

No. 2024-1285

**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

APPLE INC.,

Appellant,

v.

INTERNATIONAL TRADE COMMISSION,

Appellee,

MASIMO CORPORATION, CERCACOR LABORATORIES, INC.,

Intervenors,

On Appeal from the United States International Trade Commission
in Investigation No. 337-TA-1276

SUPPLEMENTAL BRIEF FOR APPELLANT APPLE INC.

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INTRODUCTION

The ITC’s November 14, 2025 institution of a new proceeding should not delay this Court’s pending decision. Having obtained remedial orders based on a “domestic industry” that did not exist when the complaint was filed, Masimo is now urging the ITC to apply its unsupported exclusion order to further limit how Apple Watch can be sold in the United States—all to “protect” an item (Masimo’s W1 Watch) launched post complaint for which there have been only *de minimis* sales in the four years since the case began, and which is no longer sold to consumers.

Apple respectfully submits that the new proceeding reinforces the need for this Court to vacate the exclusion order and reverse the underlying finding of a violation, or, at a minimum, vacate and remand to assess issues like domestic industry and invalidity through symmetrical, even-handed analyses—rather than wrongly watering down requirements for complainants (like Masimo) and heightening them for respondents (like Apple). The Supreme Court has emphasized the importance of courts correcting agency departures from statutory mandates, *Loper Bright Enterprises v. Raimondo*, 144 S. Ct. 2244, 2266 (2024), as has happened here.

I. PROCEDURAL HISTORY

A. The ITC Bars Importation Of Apple Watch With Blood Oxygen

The ITC instituted the investigation that is the subject of this appeal on August

18, 2021, based on allegations that Apple Watch infringed over 100 claims of five Masimo patents. Apple Opening Br. 16; Appx3703. On October 26, 2023, the ITC issued its Final Determination finding that (1) certain Apple Watch products infringed two claims of U.S. Patent No. 10,912,502 (“’502 patent”) and three claims of U.S. Patent No. 10,945,648 (“’648 patent”) and (2) a domestic industry had been established as of the complaint’s filing in mid-2021. Apple Opening Br. 18. The ITC based its domestic-industry finding on early prototypes of a Masimo watch. *See* Apple Opening Br. 31-40. Notably, the ITC relied on *different* prototypes for its technical prong and economic prong analyses. Specifically, its finding that Masimo had committed the requisite labor and capital to satisfy the economic prong was based on expenditures for items that *did not practice* the two patents found to be valid and infringed. *See* Apple Opening Br. 39.

B. Apple Seeks Approval From The Exclusion Order Enforcement Branch To Import Redesigned Watch Without Blood Oxygen

To avoid a complete ban on the importation of Apple Watch based on a single feature, Apple sought federal approval for a redesign that disabled the blood oxygen functionality (“Redesign 1 Watch”). *See* C.A. Dkt. 6 at 8 (Dec. 26, 2023) (Apple’s emergency stay motion). The Exclusion Order Enforcement (“EOE”) Branch of Customs and Border Protection held an *inter partes* proceeding in which Masimo received discovery and the full ability to present arguments to the EOE. As part of that proceeding, Masimo used “jailbreaking” software to try to reconfigure Redesign

1 Watch (inconsistent with how the device would ship to consumers), in an attempt to force it to measure blood oxygen. In that proceeding, Masimo emphasized that all asserted claims are “Limited To *Watch* Hardware and Software,” as shown on the below slide that Masimo presented at an EOE hearing on December 28, 2023:

All Claims Limited to *Watch* Hardware and Software

'502 Patent Claim 22	'648 Patent Claim 12	'648 Patent Claims 24 and 30
[19 Preamble] 19. A user-worn device ...:	[8 Preamble] 8. A user-worn device ...:	[20 Preamble] 20. A user-worn device ...:
[19A] a plurality of emitters ...;	[8A] a first set of [LEDs] ...;	[20A] a plurality of light emitting diodes (LEDs);
[19B] four photodiodes ...;	[8B] a second set of LEDs ...;	[20B] at least four photodiodes ...;
[19C] a protrusion comprising a convex surface including separate openings ...;	[8C] four photodiodes;	[20C] a protrusion comprising a convex surface and
[19D] optically transparent material within each of the openings; and	[8D] a protrusion comprising a convex surface ...;	[20D] a plurality of through holes ...; and
[19E] one or more processors ...	[8E] a plurality of openings ...;	[20E] one or more processors ...
[20] 20. The user-worn device of claim 19 further comprising a thermistor.	[8F] a separate optically transparent window ...;	[24] 24. The user-worn device of claim 20, wherein the protrusion comprises opaque material ...
[21] 21. The user-worn device of claim 20, wherein the one or more processors ...	[8G] one or more processors ...;	[30] 30. The user-worn device of claim 20, wherein the protrusion further comprises one or more chamfered edges.
[22] 22. The user-worn device of claim 21, wherein the plurality of emitters ...	[8H] a housing; and	
	[8I] a strap ...	
	[12] 12. The user-worn device of Claim 8, wherein the physiological parameter comprises oxygen or oxygen saturation.	



Attachment 1 (Madisetti Decl.) at ¶¶ 41-42;
Masimo Resp. at 4; Masimo Sur-Reply at 7

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On January 12, 2024, the EOE issued a ruling finding that the Redesign 1 “do[es] not infringe any of the asserted patent claims” and “is not subject to the LEO issued as a result of Inv. No. 337-TA-1276.” CBP HQ Ruling H335304 at 29 (Jan. 12, 2024). Apple was accordingly permitted to import Apple Watches without blood-oxygen functionality, a ruling that Masimo brought to this Court’s attention as part of its successful argument against Apple’s motion for a stay pending appeal. C.A. Dkt. 29 (notice of supplemental authority); C.A. Dkt. 33 (order).

C. Apple Seeks The EOE’s Approval To Import A Second Redesigned Watch And—When Denied—Attempts To Establish A Challenge In The Court of International Trade

In March 2024, Apple sought approval from the EOE for a second redesign (“Redesign 2 Watch”). Like Redesign 1, the Redesign 2 Watch cannot measure a user’s blood oxygen. But the Redesign 2 Watch can be used with a separate iPhone so that the *iPhone* processes PPG data and calculates and displays a blood-oxygen measurement. Apple submitted that this *combination* of devices could not infringe any of the five patent claims underlying the LEO because each of those claims recites a single, user-worn device—not a system of multiple devices—as Masimo itself had emphasized in opposing Redesign 1 before the EOE. After another *inter partes* proceeding—in which Masimo again participated fully—the EOE issued a ruling in January 2025 that found the Redesign 2 Watch in combination with a paired iPhone would infringe claim 22 of the ’502 patent and claims 12, 24, and 30 of the ’648 patent. CBP HQ Ruling H338254 at 61 (Jan. 7, 2025). As a result, Apple did not import Redesign 2 Watches at that time.

The EOE’s decisions regarding redesigns are not directly appealable, *Funai Elec. Co. v. United States*, 645 F. Supp. 2d 1351, 1355 (Ct. Int’l Trade 2009), and accordingly, Apple started the process of establishing jurisdiction for a Court of International Trade (“CIT”) proceeding, which would require the CIT to review the EOE’s ruling regarding patent infringement. Because CIT jurisdiction depends on a seizure of subject goods, *see* 28 U.S.C. § 1581, Apple informed the EOE that Apple intended to import a small set of Redesign 2 Watches. Apple’s expectation was that

the Redesign 2 Watches would be seized, and that Apple could then file a CIT complaint challenging the seizure—and thus the underlying EOE ruling. In apprising the EOE of its intent to import Redesign 2 Watches, Apple made no substantive arguments whatsoever—its communications with the EOE were wholly logistical, e.g., identifying the time and place of the importations.

D. The EOE Reconsiders Its Decision Regarding Second Redesign, And Masimo Files Suit In District Of Columbia

On August 1, 2025, the EOE issued an internal advice ruling finding that Redesign 2 Watch itself is *not* subject to the LEO and may be imported. CBP HQ Ruling H351038 at 21 (Aug. 1, 2025). Based on that ruling, Apple issued an over-the-air software update that allowed consumers who purchased Apple Watches after the LEO went into effect to update their Watches to the Redesign 2 configuration and measure blood oxygen on their paired iPhones. Since then, Apple has imported and sold Redesign 2 Watches.

On August 20, 2025, Masimo sued the EOE (but not Apple) in D.C. District Court, challenging the EOE's August 2025 ruling under the Administrative Procedure Act. *See* Complaint, *Masimo Corp. v. U.S. Customs & Border Prot.*, No. 25-cv-02749 ECF No. 1 (D.D.C. Aug. 20, 2025). The ITC subsequently intervened. During those proceedings, the ITC's counsel asserted that the proper way for Masimo to challenge the admissibility of Redesign 2 Watches was to request an adjudicative proceeding before the ITC. Masimo proceeded to file a modification

proceeding requesting that the ITC modify the LEO under this Court’s review by adding a statement that the order covers Redesign 2 Watches and any redesigns that distribute blood oxygen measuring functionality between an Apple Watch and an iPhone.

E. The ITC Institutes New Proceedings

On November 14, 2025, the ITC initiated a modification proceeding and, *sua sponte*, enforcement proceeding. *See* Order Instituting A Combined Modification and Enforcement Proceeding, *Certain Light-Based Physiological Measurement Devices and Components Thereof*, Inv. No. 337-TA-1276, USITC Pub. 863645 (Nov. 14, 2025). The ITC agreed to consider Masimo’s new argument that the combination of a Watch and an iPhone together infringed the claims, which call for “a user worn device” configured to measure oxygen saturation of a user. *Id.* at 4. The ITC, however, declined Apple’s request to consider whether Masimo still had any domestic industry that could conceivably support the new proceeding—declining notwithstanding that the existence of a domestic industry is a continuing requirement for the ITC’s 337 jurisdiction. *Id.* at 5.

II. THE NEW PROCEEDING ONLY UNDERScores THE NEED TO REVERSE OR REMAND FOR CONSISTENT, EVEN-HANDED ANALYSIS¹

A. Domestic Industry

¹ This Court should remand for all the reasons set forth by Apple in this appeal. Apple addresses below the two most directly related to the new proceeding.

Although the newly instituted proceeding could expand the scope of the existing LEO, the ITC has refused to reconsider whether Masimo established a domestic industry—either at the time of the complaint, or as of now. The Commission’s refusal is troubling, both because of the fundamental legal deficiencies in Masimo’s domestic industry case that are presently before this Court (discussed below), and because Masimo has now all but abandoned even its alleged domestic industry. As Apple has explained, Masimo has never sold its alleged domestic industry product in any more than *de minimis* quantities. Apple Reply Br. 2. And the *day after the oral argument in this appeal*, Masimo announced that it would no longer sell its W1 device (whose prototypes the Commission had relied upon) directly to consumers.² The ITC’s decision to ignore the economic reality—that there is no domestic industry to “protect” here—while it contemplates expanding its exclusion orders is inexplicable and inconsistent with its statutory mandate.

To be clear, Masimo *never* established a proper domestic industry because it failed to identify a specific “article” that satisfied *both* the technical and economic prongs as of the time the complaint was filed. The Commission’s technical prong

² *Consumer Product Support & Warranty*, www.masimo.com/contact-support/support/consumer-product-support-warranty/ [perma.cc/9CAG-9RXE] (last visited Dec. 9, 2025) (“Please note that all Masimo consumer products have been discontinued. These include: ... Masimo W1® Sport Watch”).

findings relied on five early prototypes that it found to be patent practicing. Yet in calculating the amount of Masimo's expenditures for the economic prong, the ITC improperly swept in expenditures related to two *additional* prototype devices that Masimo admitted do not practice the Asserted Patents. Apple Br. 37-40. As Apple has explained, that lack of symmetry between the two prongs is inconsistent with the language and structure of Section 337, which requires both an industry "relating to the articles protected by the patent" under 19 U.S.C. § 1337(a)(2) *and* that there be "significant" or "substantial" investment "with respect to" those same articles under § 1337(a)(3). Apple Opening Br. 24, 26. The lack of symmetry thus departs from the ITC's statutory mandate, and also conflicts with this Court's ruling in *Zircon Corp. v. ITC*, 101 F.4th 817, 823-824 (Fed. Cir. 2024), requiring economic prong evidence to "pertain to products that are covered by the [asserted] patent."

Masimo itself conceded during oral argument *no* prior decision of this Court has approved of the asymmetrical domestic industry theory the Commission applied. Oral Arg. Recording at 28:17. While the Commission's attorney (for the first time) relied on *Motorola Mobility, LLC v. ITC*, 737 F.3d 1345 (Fed. Cir. 2013) during oral argument, that case is inapposite. Indeed, Masimo did not cite *Motorola* in its briefing and for good reason—it actually supports Apple's position.

In *Motorola*, the Commission had expressly "*rejected* the assertion that [the complainant] was relying on separate products for the technical and economic

prongs.” 737 F.3d at 1351. Rather, this Court considered whether the economic prong was satisfied by evidence of investment in a “significant component[]” of the product that was “specifically tailored for use in an article protected by the patent.” *Id.* Put simply, *Motorola* was a case where there *was symmetry* between the economic and technical prongs because all expenditures were attributable to components of the patent-practicing article. *Id.* Here, unlike *Motorola*, the ITC found the technical prong satisfied based on one set of five prototypes, but undisputedly relied on a *different*, larger set of “articles” for the economic prong: those five prototypes, plus two other non-practicing models. Apple Br. 37-40.

That the Commission has launched a new investigation despite these basic defects in its domestic industry ruling underscores the need to vacate the LEO and require the Commission to comply with the statute.

B. Invalidity

During the investigation on appeal, Apple presented evidence showing that the asserted claims requiring “a user-worn device” configured to measure oxygen saturation would have been obvious over Lumidigm (Appx70389-70423). Apple Opening Br. 45-54; Apple Reply Br. 18-26. Notably, Lumidigm expressly disclosed a “wristwatch” embodiment with a “biometric reader,” Appx70402, Appx70414, and specifically taught using the biometric sensor to measure “oxygenation and/or hemoglobin levels in the blood,” Appx70417-70418, Apple Opening Br. 48-49.

Lumidigm also disclosed other embodiments using the same biometric reader, including “*a cellular telephone*,” “*a PDA* [personal data assistant],” and “*a combined cellular telephone/PDA*.” Appx70403; Appx70417.

The Commission (erroneously) found that Lumidigm did not invalidate the asserted claims because Lumidigm did not enable measuring blood oxygen specifically in the *wristwatch* embodiment. The Commission reached that conclusion even though the Masimo patents themselves did nothing more to enable wrist-based pulse oximetry—*the Masimo patents have no disclosure of a watch or wrist-based pulse oximetry*. Apple Br. 45-48; Apple Reply 19-22. Thus, just as the ITC inconsistently analyzed the two prongs of domestic industry, the ITC applied inconsistent standards of enablement to the prior art and to Masimo’s patents.

The new proceeding only invites additional inconsistency. Now the Commission is being asked to decide that an iPhone plus Apple Watch combination is “a user-worn device.” That conclusion would require ignoring the language of the claims themselves, the Commission’s prior reasoning regarding what makes a device “user-worn,” and Masimo’s own arguments about claim scope. *See, e.g., supra* p. 3 (Masimo arguing that “All Claims Limited to *Watch* Hardware and Software” (emphasis in original)). Allowing Masimo to rewrite claim scope to cover a phone/watch combination would only reinforce the inequity of holding the prior art to a different (and stricter) standard than Masimo’s asserted patents.

Respectfully submitted,

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The foregoing filing complies with the relevant type-volume limitation of the Federal Rules of Appellate Procedure, Federal Circuit Rules, and this Court's Order (ECF No. 102) because:

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