UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of	
CERTAIN LIGHT-BASED PHYSIOLOGICAL MEASUREMENT DEVICES AND COMPONENTS THEREOF	**Inv. No. 337-TA-1276**

NOTICE OF A COMMISSION DETERMINATION TO REVIEW IN PART A FINAL INITIAL DETERMINATION; REQUEST FOR WRITTEN SUBMISSIONS ON THE ISSUES UNDER REVIEW AND ON REMEDY, THE PUBLIC INTEREST, AND BONDING

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission ("Commission") has determined to review in part a final initial determination ("ID") of the presiding administrative law judge ("ALJ"), finding a violation of section 337. The Commission requests written submissions from the parties on the issues under review and submissions from the parties, interested government agencies, and other interested persons on the issues of remedy, the public interest, and bonding, under the schedule set forth below.

FOR FURTHER INFORMATION CONTACT: Ron Traud, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, 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 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, CA ("Apple") as a 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 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.

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 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 a limited exclusion order 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 cease and desist order directed to Apple. RD at 2, 5. The RD found the record did not support Apple's request for an exemption for service and repair. *Id.* at 2-3. 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.

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 respective 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.

Having reviewed the record of the investigation, including the Final ID, the parties' submissions to the ALJ, and the petitions and responses thereto, the Commission has determined to review the Final ID in part. Specifically, the Commission has determined to review (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. The Commission has determined not to review the remaining findings of the Final ID, including the finding of no violation as to the '127 patent. The Commission notes that on pages 282-83 of the Final ID, in the section entitled "Element[9]: 'a thermistor,'" the ALJ refers to claim 1 as the independent claim from which claim 9 depends. The Commission understands that reference to be a typographical error and notes that the reference should be to claim 7.

In connection with its review, the Commission requests responses to the following questions. The parties are requested to brief their positions with reference to the applicable law and the existing evidentiary record.

(1) What evidence and argument was presented to the ALJ that shows that Complainants were developing, as of the filing of the Complaint, the Masimo Watch and that the Masimo Watch would practice the Poeze and '745 patent claims?

(2) Should the Commission consider evidence post-dating the Complaint, such as the final design of the Masimo Watch, to establish that Complainants were developing a physical article that would practice the Poeze patents and the '745 patent?

(3) If the Commission considers the Masimo Watch to be a domestic industry product in the process of being established for the Poeze patents and the '745 patent, what investments and activities should the Commission consider in its analysis?

(4) What should be considered as a domestic industry product for purposes of an industry in the process of being established – the Rev Sensor products, the Masimo Watch or both? What activities and investments should be considered toward satisfying the domestic industry requirement with respect to that DI product(s)? Was it appropriate to consider investments related to the Circle and Wing Sensors (assuming they are not shown to practice the Poeze patents or the '745 patent prior to the filing of the Complaint) leading to the development of the Rev Sensor products, in finding that a domestic industry exists or is in the process of being established for the Poeze and '745 patents? *See* ID at 301-24. If the Masimo Watch is a DI product for an industry in the process of being established, would it be appropriate to consider activities and investments in products (that themselves do not practice the Poeze patents prior to the filing of the Complaint) that contributed to the development of the Masimo Watch? What investments were made for the Circle sensor, Wing sensor, and Masimo Watch prior to the Complaint being filed and what investments were made after? Should the Commission consider investments made after the Complaint was filed?

(5) Should recruiting labor expenditures be considered to contribute towards the satisfaction of the economic prong?

(6) Should executive labor expenditures generally, and executive legal labor expenditures specifically, be considered to contribute towards the satisfaction of the economic prong? How closely does their work have to be connected to the domestic industry product to be included? With respect to the executive labor included in the Final ID's analysis of a domestic industry (*see* ID at 311-313), what evidence shows the extent to which the executives' work was connected to the domestic industry product?

(7) Is there a statutory basis for considering only certain types of labor expenses with respect to articles protected by the asserted patent for purposes of satisfaction of the domestic industry requirement under section 337(a)(3)(B)?

(8) Is there a legislative history or caselaw basis for considering only certain types of labor expenses with respect to articles protected by the asserted patent for purposes of satisfaction of the domestic industry requirement under section 337(a)(3)(B)?

(9) Does Figure 7B in the Poeze Patents show two emitters, each labeled 104, where each emitter has LEDs that can emit light at or about 1610 nm, about 1640 nm, and about 1665 nm? Was Complainants' argument regarding 37 CFR 1.84(p)(4) raised in front of the ALJ, and if not, can the Commission still consider the argument? Is 37 CFR 1.84(p)(4) binding authority on the Commission and does it require the Commission to presume that each emitter set 104 is identical? If so, is that disclosure in Figure 7B sufficient to convey with reasonable clarity to those skilled in the art that, as of the filing date, the inventor was in possession of two sets of LEDs each with "an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength?"

The parties are invited to brief only the discrete issues requested above. The parties are not to brief other issues on review, which are adequately presented in the parties' existing filings.

In connection with the final disposition of this investigation, the statute authorizes issuance of, *inter alia,* (1) an exclusion order that could result in the exclusion of the subject articles from entry into the United States; and/or (2) cease and desist orders that could result in the respondents being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360, USITC Pub. No. 2843, Comm'n Op. at 7-10 (Dec. 1994).

The statute requires the Commission to consider the effects of that remedy upon the public interest. The public interest factors the Commission will consider include the effect that an exclusion order and cease and desist orders would have on: (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

In addition, the Commission requests specific briefing to address the following questions relevant to the public interest considerations in this investigation, and responses are encouraged to include evidence in support of their statements:

(1) Please identify any ongoing or formally planned studies that use the blood oxygen features of the Apple Watches. Should the Commission allow an exemption or delay the effective date of any remedial relief so as to permit importation of the infringing Apple Watches for purposes of conducting such studies? Please explain the rationale and the scope of any such exemption or delay.

(2) How should the Commission define a reasonable substitute for the infringing Apple Watches?

(3) Please identify whether any reasonable substitutes for the infringing Apple Watches are available to consumers and whether they are capable of meeting any public health and welfare concerns raised by any remedial relief in this investigation. Is or would there be sufficient supply of any such reasonable substitutes for the infringing Apple Watches? Is the Masimo W1 watch a reasonable substitute and to what extent would supply of these products be available to fill the demand?

(4) Please explain how easily the infringing features of the Apple Watches could be removed and whether Apple is working on any redesigns with respect to the infringing features and how long implementation of any redesigns would take?

(5) Is there any production of like or directly competitive products in the United States and how would such production be impacted by any remedial relief?

(6) Should the Commission include an exemption for repair and/or replacement of broken products impacted pursuant to any potential remedy, and if so, should the exemption only apply under warranty? If a repair and/or replacement exemption is included, should the cutoff date for repair and replacement be the date of the Order or the date the Order becomes final within the meaning of 19 U.S.C. 1337(j)(4)? *See Certain Fitness Devices, Streaming Components Thereof, and Systems Containing Same*, Inv. No. 337-TA-1265, Comm'n Op. at 88-92 (Mar. 23, 2023) (Public Version); *Certain Robotic Floor Cleaning Devices and Components Thereof*, Inv. No. 337-TA-1252, Comm'n Op. at 76-82 (Apr. 13, 2023) (Public Version). Should the exemption apply to products imported prior to the cutoff date or only to products sold to an end user as of the cutoff date? Should the exemption cover only parts for repair, or should it permit replacement of entire units? Please cite and discuss the evidence of record relevant to whether the Commission should include a repair and/or replacement exemption.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve, disapprove, or take no action on the Commission's determination. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

WRITTEN SUBMISSIONS: The parties to the investigation are requested to file written submissions on the issues identified in this notice. Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the RD by the ALJ on remedy and bonding.

In its initial submission, Complainants are also requested to identify the remedy sought and are requested to submit proposed remedial orders for the Commission's consideration. Complainants are also requested to identify and explain, from the record, articles that it contends are "components thereof" of the subject products, and thus potentially covered by the proposed remedial orders, if imported separately from the subject products. *See* 86 FR 46275-76. Failure to provide this information may result in waiver of any remedy directed to "components thereof" the subject products, in the event any violation may be found. Complainants are further requested to provide the HTSUS subheadings under which the accused products are imported, and to supply the identification information for all known importers of the products at issue in this investigation. The initial written submissions and proposed remedial orders must be filed no later than close of business on **June 5, 2023**. Reply submissions must be filed no later than the close of business on **June 12, 2023**. No further submissions on these issues will be permitted unless otherwise ordered by the Commission. Opening submissions are limited to **100** pages. Reply submissions are limited to **50** pages. No further submissions on any of these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (March 19, 2020). Submissions should refer to the investigation number (Inv. No. 337-TA-1276) in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf*). Persons with questions regarding filing should contact the Secretary, (202) 205-2000.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. Any non-party wishing to submit comments containing confidential information must serve those comments on the parties to the investigation pursuant to the applicable Administrative Protective Order. A redacted non-confidential version of the document must also be filed with the Commission and served on any parties to the investigation within two business days of any confidential filing. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

The Commission vote for this determination took place on May 15, 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: May 15, 2023