NOS. 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

APPEAL FROM THE UNITED STATES INTERNATIONAL TRADE COMMISSION IN INVESTIGATION NO. 337-TA-1266

BRIEF OF OMRON HEALTHCARE, INC. AS *AMICUS CURIAE* IN SUPPORT OF APPELLEE INTERNATIONAL TRADE COMMISSION AND AFFIRMANCE IN NO. 23-1553

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November 27, 2023

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 2023-1509, -1553

Short Case Caption AliveCor, Inc. v. ITC, Apple, Inc.

Filing Party/Entity Omron Healthcare, Inc.

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1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	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. ☑ None/Not Applicable	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. ☐ None/Not Applicable
Omron Healthcare, Inc.		Omron Corporation
		Omron Healthcare Co., Ltd.

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☑ None/Not Applicable ☐ Additional pages attached

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INTEREST OF AMICUS CURIAE[1]

Since introducing the first electronic thermometer in 1972, Omron Healthcare, Inc., and its related companies, have been dedicated to innovating products and services that prevent illness, stop symptoms from worsening, and maintain good health. Omron's philosophy is that a healthier world comes with zero cerebrovascular and cardiovascular events, and Omron seeks to make lives more fulfilling by helping people move forward without being restricted by health concerns.

OMRON Healthcare is the number one doctor and pharmacist recommended blood pressure monitor brand. Omron's health offerings are increasingly dominated by software and connected data that is dependent upon continual collection over time, often reflecting years of data accumulation. OMRON's Connect app, syncs with OMRON's connected blood pressure monitors and serves as a personal heart health coach, providing insights into one's blood pressure readings, guidance to manage hypertension, and incentives for behavior change. Omron's VitalSight product was designed to help the 37 million Americans who

[1] This brief is being filed without complete consent of the parties, pursuant to a motion for leave to file. No parties' counsel authored this brief in whole or in part; neither party nor party counsel contributed money that was intended to fund preparing or submitting the brief; no person other than the *amicus curiae* or its counsel contributed money that was intended to fund preparing or submitting the brief. *See* Fed. R. App. P. 29(a)(2), (a)(4).

have uncontrolled Stage 2 hypertension and live every day with a higher risk of heart attack and stroke. VitalSight is an easy-to-use service that a physician can offer to patients with high-risk levels of hypertension. Patients receive a kit delivered to their home that includes an OMRON connected blood pressure monitor and data hub that are pre-set to securely share measurements – digitally – with the patient's physician and care team. The VitalSight data hub, which can also be used at home without Wi-Fi or cellular connection, bridges health care gaps for patients in under-resourced communities. Omron's Complete™ is the first blood pressure monitor with EKG capability in a single device and represents a groundbreaking innovation for millions of Americans with AFib or a family history of irregular heartbeat.

Not a year goes by without OMRON 's innovative solutions winning several awards at product design competitions around the world. These awards honor Omron's achievements in product development that combines functionality with ease of use and state-of-the-art design. Omron's remote patient monitoring services have recently been awarded "Best of" honors at the 2022 Consumer Electronics Show (CES). INSIDER recognized VitalSight on its list of 13 most exciting health, home, and kitchen products of CES 2022, calling it "life-saving technology," particularly for "patients who can't see their doctor regularly because of location, finances, or mobility concerns." OMRON Connect was recognized as an

outstanding digital health service at the 2023 Consumer Electronics Show (CES) and selected as a TWICE Picks Awards winner at the world's largest technology and innovation showcase. Consumer Technology Association (CTA) recognized Omron's Complete™ as a CES 2020 Innovation Award honoree in the Health & Wellness category.

In developing products that benefit patients, Omron often partners with others who have innovative technologies that can benefit users of Omron's developments. In this regard, Omron collaborated with AliveCor, Inc. ("AliveCor") in connection with its 2019 introduction of its OMRON Complete, an FDA cleared, award-winning, the first of its kind blood pressure monitor with EKG capability. In connection with that collaboration, Omron has invested in AliveCor and holds an equity stake of approximately 27%.

In addition, the failure to sustain the ITC's domestic industry findings has ramifications beyond this case. Omron's *amicus* brief provides valuable insight into the adverse ramifications that an alteration in well-established law relating to the application of this requirement will have upon innovation in the U.S. and the risks it will pose to those who depend upon commercial software products generally. The brief further explains the consequences of not crediting the continuing investments in software as part of the existing domestic industry

previously established, which can have long reaching effects on U.S. industry and consumer safety.

ARGUMENT

The ITC exists to protect American industry against unfair foreign competition. Shielding an infringing imported product from challenge, and declining to protect a U.S. firm's domestic investment, countermands the legislative purpose of Section 337. AliveCor is a U.S. company with an established domestic industry that conducts most of its research and development in the United States. Section 337 exists to protect AliveCor and companies like it from improper foreign competition.

I. THE INTERNATIONAL TRADE COMMISSION PROPERLY FOUND A DOMESTIC INDUSTRY

A. Congress Has Sought to Protect the Types of Continuing Research Investments Made by AliveCor

The genesis of Section 337 can be traced to the Tariff Act of 1922, which restricted unfair trade practices, including "infringement of patents." *Lannom Mfg. Co. v. Int'l Trade Comm'n*, 799 F.2d 1572, 1576-77 (Fed. Cir. 1986) (citing U.S. TARIFF COMM'N, DUMPING AND UNFAIR COMPETITION IN THE UNITED STATES (1919)). Shortly after the Tariff Act's adoption, however, the Tariff Commission acknowledged that then "[e]xisting law … is wholly inadequate to protect domestic owners of patents from violation of their patent rights through the importation and sale of infringing articles." *See* U.S. TARIFF COMM'N, TWELFTH ANNUAL REPORT

21 (1928). From its inception in 1930, the purpose of Section 337 was "to provide relief to United States industry from unfair acts, including infringement of United States patents by goods manufactured abroad." *Lannom Mfg. Co.*, 799 F.2d at 1580.

As originally enacted, Section 337 of the Smoot-Hawley Tariff Act of 1930 prohibited unfair competition and importation "the effect or tendency of which is to destroy or substantially injure an industry, efficiently and economically operated, in the United States." *See id.* at 1576. In other words, a complainant had to show (1) a domestic industry (2) that is efficiently and economically operated, and (3) which industry is or will be substantially injured. Reflecting the economy at the time of its enactment, this requirement was met almost exclusively through evidence of domestic manufacturing activities.

These stringent threshold requirements often made it difficult for patent holders to utilize the ITC as a remedy, resulting in rights holders being "denied access to section 337 relief." *See* U.S. GEN. ACCOUNTING OFFICE, REP. NO. GAO-NSAID-86-150, INTERNATIONAL TRADE: STRENGTHENING TRADE LAW PROTECTION OF INTELLECTUAL PROPERTY RIGHTS 29 (1986) [hereinafter *GAO Report*; *see also id.* at 26, 32 (statement of Honorable Alfred Eckes, Chairman, U.S. International Trade Commission) (noting that uncertainty about what constituted a domestic industry increased the cost of ITC litigation, steering rights

holders away); DONALD KNOX DUVALL, FEDERAL UNFAIR COMPETITION ACTIONS: PRACTICE AND PROCEDURE UNDER SECTION 337 OF THE TARIFF ACT OF 1930, at 4 (Clark Boardman Co., Ltd., ed. 1991) (1992) ("[I]t is estimated that over one-half of the high cost of section 337 litigation . . . is attributable to the legal costs of satisfying the economic criteria" (citing *GAO Report, supra*, at 31)).

In testimony before Congress, ITC Chairman Alfred Eckes highlighted the outmoded limits of Section 337 with respect to an evolving U.S. economy more reliant on research and development than traditional manufacturing:

> In the absence of clear guidance from the statute and legislative history, the [ITC] ha[d] been attempting on a case-by-case basis to apply [the statute], which was written originally more than 50 years ago, to modern circumstances of trade in which U.S. based firms increasingly source out elements of production to foreign suppliers.

GAO Report, *supra*, at 26.

In 1988, responding to concerns that the domestic industry requirement failed to acknowledge more modern realities concerning evolving research dependent industries, Congress made significant amendments to Section 337. First, Congress recognized that technology investment is a long-term proposition, worthy of protection in its own right. It removed the requirement that an "efficiently and economically operated" domestic industry be established. Congress specifically provided that protection extend to non-manufacturing activities, such as research and development. *See* 19 U.S.C. § 1337(a)(3)(C); *see also John Mezzalingua*

Assocs. v. Int'l Trade Comm'n, 660 F.3d 1322, 1327 (Fed. Cir. 2011) ("Congress, believing the Commission's application of the domestic industry requirement had been too rigid, liberalized the domestic industry requirement by allowing that requirement to be satisfied by proof of non-manufacturing activity, such as licensing and research" (citing H.R. REP. NO. 100-40, pt. 1, at 157 (1987))).

Second, Congress eliminated the requirement that actual injury be shown, recognizing that the infringement of intellectual property rights itself is a substantial injury. *See* H.R. REP. NO. 100-40, pt. 1, at 156 (1987) ("The Committee believes that the injury and efficient and economic operation requirements of section 337, designed for the broad context originally intended in the statue, make no sense in the intellectual property arena. … The importation of any infringing merchandise derogates from the statutory right, diminishes the value of the intellectual property, and thus indirectly harms the public interest. Under such circumstances, the Committee believes that requiring proof of injury, beyond that shown by proof of the infringement of a valid intellectual property right should not be necessary.").

To guard against misuse of Section 337, Congress instead relied upon the requirement that the protected industry be "domestic." *See* Alex Lasher, *The Evolution of the Domestic Industry Requirement in Section 337 Investigations before the United States International Trade Commission*, 18 U. BALT. INTELL.

PROP. L.J. 157, 168 (2010) ("Although Congress understood that the continued vitality of Section 337 depended on defining 'industry' in a manner that incorporated the realities of the modern marketplace, it feared that the expanded definition could be used as a loophole by intellectual property holders who had only limited contact with the United States."). "While expanding the types of activities that could be considered in the domestic industry analysis, the Commission held firm to Congress's mandate that Section 337(a) was not to be used as a loophole to allow foreign holders of U.S. intellectual property to access its remedial powers." *Id*. at 170; *see also* H.R. REP. NO. 100-40, pt. 1, at 157 (The domestic industry "requirement was maintained in order to preclude holders of U.S. intellectual property rights who have no contact with the United States other than owning such intellectual property rights from utilizing section 337. The ITC is to adjudicate trade disputes between U.S. industries and those who seek to import goods from abroad. Retention of the requirement that the statute be utilized on behalf of an industry in the United States retains that essential nexus.").

In short, Congress has declared that a "domestic industry" extends broadly to non-manufacturing activities, such as research and development, and has extended the ITC's protection to United States industries seeking to safeguard such investments in an increasingly globalized market. Domestic research and development that exploits a patented technology and benefits domestic users of a

patented article should not be ignored merely because the research also benefits a potential future product. Continued research and development "positive[ly] and substantial[ly] impacts" a nation's economic growth. *See* ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, THE IMPACT OF R&D INVESTMENT ON ECONOMIC PERFORMANCE: A REVIEW OF THE ECONOMETRIC EVIDENCE 3-4 (OECD ed., 2015).

For software driven products, continued research effectively constitutes an extension of the product itself. Investment in a product no longer ends with its sale, nor do the expectations of its purchaser. Increasingly, commentators are identifying the failure to continue such research and development as a societal risk. *See* Melina Schleef et al., *When Smart Products Become Dumb (Again): Voluntary and Legally Required Service Updates and Their Impact on Consumers' Purchase Intention*, 7 J. SERV. MGMT. RES. 52 (2023). To prevent obsolesce, companies must make ongoing research and development investments in enhancements and support—an "expensive, time-consuming and labor intensive process." Simos Gerasimou et al., *Technical Obsolescence Management Strategies for Safety-Related Software for Airborne Systems*, 2017 SOFTWARE TECHNOLOGIES: APPLICATIONS AND FOUNDATIONS 385-393.

The dangers of failing to protect and encourage continuing investment are starkly illustrated in the area of cybersecurity. *See* Barış E. Özkan & Serol Bulkan,

Hidden Risks to Cyberspace Security from Obsolete COTS Software, 2019 11th INT'L CONFERENCE ON CYBER CONFLICT 1-19 (2019). Software obsolescence presents a significant cyber security risk that has national security implications. *Id.* (discussing how the rapid rate at which software becomes obsolete poses cybersecurity risks and could "easily become a national security problem."); *see also* Alana Maurushat & Kathy Nguyen, *The Legal Obligation to Provide Timely Security Patching and Automatic Updates*, 3 INT. CYBERSECUR. L. REV. 437, 441 (2022) ("The problem with software … is that they require updates and patching on a routine (if not daily) basis in order to make them secure."). Narrowing the scope of activities deemed to relate to an existing domestic industry provides no protection for these critical domestic investments.

B. AliveCor Has an Established Domestic Industry Which It Supports with Continuing Investment

As the ITC correctly observed, AliveCor's research investments "didn't just stop" after AliveCor was forced to discontinue its original, patented product when Apple plotted to make it incompatible with Apple's updated watch device. Appx30083-30086; Appx30198-30202; Appx12257-12263. The ITC found that AliveCor continued to exploit its patented technology through substantial investments in its KardiaBand system, and specifically in technologies forming the "core part of the invention" which "overlapped" with its established base of

cardiac monitoring systems. Appx11; Appx15-21; Appx275-277; Appx281-282; Appx286-288.

This Court has held that past expenditures may be considered to support a domestic industry claim. *See Hyosung TNS Inc. v. Int'l Trade Comm'n*, 926 F.3d 1353, 1361-62 (Fed. Cir. 2019) (There is "substantial evidence supporting the ITC's finding that Diebold's earlier substantial investment in research and development relating to the '631 patent was relevant based on the ongoing qualifying and meaningful expenditures exploiting that technology, and that there was a sufficient nexus between the earlier investment in research and the continuing expenditures. affirming that domestic industry requirement was met, in part, based on past investments in research and development relating to the patent.").

In *Hyosung*, this Court found that past research and development expenditures, combined with ongoing expenses related to supporting the patented technology, satisfied the domestic industry requirement. 926 F.3d at 1361-62 ("We see no legal error in the ITC's conclusion that a past investment may, by virtue of its connection to ongoing field service and assembly expenses, support a finding that the economic prong of the domestic industry requirement is met."). The present facts are distinguishable from cases in which all activity having a nexus to the patent had ceased. *See, e.g.*, *Motiva, LLC v. Int'l Trade Comm'n*, 716 F.3d 596,

600-601 (Fed. Cir. 2013) ("[T]here is no evidence in the record relating that [earlier] development activity to Motiva's efforts to establish a domestic industry at the time Motiva chose to file its complaint three years later.").

The Commission has consistently protected domestic companies despite the cessation of sales of a patented product, provided that other, relevant investments continue. *See, e.g., Certain Television Sets, Television Receivers, Television Tuners, & Components Thereof*, Inv. No. 337-TA-910, 2015 WL 6755093, at *37 (Oct. 30, 2015) (Comm'n Op.) ("Commission precedent indicates that where production, development or sales of protected articles have declined or even ceased entirely, a domestic industry may nevertheless be established based on past significant or substantial investments relating to the protected articles provided that complainant continues to maintain ongoing qualifying activities under section 337(a)(3) at the time the complaint is filed."); *Certain Battery-Powered Ride-On Toy Vehicles and Components Thereof*, Inv. No. 337-TA-314, Order No. 6 at 18-21 (Dec. 5, 1990) (unreviewed in relevant part) (domestic industry found to exist, where manufacturing of protected articles had ceased in favor of an improved model before the complaint was filed, based on substantial past investments in equipment, labor and capital in development and exploitation of the patent combined with continued activities supplying patented replacement units, which are a safety feature of the vehicles); *Certain Electronic Digital Media Devices and*

Components Thereof, Inv. No. 337-TA-796, 2013 WL 10734395, at *68-70 (Sept. 6, 2013) (Comm'n Op.) (finding domestic industry exists where complainant had substantial past investments in engineering and R&D related to discontinued protected articles and continued to exploit the patent through further development of existing products at the time of the complaint); *Certain Electronic Devices, Including Mobile Phones, Portable Music Players, and Computers*, Inv. No. 337-TA-701, Order No. 58 at 16-17 (Nov. 18, 2010) (unreviewed) (domestic industry satisfied based on past substantial investments in R&D for protected articles and undisputed facts showing ongoing activities with respect to protected articles including development, warranty repairs, sales, and/or maintenance of inventories in the United States at the time the complaint was filed).

As Commissioner Schmidtlein explained in *Television Sets*:

> a complainant should not be denied relief simply because the importation of infringing articles happens to take place after a domestic industry product is developed but when that product is produced, sold to customers, and/or supported by the complainant. Development and engineering costs are frequently incurred at an early stage of a product's development. Were complainants to be denied relief in such circumstances, it would enable evasion of the protection intended by Congress under section 337.

Television Sets, 2015 WL 6755093, at *40 (Separate Views of Commissioner Rhonda K. Schmidtlein) (Explaining why the Commission can consider past expenditures in assessing the domestic industry requirement).

AliveCor is a U.S. company and has established a domestic industry through the domestic development and sale of patented products which it continues to support and improve through continued innovation in products covered by the patents. AliveCor is neither a foreign company seeking to misuse the ITC's remedial powers, nor a non-practicing entity who has contributed nothing to technological advances in the United States. Section 337 exists to protect AliveCor and companies like it from improper foreign competition.

C. AliveCor's Investments Were Substantial

The ITC also correctly noted that AliveCor's continuing domestic investments were substantial, when compared to its investments overall. The ITC correctly declined an invitation to establish an absolute dollar threshold for finding substantiality. To have done so would have disadvantaged smaller domestic companies, placing protection from the ITC beyond reach except for the largest of corporations. Again, the primary purpose of the domestic industry requirement is to prevent foreign holders of U.S. intellectual property from accessing the ITC's remedial powers in aid of foreign activities.

Whether a complainant satisfies the economic prong has not been analyzed according to a rigid mathematical formula. *Certain Male Prophylactic Devices*, Inv. No. 337-TA-546, 2007 WL 9772268, at *23 (Aug. 1, 2007) (Comm'n Op.). The Commission decides the domestic industry requirement has been established

in each investigation based on "an examination of the facts in each investigation, the article of commerce, and the realities of the marketplace." *Id.* A complainant does not need to show any "minimum monetary expenditure," and does not "need to define or quantify the industry itself in absolute mathematical terms." *Certain Stringed Musical Instruments and Components Thereof*, Inv. No. 337-TA-586, 2008 WL 2139143, at *14-15 (May 16, 2008) (Comm'n Op.) ("A precise accounting [of the complainant's domestic investments] is not necessary, as most people do not document their daily affairs in contemplation of possible litigation.").

While this Court has held that "qualitative factors alone are insufficient" to show significant investment, it has acknowledged that it is appropriate to evaluate quantitative data using a *relative* measure. *See Lelo Inc. v. Int'l Trade Comm'n*, 786 F.3d 879, 884 (Fed. Cir. 2015) (citing *Certain Concealed Cabinet Hinges and Mounting Plates*, Inv. No. 337-TA-289, 1990 WL 10608981, at *11 (Jan. 8, 1990) (Comm'n Op.) ("We agree with the ALJ that 'significance' as used in the statute denotes an assessment of the relative importance of the domestic activities.")) Considerations beyond the absolute amount spent are particularly appropriate when evaluating the significance of non-manufacturing activities under subsection (C) of Section 337, as research and development investments are less easily quantifiable.

Here, the Commission had quantitative data, such as Dr. Akerman's "sufficiently detailed and pertinent headcount comparison showing it more likely than not that DI-related R&D labor expenses were substantially domestic," as well as the domestic R&D contractor expenses, which established that the domestic investment was significant. Appx20-21; Appx287-288; Appx11716-11718; Appx40011.

CONCLUSION

The court should affirm the ITC's decision to the extent it determined that AliveCor established a domestic industry under Section 337.

Respectfully submitted,

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November 27, 2023

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