

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of

**CERTAIN LIGHT-BASED
 PHYSIOLOGICAL MEASUREMENT
 DEVICES AND COMPONENTS
 THEREOF**

**Investigation No. 337-TA-1276
 (Modification/Enforcement)**

**ORDER INSTITUTING A COMBINED MODIFICATION AND ENFORCEMENT
 PROCEEDING**

On August 18, 2021, the Commission instituted the underlying investigation under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, based on a complaint filed on behalf of Masimo Corporation (“Masimo”) and Cercacor Laboratories, Inc., both of Irvine, California. 86 FR 46275 (Aug. 18, 2021). The complaint, as amended, alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain light-based physiological measurement devices and components thereof by reason of infringement of certain claims of U.S. Patent No. 10,912,501 (“the ’501 patent”); U.S. Patent No. 10,912,502 (“the ’502 patent”); U.S. Patent No. 10,945,648 (“the ’648 patent”); U.S. Patent No. 10,687,745 (“the ’745 patent”); and U.S. Patent No. 7,761,127 (“the ’127 patent”). *Id.* The amended complaint further alleged that an industry in the United States exists and/or is in the process of being established as required by section 337. *Id.* The notice of investigation named Apple Inc. of Cupertino, California (“Apple”) as the sole respondent. *Id.* at 46276. The Office of Unfair Import Investigations did not participate in this investigation. *Id.*

Before the presiding administrative law judge (“ALJ”) issued the final initial determination (“Final ID”), Complainants withdrew from the investigation certain asserted patent claims. *See* Order No. 25 (Mar. 23, 2022), *unreviewed* by Comm’n Notice (Apr. 12, 2022); Order No. 33 (May 20, 2022), *unreviewed* by Comm’n Notice (June 10, 2022). At the time of the Final ID, only claim 12 of the ’501 patent, claims 22 and 28 of the ’502 patent, claims 12, 24, and 30 of the ’648 patent, claims 9, 18, and 27 of the ’745 patent, and claim 9 of the ’127 patent remained in the investigation. Claim 18 of the ’745 patent remained at issue for purposes of the domestic industry only.

On January 10, 2023, the ALJ issued the Final ID, which found that Apple violated section 337 as to claims 24 and 30 of the ’648 patent, but not as to claim 12 of the ’501 patent, claims 22 and 28 of the ’502 patent, claim 12 of the ’648 patent, claims 9 and 27 of the ’745 patent, and claim 9 of the ’127 patent. *See* Final ID at 335–36.

On May 15, 2023, the Commission determined to review the Final ID in part. *See* 88 FR 32243, 32243–46 (May 19, 2023). The Commission requested briefing on certain issues under review and on remedy, the public interest, and bonding. *See id.*

On October 26, 2023, the Commission issued its final determination in this investigation, finding Apple in violation of section 337 as to claims 22 and 28 of the '502 patent and claims 12, 24, and 30 of the '648 patent. 88 FR 75032, 75032–33 (Nov. 1, 2023). The Commission issued: (1) a limited exclusion order (“LEO”) prohibiting the importation of light-based physiological measurement devices and components thereof that infringe one or more of claims 22 and 28 of the '502 patent and claims 12, 24, and 30 of the '648 patent; and (2) a cease and desist order (“CDO”) directed to Apple. *Id.* The Commission determined that the public interest factors did not preclude issuance of the limited exclusion order or the cease and desist order. *Id.* The Commission further determined that no bond was to be required during the period of Presidential review. *See id.*; 19 U.S.C. § 1337(j)(3).

On September 8, 2025, Masimo filed a petition with the Commission, pursuant to Commission Rule 210.76, requesting clarification of, or in the alternative, a modification proceeding to modify, the remedial orders issued against Apple. *See* Complainant Masimo’s Request for Clarification, or in the Alternative, Petition for Modification and Request for Expedited Treatment. Masimo also requested expedited treatment of its petition. *Id.* On September 15, 2025, Apple filed a response to Masimo’s petition, including objecting to the use of a modification proceeding under section 337(k) in this situation. *See* Respondent Apple Inc.’s Response to Masimo’s Request for Clarification, or in the Alternative, Petition for Modification and Request for Expedited Treatment. The Commission shortened the time for Apple to file its response. *See* Letter from Commission Secretary Barton to Counsel for Apple and Masimo, September 9, 2025. On September 22, 2025, Masimo and Apple provided a list of undisputed facts, disputed facts, and claim constructions at issue. Joint Proposed List of Undisputed Facts, Disputed Facts, and Disputed Claim Terms For September 22, 2025 Submission (“Joint Submission”).

The Commission, having reviewed the record in this investigation, including Masimo’s petition, Apple’s response thereto, and their Joint Submission, has determined to institute a combined modification and enforcement proceeding. Section 337(k)(1) provides for modification proceedings when “the conditions which led to such exclusion from entry or order no longer exist.” 19 U.S.C. § 1337(k)(1). Commission Rule 210.76 implements the Commission’s modification proceedings and provides, in pertinent part: “Whenever any person believes that changed conditions of fact or law, or the public interest, require that [a remedial order] be modified or set aside, in whole or in part, such person may request . . . that the Commission make a determination that the conditions which led to the issuance of [the remedial order] no longer exist.” 19 C.F.R. § 210.76(a)(1). Rule 210.76 further states that the request “shall include materials and argument in support thereof.” *Id.* Section 337(b) provides the Commission with the authority to enforce its remedial orders, and Commission Rule 210.75 implements the Commission’s enforcement proceedings. *See VastFame Camera, Ltd. v. Int’l Trade Comm’n*, 386 F.3d 1108, 1115 (Fed. Cir. 2004).

The Commission has determined that Masimo’s petition complies with section 337(b), section 337(k)(1), and Commission Rules 210.75 and 210.76. The Commission finds that the circumstances which lead to the LEO no longer exist and there is a changed condition of fact, inasmuch as Apple has presented a newly redesigned watch, the Apple Redesign 2 Watch, which

was not presented during the investigation below.¹ The Commission further finds that Masimo's modification petition is tantamount to a request for an enforcement of the LEO because it alleges a violation of the LEO. *See* 19 C.F.R. § 210.75(a). Accordingly, the Commission has determined that a combined modification and enforcement proceeding is proper to determine the narrow issue of whether the Apple Redesign 2 Watch should be excluded under the current terms of the LEO. The Commission notes that Masimo has not sought to enforce the CDO or to seek civil penalties. Accordingly, the Commission will not consider whether to issue civil penalties for any violation of the CDO in this proceeding, but may do so, upon request, in a subsequent proceeding.

To further define the issues, the Commission finds, as an initial matter, that the Apple Redesign 2 Watch on its own is a "wearable electronic device" with at least some "light-based pulse oximetry functionality" pursuant to paragraph 2 of the LEO, and as such, it is potentially subject to the terms of the LEO. *See* Joint Submission, ¶ 47; *Certain Light-Based Physiological Measurement Devices & Components Thereof*, Ruling Letter, Inv. No. 337-TA-1276, HQ H338254 at 13 (Jan. 7, 2025). The Commission further finds that Apple manufactured and imported into the United States the Apple Redesign 2 Watch. LEO, paragraph 1; Joint Submission, paragraphs 46, 47. Accordingly, the sole issue to be resolved in this proceeding is whether the Apple Redesign 2 Watch "infringe[s] claims 22 ... of U.S. Patent No. 10,912,502 and claims 12, 24, and 30 of U.S. Patent No. 10,945,648." LEO, paragraph 1. The Commission has held that the term "infringe" as used in the Commission's LEOs is not limited to direct infringement but may also refer to, *inter alia*, induced infringement under 35 U.S.C. § 271(b). *See e.g., Certain Voltage Regulators, Components Thereof and Products Containing Same*, Inv. No. 337-TA-564, Enforcement Comm'n Op., 2010 WL 4780068 at *4 (Aug. 3, 2010). Finally, the Commission notes that Masimo does not seek a determination of whether the Apple iPhone or the "Apple Redesign 1 Watch," *see* Joint Submission ¶¶ 26-31 (undisputed facts), should be excluded pursuant to the LEO, nor does Masimo seek a determination of whether any article infringes claim 28 of the '502 patent.

Accordingly, upon consideration of the record and the submissions in this matter, the Commission hereby ORDERS that:

1. Pursuant to Commission Rule 210.76(a), 19 C.F.R. § 210.76(a), and section 337(k)(1), Masimo's requested modification proceeding is INSTITUTED.
2. Pursuant to Commission Rule 210.75(a), 19 C.F.R. § 210.75(a), an enforcement proceeding is INSTITUTED and consolidated with the modification proceeding.

¹ This proceeding includes the Apple Redesign 2 Watch presented to CBP, Joint Submission ¶ 32 (undisputed fact), and Apple Watches subject to a recent over-the-air software update in the United States, *id.* ¶¶ 46-48, 117-118, which collectively are the "Apple Redesign Watch 2." To the extent that there are any differences between the watches presented to CBP and the watches that have been subject to a recent over-the-air update, the ALJ can address those differences in the first instance. Moreover, to the extent that the allegedly infringing functionality requires a software update to an iPhone, it is assumed for this investigation that such an update has been applied. *Id.* ¶¶ 46, 116-117.

3. For purposes of the modification and enforcement proceeding so instituted, the following are named as parties:
 - a. The complainant is Masimo Corporation of Irvine, California.
 - b. The respondent is Apple Inc. of Cupertino, California.
4. The combined modification and enforcement proceeding is hereby certified to the Chief Administrative Law Judge for designation of a presiding Administrative Law Judge (“ALJ”) who will administer the appropriate proceedings and issue a combined recommended determination on modification and enforcement initial determination (“EID”). Regardless of any Commission Rule to the contrary, including Rule 210.51(a), which is waived to expedite this proceeding, the ALJ, within fifteen (15) days of institution, is directed to set the earliest practicable target date for completion of the proceeding, but the target date shall be no later than six (6) months from institution. Pursuant to Commission Rule 210.75(a)(3), such target date is to exceed the date of issuance of the EID by two (2) months.
5. The presiding ALJ has discretion to conduct any proceedings deemed necessary, including issuing a protective order, holding hearings, taking evidence, and ordering discovery consistent with Commission rules to issue the EID.
6. The EID shall rule on the following questions, including the subsidiary claim construction issues presented by Masimo’s petition, Apple’s response thereto, and their Joint Submission:
 - a. Whether Apple directly infringes the claims recited in the LEO, including claim 22 of the ’502 patent, by importing and/or selling the Apple Redesign 2 Watch alone, including under the doctrine of equivalents; and
 - b. Whether Apple induces infringement of the claims recited in the LEO by importing and/or selling the Apple Redesign 2 Watch, including, inter alia, whether there is an underlying act of direct infringement by the Apple Redesign 2 Watch and iPhone once paired in the United States.
7. With respect to point 6a, Masimo shall advise the presiding ALJ as to whether Masimo alleges that the Apple Redesign 2 Watch alone directly infringes claims 12, 24, and 30 of the ’648 patent. If those claims are not alleged, Masimo shall confirm to the presiding ALJ that adjudication of claim 22 of the ’502 patent is sufficient to determine whether the Apple Redesign 2 Watch violates the LEO. The Commission understands that Masimo does not allege claim 28 of the ’502 patent for purposes of direct or indirect infringement against the Redesign 2 Watch, and Masimo shall confirm to the presiding ALJ that claim 28, therefore, does not preclude Apple from importing the Redesign 2 Watch.
8. Principles of claim preclusion and issue preclusion, and other doctrines that prevent litigation or relitigation of matters that were, or should have, been litigated in earlier stages of Commission proceedings will apply in this

investigation. By way of example, Masimo's domestic industry has already been litigated, and is not subject to relitigation in this proceeding. Apple may present defenses that relate to the infringement questions in point 6, including Masimo's allegedly expanded claim constructions, so as to ensure, for example, that validity aligns within infringement. This proceeding does not afford an opportunity to relitigate other defenses that were, or should have been, litigated in the underlying violation investigation. The EID shall rule on such defenses to the extent they are properly raised.

9. The presiding ALJ shall not recommend enforcement measures.
10. Regardless of any Commission Rule to the contrary, including Rules 210.75(a)(3) and 210.76(c), which are waived to expedite this proceeding, petitions for review of the EID may be filed within seven (7) days after service of the EID. Responses to any petitions for review may be filed within five (5) business days after service of the petitions. The Commission finds that good and sufficient reason exists to waive its rules and expedite this proceeding as requested by Masimo, and as recognized by the Honorable Judge Reyes of the U.S. District Court for the District of Columbia during hearings on August 29, 2025 and September 25, 2025, regarding the need for prompt relief in view of concerns that CBP rulings from January 2025 and August 2025 may be in tension. *See* 19 C.F.R. § 201.4(b). For the same reasons, the Commission delegates its authority under Rule 201.4(b) to the ALJ to waive rules pertaining to the timing of party filings and responses in order to expedite proceedings, should the ALJ explain the good and sufficient reason for such waiver.
11. Further, the EID shall become the Commission's final determination on violation thirty (30) days after service of the EID, unless the Commission orders review of the EID or changes the deadline for determining whether to review the EID.
12. The Secretary shall:
 - a. serve a copy of this order upon each party to this proceeding; and
 - b. publish notice of this order in the Federal Register.

By order of the Commission.



Lisa R. Barton
Secretary to the Commission

Issued: November 14, 2025