

No. 26-316

IN THE
Supreme Court of the United States

APPLE INC.,

Petitioner,

v.

INTERNATIONAL TRADE COMMISSION, MASIMO
CORPORATION, AND CERCACOR LABORATORIES, INC.,

Respondents.

On Petition for a Writ of Certiorari to the
United States Court of Appeals for the Federal Circuit

**BRIEF OF THE COMPUTER & COMMUNICATIONS
INDUSTRY ASSOCIATION, SOFTWARE &
INFORMATION INDUSTRY ASSOCIATION,
ALLIANCE FOR AUTOMOTIVE INNOVATION,
AND ITC MODERNIZATION ALLIANCE
AS *AMICI CURIAE* IN SUPPORT OF PETITIONER**

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INTERESTS OF *AMICI CURIAE*

The Computer & Communications Industry Association (CCIA), the Software & Information Industry Association (SIIA), the Alliance for Automotive Innovation (AAI), and the ITC Modernization Alliance (ITCMA) jointly submit this brief as *amici curiae* in support of Petitioner Apple Inc.¹

CCIA is an international, not-for-profit association that represents a broad cross-section of communications, technology, and internet industry firms that collectively 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 U.S. economy. CCIA and its members have been leaders in the research, development, and implementation of countless innovative technologies affecting domestic markets. A list of CCIA members is available at <https://ccianet.org/about/members/>.

SIIA is the principal trade association for the software and digital information industries. Through its divisions, events, and advocacy, SIIA engages industry leaders and policymakers to ensure a vibrant ecosystem—one that fosters creation, dissemination, and productive use. SIIA and its members work to proactively address issues and

¹ No counsel for any party authored this brief in whole or in part, and no person or entity other than *amici* made a monetary contribution to the preparation or submission of the brief. (Although Apple is a member of *amici* CCIA, SIIA, and ITCMA, it did not participate in the decision to file this brief or provide funding intended for this brief.) *Amici* provided timely notice of this brief to the parties.

challenges that impact their industry segments with the goal of driving innovation and growth of the information economy.

AAI is the unified voice of the automotive industry. From the manufacturers producing most vehicles sold in the United States, to autonomous vehicle innovators, to equipment suppliers, battery producers, and semiconductor makers, AAI represents the full auto industry, a sector supporting 11 million American jobs and five percent of the economy.

ITCMA is a coalition of leaders in the technology, telecom, and automotive industries dedicated to modernizing the U.S. International Trade Commission (ITC) and promoting trade practices that safeguard American industry, workforce, and consumers.

The *amici* and their members have a substantial and direct interest in the questions presented. Their members invest billions of dollars in developing and bringing complex products to market; they have a significant presence in the various U.S. markets in which they participate; and they are responsible for the design and availability of both components used in products and final products that are demanded by U.S.-based consumers. They are frequent petitioners, respondents, suppliers, and downstream customers in ITC Section 337 investigations.

An ITC exclusion order, especially when directed to just one component or feature of a complex product, is a devastating remedy. It stops the importation of that product, however minor the challenged component and however complex the supply chain of the finished product. And, because an exclusion order

is a blunt instrument that does not factor in the economic value of the patented technology, the resulting leverage can far exceed the value of the technology underlying the dispute. For companies that have already committed substantial resources to R&D, engineering, manufacturing, supply-chain development, regulatory approval, distribution, and customer relationships, the mere threat of an exclusion order can result in the loss of customers and impose enormous switching and redesign costs.

Amici and their members recognize the value of the ITC and its ability to stop infringing imports from entering the U.S. Doing so can be important for protecting members' products—and, consequently, their businesses—from imports that use their hard-earned intellectual property without permission. But *amici* want to ensure that the ITC is not abused as a forum. Making the ITC available to rights holders that do not have the requisite stake in U.S. domestic industry, as delineated in Section 337 and confirmed by the statute's legislative history, unnecessarily places *amici's* members' businesses in jeopardy, which ultimately stifles innovation.

Thus, *amici* and their members have a strong interest in ensuring that this Court grant certiorari to ensure that ITC exclusion orders are restricted to complainants with an actual domestic industry to protect, as Congress intended.

INTRODUCTION AND SUMMARY OF ARGUMENT

Congress gave the ITC an extraordinary statutory remedy—an injunction, called an exclusion order—under which a product found to be infringing may be barred from importation into the United States. And

the requirements for obtaining an injunction upon a finding of infringement from the ITC are lower than the equitable factors that must be satisfied in an Article III court.

But critically, Congress imposed an important limitation on that power—a limitation on access to the ITC in the first place. The Tariff Act of 1930, as enacted and as repeatedly amended, primarily addresses *trade*, not intellectual-property law, and Section 337 of that Act, 19 U.S.C. § 1337, is a trade statute. So a complainant seeking exclusion under Section 337 must establish the existence of an “industry in the United States” with respect to articles protected by the asserted intellectual-property right before seeking relief. 19 U.S.C. § 1337(a)(2)-(3). It is that domestic-industry requirement that ties the ITC’s exceptional exclusionary authority to its statutory mission of protecting American industry from unfair import competition.

Congress not only created that limitation in enacting the predecessor to Section 337, but has deliberately preserved that limitation. Most importantly, when amending Section 337 in 1988, Congress considered proposals that would have eliminated the domestic-industry requirement and thereby transform the ITC into a broader intellectual-property enforcement forum. But Congress rejected that approach. Instead, it expressly retained the domestic-industry requirement, while expanding it slightly to protect domestic industries built on R&D, engineering, and licensing. As Congress explained, the domestic-industry requirement preserves the “essential nexus” between the ITC’s trade authority and an industry in the United States for the specific

technology protected by the intellectual-property right in question. H.R. Rep. No. 100-40, at 157 (1987); S. Rep. No. 100-71, at 129 (1987). Congress thus made a deliberate choice: The ITC would remain a trade forum empowered to protect qualifying domestic industries, not an alternative patent court.

The decision below crosses the boundary Congress established. Congress expressly addressed R&D-based domestic industries in Section 337(a)(3)(C), requiring a “substantial investment” in the “exploitation” of the asserted intellectual-property right. Yet the Federal Circuit permitted Masimo to rely on R&D expenditures under subsection (B)’s more-general reference to the “significant employment of labor or capital,” without satisfying subsection (C)’s distinct requirements. The credited expenditures included development work associated with other Masimo devices that did not practice the asserted patents. By permitting those expenditures to establish domestic industry outside the conditions Congress expressly prescribed for R&D-based industries, the decision expands access to the ITC’s exclusionary authority beyond the limits Congress deliberately imposed.

The consequences of that reasoning extend far beyond Apple and Masimo. For companies producing automobiles, communications technologies, software-enabled devices, and other complex products incorporating thousands of technologies and complex supply chains—like *amici*’s members—expanding access to Section 337’s extraordinary injunctive remedy changes the economics of patent disputes. Greater exposure to exclusion increases the costs and uncertainty associated with investment in complex products; diverts engineering resources toward

defensive design and patent clearance; strengthens incentives to settle even dubious claims; and can translate into delayed products, reduced product choice, and higher costs for consumers.

The Federal Circuit’s statutory interpretation error and the economic consequences of that error reinforce one another. Congress confined the ITC’s extraordinary exclusionary power to disputes involving a qualifying domestic industry. The decision below opens the gates while leaving the extraordinary remedy untouched. For *amici*’s members and other innovative companies, the result is greater exposure to a remedy capable of excluding an entire complex product based on a patent covering only one of its many technologies, even where the complainant’s domestic activity fails the requirements set by Congress. The Court should grant the Petition to reverse this unwarranted and deeply problematic misinterpretation of Section 337.

ARGUMENT

The decision below warrants this Court’s review for two related reasons.

First, its pernicious effects extend well beyond this dispute. By expanding the activity that can establish 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), the Federal Circuit’s decision widens the ITC’s jurisdiction. For innovative companies like *amici*’s members, that means greater exclusion risks—with consequences for investment, innovation, competition, and consumers.

Second, that expansion conflicts with the limits Congress has enacted. Congress amended Section 337 in 1988 to delineate three distinct ways that a complainant could demonstrate that “an industry in the United States shall be considered to exist,” *id.* § 1337(a)(3). In so doing, it added R&D as a newly recognized basis for establishing a domestic industry—but expressly did so in a new subsection (C), which requires a “substantial investment” in the “exploitation” of the asserted IP right. *Id.* § 1337(a)(3)(C). The decision below permits the same R&D activity to qualify instead as a “significant employment of labor or capital” under subsection (B), *id.* § 1337(a)(3)(B), without satisfying subsection (C)’s distinct requirements that the “substantial” R&D investment specifically relate to the asserted IP’s “exploitation.” In doing so, it removes an important limitation Congress deliberately imposed on access to the ITC’s exclusionary remedy.

I. The Decision Below Will Have Far-Reaching Consequences.

Petitioner has explained at length why the Federal Circuit’s decision runs roughshod over the statutory text. *Amici* thus focus in the first instance on why the decision below is so problematic.

A. Expanded access to exclusion orders magnifies hold-up costs for innovative companies.

Section 337’s economic consequences begin with the nature of its remedy. Unlike a patent-damages award, an exclusion order can bar importation of an entire product containing an infringing component. In determining whether to extend exclusion to downstream products, the ITC may consider “the

value of the infringing articles compared to the value of the downstream products in which they are incorporated,” but relative value is only one consideration in that analysis. *Hyundai Elecs. Indus. Co. v. U.S. Int’l Trade Comm’n*, 899 F.2d 1204, 1209 (Fed. Cir. 1990) (citation omitted). The scope of exclusion thus commonly is not proportional to the patented technology’s share of the finished product’s economic value.

That distinction matters greatly for *amici*’s members, most of which are U.S. companies, and other companies developing complex products. A modern automobile, communications device, or other connected product may incorporate hundreds or thousands of technologies. By the time a patent is asserted against one of those technologies, the manufacturer may already have committed substantial resources to product design, engineering, tooling, regulatory approval, manufacturing, distribution, and customer relationships. The company often faces a choice between losing those investments due to exclusion of its product or removing or replacing the accused technology at great cost and disruption.

The complexity of modern supply chains only magnifies those costs. *See generally* Ramish Zafar, *Demystifying the AI Chip Supply Chain – Here’s How NVIDIA & Others Rely On A Complex Web Of Companies To Make Their Chips*, WCCFTECH (June 11, 2025), <https://perma.cc/T87P-RHQQ> (detailing supply chain and typical vendors for the design and manufacturer of an artificial-intelligence microchip). Consider a manufacturer of advanced computing hardware, such as an artificial-intelligence accelerator board: The manufacturer may purchase

individual components in large quantities from suppliers around the world and deliver them to contract manufacturers responsible for assembling the finished boards. If a patent dispute threatens exclusion based on a single component—even an inexpensive, readily available commodity part—replacing that component is rarely as simple as substituting one part for another. The manufacturer may need to redesign the board, qualify the replacement component, and conduct extensive testing to ensure that the modified product performs reliably and remains compatible with the larger system. It must then procure sufficient quantities of the replacement component, coordinate delivery to contract manufacturers, and integrate the change into production. That process can involve numerous suppliers and manufacturing partners across multiple countries and take months to complete.

Critically, manufacturers often cannot wait until infringement has been established before beginning that process. By the time the ITC issues an initial determination, there may be insufficient time to redesign, test, qualify, and manufacture replacement products before an exclusion order could disrupt imports. Faced with that prospect, a manufacturer must decide whether to commit substantial resources to redesigning its product while infringement remains disputed—or risk interruption of an established supply chain and the loss of investments already committed to production. The threat of exclusion therefore creates leverage well before any finding of infringement. A patent holder can demand compensation reflecting not only the value of the asserted technology, but also the enormous costs and commercial risks the manufacturer must incur to

avoid a potential disruption. Those costs may dwarf the value of the accused component itself.

An exclusion threat arising at the ITC stage thus creates bargaining leverage based not only on the value of the patented technology, but also on the respondent's cost of switching away from it. The Federal Trade Commission has described precisely that phenomenon. Once a manufacturer has incorporated a technology into a product, the threat of an injunction can permit a patent holder to bargain based on the manufacturer's switching costs—including the costs of redesign, retooling, and ensuring compatibility—rather than the technology's value when the design choice was originally made. FTC, *The Evolving IP Marketplace: Aligning Patent Notice and Remedies with Competition* 225–26 (2011), <https://perma.cc/Y9QW-VZV3>. The FTC has warned that such patent hold-up can raise prices and delay innovation. *Id.* at 234–35, 241–43.²

Section 337 makes that concern particularly acute. The ITC cannot award damages; its principal patent remedy is exclusion. And unlike injunctions in district-court patent litigation, ITC exclusion orders are not governed by the equitable framework of *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006). *See Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331,

² The BlackBerry litigation of the early 2000s is illustrative of how hold-up costs can affect settlement values in patent litigation. There, a jury awarded damages of \$23,188,570.90 after finding the patents infringed. *See NTP Inc. v. Rsch. in Motion, Ltd.*, No. 3:01-cv-00767 JRS, Dkt. 260 (E.D. Va. Nov. 21, 2002). But after an injunction was issued, the defendant settled the case for \$612,500,000, *see id.* at Dkt. 463 & Dkt. 464 (Mar. 3, 2006)—25 times the assessed value of the invention.

1358–59 (Fed. Cir. 2010). The FTC has accordingly specifically called out exclusion orders as presenting a risk of patent hold-up and has recommended construing the domestic-industry requirement in a manner that reduces that risk. *Evolving IP Marketplace* at 239–43.

The decision below heightens that concern by broadening the domestic activity that can establish eligibility for Section 337 relief. Masimo relied on R&D labor under subsection (B), largely based on investment associated with *non-patent-practicing* devices. See Pet. App. 19a–26a. While some information about those devices naturally informed later product development, including patent-practicing devices, treating such attenuated R&D activity as sufficient to establish domestic industry ignores statutory limits on the circumstances in which a patent holder may invoke the ITC’s exclusionary remedy—and thus the circumstances in which an accused importer must negotiate under the possibility of exclusion.

B. Greater exclusion discourages follow-on investment and diverts resources from innovation.

The consequences extend beyond settlement negotiations. Greater exposure to exclusion can also affect investment decisions before any exclusion order issues.

A firm deciding whether to commit additional capital, engineering resources, or product-development costs must consider the possibility that those investments will become sunk before a patent dispute arises. As the FTC has explained, uncertainty over patent rights can cause firms to undertake costly

patent clearance before beginning research and that the possibility of later injunctions can place sunk R&D investments at risk. *Evolving IP Marketplace* at 221–26. Where switching costs are high, the prospect of exclusion can therefore increase the cost and uncertainty associated with innovative activity.

Those concerns are amplified for complex products. Modern automobiles, smartphones, communications systems, and other connected devices—including the Apple Watch at issue in this litigation—incorporate numerous components and features potentially covered by different patents. A manufacturer may therefore confront patent risk not at one discrete point in development, but across many technologies incorporated into a single finished product. And because redesigning one component can require additional engineering, testing, certification, or integration work elsewhere in the product, the cost of responding to an exclusion threat can extend well beyond the accused feature itself.

The decision below increases that risk. By permitting development-stage R&D—including activity associated with non-practicing devices, *see* Pet. 19a–26a—to establish domestic industry under subsection (B), it expands the circumstances in which a complainant can invoke Section 337. Each additional credible exclusion threat requires companies to account for the increased chance that all of their investment in a product may later be placed at risk.

C. Those effects ultimately distort competition, reduce consumer choice, and increase costs.

The same mechanisms can ultimately affect competition and consumers. When a patent covers one feature of a complex product but exclusion threatens the entire product—even after substantial investments have become sunk—the patent holder’s bargaining position may reflect the respondent’s switching costs as well as the patented technology’s competitive value. As FTC Commissioner Ramirez explained to Congress in 2012, exclusion orders “can cause hold-up, distort ‘competitive conditions’ by forcing negotiation under the shadow of switching costs, impair innovation, and harm” U.S. customers. E. Ramirez, *Prepared Statement of The Fed. Trade Comm’n Before the U.S. Sen. Comm. on the Judiciary Concerning Oversight of the Impact on Competition of Exclusion Orders to Enforce Standard-Essential Patents* 9–10 (2012), <https://perma.cc/Z6P8-SNYQ>; see also *Evolving IP Marketplace* at 241–43 (hold-up arising from exclusion can distort competitive conditions, raise prices, and impair innovation).

The Department of Justice has expressed similar concerns. It has explained that an injunction threat directed to “a small but essential piece” of a larger product can permit a patent holder to capture value attributable to the implementer’s sunk investment rather than the marginal value of the patented invention, potentially discouraging the development of new products and technologies. See Christine A. Varney, Assistant Att’y Gen., Antitrust Div., U.S. Dep’t of Just., *Promoting Innovation Through Patent and Antitrust Law and Policy*, Remarks as Prepared for the Joint USPTO/FTC/DOJ Workshop (May 26,

2010), <https://perma.cc/UY8H-9WZL>. Those effects can ultimately reach consumers through delayed product introductions, reduced functionality or product choice, and higher costs.

Congress recognized that exclusion can have consequences beyond the immediate litigants. Section 337 therefore requires the ITC, before issuing an exclusion order, to consider its effects on “the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers.” 19 U.S.C. § 1337(d)(1).

But that back-end inquiry is no substitute for the domestic-industry limitation Congress imposed at the threshold. Section 337 provides that the ITC “shall” issue an exclusion order after finding a violation unless the statutory public-interest considerations counsel otherwise. *Id.* And the Federal Circuit has recognized that the ITC historically has denied exclusion on public-interest grounds only in exceptional circumstances. *Spansion*, 629 F.3d at 1359–60. The ITC rejected Apple’s public-interest objections in this very investigation. *Certain Light-Based Physiological Measurement Devices & Components Thereof*, Inv. No. 337-TA-1276, Comm’n Op. at 76–118 (Nov. 14, 2023).

The domestic-industry requirement therefore serves a different function. It determines, before the ITC reaches remedy, which patent disputes qualify for Section 337’s trade remedy in the first place. The decision below weakens that threshold by allowing a complainant to demonstrate domestic activity through development-stage R&D under subsection (B), including activity involving non-practicing

devices. The result is broader exposure to exclusion—and to the bargaining, investment, and competitive consequences accompanying that threat—for companies throughout technology-intensive sectors.

II. The Decision Below Disregards The Limits Congress Retained To Prevent The ITC From Becoming A General Patent-Enforcement Forum.

The decision below does more than expand the activities that can establish a domestic industry. It authorizes access to the ITC’s extraordinary exclusionary remedy beyond the limits Congress established to preserve the ITC’s trade-focused mission.

When Congress amended Section 337 in 1988, it confronted the question whether the ITC should remain a forum for protecting domestic industry against unfair imports, or should become a broader forum for enforcing intellectual-property rights. Congress expressly rejected the latter course by retaining the domestic-industry requirement, preserving what it called the “essential nexus” between the ITC’s authority and an industry in the United States for the specific patented technology. H.R. Rep. No. 100-40, at 157.

That choice is central to this case. Congress expanded Section 337 to protect domestic industries built on R&D, engineering, and licensing, but it did not authorize patent owners to invoke the ITC’s exclusionary power without satisfying the statutory conditions that connect those activities to a qualifying domestic industry. By permitting R&D to establish domestic industry under subsection (B) without satisfying the stricter requirements Congress

imposed in subsection (C), the decision below authorizes the ITC to exercise its exclusionary authority beyond the boundary Congress deliberately imposed.

This Court has repeatedly emphasized that federal agencies must operate within the authority Congress has conferred. Courts must independently determine the limits of agency authority, and ensure that agencies remain within them. *See Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 395–96 (2024). And the Court has been particularly attentive to agency interpretations that claim consequential powers beyond those Congress reasonably authorized. *E.g.*, *West Virginia v. EPA*, 597 U.S. 697, 721–24 (2022). The lower court ignored those principles here. Congress expressly retained the domestic-industry requirement to prevent the ITC from becoming a general intellectual-property enforcement forum. The Federal Circuit’s interpretation permits the ITC to exercise its extraordinary exclusionary authority beyond that deliberately preserved statutory boundary.

A. Congress retained the domestic-industry requirement to confine the ITC to its trade-focused mission.

Section 337 has always been a trade remedy tied to domestic industry. Indeed, its predecessor prohibited unfair acts in importation only where they threatened to “destroy or substantially injure an industry, efficiently and economically operated, in the United States,” Tariff Act of 1922, ch. 356, § 316, 42 Stat. 858, 943, and Congress retained that domestic-industry nexus when it substantially revised Section

337 in 1974. *See* Trade Act of 1974, Pub. L. No. 93-618, § 341, 88 Stat. 1978, 2053–54.

By the 1980s, however, uncertainty had developed over what domestic activities could constitute an “industry.” The ITC had recognized domestic manufacturing activity involving land, labor, and capital, but had rejected domestic-industry showings based on certain R&D and licensing activities. *See InterDigital Commc’ns, LLC v. Int’l Trade Comm’n*, 707 F.3d 1295, 1300–03 (Fed. Cir. 2013). Congress responded in 1988. And the manner in which it did is critical here.

Congress considered proposals that would have eliminated the domestic-industry requirement altogether. But those proposals encountered opposition because they threatened to transform the ITC from a trade-focused institution into a general intellectual-property enforcement forum. Indeed, as the Federal Circuit has recounted, then-ITC Chair Paula Stern opposed eliminating the requirement, warning against converting the ITC into an intellectual-property court. *See id.* at 1302–03; *see also* 132 Cong. Rec. 30459, 30816 n.5 (1986) (expressing concern that eliminating the requirement “would transform the ITC into an intellectual property court”).

Congress rejected that expansion. Rather than eliminate the domestic-industry requirement, it retained the requirement as an express limitation on the ITC’s authority. Congress thus preserved a distinction between ordinary patent enforcement available in federal court, and the extraordinary exclusionary remedy available at the ITC to protect qualifying domestic industries.

The legislative history makes that choice unmistakable. Congress explained that 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.” H.R. Rep. No. 100-40, at 157; S. Rep. No. 100-71, at 129. And it explained why that limitation matters: “The purpose of 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.” H.R. Rep. No. 100-40, at 157.

Congress nevertheless recognized that American industries increasingly created value through activities other than traditional manufacturing. Representative Kastenmeier—the chairman of the Judiciary Subcommittee on Courts, Intellectual Property, and the Administration of Justice from 1969 to 1991—initially proposed to define a domestic industry to include “a substantial investment in facilities or activities related to the exploitation of patents,” expressly including “research, development, licensing, sales, and marketing.” See H.R. 4539, 99th Cong. § 202(a) (1986) (emphasis omitted); see *Lashify, Inc. v. Int’l Trade Comm’n*, 130 F.4th 948, 960–61 (Fed. Cir. 2025). Kastenmeier emphasized that the proposal would protect universities and small businesses that invested domestically in innovation without necessarily engaging in domestic manufacturing. 132 Cong. Rec. 7119 (1986). But Kastenmeier was equally clear that the proposal would not “delete the domestic industry

requirement.” *Trade Reform Legislation: Hearings Before the Subcomm. on Trade of the H. Comm. on Ways & Means*, 99th Cong. 818 (1986).

Congress ultimately adopted a more specific, three-part definition. H.R. 4747 distinguished the traditional bases for domestic industry from newly recognized forms of intellectual-property exploitation:

(A) significant investment in plant and equipment; (B) significant employment of labor or capital; or (C) substantial investment in its exploitation, including engineering, research and development, or licensing.

Lashify, 130 F.4th at 961 (quoting H.R. 4747, 99th Cong. § 2(a)(1) (1986)). That structure became law in the Omnibus Trade and Competitiveness Act of 1988. Pub. L. No. 100-418, § 1342, 102 Stat. 1107, 1212–13; 19 U.S.C. § 1337(a)(3).

That distinction was deliberate. As both committee reports explained, “[t]he first two factors” reflected grounds the ITC had previously used to find a domestic industry. S. Rep. No. 100-71, at 129; H.R. Rep. No. 100-40, at 157. But the third factor “goes beyond [the] ITC’s recent decisions in this area.” *Ibid.* Congress thus expressly extended protection to domestic R&D, engineering, and licensing activities, but conditioned that additional basis for establishing domestic industry on a “substantial investment” in the “exploitation” of the intellectual-property right. 19 U.S.C. § 1337(a)(3)(C).

B. The decision below exceeds the limits Congress established to preserve that mission.

The decision below authorizes precisely the expansion of the ITC’s patent-enforcement authority that Congress sought to prevent. Congress did not retain the words “industry in the United States” while at the same time permitting virtually any domestic activity associated with a patent to establish eligibility for Section 337 relief. Rather, it specified the activities capable of establishing a qualifying industry and expressly addressed R&D in subsection (C), requiring “substantial investment” in the “exploitation” of the intellectual-property right. 19 U.S.C. § 1337(a)(3)(C). Those requirements give substantive effect to the specific domestic-industry boundary Congress chose to impose.

The Federal Circuit’s interpretation permits complainants to circumvent that boundary. Respondent Masimo’s economic-prong showing rested on R&D expenditures under subsection (B), most notably development work associated with earlier devices that did not practice the asserted patents. The Federal Circuit permitted that activity to contribute to the domestic-industry showing based on a relevance to later patent-practicing prototypes, without requiring Masimo to satisfy subsection (C)’s distinct requirements. *See* Pet. App. 19a–26a.

The result is not merely a different method of accounting for domestic investment. It allows complainants to invoke the ITC’s exclusionary authority based on R&D without satisfying the conditions Congress expressly prescribed for R&D-based domestic industries. As Petitioner explains, the

Federal Circuit’s interpretation cannot be reconciled with the distinct statutory provisions Congress enacted. *See* Pet. 19–27. The legislative history reveals an additional and equally important defect: That interpretation authorizes an expansion of the ITC’s institutional role beyond the limits Congress deliberately established.

Congress understood that allowing intellectual-property owners to invoke Section 337 without a qualifying domestic industry would transform the ITC into a general patent-enforcement forum. That is why it rejected proposals to eliminate the domestic-industry requirement and retained the requirement to preserve the “essential nexus” between the ITC’s trade authority and domestic industry. H.R. Rep. No. 100-40, at 157. And that is why Congress expressly prescribed the conditions under which newly recognized activities such as R&D could establish a domestic industry.

The decision below cannot be reconciled with that choice. By permitting R&D to establish domestic industry through subsection (B) without satisfying subsection (C)’s distinct requirements, the Federal Circuit authorizes access to the ITC’s exclusionary remedy outside the limits Congress established for that activity. It thereby moves the ITC toward the broader intellectual-property enforcement role Congress expressly declined to authorize.

That expansion is particularly consequential given the economic effects described in Part I. The ITC’s exclusionary remedy can impose costs far exceeding the economic value of the patented technology, affecting investment, innovation, competition, and consumers. Congress made that

extraordinary remedy available to protect qualifying domestic industries—not as a general alternative to federal-court patent enforcement. The domestic-industry requirement is the statutory boundary that preserves that distinction.

The decision below crosses that boundary. This Court’s review is warranted to restore the limits Congress expressly imposed on the ITC’s exclusionary authority.

CONCLUSION

The Court should grant the Petition.

Respectfully submitted.

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