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**

NOTICE OF THE COMMISSION'S FINAL DETERMINATION FINDING A VIOLATION OF SECTION 337; ISSUANCE OF A LIMITED EXCLUSION ORDER AND A CEASE AND DESIST ORDER; TERMINATION OF THE INVESTIGATION

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has found a violation of section 337 in the above-captioned investigation. The Commission has determined to issue: (1) a limited exclusion order ("LEO") prohibiting the unlicensed entry of infringing wearable electronic devices with light-based pulse oximetry functionality and components thereof covered by certain claims of U.S. Patent Nos. 10,912,502 or 10,945,648 that are manufactured by or on behalf of, or imported by or on behalf of, respondent Apple, Inc. ("Apple") or any of its affiliated companies, parents, subsidiaries, or other related business entities, or its successors or assigns; and (2) a cease and desist order ("CDO") directed against Apple and any of its affiliated companies, parents, subsidiaries, or other related business entities, or its successors or assigns. This investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Ronald A. Traud, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street S.W., Washington, D.C. 20436, telephone (202) 205-3427. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at https://edis.usitc.gov. For help accessing EDIS, please email EDIS3Help@usitc.gov. General information concerning the Commission may also be obtained by accessing its Internet server at https://www.usitc.gov. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on August 18, 2021, based on a complaint filed on behalf of Masimo Corporation and Cercacor Laboratories, Inc., both of Irvine, CA (collectively, "Complainants"). 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

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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 of Cupertino, California as the sole respondent. *Id*. at 46276. The Office of Unfair Import Investigations is not participating in this investigation. *Id*.

Complainants previously withdrew certain asserted claims pursuant to Order No. 25 (Mar. 23, 2022), *unreviewed* by Comm'n Notice (Apr. 12, 2022), and Order No. 33 (May 20, 2022), *unreviewed* by Comm'n Notice (June 10, 2022). 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 remain in the investigation. Claim 18 of the '745 patent is still at issue for purposes of the domestic industry only.

On January 10, 2023, the presiding administrative law judge ("ALJ") issued the final initial determination ("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 January 24, 2023, the ALJ issued a Recommended Determination on remedy and bonding ("RD") should a violation be found in the above-captioned investigation. The RD recommended that, if the Commission finds a violation, it should issue an LEO directed to certain wearable electronic devices with light-based pulse oximetry functionality and components thereof that are imported, sold for importation, and/or sold after importation by Apple; and a CDO directed to Apple. RD at 2, 5. The RD additionally recommended that the Commission set a zero percent (0%) bond (*i.e*., no bond) during the sixty-day period of Presidential review. *Id*. at 6. In its notice instituting this investigation, the Commission did not instruct the ALJ to make findings and recommendations concerning the public interest. *See* 86 FR at 46275–76.

On January 23, 2023, Complainants and Apple each filed a petition for review. On January 31, 2023, Complainants and Apple each filed responses to the other party's petitions.

On February 23, 2023, the parties filed their public interest statements pursuant to 19 CFR 210.50(a)(4). The Commission received numerous comments on the public interest from non-parties.

On May 15, 2023, after considering the parties' petitions and responses thereto, the Commission determined to review the Final ID in part. *See* 88 FR 32243, 32243–46 (May 19, 2023). In particular, the Commission determined to review the following findings of the Final ID:

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(1) the domestic industry with regard to the '501 patent, the '502 patent, the '648 patent, and the '745 patent;

(2) obviousness with regard to the '501 patent, the '502 patent, the '648 patent, and the '745 patent;

(3) written description with regard to claim 28 of the '502 patent and claim 12 of the '648 patent;

(4) claim construction and infringement with regard to the '745 patent; and

(5) subject matter jurisdiction.

Id. The Commission requested briefing on certain issues under review and on remedy, the public interest, and bonding. *See id*.

On June 5, 2023, the parties filed their written submissions on the issues under review and on remedy, public interest, and bonding, and on June 12, 2023, the parties filed their reply submissions. The Commission also received numerous comments on the public interest from non-parties.

Having reviewed the record in this investigation, including the written submissions of the parties, the Commission affirms with modifications the Final ID's domestic industry findings (both economic and technical prong) as to the '501, '502, '648, and '745 patents. The Commission additionally affirms with modifications the Final ID's conclusion that the asserted claims of the '501 patent are obvious, but the asserted claims of the '502, '648, and '745 patents are not obvious. The Commission has determined to reverse the Final ID's finding that Apple proved by clear and convincing evidence that claim 28 of the '502 patent and claim 12 of the '648 patent are invalid for lack of written description. Furthermore, the Commission affirms the Final ID's claim construction related to the recited term "first shape" and the related conclusion that the Accused Products do not satisfy elements [1B] and [20B] of the '745 patent. The Commission additionally vacates the Final ID's finding that the Commission has subject matter jurisdiction over the investigation and instead finds that the Commission has statutory authority over the investigation. The Commission affirms the remainder of the Final ID that is not inconsistent with the Commission's opinion issued concurrently herewith. As a result, the Commission finds that Apple has violated section 337 as to claims 22 and 28 of the '502 patent and claims 12, 24, and 30 of the '648 patent.

The Commission has determined that the appropriate form of relief is an LEO prohibiting (1) the unlicensed entry of infringing wearable electronic devices with light-based pulse oximetry functionality and components thereof manufactured by or on behalf of Apple or any of its affiliated companies, parents, subsidiaries, or other related business entities, or its successors or assigns. The Commission has also determined to issue a CDO against Apple. The Commission has determined to include an exemption to the remedial orders for service or repair

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or, under warranty terms, replacement of products purchased prior to the end of the period of Presidential review.

The Commission has further determined that the public interest factors enumerated in subsections (d)(l) and (f)(1) (19 U.S.C. 1337(d)(l), (f)(1)) do not preclude issuance of the above-referenced remedial orders. Additionally, the Commission has determined to impose a bond of zero (0%) (*i.e.*, no bond) of entered value of the covered products during the period of Presidential review (19 U.S.C. 1337(j)). This investigation is terminated.

The Commission vote for this determination took place on October 26, 2023.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR Part 210).

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: October 26, 2023

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