently conducting a review of the validity of the relevant patents and has delivered an initial indication (via institution decision) that the patents are likely invalid. Consulting with the USPTO, which has the power to actually cancel patents, would be appropriate, particularly where—as here—the USPTO is already conducting an investigation into the validity of the patents.

VII. A DELAY OF REMEDY WOULD BE APPROPRIATE IN THIS CASE

Even if the Commission finds the asserted patents to be both valid and infringed, an exclusion order would be inappropriate because of the impacts on public health and welfare and the lack of advantage to any U.S. manufacturing. A parallel district court case is ongoing; were the Commission to deny exclusion, AliveCor could still obtain a remedy.

Even if the Commission does determine that an exclusion order should issue, it would be appropriate to hold that exclusion order in abeyance until after the USPTO issues its FWDs in the relevant IPRs. There would be no harm to AliveCor, given the short duration of abeyance, and waiting until after issuance of a FWD would help the Commission avoid issuing an exclusion order based on patents that might be found invalid shortly before the order could go into effect. A limited delay of the order in order to take into account the USPTO's input would be appropriate, especially as it would fulfill the Commission's statutory mandate to consult with other agencies as appropriate.

VIII. CONCLUSION

Given that the statutory public interest factors weigh against exclusion, *amici* submit that the exclusion order should be denied on public interest grounds. *Amici* also submit that the Commission should consider delaying the final determination to take into account the outcome of the USPTO's validity reviews, due shortly after the Commission's target FD date.

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Respectfully submitted,

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