No. 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.

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

BRIEF OF *AMICUS CURIAE* COMPUTER & COMMUNICATIONS INDUSTRY ASSOCIATION

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CERTIFICATE OF INTEREST

I certify that the following information is accurate and complete to the best of my knowledge.

Dated: August 14, 2023 */s/ Joshua Landau*

Joshua Landau

1. Represented Entities	**2. Real Parties in Interest**	**3. Parent Corporations and Stockholders**
Computer & Communications Industry Association	Same	None

4. Legal Representatives
None

5. Related Cases
None

6. Organizational Victims and Bankruptcy Cases
Not Applicable

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STATEMENT OF INTEREST

The Computer & Communications Industry Association ("CCIA") is an international nonprofit association representing a broad cross section of communications and technology firms. For more than fifty years, CCIA has promoted open markets, open systems, and open networks. CCIA members[1] employ more than 1.6 million workers, invest more than $100 billion in research and development, and contribute trillions of dollars in productivity to the global economy. CCIA regularly files *amicus* briefs in this and other courts to promote balanced patent policies.

The International Trade Commission ("ITC")'s authority under 19 U.S.C. § 1337 ("§ 337") was intended to protect domestic industry from unfair foreign competition, particularly from companies not subject to jurisdiction in the U.S. courts. CCIA and its members are concerned that the ITC has gone far beyond its statutory authority and purpose in the underlying case, as well as other such cases.

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[1] CCIA's members are listed at https://www.ccianet.org/members. Appellant-intervenor Apple is a member of CCIA, but was not involved in the preparation or authorship of this brief, nor did they make a contribution to fund the preparation or submission of this brief.

As product manufacturers, patent licensors and licensees, and patent owners, CCIA's members face significant harms from the ITC's overreach. While the ITC was created to protect domestic industry from unfair foreign competition, U.S.-based industries instead face the prospect of losing access to the U.S. market—in some cases, as a result of patents owned by foreign entities with no U.S. presence. The ITC does this in part by ignoring the public interest requirement contained in § 337 and by minimizing the domestic industry requirement also contained therein.

The ITC's failures to abide by its statutory obligations impose significant cost and risk on CCIA's members, forcing them to divert their resources away from innovative activity to address these threatened disruptions to their U.S.-based industrial activity. These outcomes are precisely opposite to the outcomes that Congress intended to achieve in passing § 337.

Pursuant to Fed. R. App. P. 29(a)(4)(e), no counsel for a party to the case underlying the pending petition for writ of mandamus authored this brief in whole or in part, and no party or party's counsel made a monetary contribution intended to fund the preparation or

submission of this brief. No person other than *amicus* or their counsel made a monetary contribution to fund the preparation or submission of this brief.

INTRODUCTION

The ITC exists to protect American industry against unfair foreign competition. But the ITC has expanded well beyond that, adjudicating cases in which a foreign entity asserts a patent against an American defendant, or, as in this case, adjudicating disputes between two American entities.

The present case presents three primary concerns for CCIA and its members.

First, in the process of going beyond its core role of adjudicating unfair foreign trade issues, the ITC has ignored a critical element of its statute—the requirement that a domestic industry exist to be injured by the alleged unfair foreign competition. Absent such an industry, while remedies may be available in other courts, the ITC lacks the statutory authority to issue an exclusion order. But the ITC often minimizes this requirement, including in this case.

Second, even were the ITC to abide by its requirement to recognize equitable interests in the public interest process, its analysis of the public interest often fails to actually accord the public interest any credit. The ITC has not denied an exclusion order on the basis of

the public interest since 1984, and frequently asserts that the public interest in enforcing intellectual property outweighs public interests in health and safety. Further, the ITC often credulously accepts assertions that competitors can replace an excluded product, even when those assertions—as in this case—are at odds with the practical realities of supply chains and limited manufacturing capacities.

Finally, while CCIA's members rely on the district courts to carefully balance equitable factors when determining whether to grant an injunction, the ITC does not conduct the same inquiry. The ITC does so despite its statutory requirement to recognize equitable defenses and defend the public interest.

Congress required that the ITC consider equity and the public interest, and limited the ITC's ability to issue a remedy solely to those circumstances in which an "industry in the United States, relating to the articles protected by the patent … exists or is in the process of being established." 19 U.S.C. § 1337(a)(2). This Court should ensure that the ITC restrains itself to those circumstances, emphasizing its role regarding unfair **foreign** competition, rather than permitting it to continue to overreach its statutory mandate.

ARGUMENT

I. The ITC Is A Trade Agency, Not A Patent Court

The ITC is an independent agency created to administer trade remedy laws and maintain the U.S. tariff schedule. The ITC's history makes plain the foreign-focused nature of the agency, as does the statutory text. That mission is one the ITC has moved away from in the context of patent infringement allegations. Instead, the ITC embraces investigations against domestic companies, whether by foreign or domestic complainants.

The ITC's fundamental authority stems from a trade statute intended to protect domestic industries from unfair foreign competition. This history informs the proper scope of the ITC's statutory authority, a scope the underlying decision exceeds.

A. The ITC Is Fundamentally Intended To Address Unfair Foreign Competition, Not To Provide Additional Venues To Litigate Against Domestic Entities

Section 337's origins are found in the Tariff Acts of 1922 and 1930, which addressed unfair competition in importation. The 1922 Act tasked the Commission with investigating "unfair methods of competition and unfair acts in the importation of articles." Tariff Act of

1922 § 316, Pub. L. 67-318, 42 Stat. 858, 943 (1922). Eight years later, the 1930 Tariff Act tasked the Commission with investigating "unfair methods of competition and unfair acts in the importation of articles." Tariff Act of 1930, Pub. L. 71-361, 46 Stat. 590, 703 (1930).

Neither the 1922 nor the 1930 Act mention patents; in both, the duties of the Commission focused on importation and import trade. As a GAO report concluded, § 337 was "intended as a trade statute to protect U.S. firms and workers against all types of unfair **foreign** trade practices." U.S. Gen. Accounting Office, Rep. No. GAO-NSAID-86-150, *International Trade: Strengthening Trade Law Protection of Intellectual Property Rights* at 3 (1986) (emphasis added).

Even when patents were explicitly added to the Commission's jurisdiction in the 1988 Omnibus Trade and Competitiveness Act, it was in the context of importation with the expectation that it would be used to address products made by foreign entities who were not amenable to suit in the district courts. Omnibus Trade and Competitiveness Act of 1988 § 1341(a)(2), Pub. L. No. 100-418, 102 Stat. 1107, 1212 (1988). While the Commission conducted investigations of unfair practices based on patents as part of its general authority over unfair trade

practices, it was not until 1988 that the statute mentioned patent infringement. And even then, the focus remained on foreign companies—in fact, the 1988 Act explicitly stated that the amendment of § 337 was necessary because the existing § 337 had "not provided United States owners of IP rights with adequate protection against **foreign companies** violating such rights." 102 Stat. 1107, 1211-12 (emphasis added).

Because it is a trade agency, not a judicial body or patent agency, the ITC is not overseen by the Judiciary Committees, who have jurisdiction over the courts and patent law, but instead by the House Ways & Means and Senate Finance Committees. These committees oversee foreign trade policy, providing further evidence Congress considers the ITC's primary function to be trade-related, not patent-related. Bills amending § 337 are referred to those committees, even if they solely impact the Committee's authority over patents. *See, e.g.*, H.R. 2189, 115th Cong (2017). Congress, as it did when enacting § 337, continues to see the ITC as an agency focused on unfair foreign trade, not on patents.

B. The ITC Has Ignored Congress's Intent, Instead Providing A Venue Consistently Used Against Domestic Entities

An empirical analysis of every § 337 case filed from 1995 through 2007 found that at least one domestic respondent was named in 87% of ITC investigations and that 15% named only domestic respondents. *See* Colleen Chien, *Patently Protectionist*, 50 Wm. & Mary L. Rev. 63, 88 (2008). This pattern has continued in the intervening decade. For example, in 2016, 85% of ITC investigations named a domestic corporation as a respondent. *See* Bill Watson, *Preserving the Role of the Courts Through ITC Patent Reform*, R Street Shorts 57 (Mar. 2018).

One consequence of this embrace of adjudicating cases against domestic respondents is that defendants are deprived of protections they would receive in district court. As the primary example, in cases where the *eBay* factors would prevent a plaintiff from receiving a district court injunction the plaintiff can instead go to the ITC for an exclusion order, rendering *eBay* a dead letter. *See eBay Inc. v. MercExchange, L.L.C.,* 547 U.S. 388 (2006).

For CCIA's members, this represents a serious problem. District courts balance equity in deciding whether to issue injunctions. The ITC

does not. As a result, litigants who can no longer obtain inequitable injunctions in district courts have flocked to the ITC. And because of the severe threat of having their products taken off-market and losing income as a result, U.S. companies often cannot afford to appeal the ITC's decision, forcing them to pay license fees far in excess of the value of the patented technology. *See* Erik Hovenkamp & Tom Cotter, *Anticompetitive Patent Injunctions*, 100 Minn. L. Rev. 871, 884-85 (2016). The resulting situation harms public access to innovative products, often over trivial incremental feature patents, even when the patent holder is minimally harmed and when that harm can be recompensed monetarily rather than by exclusion.

This threat is all the more concerning when the complainant does not actually have a product on market and/or cannot replace the article proposed to be excluded.

II. The ITC Is Intended To Protect Domestic Industry, But Is Actually Used Against It In Cases Such As This One

As a trade statute dedicated to protecting American industry, § 337 requires that there actually be a domestic industry exploiting the asserted patent in order to provide a remedy. This requirement is essential to ensuring that the ITC does not become simply an additional

patent litigation forum. This case is an example of the ongoing erosion of this requirement at the ITC.

A. The Alleged Domestic Industry Does Not Exist, And Holding That It Does Would Effectively Vitiate The Domestic Industry Requirement

Section 337 requires that "an industry in the United States, relating to the articles protected by the patent … exists or is in the process of being established." 19 U.S.C. § 1337(a)(2). This statutory text does not require that an industry have existed at some point in the past. Instead, it requires that the industry must exist now or be expected to exist in the near future. This accords with the purpose of the ITC—the protection of domestic industry. If a domestic industry existed in the past, but no longer exists, the ITC is not an appropriate forum.

Further, that domestic industry must relate to the patent. Here, domestic industry has been alleged based on general investments into facilities, a discontinued product, and a pair of confidential products yet to be released. The discontinued product is not an industry that "exists", even if a product that embodies only a part of a patent claim can be considered to be an article that is "protected by the patent" in

question. 19 U.S.C. § 1337(a)(2). And holding that an article that embodies only a part of a patent claim is sufficient to establish a domestic industry related to that patent would completely vitiate the requirement, particularly given that many patent claims are to novel combinations of pre-existing elements.

Further, as the Commission and AliveCor alike recognize, the "KardiaBand System" includes products not manufactured or sold by AliveCor—specifically, an Apple Watch. Effectively, AliveCor relies on Apple's own products as a component of their alleged domestic industry, as they must because they do not themselves make a product that actually practices the claims.

Finding that domestic industry exists in this circumstance would permit patent holders to patent complete systems and then manufacture a small component of that system as their domestic industry, effectively reading the nexus requirement out of the economic prong of domestic industry. Alternately, it would permit them to purchase and sell a respondent's product alongside something of their own and allege that that constitutes a domestic industry.

B. The Alleged Investment Is Insubstantial With Respect To Potential Domestic Industry Products

The Commission relies on 19 U.S.C. § 1337(a)(3)(C) to establish domestic industry. To find domestic industry under subsection (C), there must be a "substantial investment" in exploiting the asserted patent. Key to this is that the investment must be "substantial."

AliveCor relies upon ongoing support of the KardiaBand for existing users as the required nexus to the patent for its investments in ongoing research and development. However, the research and development is not directed solely or even mostly to KardiaBand. Instead, it is aimed at the development of an as-yet-unreleased product and no nexus has been shown to the asserted patents for that product. At most, the correct question to determine whether that expenditure reflects a "substantial investment" in exploitation of the patent is whether the quantitative amount of that R&D spending that benefits KardiaBand users is a substantial portion of the full expenditures.

Here, it appears unlikely that any analysis could find a substantial investment. As this Court held in *Lelo*, this prong requires a quantitative analysis showing a substantial or significant increase in

investment "by virtue of the claimant's asserted commercial activity in the United States." *Lelo Inc. v. Int'l Trade Comm'n*, 786 F.3d 879, 883 (Fed. Cir. 2015). Here, it appears that any benefit to the KardiaBand product is incidental at best; the expenditures would be effectively identical if KardiaBand did not exist. Under this reading, a patent holder could establish domestic industry by investing in a product in the same general arena as the patent and attributing unspecified benefits to an otherwise inapplicable product as their domestic industry. Treating such an investment as a "substantial investment" in exploiting the patent would contradict *Lelo* and read the nexus requirement out.

III. The ITC Continues To Pay Lip Service To The Public Interest Requirements

The International Trade Commission is required to, before issuing an exclusion order, examine the public interest to ensure that exclusion does not harm the public. 19 U.S.C. § 1337(d). But in the past 30 years, the Commission has not once found that it does. It simply beggars belief to think that not a single case of the hundreds the Commission has heard in the past 30 years has been one in which the public interest would rise to a sufficient level to outweigh exclusion.

While there are numerous flaws in the Commission's public interest analysis, the most egregious is the Commission's finding that separate devices would be a sufficient substitute.

A. Wearable Devices Combined With Portable ECG Devices Are Not A Reasonable Alternative

The Commission found explicitly that "wearable devices that have IRN and HHRN functionality along with portable ECG devices represent a reasonable alternative to the Apple watches to be excluded." ITC 337-TA-1266, Commission Opinion at 73 (Jan. 20, 2023). But, as CCIA explained to the Commission during the public interest submission process, this is incorrect.

As even AliveCor's expert noted during the hearings before the ALJ, requiring a user to obtain and utilize a separate EKG device is often an inadequate substitute. ITC 337-TA-1266, Hearing Transcript (Jafari) at 292-293. 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.

B. Because Atrial Fibrillation Is Often Asymptomatic, Separate Devices Would Not Help A Significant Portion Of The Patient Population

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. ITC 337-TA-1266, Hearing Transcript (Albert) at 50. 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. *Id*. This is exacerbated by the fact that even in symptomatic cases, the fibrillation may not be of extended duration. In such paroxysmal atrial fibrillation, by the time a separate device is obtained, the fibrillation may have passed, leading to further delays in diagnosis and difficulties in convincing medical professionals the problem truly exists.

Afib can be a major health problem, creating a significant increase in the risk of suffering a serious stroke and likely causing up to one third of all such strokes. *Id*. 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.

Given these significant differences between an integrated solution, like the Apple Watch, and a two-device solution, the Commission's finding that a two-device solution would be a sufficient alternative, and thus its public interest finding, is in error.

IV. The ITC Has Abandoned The Equitable Principles Enshrined In Its Public Interest Factors To The Detriment Of American Industry

The ITC was created to address unfair foreign competition. Part of the concern was that foreign entities could escape the jurisdiction of the U.S. court system and send their products into the country without any way for domestic industries to remedy the foreign competitor's unfair act. But that is not why many modern complainants, including the complainant in this case, utilize the ITC. The majority of modern ITC investigations involve respondents over whom the district courts have no difficulty establishing jurisdiction.

A. Complainants File Additional Cases In The ITC To Obtain Relief A District Court Would Reject Under eBay

In fact, *most* ITC cases are conducted simultaneously with district court litigation between the same parties, on the same patents. In the same exhaustive analysis of ITC investigations from 1995-2007, two thirds of ITC cases had a parallel district court litigation—and the ITC case was almost always initiated after the district court case had been filed. Chien, *Patently Protectionist* at 92-93. Complainants are not forced to utilize the ITC because the courts are unavailable.

Instead, complainants go to the ITC in order to bypass the equitable protections the Supreme Court set forth in *eBay*. ITC exclusion orders are a type of injunctive relief—an order that the products involved will be barred from entry into the U.S. Courts have treated exclusion orders as injunctive relief, even while declining to apply *eBay*. *See, e.g.*, *Spansion, Inc. v. Int'l Trade Com'n*, 629 F.3d 1331, 1359 (Fed. Cir. 2010).

By going to the ITC, litigants can obtain injunctive relief that a district court would refuse as inequitable. As a result, "the ITC's practices have undone many of the desirable consequences of *eBay*."

Colleen Chien & Mark Lemley, *Patent Holdup, the ITC, and the Public Interest*, 98 Cornell L. Rev. 1, 4 (2012).

B. Congress Intended The ITC To Use The Traditional Principles Of Injunctive Relief

As this Court held in *eBay*, a "major departure from the long tradition of equity practice should not be lightly implied." *eBay*, 547 U.S. at 391. The ITC's statute illustrates that no such departure was intended.

First, Congress wrote into the statute that same long equitable tradition. In particular, the ITC is explicitly required to consider the impact of exclusion on the public health and welfare, competitive conditions in the U.S., the production of competitive articles, and U.S. consumers. 19 U.S.C. § 1337(d). If those considerations weigh against exclusion, the ITC should not issue an exclusion order. These explicit statutory requirements are consistent with the third and fourth *eBay* factors—the balance of hardships and the public interest.

Second, Congress explicitly addressed the notion of equity in the remedy. The ITC's statute explicitly states that "all legal and equitable defenses may be presented in all cases." 19 U.S.C. § 1337(c). Casting the equitable protections discussed in *eBay* as something other than a

defense against the application of an inequitable injunction elevates form over substance.

Given these clear indications, Congress intended the ITC to conduct an equitable balancing between the interests of the patent holder and the public interest. Even if this Court maintains the distinction between the injunctive relief available in the district courts and the ITC's exclusionary remedy, the Commission's failure to actually balance these interests in this case, along with many others, requires a remedy.

CONCLUSION

The International Trade Commission was intended to protect American industry from unfair foreign competition. This case would harm American industry and lacks any involvement of foreign entities. Upholding the Commission's legally and factually erroneous opinion would result in ongoing harm to American industry and continue a trend in which the Commission is seen as a way to sidestep the protections American innovators receive in district court.

Given the errors in the Commission's opinion and the negative impact upholding it would have on American industry, this Court should reverse the Commission's findings on domestic industry and the public interest and vacate the Commission's exclusion order.

August 14, 2023

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION

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August 14, 2023 /s/ Joshua Landau

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CERTIFICATE OF SERVICE

I hereby certify that on August 14, 2023, I caused the foregoing **Brief of *Amicus Curiae* Computer & Communications Industry Association** to be electronically filed with the Clerk of the Court using CM/ECF, which will automatically send email notification of such filing to all counsel of record.

August 14, 2023 /s/ Joshua Landau

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