No. 2024-1285

IN THE
United States Court of Appeals
FOR THE FEDERAL CIRCUIT

APPLE INC.,

Appellant,

v.

INTERNATIONAL TRADE COMMISSION,

Appellee,

MASIMO CORPORATION, CERCACOR LABORATORIES, INC.,
Intervenors.

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

SUPPLEMENTAL BRIEF OF INTERVENORS MASIMO CORPORATION AND CERCACOR LABORATORIES, INC.

Jonathan E. Bachand
KNOBBE, MARTENS, OLSON & BEAR, LLP
1717 Pennsylvania Avenue N.W.
Suite 900
Washington, DC 20006
(202) 640-6400

Joseph R. Re
Principal Counsel
Stephen C. Jensen
Sheila N. Swaroop
Brian C. Claassen
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street, 14th Floor
Irvine, CA 92614
(949) 760-0404

Counsel for Intervenors Masimo Corporation and Cercacor Laboratories, Inc.

December 9, 2025

CERTIFICATE OF INTEREST

Counsel for Intervenors Masimo Corporation and Cercacor Laboratories, Inc. certifies the following:

1. The full name of the parties represented by me is:

Masimo Corporation
52 Discovery
Irvine, CA 92618
Telephone: 949-297-7000

Cercacor Laboratories, Inc.
15750 Alton Pkwy
Irvine, CA 92618
Telephone: 800-610-8522

2. The name of the real party in interest represented by me is:

N/A

3. Full name of all parent corporations and all publicly held companies that own 10 percent or more of the stock of the party represented by me are:

Masimo Corporation has no parent corporation. BlackRock, Inc. owns at least 10% of Masimo Corporation's stock.

Cercacor Laboratories, Inc. has no parent corporation and no publicly held company owns at least 10% of Cercacor Laboratories, Inc's stock.

4. Other than those who have already made an appearance in this Appeal, the name of all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this Court are:

Knobbe, Martens, Olson & Bear, LLP: Ted M. Cannon, Brian C. Claassen, Irfan A. Lateef, Alan G. Laquer, Kendall M. Loebbaka, Carol Pitzel Cruz, Douglas B. Wentzel, Daniel C. Kiang, William R. Zimmerman, Karl W. Kowallis, and Matthew S. Friedrichs.

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal are as follows:

Apple Inc. v. Masimo Corp., 1:22-cv-01378 (D. Del).

6. Information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees):

None.

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: December 9, 2025 By: /s/ *Joseph R. Re*
Joseph R. Re

Counsel for Intervenors
Masimo Corporation and
Cercacor Laboratories, Inc.

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OTHER AUTHORITIES

STATEMENT OF RELATED CASES

No other appeal was ever filed in this or any other appellate court from Investigation No. 337-TA-1276 (the "Investigation"). This Court's decision in this appeal may affect *Apple Inc. v. Masimo Corp*., No. 1:22-cv-01378 (D. Del.).

In response to this Court's Order of December 1, 2025, Intervenors Masimo and Cercacor ("Masimo") maintain that the Commission's November 2025 institution of the combined modification and enforcement proceeding concerning the Apple Redesign 2 Watch ("combined proceeding") does ***not*** affect this Court's review of the Limited Exclusion Order ("LEO") currently on appeal. *See* ECF No. 102, at 2. This Court regularly conducts appeals while modification or enforcement proceedings are pending at the Commission, and nothing justifies departing from that practice here. Thus, this Court is free to affirm the LEO and the Commission's Final Determination in support thereof.

I. THIS APPEAL HAS A CLOSED RECORD WITHOUT ANY MENTION OF THE APPLE 2 REDESIGN WATCH

A. This Appeal Involves Only The One Watch Design The Commission Adjudicated

Apple appealed the Commission's Final Determination of October 26, 2023 excluding Apple Watches that infringe five claims of Masimo's U.S. Patent Nos. 10,912,502 and 10,945,648. 88 Fed. Reg.75,032, 75,033 (Nov. 1, 2023); ECF No. 1. This Court has jurisdiction over the appeal pursuant to 28 U.S.C. § 1295(a)(6). *See* ECF No. 54-1, at 1 (Apple's Jurisdictional Statement). The appeal was submitted for decision after the Court heard oral argument on July 7, 2025. Only the one adjudicated Apple Watch design is at issue on this appeal. Appx9.

B. The Combined Proceeding Concerns A Redesign That Apple First Disclosed After The Commission's Final Determination

On October 27, 2023, one day after the Commission's Final Determination, Apple asked the Exclusion Order Enforcement Branch of U.S. Customs and Border Protection ("CBP") to rule that a redesigned version of the Apple Watch, which ***disabled*** the blood oxygen feature, was not subject to the Commission's remedial orders. ECF No. 8, at 2 n.2 (Apple Emergency Motion to Stay). In January 2024, after conducting an *inter partes* proceeding, CBP permitted entry of that first redesign. That first redesign is not at issue here.

In March 2024, months after Apple filed this appeal, Apple sought approval from CBP to import a second redesigned version of Apple Watch ("Redesign 2 Watch"). Addendum, Ex. 1 (January 2025 CBP Ruling). As Apple represents in its Rule 28(j) letter prompting this supplemental brief, the Apple Redesign 2 Watch ***enables*** the blood oxygen feature by relocating some data processing from the Apple Watch to a paired iPhone. ECF No. 101, at 1. This Redesign 2 Watch contrasts with adjudicated Apple Watch, which contained all of the processing necessary to calculate or output blood oxygen values. *See, e.g.*, Appx39, 47, 52, 54 (Final Initial Determination finding no dispute on "processor" limitations).

In January 2025, CBP denied Apple's request to import the Redesign 2 Watch, finding that the combination of the Redesign 2 Watch and iPhone directly infringes and therefore should be excluded by the LEO. Addendum, Ex. 1 (January 2025 CBP

Ruling) at 61. Thereafter, Apple initiated an *ex parte* CBP proceeding, resulting in CBP issuing an Internal Advice Ruling allowing Apple to import the Redesign 2 Watch. Addendum, Ex. 2 at 18. On August 14, 2025, Apple announced it would "introduce a redesigned Blood Oxygen feature" through "an iPhone and Apple Watch software update." Addendum, Ex. 3 (Aug. 2025 Press Release). Masimo then petitioned the Commission, which instituted the combined proceeding. ECF No. 101, at 3-4. That proceeding is limited to whether the "Apple Redesign 2 Watch should be excluded under the current terms of the LEO." 90 Fed. Reg. at 51,792.

It is undisputed that Apple's Redesign 2 Watch "was not presented during the investigation" that is now the subject of this appeal. ECF No. 101, at 3-4. Thus, the Redesign 2 Watch is not before this Court.

C. The Commission's November 2025 Institution Decision Assumes This Court Will Decide This Appeal On The Adjudicated Watch

In its institution decision for the combined proceeding, the Commission confirmed: "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." *Id*. at 4-5. The Commission also confirmed that "Masimo's domestic industry has already been litigated, and is not subject to relitigation in this proceeding." *Id.* at 5. By these rulings, the Commission is clearly expecting this

Court to decide this appeal on the record from the underlying investigation concerning the adjudicated design.

The combined proceeding is governed by the parties' joint procedural schedule, and the issues to be presented there all pertain to the Redesign 2 Watch.

II. THE COMBINED PROCEEDING ON THE REDESIGN 2 WATCH DOES NOT AFFECT THIS COURT'S JURISDICTION

Section 1295(a)(6) authorizes this Court to hear appeals from final determinations of the Commission. *Realtek Semiconductor Corp. v. ITC,* 140 F.4th 1375, 1379-80 (Fed. Cir. 2025). As this Court recently explained, "final determinations under subsections (d), (e), (f) or (g) [of 19 U.S.C. § 1337] are appealable directly 'to the United States Court of Appeals for the Federal Circuit for review in accordance with chapter 7 of title 5.'" *Id.* at 1379 (quoting § 1337(c)). This Court unquestionably has jurisdiction over the present appeal. *See* ECF No. 54-1, at 1 (Apple's Jurisdictional Statement citing 28 U.S.C. § 1295(a)(6)). Indeed, in opposing Masimo's request for a modification proceeding, Apple argued that this Court had exclusive jurisdiction over this appeal such that the Commission should wait for this Court to rule before proceeding. Addendum, Ex. 4 at 9-12.

The institution of the combined enforcement and modification proceeding on the Redesign 2 Watch has no effect on this Court's jurisdiction to decide the present appeal. This Court regularly adjudicates appeals while enforcement and/or modification proceedings are pending at the Commission, and this Court has

confirmed that practice. In *In re Koki Holdings Am. Ltd.*, 830 F.App'x 320, 321-23 (Fed. Cir. Nov. 25, 2020), an accused infringer sought mandamus to halt a modification proceeding on redesigned products, arguing that the Commission lacked authority to institute those proceedings during an appeal to this Court of an exclusion order. This Court denied the mandamus petition (*id.*) and then decided the appeal. *See Koki Holdings Am., Ltd. v. ITC*, 22 F.4th 1369 (Fed. Cir. 2022). The Commission has also held that it can conduct modification proceedings during the pendency of an appeal to this Court. *See Certain Marine Sonar Imaging Devices*, 337-TA-921, Comm'n Op. at 4-6 (Aug. 29, 2016).

In *Cisco Sys., Inc. v. ITC*, Case No. 17-2289, Order at 3 (Fed. Cir. Sept. 22, 2017) (ECF No. 57), this Court referred an infringement question regarding a redesign to a modification proceeding at the Commission while maintaining jurisdiction over the appeal on the original design until the parties agreed to voluntarily dismiss. *Id.*, Order (Fed. Cir. Aug. 27, 2018) (ECF No. 121). Once the Commission decides an enforcement or modification proceeding, that decision is separately appealable to this Court. *DeLorme Publ'g Co. v. ITC*, 805 F.3d 1328, 1331 (Fed. Cir. 2015) (appeal from enforcement proceeding); *Crucible Materials Corp. v. ITC,* 127 F.3d 1057, 1060-61 (Fed. Cir. 1997) (same); *Allied Corp. v. ITC*, 850 F.2d 1573, 1580 (Fed. Cir. 1988) (appeal from modified exclusion order). Thus, as in the present case, parties can proceed on two concurrent and separate tracks: (1)

appeal a Commission final determination on an adjudicated product design and (2) proceed before the Commission in a modification and/or enforcement proceeding about a subsequent product design. And because Apple is still contesting the LEO through appeal, this Court continues to possess jurisdiction.

III. THE COMBINED PROCEEDING DOES NOT AFFECT THIS COURT'S REVIEW OF ANY ISSUE ON APPEAL

The ongoing combined proceeding, no matter how decided, cannot affect this Court's review of any of the issues currently pending in this appeal. The Commission correctly identified the following six issues on this appeal:

1. Whether substantial evidence supports the Commission's finding that Masimo created a patent-practicing article by the time the complaint was filed, thus satisfying the technical prong of the domestic industry requirement.

2. Whether substantial evidence supports the Commission's crediting of Masimo's labor investments, which are indisputably significant, thus satisfying the economic prong of the domestic industry requirement.

3. Whether substantial evidence supports the Commission's finding that Apple failed to show that the asserted claims were obvious.

4. Whether substantial evidence supports the Commission's finding that Apple failed to show that the asserted claims lacked written description support.

5. Whether the Commission properly construed the claim terms "over"/"above" and "openings"/"through holes," constructions under which Apple's products indisputably infringe.

6. Whether the Commission properly exercised its discretion in rejecting Apple's prosecution laches defense.

ECF No. 59, at 1; *see* ECF No. 54-1, at 6-7 (Apple's Statement of Issues); ECF No. 61, at 2 (Masimo's Statement of Issues). As explained, the combined proceeding at the Commission cannot affect this Court's review of any of these six issues. Indeed, the irrelevance of the combined proceeding is confirmed by Apple's Rule 28(j) letter, which fails to refer "to the page of the brief or to a point argued orally" as required by the rule.

A. The Parties Agree The Combined Proceeding Will Not Affect This Court's Review of Domestic Industry (Issues 1-2)

As explained, the Commission's institution decision confirmed that "Masimo's domestic industry has already been litigated, and is not subject to relitigation in this proceeding." ECF No. 101, at 5. As a result, the combined proceeding cannot affect this Court's review of the two domestic industry issues. Indeed, Apple agreed in its Rule 28(j) letter. *Id.* at 1. There, Apple also emphasized that "the record relating to the domestic industry requirement remains solely the record presently before this Court." *Id*.

B. The Combined Proceeding Will Not Affect This Court's Review of Apple's Failed Obviousness Defense (Issue 3)

The combined proceeding will not affect Apple's appeal of the Commission's determinations on non-obviousness, which rejected Apple's single-reference defense based on Lumidigm for two independent reasons. First, Apple asserted it

would have been obvious to modify Lumidigm's wristwatch embodiment to measure oxygen saturation. Appx118-123. The Commission rejected that defense, finding a POSITA would have been unable to modify that wristwatch embodiment to measure oxygen saturation and would not have had a reasonable expectation of success with such a modification. *Id.* Second, Apple failed to demonstrate that its asserted prior art disclosed "optically transparent material within each of the openings" and similar limitations in the asserted patents. Appx394-98, 400-402.

The disputes in the combined proceeding relate to the terms "user-worn device" and the "device comprising." Addendum, Ex. 5 (Excerpt of Sept. 22, 2025 Joint Submission to Commission) at 29. Apple is pursuing constructions of these terms because the Redesign 2 Watch relocates some processing to the paired iPhone. But these claim constructions cannot affect the obviousness arguments raised on appeal. Apple never sought any construction of "user-worn device" because the asserted prior art embodiment—Lumidigm's wristwatch—was undisputedly a "user-worn device." *See* Appx94 (Final Initial Determination, depicting Lumidigm wristwatch of Figure 8B). Similarly, Apple never sought any construction of the "device comprising" because Lumidigm's wristwatch was undisputedly a single device. *Id*. Thus, the combined proceeding will not affect this Court's review of the Commission's obviousness determination. Indeed, Masimo maintains that Apple cannot raise any obviousness defense in that proceeding.

C. The Combined Proceeding Will Not Affect This Court's Review of Apple's Failed Written-Description Defense (Issue 4)

Apple has not identified any claim term in the combined proceeding that would affect this Court's review of Apple's failed written-description defense. Apple argued that the Commission erred in finding written description support for (1) the recited combinations of features and (2) "two sets of LEDs." ECF No. 54-1, at 55-59. The Commission properly rejected that defense in view of Apple's conclusory expert testimony, finding the written description requirement was satisfied by the specification as explained by Masimo's expert. Appx419-24. Thus, the combined proceeding will not affect this Court's review of this issue.

D. The Combined Proceeding Will Not Affect This Court's Review of The Appealed Claim Constructions (Issue 5)

The parties have identified the potential for two claim construction disputes in the combined proceeding relating to the terms "user-worn device" and the "device comprising." Addendum, Ex. 5 at 29. Unsurprisingly, Apple never sought any construction of those terms or suggested the Commission misapplied those terms because every adjudicated Apple Watch was undisputedly a single "user-worn device." Instead, Apple asked this Court to review the Commission's constructions of different terms—"over"/"above" and "openings"/"through holes." *See* ECF No. 54-1, at 60-63. Accordingly, because the combined proceeding will not address

either of the two constructions on appeal, that proceeding will not affect this Court's review of the Commission's constructions of those terms.

E. The Combined Proceeding Will Not Affect This Court's Review of Apple's Failed Prosecution Laches Defense (Issue 6)

The scope of the combined proceeding prohibits re-litigation of Apple's failed prosecution laches defense. While the Commission's institution decision explained that Apple may present defenses "to ensure that validity aligns within infringement," the Commission also explained that the proceeding "does not afford an opportunity to relitigate ***other defenses*** that were, or should have been, litigated in the underlying violation investigation." ECF No. 101, at 5 (emphasis added). Thus, the combined proceeding cannot affect this Court's review of prosecution laches.

IV. CONCLUSION

The combined proceeding does not affect this Court's review of this appeal, either jurisdictionally or substantively.

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: December 9, 2025

By: /s/ *Joseph R. Re*
Joseph R. Re
Stephen C. Jensen
Sheila N. Swaroop
Jonathan E. Bachand
Brian C. Claassen

Counsel for Intervenors
Masimo Corporation and
Cercacor Laboratories, Inc.

CERTIFICATE OF COMPLIANCE

1. This Supplemental Brief complies with the 10-page limit set by this Court's Order of December 1, 2025. ECF No. 102.

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). This brief has been prepared in a proportionally spaced typeface using Microsoft Word in 14 point font Times New Roman.

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: December 9, 2025

By: /s/ *Joseph R. Re*
Joseph R. Re

Counsel for Intervenors
Masimo Corporation and
Cercacor Laboratories, Inc.

MASIMO ADDENDUM

EXHIBIT 1

U.S. Department of Homeland Security
Washington, DC 20229

U.S. Customs and Border Protection

HQ H338254

January 7, 2025

OT:RR:BSTC:EOE H338254 ACC / WMW

CATEGORY: 19 U.S.C. § 1337; Unfair Competition

Mark D. Selwyn
WilmerHale
2600 El Camino Real
Suite 400
Palo Alto, California 94306

VIA EMAIL: mark.selwyn@wilmerhale.com

RE: Ruling Request; U.S. International Trade Commission; Limited Exclusion Order; Investigation No. 337-TA-1276; Certain Light-Based Physiological Measurement Devices and Components Thereof

Dear Mr. Selwyn:

Pursuant to 19 C.F.R. Part 177, the Exclusion Order Enforcement Branch, Regulations and Rulings, U.S. Customs and Border Protection ("CBP") issues this ruling letter, based on a request from Apple Inc. ("Apple") submitted on March 26, 2024 ("Ruling Request"), holding that the articles at issue, related to certain redesigned versions of the Apple Watch, as described below, are subject to the limited exclusion order ("LEO") that the U.S. International Trade Commission ("ITC" or "Commission") issued as a result of Investigation No. 337-TA-1276 ("the 1276 investigation") under Section 337 of the Tariff of 1930, as amended, 19 U.S.C. § 1337.

We further note that determinations of the Commission resulting from the underlying investigation or a related proceeding under 19 C.F.R. Part 210 are binding authority on CBP and, in the case of conflict, will by operation of law modify or revoke any contrary CBP ruling or decision pertaining to Section 337 exclusion orders.

This ruling letter is the result of a request for an administrative ruling under 19 C.F.R. Part 177 that was conducted on an *inter partes* basis. The proceeding involved the two parties with a direct and demonstrable interest in the question presented by the Ruling Request: (1) your client, Apple, the ruling requester and respondent in the 1276 investigation; and (2) Masimo Corporation

and Cercacor Laboratories, Inc. ("Masimo"), the patent owner and complainant in the 1276 investigation. See, e.g., 19 C.F.R. § 177.1(c).

The parties were asked to identify in their submissions confidential information, including information subject to the administrative protective order in the underlying investigation, with [[red brackets]]. See 19 C.F.R. §§ 177.2, 177.8. Consistent with the above, the parties are directed to identify information in this ruling that should be bracketed in red [[ ]] because it constitutes confidential information, as defined below, such that it should be redacted from the public version of this ruling that will be published in accordance with 19 C.F.R. § 177.10. The parties are to contact the EOE Branch within ten (10) business days of the date of this ruling letter to identify such information with brackets. See, e.g., 19 C.F.R. § 177.8(a)(3).

Please note that disclosure of information related to administrative rulings under 19 C.F.R. Part 177 is governed by, for example, 6 C.F.R. Part 5, 31 C.F.R. Part 1, 19 C.F.R. Part 103, and 19 C.F.R. § 177.8(a)(3). See, e.g., 19 C.F.R. § 177.10(a). In addition, CBP is guided by the laws relating to confidentiality and disclosure, such as the Freedom of Information Act ("FOIA"), as amended (5 U.S.C. § 552), the Trade Secrets Act (18 U.S.C. § 1905), and the Privacy Act of 1974, as amended (5 U.S.C. § 552a). A request for confidential treatment of information submitted in connection with a ruling requested under 19 C.F.R. Part 177 faces a strong presumption in favor of disclosure. See, e.g., 19 C.F.R. § 177.8(a)(3). The person seeking this treatment must overcome that presumption with a request that is appropriately tailored and supported by evidence establishing that: the information in question is customarily kept private or closely-held and either that the government provided an express or implied assurance of confidentiality when the information was shared with the government or there were no express or implied indications at the time the information was submitted that the government would publicly disclose the information. See Food Marketing Institute v. Argus Leader Media, 139 S. Ct. 2356, 2366 (2019) (concluding that "[a]t least where commercial or financial information is both customarily and actually treated as private by its owner and provided to the government under an assurance of privacy, the information is 'confidential' within the meaning of exemption 4."); see also U.S. Department of Justice, Office of Information Policy (OIP): Step-by-Step Guide for Determining if Commercial or Financial Information Obtained from a Person is Confidential Under Exemption 4 of the FOIA (updated 10/7/2019); see also OIP Guidance: Exemption 4 after the Supreme Court's Ruling in Food Marketing Institute v. Argus Leader Media (updated 10/4/2019).

I. BACKGROUND

A. ITC Investigation No. 337-TA-1276

1. Procedural History At The ITC

The Commission instituted Investigation No. 337-TA-1276 on August 21, 2021, based on a complaint filed by Masimo Corporation of Irvine, California and Cercacor Laboratories, Inc. of Irvine, California. Certain Light-Based Physiological Measurement Devices and Components Thereof, Inv. No. 337-TA-1276, EDIS Doc. ID 808521, Public Commission Opinion (Nov. 14, 2023) ("Comm'n Op.") at 2 (citing 86 Fed. Reg. 46275-76 (Aug. 18, 2021)). The complaint, as supplemented, alleged a violation of section 337 by reason of infringement of certain claims of

U.S. Patent Nos. 10,945,648 ("the '648 patent"), 10,912,502 ("the '502 patent"), 10,912,501 ("the '501 patent"), 10,687,745 ("the '745 patent"), and 7,761,127 ("the '127 patent"). Comm'n Op. at 3. The notice of investigation named Apple as the sole respondent. Id. at 3. The Commission's Office of Unfair Import Investigations ("OUII") was not named as a party in the investigation. Id.

On January 10, 2023, the presiding Administrative Law Judge ("ALJ") issued a final initial determination, Certain Light-Based Physiological Measurement Devices and Components Thereof, Inv. No. 337-TA-1276, EDIS Doc. ID 1950712, Public Final Initial Determination (January 10, 2023) ("FID"), finding a violation of section 337. Id. at 4. Specifically, the ALJ determined that a violation of section 337 occurred in the importation into the United States, the sale for importation, or the sale within the United States after importation, of the accused products due to infringement of certain claims of the '648 patent. Id.

On May 15, 2023, the Commission issued a notice in which it determined to review in part the FID and requested submissions responding to the Commission's questions on review and remedy, the public interest, and bonding. Id. at 6 (citing 88 Fed. Reg. 32243-46 (May 15, 2023)). The Commission, in its review of the FID, found a violation of section 337 as to the '502, and '648 patents and determined that the appropriate remedy was a limited exclusion order directed to Apple. Id. at 54.

In the limited exclusion order, the Commission ordered that "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 are excluded from entry for consumption into the United States, entry for consumption from a foreign-trade zone, or withdrawal from a warehouse for consumption, for the remaining terms of the Asserted Patents, except under license from, or with the permission of, the patent owner or as provided by law." Certain Light-Based Physiological Measurement Devices and Components Thereof, Inv. No. 337-TA-1276, EDIS Doc. ID 2011470, Limited Exclusion Order (Oct. 26, 2023) at 2, ¶ 1 ("1276 LEO"). The Commission further defined the articles covered by the limited exclusion order as "wearable electronic devices with light-based pulse oximetry functionality and components thereof." Id. at 2, ¶ 2.

2. The Patents And Claims In The 1276 LEO

The 1276 LEO prohibits the unlicensed entry for consumption of light-based physiological 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. 1276 LEO at 2, ¶ 1. These patents share a common specification and are collectively referred to as the "Poeze patents." FID at 19-20. The Commission described these patents as covering "non-invasive physiological sensors for measuring blood constituents or analytes using multi-stream spectroscopy." Id. at 20. The "sensors use an emitter that [] uses optical radiation at different wavelengths to measure blood analytes like glucose, hemoglobin, or oxygen saturation." Id. "The sensors are connected to handheld or portable monitoring devices that can be attached to a patient's body." Id.

a. Claims 22 and 28 of the '502 Patent

The '502 patent is titled "User-Worn Device for Noninvasively Measuring a Physiological Parameter of a User . . . [and] describes non-invasive physiological sensors for measuring blood constituents or analytes using multi-stream spectroscopy.'" FID at 25 (citing '502 patent at 7:18-26) (internal quotation marks omitted). Claim 22 depends from claims 19, 20, and 21. Id. at 25. Claims 19-22 and independent claim 28 of the '502 patent are reproduced below:

> 19. A **user-worn device configured to non-invasively measure an oxygen saturation of a user**, the user-worn device comprising:
>
> a plurality of emitters configured to emit light, each of the emitters comprising at least two light emitting diodes (LEDs);
>
> four photodiodes arranged within the user-worn device and configured to receive light after at least a portion of the light has been attenuated by tissue of the user;
>
> a protrusion comprising a convex surface including separate openings extending through the protrusion and lined with opaque material, each opening positioned over a different one associated with each of the four photodiodes, the opaque material configured to reduce an amount of light reaching the photodiodes without being attenuated by the tissue;
>
> optically transparent material within each of the openings; and
>
> **one or more processors configured to** receive one or more signals from at least one of the four photodiodes and **output measurements** responsive to the one or more signals, the measurements **indicative of the oxygen saturation of the user**.
>
> 20. The user-worn device of claim 19 further comprising a thermistor.
>
> 21. The user-worn device of claim 20, wherein the one or more processors are further configured to receive a temperature signal from the thermistor and adjust operation of the user-worn device responsive to the temperature signal.
>
> 22. The user-worn device of claim 21, wherein the plurality of emitters comprise at least four emitters, and wherein each of the plurality of emitters comprises a respective set of at least three LEDs.
>
> 28. A **user-worn device configured to non-invasively measure an oxygen saturation of a user**, the user-worn device comprising:
>
> a first set of light emitting diodes (LEDs), the first set of LEDs comprising at least an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength;

a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength;

four photodiodes arranged in a quadrant configuration on an interior surface of the user-worn device and configured to receive light after at least a portion of the light as been attenuated by tissue of the user;

a thermistor configured to provide a temperature signal;

a protrusion arranged above the interior surface, the protrusion comprising:

a convex surface;

a plurality of openings in the convex surface, extending through the protrusion, and aligned with the four photodiodes, each opening defined by an opaque surface configured to reduce light piping; and

a plurality of transmissive windows, each of the transmissive windows extending across a different one of the openings;

at least one opaque wall extending between the interior surface and the protrusion, wherein at least the interior surface, the opaque wall and the protrusion form cavities, wherein the photodiodes are arranged on the interior surface within the cavities;

one or more processors configured to receive one or more signals from at least one of the photodiodes and **calculate an oxygen saturation measurement of the user**, the one or more processors further configured to receive the temperature signal;

a network interface configured to wirelessly communicate the oxygen saturation measurement to at least one of a mobile phone or an electronic network;

a **user interface** comprising a touch-screen display, wherein the user interface is **configured to display indicia responsive to the oxygen saturation measurement** of the user;

a storage device configured to at least temporarily store at least the measurement; and a strap configured to position the user-worn device on the user.

FID at 22-24; see also ’502 patent at 46:22-54 and 47:13-23 (emphasis added).

b. Claims 12, 24, and 30 of the ’648 Patent

The '648 patent is titled "User-Worn Device for Noninvasively Measuring a Physiological Parameter of a User . . . [and] describes non-invasive physiological sensors for measuring blood constituents or analytes using multi-stream spectroscopy." FID at 20 (citing '502 patent at 7:18-26) (internal quotation marks omitted). Claim 12 depends from claim 8 and claims 24 and 30 both depend from claim 20. Id. at 24. Claims 8, 12, 20, 24, and 30 of the '648 patent are reproduced below:

> 8. A user-worn device **configured to** non-invasively determine measurements of a physiological parameter of a user, the user-worn device comprising:
>
> [8A] first set of light emitting diodes (LEDs), the first set comprising at least an LED configured to emit light at a first wavelength and at least an LED configured to emit light at a second wavelength;
>
> [8B] a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength;
>
> [8C] four photodiodes;
>
> [8D] a protrusion comprising a convex surface, at least a portion of the protrusion comprising an opaque material;
>
> [8E] a plurality of openings provided through the protrusion and the convex surface, the openings aligned with the photodiodes;
>
> [8F] a separate optically transparent window extending across each of the openings;
>
> **[8G] one or more processors configured to receive one or more signals from at least one of the photodiodes and output measurements of a physiological parameter of a user**;
>
> [8H] a housing; and
>
> [8I] a strap configured to position the housing proximate tissue of the user when the device is worn.
>
> 12. The user-worn device of claim 8, **wherein the physiological parameter comprises oxygen or oxygen saturation**.
>
> 20.The user-worn device configured to non-invasively determine measurements of a user's tissue, the user-worn device comprising:
>
> [20A] a plurality of light emitting diodes (LEDs);

> [20B] at least four photodiodes configured to receive light emitted by the LEDs, the four photodiodes being arranged to capture light at different quadrants of tissue of a user;
>
> [20C] a protrusion comprising a convex surface and a plurality of through holes, each through hole including a window and arranged over a different one of the at least four photodiodes; and
>
> **[20D] one or more processors configured to receive one or more signals from at least one of the photodiodes and determine measurements of oxygen saturation of the user**.
>
> 24. The user-worn device of claim 20, wherein the protrusion comprises opaque material configured to substantially prevent light piping.
>
> 30. The user-worn device of claim 20, wherein the protrusion further comprises one or more chamfered edges.

FID 24-25; see also '648 Patent, Col. 44:51-47:7 (emphasis added).

3. The Legacy Products Found To Infringe In The Underlying Investigation

The legacy products in the underlying investigation consisted of two generations of Apple Watches (models 6 and 7), as well as certain models still in development. Comm'n Op at 14-15. The legacy products were found to practice each limitation from claims 12, 24, and 30 of the '648 patent and claims 22 and 28 of the '502 patent. Id. at 49, 52, 55. Based on the petitions received from the parties after the ALJ's FID, the Commission did not review whether the legacy products practiced the relevant claims of the '502 and '648 patents but did review whether the asserted patent claims were obvious. See Comm'n Op. at 6. Ultimately, the Commission found violations of Section 337 with respect to claims 22 and 28 of the '502 patent and claims 12, 24, and 30 of the '648 patent. Id. at 123. However, no violation of Section 337 was found with respect to the '745 patent or '501 patent. Id. When discussing infringement of the '745 patent, the ALJ noted that there was "no dispute that Apple has provided instructions to its users for pairing the accused products with Apple iPhones to monitor blood oxygen through Apple's Health app." FID at 198. The "parties [did] not dispute that the currently-existing Apple Watch Series SE [did] not infringe the Asserted Patents because it is not equipped to measure to blood oxygen saturation of a user." Comm'n Op. at 14.

a. Commission Findings Regarding the '502 Patent

In the underlying investigation, the parties did not dispute that the legacy products practiced claim 22 of the '502 patent, as construed during the underlying investigation. FID at 40-44. As such, the legacy products were found to be a user-worn device configured to non-invasively measure an oxygen saturation of a user. Id. at 40. It was uncontested that the legacy products contained a plurality of emitters and photodiodes configured to receive light. Id. Instead, Apple disputed infringement of claim 22 of the '502 patent based on its proposed constructions for the claim terms "over" and "openings." Id. at 41. Specifically, Apple argued that the legacy products did not practice limitation 19C from claim 22 of the '502 patent based on its proposed

constructions. Id. Apple's proposed constructions, however, were rejected. Id. Similarly, during the 1276 investigation, there was "no dispute that each of the [legacy products] contain[ed] processors that receive signals from the photodiodes and output measurements of oxygen saturation." Id. at 42. Further, the ALJ found that the evidence discussed "in the context of the 'processors' limitation of '501 patent claim 1" showed "that this limitation [was] met." Id. at 39, 42 ("There is no dispute that the Accused Products have processors that receive signals from the photodiodes and calculate measurements of physiological parameters. Dr. Madisetti [Masimo's expert] identifies an M10 application processor running Apple's Scandium algorithm to calculate oxygen saturation and pulse rate.") (internal citations omitted). Finally, the accused products were found to contain a plurality of emitters composed of LEDs. Id. at 43.

b. Commission Findings Regarding the '648 Patent

In the underlying investigation, the parties did not dispute that the legacy products practiced claim 12 of the '648 patent, as construed during the underlying investigation. FID at 49-52. Apple disputed infringement of claim 12 of the '648 patent based on proposed constructions of the term "openings." FID at 51. Specifically, Apple argued that the legacy products do not practice limitation 8E from claim 12 of the '648 patent based on its proposed construction. FID at 51. Apple's proposed construction, however, was rejected during the underlying investigation. Id.

In the underlying investigation, the parties did not dispute that the legacy products practiced claim 24 of the '648 patent, as construed during the underlying investigation. FID at 53-55. Apple disputed infringement of claim 24 of the '648 patent based on proposed constructions for the claim terms "over" and "through holes." FID at 54. Specifically, Apple argues that the legacy products did not practice limitation 20D from claim 24 of the '648 patent based on its proposed constructions. Id. Apple's proposed constructions for the claim terms, however, was rejected during the underlying investigation. Id. Claim 30 of the '648 patent is a dependent claim that depends from claim 20. Other than proposing constructions for the claim terms "over" and "through holes" which appear in limitation 20D from claim 24 of the '648 patent, Apple did not dispute that the legacy products infringe claim 30 of the '648 patent, as construed during the underlying investigation. FID at 55.

B. 19 C.F.R. Part 177 Ruling Request

1. Apple's Previous Ruling Request ("*Apple I*")

On October 27, 2023, Apple requested an administrative ruling under 19 C.F.R. Part 177 that its redesigned Apple Watches were not subject to the 1276 LEO because they did not infringe any claims of the '502 and '648 patents. See CBP HQ Ruling H335304 (dated January 12, 2024) at 8. In its ruling request, Apple stated that as redesigned the Apple Watches were no longer reasonably capable of satisfying the claim limitations at issue in the 1276 LEO. See H335304 at 1. Specifically, Apple's argument was based on the pairing process between the redesigned Apple Watch and an unmodified iPhone such that the pulse oximetry functionality was disabled. See H335304 at 11. Nonetheless, Masimo argued that an ability existed that allowed the redesigned Apple Watch to practice the claim limitations at issue. Id. at 13. Specifically, Masimo attempted

to show that the infringing pulse oximetry functionality, while disabled, could nonetheless be enabled "after (1) jailbreaking the iPhones used for pairing with the Redesigned Watches that is needed to activate the Watches and put them into operation; and (2) installing third-party software[.]" Id. at 29. Relying on the relevant case law, the EOE Branch concluded that "the products designed and manufactured by Apple cannot infringe without modification—the modification of jailbreaking the iPhones that is needed for pairing with the Redesigned Watches for their operation and the installation of the software." Id. at 28. Accordingly, the EOE Branch concluded that the redesigned Apple Watches did not infringe the '502 and '648 patents and were not subject to the exclusion order.

2. Procedural History Regarding The Current Ruling Request

On March 26, 2024, Apple submitted another request an administrative ruling pursuant to 19 C.F.R. Part 177, which included Attachments A-H. Apple Submission to EOE Branch, dated March 26, 2024. Apple request concerns its "Redesign 2 Watch" as described in greater detail below. Notably, the redesign [[ ]] but the processing responsible for the final calculation of a user's blood oxygen saturation has been moved from the Apple Watch to the iPhone. Ruling Request at 2. According to Apple, this modification places the Redesign 2 Watch outside the scope of the 1276 LEO because it cannot infringe the patents at issue. Id. at 3. On March 27, 2024, the EOE Branch sent an email to Apple, confirming receipt of its Ruling Request and proposed procedural schedule. EOE Branch Email to Parties (dated March 27, 2024). On March 27, 2024, Apple confirmed that a redacted copy of the Ruling Request was sent to Masimo and that an unredacted copy of the Ruling Request would be sent to Masimo upon confirmation that the existing NDA would apply to the second Ruling Request. Apple Email to EOE Branch (dated March 27, 2024). On March 28, 2024, Masimo submitted a letter to the EOE Branch regarding Apple's actions with respect to importation of prototypes, compliance with the remedial order, and Apple's use of Masimo CBI subject to the protective order established at the Commission. Masimo Email to EOE Branch (dated March 28, 2024). The letter also provided a proposed procedural schedule.

On March 28, 2024, the EOE Branch had an initial conference call with Apple and Masimo, during which both parties agreed to conduct this proceeding on an *inter partes* basis as administered by the EOE Branch. The EOE Branch and parties also discussed the procedural schedule, with the EOE Branch requesting that the parties submit a joint proposed schedule on March 29, 2024, and if the parties were unable to agree on such a schedule to submit a status update that day. EOE Branch Email to Parties (dated March 28, 2024). On March 29, 2024, both parties submitted an update regarding the difficulty agreeing to an NDA and their respective proposed procedural schedules. Apple Email to EOE Branch (dated March 29, 2024); see also Masimo Email to EOE Branch (dated March 29, 2024). On April 4, 2024, the EOE Branch requested that the parties provide a written submission regarding their disagreements with regard to the creation of an NDA. EOE Branch Email to Parties (dated April 2, 2024). On April 3, 2024, both parties submitted a statement regarding the NDA. Apple Email to EOE Branch (dated April 3, 2024); see also Masimo Email to EOE Branch (dated April 3, 2024). On April 5, 2024, the EOE Branch had a conference call regarding the issues involved with establishing an NDA. The EOE Branch requested that the parties execute an NDA and requested the parties submit an executed NDA by April 8, 2024. EOE Branch Email to Parties (dated April 5, 2024). On March 29, 2024,

both parties submitted an update regarding the difficulty agreeing to an NDA and their respective proposed procedural schedules. Apple Email to EOE Branch (dated April 9, 2024); see also Masimo Email to EOE Branch (dated April 10, 2024). The EOE Branch established and distributed the procedural schedule for this *inter partes* proceeding. EOE Branch Email to Parties (dated April 10, 2024).

On May 3, 2024, Masimo requested a conference call regarding access to the source code of the Redesign 2 Watch. Masimo Email to Parties (dated May 3, 2024). On May 6, 2024, the EOE Branch held a conference call with Apple and Masimo regarding the dispute over source code for the Redesign 2 Watch and requested that the parties provide a submission detailing the respective positions on source code. EOE Branch Email to Parties (dated May 6, 2024). On May 7, 2024, both parties submitted their positions on the source code necessary to determine whether the Redesign 2 Watch infringes the relevant patents. Apple Email to EOE Branch (dated May 7, 2024); see also Masimo Email to EOE Branch (dated May 7, 2024). On May 8, 2024, EOE Branch requested that Apple provide the source code to Masimo and extended the dates on the procedural schedule. EOE Branch Email to Parties (dated May 8, 2024).

On June 7, 2024, Masimo provided its response to the Ruling Request, which included attachments 1-20 (collectively, "Masimo Response"). On June 14, 2024, Apple provided its reply to Masimo's response, which included Attachments I through J (collectively, "Apple Reply"). On June 21, 2024, Masimo provided its sur-reply ("Masimo Sur-Reply") to the Apple Reply. On June 28, 2024, the EOE Branch conducted an oral discussion with the parties, with each party providing a presentation ("Apple Oral Discussion Presentation" and "Masimo Oral Discussion Presentation" respectively). Lastly, on July 5, 2024, the parties submitted post oral discussion submissions ("Apple Post Oral Discussion Submission" and "Masimo Post Oral Discussion Submission" respectively).

3. The Articles at Issue

The articles at issue in the Ruling Request consist of certain Apple Watches, and iPhones that are paired to those Apple Watches, with embodiments or modifications that, as detailed below, were not developed at the time of the investigation at the Commission and therefore were not accused of infringement during that investigation. Apple refers to the Apple Watches at issue in this administrative ruling as the "Redesign 2 Watch" and the iPhone at issue in this administrative ruling as the "Redesigned iPhone." Additionally, the models for which Apple has requested a ruling are (1) the Apple Watch Series 8 and 9 and (2) the Apple Watch Ultra and Ultra 2. See Ruling Request at 9. Regarding its product models, the legacy Apple Watch Series 6, 7, and 8 were accused and found to infringe during the underlying investigation. Id. The Apple Watch Series 9, and the Ultra and Ultra 2, were not accused as they were introduced in the United States after Masimo filed its complaint at the Commission. Id.

The models at issue in the Ruling Request, as referenced above, are depicted below:

Apple Watch Series 8

Apple Watch Series 9

Apple Watch Ultra

Apple Watch Ultra 2

a. Apple Watch Series 8, 9, Ultra, and Ultra 2

At the time of filing of the complaint at the Commission, the Apple Watch Series 8, 9, Ultra, and Ultra 2 did not exist and were released only after the evidentiary hearing in the underlying investigation. See CBP HQ Ruling H334304 at 9. The Commission included the Apple Watch Series 8 in its determination regarding the accused products. See Comm'n Op. at 13-14. In its Ruling Request, and as described in more detail below, Apple argues that its redesign for the

Apple Watch Series 8, 9, Ultra, and Ultra 2 removes these articles from the scope of the 1276 LEO. See Ruling Request at 18.

b. Redesign Under Consideration

The Redesign 2 Watch at issue in this Ruling Request comprises of three primary aspects. The first aspect is implemented on the articles at issue, in that every Apple Watch with pulse oximetry capability destined to be sold in the United States and Puerto Rico is hardcoded with a part number ending in LW/A. See Ruling Request at 19. The second aspect involves [[

]]. Id. The third aspect involves adding source code to the Redesigned iPhone for blood oxygen processing and results notification. Id. at 20. This source code change to the Redesigned iPhone moves processors for the final calculation of blood oxygen saturation from the Redesign 2 Watch to the Redesigned iPhone. See Masimo Response at 2. As such, in Apple's view, [[

]] record binary photoplethysmography ('PPG') signals and "send[] them to [the] iPhone for blood oxygen processing." Ruling Request at 1-2, 18 (emphasis added); see also Masimo Response at 8.

As Masimo explained with respect the redesigned functionality, "the LW/A 2 Watch[1] emits red and infrared light, detects light with four photodetectors, [[

]] Masimo Post-Oral Discussion Submission at 10. Masimo provides the following chart explaining how the pulse oximetry functionality and processing is divided between the Redesign 2 Watch and the Redesigned iPhone:

[[ ]]

[1] The parties in this *inter partes* proceeding at times refer to the Redesign 2 Watch as the LW/A 2 Watch.

Masimo Oral Discussion Slides at 21.

In Apple's redesign, the PPG measurements for both wavelengths (*i.e.*, PPG for red light and PPG for infrared light) are done on the LW/A 2 Watch. Attachment 1 to Masimo Response ("Madisetti Declaration") at ¶¶ 50-52; see also Masimo Post Oral Discussion Submission at 11; see also Apple Reply at 22 [[

]] Id.; see also Masimo Post Oral Discussion Submission at 11; see also Apple Reply at 3 ("[Complainant] acknowledges that the relevant functionality has been relocated to the Redesigned iPhone [and] processors of the LW/A 2 Watch are configured to output PPG signals with information that can be used, and is used, by the iPhone to compute the user's oxygen saturation measurement.").

Significantly, in this *inter partes* proceeding, as noted below, the EOE Branch finds that there is no dispute among the parties (1) as to operation of the articles at issue; (2) that, in the articles at issue, [[

]]; (3) that Apple admits it has "moved" or "relocated" certain processors for the final calculation of blood oxygen saturation from the Redesign 2 Watch to the Redesigned iPhone; and (4) that, other than their location, [[

]].

- "Complainants do not dispute the operation of the Redesign 2 Watch or Redesigned iPhone. Indeed, Complainants' Response does not contest any factual statements set forth in Apple's Request. In particular, no dispute remains regarding (1) the operation of the Redesign 2 Watch or Redesigned iPhone; (2) the functionality or operating location of any source code; (3) the user interfaces presented on the Redesign 2 Watch and Redesigned iPhone; or (4) the 'fixed and final' nature of Apple's redesign."

  Apple Reply at 3.

- "Apple did not dispute any of Masimo's evidence or explanation of the operation of Apple's attempted work-around. Reply at 3-4. That included that the [[ ]] ***as the adjudicated infringing Apple Watches***, and that [[ ]]. Response at 8, 12."

  Masimo Sur-Reply at 3 (emphasis added)

- "Complainants concede that the Redesign 2 Watch no longer calculates a user's blood oxygen saturation, and that all functionality for doing so has been moved to the Redesigned iPhone."

  Apple Reply at 1-2

- "Apple relocated the processing for blood oxygen saturation measurements to the Redesigned iPhone."
  Apple Reply at 16

- "Apple has [[ ]] needed to allegedly 'measure,' 'determine,' 'calculate,' or 'output' a user's blood oxygen saturation on the Redesign 2 Watch and moved these functions to the Redesigned iPhone."
  Apple Post-Oral Discussion Submission at 1

- "[T]he processors that perform [pulse oximetry] functionality are now in the [ ] iPhone."
  Masimo Response at 5 (quoting the Ruling Request at 31)

II. ISSUE

Whether Apple has carried its burden, as detailed below, to show that the articles at issue do not infringe the relevant claims of the asserted patents and are not subject to the Commission's limited exclusion order. Specifically, the issues to address are whether Apple has established that: (1) the Apple Watch, as redesigned, is not a "covered article" as defined by the limited exclusion order and for purposes of the 1276 investigation; (2) the Apple Watch, as redesigned, when considered alone, does not infringe claim 22 of the '502 patent; (3) the Apple Watch and iPhone, as redesigned, when considered in combination, do not infringe claim 22 of the '502 patent or claims 12, 24, or 30 of the '648 patent; and (4) the Apple Watch and iPhone, as redesigned, when considered in combination, do not infringe claim 22 of the '502 patent or claims 12, 24, or 30 of the '648 patent under the doctrine of equivalents as applied by CBP. Apple's arguments that the articles at issue are not infringing or fall outside the scope of the limited exclusion order are addressed below.

III. LEGAL FRAMEWORK

A. Section 337 Exclusion Order Administration

The Commission shall investigate any alleged violation of section 337 to determine, with respect to each investigation conducted by it under this section, whether there is a violation of this section. See 19 U.S.C. § 1337(b)(1) and (c). If the Commission determines, as a result of an investigation under this section, that there is a violation of this section, it shall direct that the articles concerned, imported by any person violating the provision of this section, be excluded from entry into the United States unless the Commission finds based on consideration of the public interest that such articles should not be excluded from entry. See 19 U.S.C. § 1337(d)(1).

When the Commission determines that there is a violation of section 337, it generally issues one of two types of exclusion orders: (1) a limited exclusion order or (2) a general exclusion order. See Fuji Photo Film Co., Ltd. v. ITC, 474 F.3d 1281, 1286 (Fed. Cir. 2007). Both types of orders direct CBP to bar infringing products from entering the country. See Yingbin-Nature (Guangdong) Wood Indus. Co. v. ITC, 535 F.3d 1322, 1330 (Fed Cir. 2008). "A limited exclusion order is 'limited' in that it only applies to the specific parties before the Commission in the investigation. In contrast, a general exclusion order bars the importation of infringing products by everyone,

regardless of whether they were respondents in the Commission's investigation." Id. A general exclusion order is appropriate only if two exceptional circumstances apply. See Kyocera Wireless Corp. v. ITC, 545 F.3d 1340, 1356 (Fed. Cir. 2008). A general exclusion order may only be issued if (1) "necessary to prevent circumvention of a limited exclusion order," or (2) "there is a pattern of violation of this section and it is difficult to Identify the source of infringing products." 19 U.S.C. § 1337(d)(2); see Kyocera, 545 F.3d at 1356 ("If a complainant wishes to obtain an exclusion order operative against articles of non-respondents, it must seek a GEO [general exclusion order] by satisfying the heightened burdens of §§ 1337(d)(2)(A) and (B).").

In addition to the action taken above, the Commission may issue an order under 19 U.S.C. § 1337(i) directing CBP to seize and forfeit articles attempting entry in violation of an exclusion order if their owner, importer, or consignee previously had articles denied entry on the basis of that exclusion order and received notice that seizure and forfeiture would result from any future attempt to enter articles subject to the same. An exclusion order under § 1337(d)—either limited or general—and a seizure and forfeiture order under § 1337(i) apply at the border only and are operative against articles presented for customs examination or articles conditionally released from customs custody but still subject to a timely demand for redelivery. See 19 U.S.C. §§ 1337(d)(1) ("The Commission shall notify the Secretary of the Treasury of its action under this subsection directing such exclusion from entry, and upon receipt of such notice, the Secretary shall, through the proper officers, refuse such entry."); id. at (i)(3) ("Upon the attempted entry of ***articles*** subject to an order issued under this subsection, the Secretary of the Treasury shall immediately notify all ports of entry of the attempted importation and shall identify the persons notified under paragraph (1)(C)."") (emphasis added).

Significantly, unlike district court injunctions, the Commission can issue a general exclusion order that broadly prohibits entry of articles that violate section 337 of the Tariff Act of 1930 without regard to whether the persons importing such articles were parties to, or were related to parties to, the investigation that led to issuance of the general exclusion order. See Vastfame Camera, Ltd. v. ITC, 386 F.3d 1108, 1114 (Fed. Cir. 2004). The Commission also has recognized that even limited exclusion orders have broader applicability beyond just the parties found to infringe during an investigation. See Certain GPS Devices and Products Containing Same, Inv. No. 337-TA-602, Comm'n Op. at 17, n.6, Doc ID 317981 (Jan. 2009) ("We do not view the Court's opinion in Kyocera as affecting the issuance of LEOs [limited exclusion orders] that exclude infringing products made by respondents found to be violating Section 337, but imported by another entity. The exclusionary language in this regard that is traditionally included in LEOs is consistent with 19 U.S.C. § 1337(a)(1)(B)-(D) and 19 U.S.C. § 1337(d)(1).").

Moreover, "[t]he Commission has consistently issued exclusion orders ***coextensive with the violation*** of section 337 found to exist." See Certain Erasable Programmable Read Only Memories, Inv. No. 337-TA-276, Enforcement Proceeding, Comm'n Op. at 11, Doc ID 43536 (Aug. 1991) (emphasis added). "[W]hile individual models may be evaluated to determine importation and [violation], the Commission's jurisdiction extends to all models of [violative] products that are imported at the time of the Commission's determination and to all such products that will be imported during the life of the remedial orders." See Certain Optical Disk Controller Chips and Chipsets, Inv. No. 337-TA-506, Comm'n Op. at 56-57, USITC Pub. 3935, Doc ID 287263 (July 2007).

Lastly, despite the well-established principle that "the burden of proving infringement generally rests upon the patentee [or plaintiff]," Medtronic, Inc. v. Mirowski Family Ventures, LLC, 571 U.S. 191 (2014), the Commission has held that Medtronic is not controlling precedent and does not overturn its longstanding practice of placing the burden of proof on the party who, in light of the issued exclusion order, is seeking to have an article entered for consumption. See Certain Sleep-Disordered Breathing Treatment Systems and Components Thereof, Inv. No. 337-TA-879, Advisory Opinion at 6-11. In particular, the Commission has noted that the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") "has upheld a Commission remedy which effectively shifted the burden of proof on infringement issues to require a company seeking to import goods to prove that its product does ***not*** infringe, despite the fact that, in general, the burden of proof is on the patentee to prove, by a preponderance of the evidence, that a given article ***does*** infringe[.]" Certain Integrated Circuit Telecommunication Chips, Inv. No. 337-TA-337, Comm'n Op. at 21, n.14, USITC Pub. 2670, Doc ID 217024 (Aug. 1993) (emphasis in original) (citing Sealed Air Corp. v. ITC, 645 F.2d 976, 988-89 (C.C.P.A. 1981)).

This approach is supported by Federal Circuit precedent. See Hyundai Elecs. Indus. Co. v. ITC, 899 F.2d 1204, 1210 (Fed. Cir. 1990) ("Indeed, we have recognized, and Hyundai does not dispute, that in an appropriate case the Commission can impose a general exclusion order that binds parties and non-parties alike and ***effectively shifts to would-be importers of potentially infringing articles, as a condition of entry, the burden of establishing noninfringement***. The rationale underlying the issuance of general exclusion orders—placing the risk of unfairness associated with a prophylactic order upon potential importers rather than American manufacturers that, vis-a-vis at least some foreign manufacturers and importers, have demonstrated their entitlement to protection from unfair trade practices—applies here [in regard to a limited exclusion order] with increased force.") (emphasis added) (internal citation omitted).

B. Patent Infringement

Determining patent infringement requires two steps. Advanced Steel Recovery, LLC v. X-Body Equip., Inc., 808 F.3d 1313, 1316 (2015). The first is to construe the limitations of the asserted claims and the second is to compare the properly construed claims to the accused product. Id. To establish literal infringement, every limitation recited in a claim must be found in the accused product whereas, under the doctrine of equivalents, infringement occurs when there is equivalence between the elements of the accused product and the claimed elements of the patented invention. Microsoft Corp. v. GeoTag, Inc., 817 F.3d 1305, 1313 (Fed. Cir. 2016). One way to establish equivalence is by showing, on an element-by-element basis, that the accused product performs substantially the same function in substantially the same way with substantially the same result as each claim limitation of the patented invention, which is often referred to as the function-way-result test. See Intendis GmbH v. Glenmark Pharms., Inc., 822 F.3d 1355, 1361 (Fed. Cir. 2016).

As for the first step above, "claim construction is a matter of law." SIMO Holdings, Inc. v. H.K. uCloudlink Network Tech., Ltd., 983 F.3d 1367, 1374 (Fed. Cir. 2021). Moreover, the ultimate construction of a claim limitation is a legal conclusion, as are interpretations of the patent's intrinsic evidence (the patent claims, specifications, and prosecution history).

UltimatePointer, L.L.C. v. Nintendo Co., 816 F.3d 816, 822 (Fed. Cir. 2016) (citing Teva Pharms. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831, 841, 190 L. Ed. 2d 719 (2015).[2] "Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). "In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges." Id. at 1314. In others, courts look to public sources such as "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." Id.

"To begin with, the context in which a term is used in the asserted claim can be highly instructive." Phillips, 415 F.3d at 1314 ("To take a simple example, the claim in this case refers to 'steel baffles,' which strongly implies that the term 'baffles' does not inherently mean objects made of steel."). The context in which a claim term is used also includes the full chain of dependence as well as the remaining suite of claims and the written description. See Inline Plastics Corp. v. EasyPak, LLC, 799 F.3d 1364, 1371 (Fed. Cir. 2015) ("Since the specification explicitly mentions the 'alternative' . . . there can be no debate concerning the application of the doctrine of claim differentiation.").

The second step to establish infringement involves a comparison of the claims, as properly construed, to the accused product, which is a question of fact. Apple Inc. v. Samsung Elecs. Co., Ltd., 839 F.3d 1034, 1040 (Fed. Cir. 2016) (en banc).

C. Patent Infringement Based On Capability Or Actual Operation

The Federal Circuit has held that, for infringement under the two-step inquiry described above, a device only needs to be capable of operating according to the relevant claim limitations while others have found that a device does not infringe unless it actually operates as claimed. See INVT SPE LLC v. ITC, 46 F.4th 1361, 1371 (Fed. Cir. 2022) (citing Finjan, Inc. v. Secure Computing Corp., 626 F.3d 1197, 1204 (Fed. Cir. 2010) for the former and ParkerVision, Inc. v. Qualcomm Inc., 903 F.3d 1354, 1361 (Fed. Cir. 2018) for the latter). "Whether infringement requires actual performance of the recited functions by the accused device depends on the claim language." INVT, 46 F.4th at 1371. "[T]he most straightforward example of this is the common distinction between method claims and apparatus claims" where "non-method claims describe capabilities without requiring that any software components be 'active' or 'enabled'" and method claims that "require[] actual performance of each claimed step." Id. (quoting Finjan, 626 F.3d at 1204-05, 1206).

Nevertheless, "differences exist between apparatus claims as well, depending on the claim language. [The Federal Circuit has] construed some apparatus claims to require an infringing device to actually perform and operate according to the functional terms recited in the claim" but "construed other apparatus claims to require only capability[.]" INVT at 1371. For example, in Finjan, because the "defendants admitted [the] program code for the relevant function . . . was

[2] Although claim construction is a question of law, the consideration of extrinsic evidence may constitute a subsidiary finding of fact. Teva, 135 S. Ct. at 841, 190 L. Ed. 2d at 733.

literally present on all accused devices, the claim was infringed 'in the same way that an automobile engine for propulsion exists in a car even when the car is turned off.'" INVT at 1373 (quoting Finjan at 1205). "The presence of that programming in the accused products was all that was necessary for establishing infringement." Id. "In other words, the claims recite[d] a device with *the capability of performing the recited functions when in operation* ***without any modification or further programming***." Id. at 1374. "To determine if an accused device is a device with the 'capability' of performing the recited functions, it must be able to perform those functions when it is activated and put into operation." Id. at 1375. Accordingly, the Federal Circuit has established that for infringement of:

> a claim that recites capability and not actual operation, an accused device "need only be capable of operating" in the described mode. Intel Corp. v. U.S. Int'l Trade Comm'n, 946 F.2d 821, 832 (Fed. Cir. 1991). Thus, depending on the claims, "an accused device may be found to infringe if it is ***reasonably capable*** of satisfying the claim limitations, even though it may also be capable of noninfringing modes of operation." Hilgraeve Corp. v. Symantec Corp., 265 F.3d 1336, 1343 (Fed. Cir. 2001).

Finjan, 626 F.3d at 1204 (emphasis added).

Moreover, the Federal Circuit has held that an accused device is considered "reasonably capable" of satisfying the claim limitations when one can enable the mode that would infringe "without significant alteration." See INVT, 46 F.4th at 1373-75 ("We held [in Silicon Graphics and Fantasy Sports] that the apparatus claim directed to a computer, claimed in functional terms, is nonetheless infringed so long as the product is *designed in such a way as to enable a user of that [product] to utilize the function . . .* ***without having to modify [the product]—i.e., capable of the functions***.") (quoting Silicon Graphics, Inc. v. ATI Techs., Inc., 607 F.3d 784, 795 (Fed. Cir. 2010) and Fantasy Sports Props., Inc. v. Sportsline.com, Inc., 287 F.3d 1108, 1118 (Fed. Cir. 2002) (internal quotation marks omitted) (emphasis added); see also Versata Software, Inc. v. SAP Am., Inc., 717 F.3d 1255, 1262 (Fed. Cir. 2013) ("[A] device does not infringe simply because it is possible to alter it in a way that would satisfy all the limitations of a patent claim[.]") (quoting High Tech Med. Instrumentation v. New Image Indus., Inc., 49 F.3d 1551, 1555 (Fed. Cir. 1995).

> In sum, when the asserted claims recite capability, *our case law supports finding infringement by a 'reasonably capable' accused device on a case-by-case basis particularly where . . . there is evidence that the accused device is* ***actually used in an infringing manner and can be so used without significant alterations***.

Ericsson, Inc. v. D-Link Sys., Inc., 773 F.3d 1201, 1217 (Fed. Cir. 2014) (emphasis added).

Consequently, the Federal Circuit has confirmed that "[a]n accused device may be found to infringe if it is reasonably capable of satisfying the claim limitations." Provisur Techs., Inc. v. Weber, Inc., 119 F.4th 948, [*7] (Fed. Cir. 2024) (quoting Hilgraeve Corp. v. Symantec Corp., 265 F.3d 1336, 1343 (Fed. Cir. 2001)). However, "a device does not infringe simply because it is possible to alter it in a way that would satisfy all the limitations of a patent claim." Id. (quoting High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc., 49 F.3d 1551, 1555 (Fed. Cir.

1995)). Instead, the Federal Circuit has "*held an accused device to meet the capability standard if it is* ***readily configurable*** *to infringe*. Id. (emphasis added) (citing Fantasy Sports, 287 F.3d at 1118 (explaining an accused device infringes where the user must only activate the functions already present) and Finjan, 626 F.3d at 1205 (for the same)). Such an "infringement scenario" arises "where customers can simply activate the infringing configuration." Id.

Finally, for "configured to" claim limitations, the EOE Branch has "determined to adopt the position the Federal Government has taken previously that the claim term 'configured to' should be construed to mean 'programmed to, as opposed to being merely capable of, performing a task.'" CBP HQ Ruling H335304 at 23. On this point, the Federal Government's view is that "the Federal Circuit has recognized that the plain and ordinary meaning of the term 'configured to' is synonymous with 'made to' or 'designed to,' in contrast to being 'merely capable of' or 'suitable for.'" Id. (citing Wanker v. United States, 152 Fed. Cl. 219, 253-254 (2021) (referencing Gov't's Op. Cl. Constr. Br. at 24-25)). Accordingly, except in cases where the Commission has provided an express construction that differs from the above or where the intrinsic evidence requires a departure from it, the EOE Branch will construe the term "configured to" as "programmed to, as opposed to being merely capable of, performing a task."

IV. LAW AND ANALYSIS

A. Apple's Position That The Redesign 2 Watch By Itself Or In Combination With The Redesigned iPhone Is Not A "Covered Article"

As a preliminary matter, Apple alleges that the Redesign 2 Watch simply lacks pulse oximetry functionality and therefore falls outside the scope of the "covered articles" that are subject to the limited exclusion order. Ruling Request at 29-30 (citing Certain Automated Mechanical Transmission Systems For Medium-Duty and Heavy-Duty Trucks and Components Thereof, Inv. No. 337-TA-503, Commission Opinion at 4 (May 9, 2005)). Specifically, Apple contends that, "[w]ithout blood oxygen ***processing or measurements***, Apple's Redesign 2 Watch lacks ***the*** pulse oximetry functionality required to meet the definition of "covered articles" under the 1276 LEO." Id. at 29. (emphasis added). This argument is focused on Apple's position that "the Redesign 2 Watch does not calculate, output, measure, or determine results for any PPG signals, [such that] without these features, it does not contain the pulse oximetry functionality required for 'covered articles' under the 1276 LEO." Id. at 30; see also Apple's Reply at 4 ("***Without that processing [****for the final calculation of a user's blood oxygen saturation****], the Redesign 2 Watch cannot provide pulse oximetry functionality***. Because the Redesign 2 Watch lacks 'light-based pulse oximetry functionality,' it falls outside the scope of the 1276 LEO."). Apple concludes that, given its view above, "no further noninfringement analysis is necessary" to determine that the Redesign 2 Watch falls outside the limited exclusion order's scope and therefore is admissible into the United States. Id.

Additionally, in response to Masimo's arguments that "that the combination of the Redesign 2 Watch and Redesigned iPhone are together a 'covered article' that contains light-based pulse oximetry[,]" Apple takes the position that "those arguments *directly contradict both the* ***plain language of the ITC's remedial orders*** *and* ***Complainants' prior representations that only [the] Apple Watch was accused***. *Complainants cannot* ***expand*** *either the scope of the remedial orders*

or *their accusations to that which was not accused* ***in the underlying Investigation***." Apple's Reply at 2 (emphasis added). On this basis, Apple's contends that the Redesigned iPhone cannot constitute a "covered article."

As explained in more detail below, Apple is wrong, legally and factually, with respect to each of the "covered article" arguments above. First, Apple's argument that Masimo's theory of infringement – regarding the combination of the Redesign 2 Watch and Redesigned iPhone – contradicts its "prior representations" or is "expanding" the scope of the exclusion order misunderstands the nature of Commission investigations and remedial orders under Section 337, which, as the precedent discussed below confirms, are ***not*** limited to the products accused of infringement. Instead, such remedial orders extend to any article that **(i)** is subject to the scope of the investigation – as governed by the notice of investigation with the plain language definition – and **(ii)** is covered by the relevant claims included in the exclusion order under the traditional two-step test for patent infringement.

Applying the above to the admissibility question in this *inter partes* proceeding, Apple has not carried its burden to show that the articles at issue are not "wearable electronic devices with light-based pulse oximetry functionality and components thereof," as set forth in the exclusion order's articulation of "covered articles." See 1276 LEO at 2, ¶ 2. As indicated below, Apple has not offered a definition of "wearable" or shown why, under the term's plain meaning as found in dictionary definitions, it would not apply to the articles at issue. Furthermore, Apple's view that "pulse oximetry functionality" only refers to the processors that perform the final blood oxygen calculation – such that their [[ ]] and addition to the Redesigned iPhone would take the former device outside the exclusion order's scope – is incorrect if for no other reason than *other features and functionality* responsible for performing pulse oximetry (such as *emitters* and *photodiodes*) indisputably remain on the Redesign 2 Apple Watch. Lastly, as the Commission has confirmed and the EOE Branch has applied when administering remedial orders under Section 337, the touchstone for determining whether articles are subject to an exclusion order is the traditional two-step test for patent infringement, such that Apple is mistaken that no further infringement analysis is necessary to determine admissibility in this *inter partes* proceeding.

1. Commission Precedent Regarding The Scope Of Its Remedial Orders Under Section 337

"The Commission, as is its long-established practice, does not limit [an exclusion order] to covered products that were actually adjudicated to infringe [during the underlying investigation]." Certain Movable Barrier Operator Systems and Components Thereof, Inv. No. 337-TA-1118, EDIS Doc. ID 839790, Remand Commission Opinion at 48 (Public) (December 20, 2024). "Consistent with [that] long-standing practice, the scope of [exclusion orders] includes all [ ] infringing [devices subject to the scope of the investigation], *whether they have been adjudicated in the investigation or were later introduced*." Certain Road Construction Machines and Components Thereof, Inv. No. 337-TA-1088 (Modification), Commission Opinion, Doc. ID 719534 (Sept. 14, 2020) at 12-13 (emphasis added). "This coverage is to ensure that the exclusion order affords the complainant 'complete relief' and cannot be 'easily circumvented.'" Certain Movable Barrier Operator Systems and Components Thereof, Inv. No. 337-TA-1118, EDIS Doc.

ID 839790, Remand Commission Opinion at 48 (Public) (December 20, 2024) (citing Certain Graphics Systems, Components Thereof, and Consumer Products Containing Same, Inv. No. 337-TA-1044, Comm'n Op. at 66 (Sept. 18, 2018); see also Certain Human Milk Oligosaccharides and Methods of Producing Same, Comm'n Op. at 19-20, 2020 WL 3073788 at *11 (June 20, 2020) (redesigned products may still fall within the scope of the remedial orders even if they were not adjudicated for infringement in the original investigation), aff'd, Jennewein Biotechnologie GmbH v. Int'l Trade Comm'n, 2021 WL 4250784 (Fed. Cir. Sept. 17, 2021) (unpublished)).

As an example, in Certain Audio Players & Controllers, Components Thereof, and Prods. Containing the Same, the Commission "followed its customary practice and declined the respondent's request to limit the LEO only to those products adjudicated as infringing and not to extend the LEO 'to other Google products within the scope of the investigation for which [complainant] deliberately chose not to accuse of infring[ement].'" Certain Graphics Systems, Components Thereof, and Digital Televisions Containing The Same, Inv. No. 337-TA-1318, EDIS Doc. ID 822069, Commission Opinion on Respondent Realtek Semiconductor Corporation's Petition for Reconsideration at 15 (Public) (May 22, 2024) (citing Inv. No. 337-TA-1191 ("Audio Players"), Comm'n Op. at 24-25 (Feb. 1, 2022) and Audio Players, Respondent Google's Submission on Remedy, Bond, and Public Interest at 14-15 (Dec. 2, 2021)). The Commission explained:

> A Commission order is typically not limited to the accused products, but includes ***all products within the scope of the investigation that are covered by the patent claims as to which a violation has been found***. See Certain Road Construction Machines & Components Thereof, Inv. No. 337-TA-1088 ("Road Construction Machines") (Modification), Comm'n Op. at 22-34 (Aug. 31, 2020).

Audio Players, EDIS Doc. ID 762093, Comm'n Op. at 25 n.19 (emphasis added) (Public) (Feb. 1, 2022).

Consistent with this view, the Commission has pointed out that "[n]owhere does section 337 state that a remedial order is limited to products that were actually adjudicated during the investigation and found to infringe the patent(s) in question." Certain Movable Barrier Operator Systems and Components Thereof, Inv. No. 337-TA-1118, EDIS Doc. ID 839790, Remand Commission Opinion at 50 (Public) (December 20, 2024). The Commission's finding of a violation provides the basis for the Commission to order the exclusion of the "articles concerned[.]" Id. Moreover, section 337 states that the Commission, after finding a patent-based or other IP-based violation, "shall direct that the articles concerned, imported by any person violating the provision of this section, be excluded from entry into the United States," subject to public interest concerns. Id. The Commission's interpretation of the statute is that "[t]he 'articles concerned' are 'articles that infringe' the patent claim(s) in question and are imported, sold for importation, or sold in the United States after importation by the respondent found in violation. See id. § 1337(a)(1)(B). ***Thus, once a respondent is found to have violated section 337 with respect to a given patent(s), the Commission shall issue an exclusion order precluding that respondent from importing in the future any articles that infringe the patent(s) in question***." Id. at 50-51 (emphasis added).

"An exclusion order is forward looking only [as] there is no recovery or penalty in the Commission for past unlawful acts of infringement or importation. Section 337 does not limit, and it would make no sense to limit, an exclusion order to past acts of infringement (i.e., products adjudicated as infringing) but not cover imports of future infringing products, even if they have not been adjudicated. Otherwise, a respondent could easily avoid an exclusion order merely by relabeling an adjudicated product or making some non-substantive changes to that product." Id. at 51.

Significantly, the Federal Circuit and its predecessor have long upheld the Commission's practice and interpretation as to the scope of exclusion orders. Certain Graphics Systems, Components Thereof, and Digital Televisions Containing The Same, Inv. No. 337-TA-1318, EDIS Doc. ID 822069, Commission Opinion on Respondent Realtek Semiconductor Corporation's Petition for Reconsideration at 14-15 (Public) (May 22, 2024) (citing Hyundai Elecs. Indus. Co. v. Int'l Trade Comm'n, 899 F.2d 1204, 1210 (Fed. Cir. 1990) (upholding the Commission's practice of "shift[ing] to would-be importers of potentially infringing articles, as a condition of entry, the burden of establishing noninfringement" and "placing the risk of unfairness associated with a prophylactic order upon potential importers rather than American manufacturers"); see also Sealed Air Corp. v. Int'l Trade Comm'n, 645 F.2d 976, 988-89 (C.C.P.A. 1981). In this regard, the Federal Circuit has recognized that "the Commission, like other administrative agencies, has considerable latitude in shaping the form, scope, and extent of a remedial order." Cisco Sys., Inc. v. ITC, 873 F.3d 1354, 1363 (Fed. Cir. 2017) (citing Viscofan, S.A. v. Int'l Trade Comm'n, 787 F.2d 544, 548 (Fed. Cir. 1986)). "Such a holding rests on basic principles of administrative law that pre-date the Supreme Court's 1984 Chevron decision, and recognize the considerable latitude agencies are afforded in choosing and shaping their remedies."[3] Certain Movable Barrier Operator Systems and Components Thereof, Inv. No. 337-TA-1118, EDIS Doc. ID 839790, Remand Commission Opinion at 51 (Public) (December 20, 2024). Accordingly, the Commission has "***broad*** discretion in selecting the form, scope, and extent of the remedy." Viscofan, 787 F.2d at 548 (Fed. Cir. 1986) (emphasis added). Certain Movable Barrier Operator Systems and Components Thereof, Inv. No. 337-TA-1118, EDIS Doc. ID 839790, Remand Commission Opinion at 51-52 (Public) (December 20, 2024); see also Audio Players, EDIS Doc. ID 762093, Comm'n Op. at 22 (Public) (Feb. 1, 2022).

Accordingly, it is not a question of "expanding" the scope of the exclusion order, as Apple puts it, but instead applying the ***broad*** remedial order as defined by the Commission and consistent with its precedent "to afford[] the complainant 'complete relief' [that] cannot be 'easily circumvented.'" Certain Movable Barrier Operator Systems and Components Thereof, Inv. No. 337-TA-1118, EDIS Doc. ID 839790, Remand Commission Opinion at 48 (Public) (Dec. 20,

[3] The Commission has found that its practice of extending exclusion orders to cover all of a respondent's infringing products, and not just those that were actually adjudicated as infringing during the underlying investigation, has not been disturbed by the U.S. Supreme Court's recent decision in Loper Bright that overruled the Chevron doctrine. Certain Movable Barrier Operator Systems and Components Thereof, Inv. No. 337-TA-1118, EDIS Doc. ID 839790, Remand Commission Opinion at 48-50 (analyzing Loper Bright Enters. v. Raimondo, 144 S. Ct. 2244, 2273 (2024) in overruling Chevron, U.S.A., Inc. v. NRDC, Inc., 467 U.S. 837 (1984)). Specifically, in response to a respondent raising such an argument, the Commission held that "overruling Chevron does not automatically overrule or even call into question the Commission's interpretation of section 337 or its established practice of issuing LEOs that cover all of a respondent's infringing products, and not merely those adjudicated as infringing during the investigation." Id. at 50.

2024) (citing Certain Graphics Systems, Components Thereof, and Consumer Products Containing the Same, Inv. No. 337-TA-1044, EDIS Doc. ID 656082, Commission Opinion at 66 (Public) (Sept. 18, 2018)).

As for Apple's view that Masimo's position in this *inter partes* proceeding contradicts Masimo's "prior representations" that formed its infringement contentions regarding the legacy Apple Watch during the underlying investigation, as shown above, that argument is inconsistent with the Commission precedent making clear that remedial orders under Section 337 are not limited to the articles accused and found to infringe. Instead, such orders extend to all of a respondent's articles that are subject to the investigation, as defined by the plain language description, and covered by the infringed patent claims included in the exclusion order. Apple's arguments to the contrary ignore this Commission precedent.

Moreover, Apple fails to acknowledge, with respect to Masimo's infringement contentions during the investigation at the ITC, that there was no basis for Masimo to accuse the iPhone of infringement, prior to the redesigns at issue in this proceeding, because at that point Apple had ***not yet*** moved the pulse oximetry processing functionality to the iPhone. Instead, there is no dispute that the light-based pulse oximetry functionality, including the processing functionality, was on the legacy Apple Watches that Masimo accused of infringement and were found to infringe at the Commission. However, as noted above, the nature of those infringement contentions does not limit the reach of the Commission's remedial orders, even if this functionality had been present. See Certain Audio Players & Controllers, Components Thereof, and Prods. Containing the Same, Inv. No. 337-TA-1191 ("Audio Players"), Comm'n Op. at 24-25 (Feb. 1, 2022) ("[T]he Commission followed its customary practice and declined respondent Google LLC's request to ***limit*** the LEO ***only to those products adjudicated as infringing and not to extend the LEO "to other Google products within the scope of the investigation for which [complainant] deliberately chose not to accuse of infring[ement]***.") (emphasis added).

Furthermore, to the extent Apple is arguing that Masimo's position in this *inter partes* proceeding regarding the relevance of the Redesigned iPhone contradicts a position that Masimo advanced in *Apple I*, such that in Apple's view Masimo is estopped from taking the position adopted here, Apple's argument does not acknowledge that Masimo ***did not prevail*** on its arguments in *Apple I*. Instead, the EOE Branch correctly rejected Masimo's arguments as contrary to binding Federal Circuit precedent. In apply the relevant case law, the EOE Branch considered the redesigned Apple Watches as well as the iPhone in Apple's pairing method "as designed and manufactured for importation and sale in the United States" when reaching the conclusion that the articles at issue were programmed to disable the claimed functionality. See CBP HQ Ruling H335304 at 26. Therefore, if anything, it was Apple that prevailed on the position in *Apple I* that CBP should take into consideration both the Apple Watch and iPhone for purposes of the admissibility determination and, as such, if any party is estopped on these grounds as having prevailed before the EOE Branch, it would be Apple.

However, to the extent Apple is instead arguing, based on statements from the prior *inter partes* proceeding, that Masimo has ***conceded*** (see Apple Reply at 6) or ***admitted*** (see Apple Reply at 7) that another device, such as the Redesigned iPhone in this *inter partes* proceeding, cannot be covered by the relevant patent claims, Apple has not identified the proper standard for the EOE

Branch to apply. In the absence of identifying such a standard, the EOE Branch considers that it would need to evaluate these arguments under the patent doctrine of disclaimer or disavowal. "The standard for disavowal of patent claim scope is [] exacting." Thorner v. Sony Comput. Entm't Am. LLC, 669 F.3d 1362, 1366 (Fed. Cir. 2012). To determine whether a patent holder disclaimed or otherwise surrendered claim scope that comes within the claim language, the consideration is whether, "despite the apparent ordinary meaning evident from the intrinsic evidence," the patent holder "acted with sufficient clarity" to "disclaim the plain meaning or prescribe a special definition." K-Fee Sys. GmbH v. Nespresso USA, Inc., 89 F.4th 915, 923 (Fed. Cir. 2023). Most importantly, disclaimer or disavowal of claim scope "must be both ***clear and unmistakable***." Id. (emphasis added) (quoting Baxalta Inc. v. Genentech, Inc., 972 F.3d 1341, 1348 (Fed Cir. 2020) (quoting 3M Innovative Properties Co. v. Tredegar Corp., 725 F.3d 1315, 1325 (Fed. Cir. 2013))).

A statement made by a patent owner during an administrative proceeding, such as an *inter partes* proceeding under 19 C.F.R. Part 177, could support a finding of disclaimer. See Aylus Networks, Inc. v. Apple Inc., 856 F.3d 1353, 1361 (Fed. Cir. 2017). However, any statements that are "ambiguous or amenable to multiple reasonable interpretations" will not constitute a disclaimer of claim scope. Technology Properties Ltd. v. Huawei Technologies Co., Ltd., 849 F.3d 1349, 1358 (Fed. Cir. 2017). The EOE Branch does not find that Masimo's statements during *Apple I*, as to whether the iPhone should be taken into consideration for purposes of the admissibility determination, rise to the level of a "clear and unmistakable" disclaimer or disavowal of claim scope. For instance, based on the representative statements below, it is clear that Masimo's position was that the EOE Branch should not consider the iPhone to reach the admissibility determination. However, as already indicated above, the EOE Branch rejected Masimo's arguments and ruled against it on those grounds.

- "Apple did not change any of the infringing [[ ]] when creating the LW/A Watches. Apple also did not [[ ]]. Instead, as Apple admits, it merely [[ ]] to the infringing Apple Watches and the iPhones paired with those watches."

  Masimo Response at 4 in *Apple I*.

- "Apple's arguments regarding the iPhone and the 'system' are at best misleading. The adjudicated products at issue in this Investigation are the Apple Watches. The 1276 LEO excludes 'wearable electronic devices with light-based pulse oximetry functionality.' Limited Exclusion Order, EDIS Doc. ID 807002 (Oct. 26, 2023) ('1276 LEO') at 2. The ITC proceedings addressed only exclusion of Apple Watches with pulse oximetry functionality. Masimo never attempted to exclude the iPhones that are used to activate those adjudicated watches. For that reason, arguments about the iPhone features have no relevance to the issue of direct infringement."

  Masimo Sur-Reply at 2 in *Apple I*

- "Masimo agrees with this fundamental principle because the principle applies only to alterations or modifications to the accused device itself. Apple misdirects this principle by focusing on attributes not part of the accused device. In particular, Apple argues that modifications to the iPhone avoid infringement liability for the LW/A Watch."

  Masimo Sur-Reply at 3 in *Apple I*

- "The EOE Branch asked 'why modifying the iPhone is not a sufficient basis for non-infringement. Oral Discussion Tr. at 151:21-152:10. The answer is straightforward: because the iPhone is not an accused device; any modification to an unaccused device is irrelevant to the infringement inquiry."

  Masimo Post-Oral Discussion Submission at Sur-Reply at 8 in *Apple I*

Therefore, based on the Commission precedent cited above, Apple is incorrect as a matter of law that Masimo is precluded from presenting its theory of infringement in this *inter partes* proceeding because the iPhone was not accused of infringement during the underlying investigation and it is wrong that Masimo's prior statements from the previous *inter partes* proceeding foreclose Masimo from presenting this theory since the EOE Branch rejected Masimo's arguments – such that Masimo did not prevail – and therefore is not estopped from making these arguments. Lastly, as indicated above, Masimo's statement in *Apple I* do not constitute a sufficient basis to find a disclaimer or disavowal of claim scope.

As with remedial orders from other investigations under Section 337, "[t]he exclusion order in this case is routine in form." Certain Road Construction Machines and Components Thereof, Inv. No. 337-TA-1088, EDIS Doc. ID 719534, Commission Opinion at 12 (Sep. 14, 2020). Consistent with the Commission's long-standing practice discussed above, the scope of this limited exclusion order includes all Apple "wearable electronic devices with light-based pulse oximetry functionality and components thereof" that infringe the asserted patents, regardless of whether they have been adjudicated in the underlying investigation or were later introduced. Certain Light-Based Physiological Measurement Devices and Components Thereof, Inv. No. 337-TA-1276, EDIS Doc. ID 807002, Limited Exclusion Order for Apple, Inc. at ¶¶ 1-2 (Public) (Oct. 26, 2023). Therefore, the proper next step is to consider the meaning of "wearable electronic devices" and the application of that meaning to the articles at issue in this *inter partes* proceeding. The analysis below turns to this first aspect of the consideration.

2. The Scope Of Section 337 Investigations Are Defined By Their Notice of Investigation And The Plain Language Descriptions Therein

As a starting point, neither party cites the relevant Commission Rule that establishes the scope of the Commission's investigations under Section 337 and, therefore, governs proper administration its remedial orders. "Pursuant to Commission Rule 210.10(b)(l) (19 C.F.R. § 210.10(b)(l)) and as stated in the [Commission's Notice of Investigation ("NOI")], the plain language description of the accused products or category of accused products [] defines the scope of this investigation[.]" Certain Toner Supply Containers and Components Thereof, Inv. No. 337-TA-1260, EDIS Doc. ID 777011, Commission Opinion at 15 (Public) (Aug. 3, 2022). Pursuant to the Commission's regulations, "[a]n investigation shall be instituted by the publication of a notice in the Federal Register. ***The notice will define the scope of the investigation in such plain language as to make explicit what accused products or category of accused products provided in accordance with § 210.12(a)(12) will be the subject of the investigation***, and may be amended as provided in § 210.14(b) and (c)." 19 C.F.R. § 210.10(b)(l) (emphasis added). Furthermore, Commission Rule 210.12(a)(12) provides that the complaint shall "[c]ontain a clear statement in plain English of the category of products accused. For example, the caption of the investigation

might refer to 'certain electronic devices,' but the complaint would provide a further statement to identify the type of products involved in plain English such as mobile devices, tablets, or computers." 19 C.F.R. § 210.12(a)(12).

As such, it is the Commission's notice of investigation with its "plain language description of the accused products or category of accused products [that] defines the scope of the investigation." Certain Graphics Systems, Components Thereof, and Digital Televisions Containing The Same, Inv. No. 337-TA-1318, EDIS Doc. ID 814860, Commission Opinion at 55, FN 42 (Public) (Feb. 23, 2024); see also Certain Lithium Ion Batteries, Battery Cells, Battery Modules, Battery Packs, Components Thereof, And Processes Therefor, Inv. No. 337-TA-1159, EDIS Doc. ID 735927, Commission Opinion ("1159 Comm'n Op.") (Public) (March at 4, 2021) at 80-81 ("The notice [of investigation] will define the scope of the investigation in such plain language as to make explicit what accused products or category of accused products . . . will be the subject of the investigation" and "any relief must be limited to the plain English statement.").

The investigation title for ITC Inv. No. 337-TA-1276 is "Light-Based Physiological Measurement Devices and Components Thereof." 1276 LEO at 1. However, in the notice instituting the 1276 investigation, the Commission described the plain English language statement of the articles at issue as "wearable electronic devices with light-based pulse oximetry functionality and components thereof[.]" Certain Light-Based Physiological Measurement Devices and Components Thereof, Inv. No. 337-TA-1276, EDIS Doc. ID 749538, Institution of Investigation (August 13, 2021). Notably, although both parties argue about the application of this plain language description for the articles at issue, particularly with respect to consideration of the Redesign 2 Apple Watch in combination with the Redesigned iPhone, neither party offers a definition of the term "wearable." Nevertheless, based on the Commission authority cited above, especially that confirming the nature of this plain language description, it is clear that the meaning of this term is amenable to a dictionary definition.

The Oxford English Dictionary defines "wearable" as "capable of being worn" and "fit or suitable to be worn." 20 Oxford English Dictionary 49 (2d ed. 1989). Merriam-Webster offers a nearly identical definition. See Merriam-Webster Online Dictionary, https://www.merriam-webster.com/dictionary/wearable (last visited January 7, 2025). Accordingly, for purposes of this exclusion order, an electronic device is considered wearable if, under the narrowest definition, it is suitable for being worn and, under the broadest definition, it is merely capable of being worn. Not only has Apple failed to provide a definition of this key term, it has not submitted any record evidence on the factual question why, in its view, the Redesigned iPhone is not "wearable" and, therefore, has not demonstrated why it would not meet the standard under either definition above. As such, Apple has not provided any basis for the EOE Branch to conclude that the Redesigned iPhone is incapable of being worn or is not suitable for this purpose. Consequently, Apple has failed to carry its burden with respect to its argument that the Redesign 2 Watch in combination with the Redesigned iPhone is not a "wearable" electronic device with light-based pulse oximetry functionality.

Notwithstanding the above, it is not enough that an electronic device is suitable or capable of being worn to fall within the scope of the investigation. Such an electronic device must have light-based pulse oximetry functionality. Apple argues that, by [[ ]] that

are responsible for the final calculation of the user's blood oxygen saturation, the Redesign 2 Watch is devoid of light-based pulse oximetry functionality. Apple does not cite any authority or a definition of the phrase light-based pulse oximetry functionality. For its part, Masimo responds that "Apple's 'covered articles' argument fails [since] Apple admits that the LW/A 2 Watch [[ ]] as the adjudicated infringing Apple Watches [from the underlying investigation]." Masimo Response at 12. Masimo specifically points out that "Apple presented an attempted work-around that keeps [[ ]] final processing to its companion device required for operation of the Watch, the paired Redesigned iPhone." Masimo Sur-Reply at 6. As such, Masimo concludes that the Redesign 2 Watch itself is a "covered article" requiring an infringement analysis to determine whether the articles at issue are subject to the limited exclusion order. Masimo Response at 12; see also Masimo Sur-Reply at 22 ("[S]kipping the infringement analysis here would be contrary to law" because "exclusion orders 'apply to any articles—new, modified, or otherwise—that are 'covered by' the patent claims.'") (quoting CBP HQ Ruling H297262 at 17).

The EOE Branch finds that Apple's reading of the plain language definition is far too narrow. For instance, the Abstract of the '502 patent notes that, in disclosing "noninvasive methods, devices, and systems for measuring various blood constituents or analytes," a particular embodiment includes "a light source [that] comprises LEDs and super-luminescent LEDs [and a] detector [that] comprises a plurality of photodetectors[.]" Furthermore, the asserted claims in the '502 patent, *inter alia*, recite "a plurality of emitters," "four photodiodes," and "a protrusion," none of which does Apple dispute are still present on the Redesign 2 Apple Watch. '502 Patent, col. 46:22-44. As such, Apple's reading of "light-based pulse oximetry functionality" that ignores the features and functionalities above, is too limited and, even with certain processors relocated to the Redesigned iPhone, does not automatically take the Redesign 2 Apple Watch outside the scope of the investigation. This conclusion is further supported by the fact that one of Masimo's theories of infringement in this *inter partes* proceeding contends that the Redesign 2 Apple Watch, by itself and without consideration of the Redesigned iPhone, meets every limitation in Claim 22 of the '502 patent. Accordingly, the EOE Branch rejects Apple's argument that the Redesign 2 Watch is not a "covered article" that is outside the scope of the investigation.

Apple's reliance on Certain Automated Mechanical Transmission Systems does not require a different conclusion. Apple cites the Commission Opinion in that investigation as support for its position that the articles at issue fall outside the scope of the 1276 LEO because to do otherwise would improperly expand the scope of the remedial order. See Apple Reply at 5, FN 4. In the 503 investigation, the Commission found that the remedial order did not "cover AMT systems for ***other vehicles***" when "the notice of investigation identified the infringing products as AMT systems ***for medium-duty and heavy-duty trucks***, and components thereof." Certain Automated Mechanical Transmission Systems For Medium-Duty and Heavy-Duty Trucks, and Components Thereof, Inv. No. 337-TA-503, EDIS Doc. ID 230547, Commission Opinion at 4 (emphasis added) (Public) (May 9, 2005). Although not cited by Apple, the "other vehicles" referenced in the administrative record during the investigation at the Commission were "passenger cars, construction machinery, cranes, coaches and city buses." Certain Automated Mechanical Transmission Systems For Medium-Duty and Heavy-Duty Trucks, and Components Thereof, Inv. No. 337-TA-503, EDIS Doc. ID 217736, Respondent's Post-hearing Statement at 126 (Public) (November 5, 2004). The Commission's findings, therefore, were based on the distinction between vehicles qualifying as

trucks, which were expressly included in notice of investigation's plain English statement (*i.e.*, Medium-Duty and Heavy-Duty ***Trucks***) and the vehicles enumerated above that do not qualify as such in the first instance. While "passenger cars, construction machinery, cranes, coaches and city buses" may constitute vehicles in the broadest sense, and some could have an automated mechanical transmission system, there is no plausible basis to consider such vehicles as trucks and therefore no need to consider whether they were trucks *with a medium-duty or heavy-duty transmission system*.

Since Apple has not carried its burden to show that the Redesign 2 Watch, by itself or in combination with the Redesigned iPhone, is not a "covered article," the question turns to the primary test, as outlined below, regarding application of a Section 337 exclusion and, specifically, whether the articles at issue are covered by the relevant patent claims under the traditional test for patent infringement.

3. Patent Infringement Is The Touchstone For Determining Whether An Article Is Subject To An Exclusion Order Under Section 337

In applying the Commission's precedent concerning its remedial orders under Section 337, the EOE Branch has recognized that "an infringement analysis is required and remains the test to determine admissibility under Section 337 absent specific direction from the Commission, such as in an exclusion order with express indication in any Commission Opinion from the underlying investigation." CBP HQ Ruling H325119 (dated November 30, 2023) at 20. As the EOE Branch further explained:

> The scope of the exclusion order, however, is best understood to encompass articles "covered by" the relevant patent claims, the infringement of which formed the basis of the violation of Section 337 in the underlying investigation and resulted in the issuance of the exclusion order. As [the Commission] has repeatedly confirmed: "The Commission's long-standing practice is to direct its remedial orders to all products ***covered by the patent claims*** as to which a violation has been found, rather than limiting its orders only to those specific models selected for the infringement analysis[.] [W]hile individual models may be evaluated to determine importation and infringement, the Commission's jurisdiction extends to all models of ***infringing products*** that are imported at the time of the Commission's determination ***and to all such products that will be imported during the life of the remedial orders.***" Certain Road Construction Machines and Components Thereof, Inv. No. 337-TA-1088 (Modification), Commission Opinion, Doc. ID 719534 (Sept. 14, 2020) at 13 (emphasis added) (quoting Optical Disk Controller Chips and Chipsets and Products Containing Same, including DVD Players and PC Optical Storage Devices, Inv. No. 337-TA-506, Comm'n Op. at 56-57 (Sept. 28, 2005) (that quoted Certain Hardware Logic Emulation Systems & Components Thereof, Inv. No. 337-TA-383, Comm'n Op., 1998 WL 307240, *9 (Mar. 31, 1998))).
>
> Moreover, the Commission has spoken to this exact question whether, for purposes of Section 337, a redesigned article may be considered to fall within an exclusion order's scope ***without first determining infringement***. The Commission made

clear, during a modification proceeding in a different investigation, that, as in this *inter partes* proceeding, the patent holder has point[ed] to no law that would authorize the Commission to determine whether previously unadjudicated products fall within the scope of remedial orders without first determining whether those products infringe the relevant claims of the patent-at-issue. In fact, the Commission has explicitly found that the issue is "whether the language of the claims reads on the redesigned products as required under the standard two-part infringement analysis." Certain Network Devices, Related Software and Components Thereof (II) (Modification 2), Inv. No. 337-TA-945, EDIS Doc. ID 650147, Public Commission Opinion (Jul. 12, 2018) at 22 (emphasis added) (citing Certain Network Devices, Related Software and Components Thereof (I), Inv. No. 337-TA-945 (Enforcement), Comm'n Order at (3) (Aug. 4, 2017); see MBO Labs, Inc v. Becton, Dickinson & Co., 474 F.3d 1323, 1329 (Fed. Cir. 2007).

As such, it is understood that "[t]he Commission has always issued its orders in terms of 'infringing' products, and has always intended them, as in this case, to prohibit to [sic] future importation or sale of products which were not specifically adjudged infringing in the violation proceeding, but do in fact infringe. The Commission has consistently issued exclusion orders coextensive with the violation of section 337 found to exist. Thus, in cases where the violation found involves infringement of patent claims, the Commission has consistently ordered the exclusion of articles which infringe the relevant patent claims." Certain Erasable Programmable Read Only Memories, Inv. No. 337-TA-276, Enforcement Proceeding, Comm'n Op. at 11, EDIS Doc ID 43536 (Aug. 1991). Therefore, infringement is the touchstone for admissibility questions under 19 C.F.R. § 177 when administering a Section 337 exclusion order as "the language of the patent claims are controlling as to the scope of the remedial orders[,]" Certain Digital Video Receivers and Hardware and Software Components Thereof, Inv. No. 337-TA-1001, EDIS Doc. ID 630893, Public Commission Opinion (Dec. 6, 2017) at 37, and not whether an article qualifies as the type of commodity identified in the notice of investigation or falls under a plain English statement regarding the category of products included with the exclusion order.

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"[The Commission's] orders direct [Customs] to bar ***infringing products*** from entering the country," Yingbin-Nature, 535 F.3d at 1330 (emphasis added), and it is "the language of the patent claims [that] control[s] as to the scope of the remedial orders." Certain Digital Video Receivers and Hardware and Software Components Thereof, Inv. No. 337-TA-1001, EDIS Doc. ID 630893, Public Commission Opinion (Dec. 6, 2017) at 37.

Accordingly, when CBP decides under 19 C.F.R. § 177 whether an article is subject to an exclusion order under Section 337, it is not enough that the article is the same type of commodity identified in the Commission's notice of investigation from the underlying matter. Instead, the Commission has made clear that the traditional test

> for patent infringement remains the one for CBP to apply when administering an exclusion order.

CBP HQ Ruling H325119 at 20-23.

As indicated above, both Commission and EOE Branch precedent makes clear that the traditional test for patent infringement remains the touchstone for CBP when administering a Section 337 exclusion order. Accordingly, the test that the EOE Branch must apply requires an analysis whether an unadjudicated article that falls within the scope of the underlying investigation infringes any claims from the patents at issue based on the traditional two-step approach noted above. The analysis below turns to consideration of this test and whether Apple has carried its burden to show (i) that the Apple Watch, as redesigned, when considered alone, does not infringe claim 22 of the '502 patent; (ii) that the Apple Watch and iPhone, as redesigned, when considered in combination, do not infringe claim 22 of the '502 patent or claims 12, 24, or 30 of the '648 patent; or (iii) that the Apple Watch and iPhone, as redesigned, when considered in combination, do not infringe claim 22 of the '502 patent or claims 12, 24, or 30 of the '648 under the doctrine of equivalents as applied by CBP.

B. Admissibility Question Regarding Infringement of Claim 22 From The '502 Patent By The Redesign 2 Watch When Considered Alone

Masimo's first theory of infringement is that the Redesign 2 Watch, when considered alone, literally infringes Claim 22 of the '502 patent. Masimo Response at 2. The basis for its contention is centered on Masimo's view that "the LW/A 2 Watch-measured PPGs are 'indicative of' oxygen saturation[.]" Masimo Post Oral Discussion Submission at 13. Apple disagrees with Masimo and makes two arguments. First, Apple argues that the Redesign 2 Watch alone does not infringe claim 22 of the '502 patent because "the preamble is limiting" and, as such, the Redesign 2 Watch cannot infringe as it is not a user-worn device "configured to non-invasively measure an oxygen saturation of a user" as required by the preamble in claim 19 and from which claim 22 depends. Apple Reply at 2. Second, Apple argues that "even if the preamble was not limiting[], the Redesign 2 Watch does not satisfy the other limitations of claim 22 because the Watch itself cannot output 'measurements' responsive to the recorded PPG signals, and the individual PPG signals themselves are not 'indicative of' oxygen saturation." Id.

The parties agree that the phrase "user-worn device" recited in the preamble is limiting but disagree whether the remainder of the preamble reciting "configured to non-invasively measure an oxygen saturation" is limiting as well. See Apple Reply at 20; see also Masimo Response at 17. Apple argues that the preamble is limiting for two reasons. First, Apple argues that Masimo should be "judicially estopped" from adopting a position that the "configured to" language in the preamble of Claim 22 is not limiting because the "[t]he parties [] stipulated that all preambles of all asserted claims are limiting" during the underlying investigation and Masimo has "benefited from that position[.]" Apple Reply at 18-19; see also Apple Post-Oral Discussion Submission at 8. Masimo disagrees and argues that the stipulation should not apply in this *inter partes* proceeding because "the parties expressly limited the stipulation to the 'Investigation only.'" Masimo Sur-Reply at 5. Masimo further argues that "there is nothing 'clearly inconsistent' in Masimo's positions" because the Commission also found "that [the prior art reference] Lumidigm did not

satisfy 'several other Limitations' of Claim 22" in addition to not satisfying the preamble. Masimo Sur-Reply at 7. Second, Apple argues that that the "the 'configured to' language in the preamble … is limiting [based on Federal Circuit precedent] because it states a 'necessary and defining aspect of the claimed invention.'" Apple Reply at 20 (citing On Demand Mach. Corp. v. Ingram Indus., 442 F.3d 1331, 1343 (Fed. Cir. 2006)). Masimo disagrees and argues that "the preamble's 'configured to' clause is non-limiting statement of use." Masimo Sur-Reply at 5.

Although not expressly raised by the parties, it become evident to the EOE Branch during its review and analysis of the parties' arguments that the Commission may have already addressed the answer to this issue during the underlying investigation and, in such a case, would have reached a determination that, under 19 C.F.R. Part 210, is binding on CBP and must be applied in this *inter partes* proceeding. When confronting such a possibility, the EOE Branch may, in its discretion, request confirmation or clarification from the Commission on the issue presented. See CBP HQ Ruling H325116 / HQ H325117 (dated May 27, 2022) at 11 ("On April 21, 2022, the EOE Branch sent a letter to the Commission seeking 'confirmation or clarification whether the Commission reached any finding or determination whether the [respondent's] legacy products satisfied the obstruction detector limitation based on (1) the safety reversing sensors, (2) the processor, or (3) the RF transceiver present on the legacy products.' Certain Moveable Barrier Operator Systems and Components Thereof, Inv. No. 337-TA-1209, EDIS Doc. ID 770512, Letter from U.S. Customs and Border Protection Regarding Clarification on a Commission Determination (April 11, 2022) (Confidential); Certain Moveable Barrier Operator Systems and Components Thereof, Inv. No. 337-TA-1209, EDIS Doc. ID 770511, Letter from U.S. Customs and Border Protection Regarding Clarification on a Commission Determination (April 11, 2022) (Public) at 2.").

Such requests generally ask whether the Commission, in reaching a final determination that there is a violation of Section 337, addressed the specific issue under consideration and, if so, what was the outcome for that precise issue. In this matter, the relevant question concerns the ALJ's findings whether the preamble limitations of claim 19 from the '502 patent are met by the Lumidigm prior art reference. See FID at 118; see also FID at 114 ("In consideration of the parties' arguments, the undersigned finds that the evidence of record fails to show that one of ordinary skill would have been enabled to measure oxygen saturation in the Lumidigm wristwatch."). To confirm whether the Commission found or determined that the preamble of claim 19 of the '502 patent (from which claim 22 depends, as noted above) was limiting, the EOE Branch sent a request for confirmation or clarification to the Commission on September 13, 2024. See EOE Branch Request for Confirmation or Clarification (dated September 13, 2024). Specifically, the EOE Branch made the following request to the Commission:

> It is our understanding that in the underlying investigation the Commission found a violation of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, based on infringement of claims 22 and 28 of U.S. Patent No. 10,912,502 ("the '502 patent") and claims 12, 24, and 30 of U.S. Patent No. 10,945,648 ("the '648 patent") by Apple, Inc. ("Apple"). During the underlying investigation, the parties stipulated [[
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>]]."
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> Certain Light-Based Physiological Measurement Devices and Components

> Thereof, Inv. No. 337-TA-1276, EDIS Doc. ID 770692, Joint Stipulation of Facts (May 13, 2022) (confidential) at 2. In determining whether the accused wearable electronic devices (i.e., Apple Watch products) infringed claim 22 of the '502 patent, the Administrative Law Judge noted "[t]here is no dispute that the Accused Products meet the limitations of the preamble of '502 patent claim 19, which requires '[a] user-worn device configured to non-invasively measure an oxygen saturation of a user.'" Certain Light-Based Physiological Measurement Devices and Components Thereof, Inv. No. 337-TA-1276, EDIS Doc. ID 1950712, Final Initial Determination (January 10, 2023) ("FID") (public) at 40. Moreover, in discussing Apple's invalidity arguments for the relevant claims in the '502 patent, the Administrative Law Judge found that claim 22 was not rendered obvious by Lumidigm, alone or in combination with other prior art, because "Apple has not shown that the preamble limitations of '502 patent claim 19 are met by Lumidigm." FID at 118. See also FID at 114 ("In consideration of the parties' arguments, the undersigned finds that the evidence of record fails to show that one of ordinary skill would have been enabled to measure oxygen saturation in the Lumidigm wristwatch.").
>
> In the context of a request for an administrative ruling under 19 C.F.R. Part 177, an issue has arisen with respect to the Commission's findings during the underlying investigation. Specifically, the EOE Branch is seeking confirmation or clarification whether the Commission found or determined that the preamble of claim 19 of the '502 patent (from which claim 22 depends) was limiting. If the Commission found or determined the preamble to be limiting, we request the Commission's confirmation or clarification regarding whether it found the preamble to be limiting in its entirety or only found certain parts of the preamble to be limiting and, if so, which parts (e.g., "a user worn device" or "configured to" or "non-invasively measure an oxygen saturation of a user" or a combination thereof).

EOE Branch Request to ITC for Confirmation or Clarification (dated September 13, 2024).

The Commission replied with a letter to the EOE Branch and confirmed that it found the preamble in claim 19 of the '502 patent to be limiting ***in its entirety***. Specifically, the ITC stated:

> Thank you for your letter of September 13, 2024, seeking clarification as to the proceedings in the above-referenced investigation, Certain Light-Based Physiological Measurement Devices and Components Thereof, Inv. No. 337-TA-1276. Specifically, you seek confirmation or clarification regarding whether and to what extent the Commission found or determined that the preamble is limiting in claim 19 of U.S. Patent No. 10,912,502 ("the '502 patent"). In sum, the Commission considered the entirety of the preamble of claim 19 of the '502 patent to be limiting.
>
> In the above-referenced investigation, the Commission found a violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, based on infringement of claims 22 and 28 of the '502 patent, among others, by Respondent Apple Inc.

("Apple"). See 88 Fed. Reg. 74032-33 (Nov. 1, 2023). Complainants Masimo Corporation and Cercacor Laboratories, Inc. (collectively "Masimo") asserted several other patents in the investigation, including U.S. Patent No. 10,912,501 ("the '501 patent"), which is relevant to this issue and is in the same patent family as the '502 patent. Id.

In the '502 patent, claim 22 depends from claim 19, which includes preamble language describing "[a] user-worn device configured to non-invasively measure an oxygen saturation of a user." See Light-Based Physiological Measurement Devices, Commission Opinion ("Comm'n Op.") at 8-10, EDIS Doc. ID 808521 (Public Version) (Nov. 14, 2023).

As you have recognized, the parties filed a joint stipulation wherein Masimo stipulated that "[f]or purposes of this Investigation only, Masimo does not contest that the preambles of the claims of the '501 patent, the '502 patent, [among others,] are limiting on the claims." Light-Based Physiological Measurement Devices, Joint Stipulation of Facts ¶ 9, EDIS Doc. ID 770692 (Confidential) (May 13, 2022). This stipulation was cited in the Final Initial Determination in the context of infringement for claim 1 of the '501 patent, which contains similar language to claim 19 of the '502 patent. Light-Based Physiological Measurement Devices, Final Initial Determination ("Final ID") at 34 n.8, EDIS Doc. ID 789795 (Public Version) (Jan. 10, 2023).

When addressing infringement of claims 19 and 22 of the '502 patent, the Final ID recognized that "[t]here is no dispute that the Accused Products meet the limitations of the preamble of '502 patent claim 19." Id. at 40. The Final ID cited evidence, first discussed in the context of the '501 patent, showing that "the Accused Products are watches configured to measure blood oxygen saturation." Id. at 34. The Commission determined not to review the Final ID's findings with respect to infringement regarding the '501 patent and the '502 patent. See 88 Fed. Reg. 32243-46 (May 19, 2023).

In the context of the technical prong of the domestic industry requirement, the Final ID found that certain prototype devices met the limitations of claim 28 of the '502 patent, which has the same preamble language as claim 19. Final ID at 68-69. The Final ID referenced an earlier discussion of similar preamble language in the '501 patent, finding that the prototype devices measured blood oxygen saturation and met the "user-worn" limitation. Id. (citing Id. at 60-63). The Commission determined to review the Final ID's domestic industry findings and affirmed the existence of a domestic industry with respect to the '502 patent without modifying the Final ID's technical prong analysis. Comm'n Op. at 66-68.

In the context of invalidity, the Final ID found that a prior art reference, U.S. Patent No. 7,620,212 (RX-0411, "Lumidigm"), did not meet the preamble limitations of claim 19 of the '502 patent, because Lumidigm did not enable the measurement of oxygen saturation in its only user-worn embodiment, which was a wristwatch.

> Final ID at 113-118. The Final ID further found that claim 22 of the '502 patent was not shown to be obvious in view of Lumidigm based on the failure to meet these preamble limitations and other limitations in the claims. Id. at 113-27. The Commission determined to review the Final ID's obviousness findings and affirmed the Final ID's analysis of the preamble language of claim 19 of the '502 patent. Comm'n Op. at 22-23. The Commission also affirmed, with modified reasoning, the Final ID's determination that claim 22 of the '502 patent was not shown to be obvious in view of Lumidigm. Id. at 21-49.
>
> In accordance with the foregoing, we confirm that the Commission found the preamble of claim 19 of the '502 patent to be limiting. The Commission explicitly discussed the preamble language of claim 19 in the context of infringement and invalidity. See Final ID at 34, 40, 115-118; Comm'n Op. at 22-23. With respect to the specific preamble phrases identified in your letter, the Commission's infringement and invalidity analysis explicitly considered "a user-worn device," "configured to," and "non-invasively measure an oxygen saturation of a user" as claim limitations. See Final ID at 34, 40, 115-118; Comm'n Op. at 22-23. The Commission also relied on identical preamble language in claim 28 of the '502 patent with respect to the technical prong of the domestic industry requirement. See Final ID at 60-63, 68-69. Accordingly, the Commission considered the entirety of the preamble of claim 19 of the '502 patent to be limiting.

Certain Light-Based Physiological Measurement Devices and Components Thereof, Inv. No. 337-TA-1276, EDIS Doc. ID 833876, Response to Letter of Clarification (Public) (Oct. 2, 2024).

The administrative record in this *inter partes* proceeding confirms that Apple has based its non-infringement position for the Redesign 2 Watch, in reply to Masimo's "watch only" theory of infringement for purposes of claim 22 of the '502 patent, on the device not satisfying every clause in the preamble and specifically that the limitations in the preamble require a device to be "configured to non-invasively measure an oxygen saturation of a user." See Ruling Request at 30; see also Apply Reply at 21 ("There is nothing inconsistent about the preamble's requirement that the *user-worn device* be 'configured to non-invasively measure an oxygen saturation of a user' and the body's additional requirement that the *measurements* themselves be 'indicative of the oxygen saturation of the user.' Put differently, the 'indicative of the oxygen saturation of the user' limitation in the body of the claim specifies the characteristics of the *measurements* output by the one or more processors, while the preamble recites the characteristics of the *user-worn device itself*.") (emphasis in original). In essence, Apple's argument is that, irrespective of the meaning for "measurements . . . indicative of" in the claim body, the "measure an oxygen saturation of a user" in the preamble, if limiting (as the Commission has confirmed above), requires that an accused device perform the final calculation, or at least be programmed to perform that calculation under the "configured to" construction discussed above.

As indicated in its response, Masimo recognizes that Apple has presented such a non-infringement argument with respect to the preamble text reciting "non-invasively measure an oxygen saturation of a user." See Masimo Response at 13 (reproduced below).

B. Apple Argues Non-Infringement Based Only On The "Configured To" Limitations

Apple and its expert argue non-infringement based only on the following claim language:

'502 Patent Element 19[Pre]	"a user-worn device configured to non-invasively measure an oxygen saturation of a user"
'502 Patent Element 19[E]	"one or more processors configured to … output measurements … indicative of the oxygen saturation of the user"
'502 Patent Element 28[Pre]	"a user-worn device configured to non-invasively measure an oxygen saturation of a user"
'502 Patent Element 28[I]	"one or more processors configured to … calculate an oxygen saturation measurement of the user"
'502 Patent Element 28[J]	"a network interface configured to wirelessly communicate the oxygen saturation measurement"
'502 Patent Element 28[K]	"user interface [] configured to display indicia responsive to the oxygen saturation measurement."
'648 Patent Element 8[Pre]	"a user-worn device configured to non-invasively determine measurements of a physiological parameter"
'648 Patent Element 12	"one or more processors configured to receive one or more signals from at least one of the photodiodes and output measurements of a physiological parameter of a user" and "wherein the physiological parameter comprises oxygen or oxygen saturation"
'648 Patent Element 20[E]	"one or more processors configured to receive one or more signals from at least one of the photodiodes and determine measurements of oxygen saturation of the user"

Despite this recognition, Masimo has not presented a theory of infringement regarding how this aspect of the claim is satisfied if the preamble, in its entirety, is found to be limiting. Instead, Masimo has relied solely on its argument that it would be improper, for the reasons articulated in its submissions, to find this clause in the preamble to be limiting. Therefore, in light of the Commission's confirmation or clarification, and due to the lack of an infringement contention from Masimo that the Redesign 2 Watch, by itself, satisfies the entirety of the preamble in claim 19 of the '502 patent (specifically the limitation "configured to non-invasively measure an oxygen saturation of a user"), the EOE Branch finds that Masimo has not presented a complete theory of infringement with respect to all limitations.

Given the lack of a complete infringement contention, the EOE Branch finds that Masimo's theory of infringement for the Redesign 2 Watch, when considered ***alone*** for purposes of claim 22 of the '502 patent, is not a basis to refuse the article's entry pursuant to the 1276 LEO. See Greenlaw v. United States, 554 U.S. 237, 243 (2008) ("In our adversary system, in both civil and criminal cases, in the first instance and on appeal, *we follow the principle of party presentation.* ***That is, we rely on the parties to frame the issues for decision and assign to courts the role of neutral arbiter of matters the parties present***.") (emphasis added); see also Astellas Pharma, Inc. v. Sandoz Inc., 2024 U.S. App. LEXIS 23669, at *12 (Fed. Cir. 2024) ("It is for the parties—not the court—to chart the course of the litigation."); see also Certain Robotic Floor Cleaning Devices

and Components Thereof, Inv. No. 337-TA-1252, Initial Determination on Violation of Section 337 and Recommended Determination on Remedy and Bonding, EDIS Doc. ID 783814 (Public) (October 7, 2022) at 10, FN 16 ("***Given that [complainant] did not dispute that the [relevant] products in this category are non-infringing, this Initial Determination finds no reason to conclude otherwise***.") (emphasis added), aff'd, Notice of Commission Final Determination Finding a Violation of Section 337, EDIS Doc. ID 792838 (Public) (March 21, 2023) ("All findings in the FID that are not inconsistent with the Commission's determination are affirmed."); see also CBP HQ Ruling HQ H340844 (dated September 27, 2024) at 6-7.

C. Admissibility Question Regarding Infringement Of The Asserted Patent Claims When The Redesign 2 Watch And Redesigned iPhone Are Considered In Combination

Masimo's second theory of infringement is that "the LW/A 2 Watch and iPhone together are 'a user-worn device' as claimed" and thereby "provide the pulse oximetry functionality that Apple now argues is missing from the Watch alone." Masimo Response at 25. Specifically, according to Masimo, "the LW/A 2 Watch and iPhone together literally infringe four claims—Claim 22 of the '502 Patent and Claims 12, 24, and 30 of the '648 Patent." Id.

In response to Masimo's argument "that the combination of the Redesign 2 Watch and Redesigned iPhone directly infringes claim 22 of the '502 patent and claims 12, 24, and 30 of the '648 patent" under a theory of "distributed processing" over multiple devices, Apple argues that "[t]he adjudicated claims, however, only cover a ***single*** 'user-worn device.'" Apple Reply at 2 (emphasis added). Specifically, Apple's argument is based on its view (1) that considering the Redesign 2 Watch and Redesigned iPhone in combination is contrary to the intrinsic evidence from the asserted patents; (2) that Masimo is estopped from making its "distributed processing" argument based on the responses to Apple's invalidity arguments during the underlying investigation; and (3) that, even if the asserted claims are not limited to a single device, the Redesigned iPhone as a factual matter is not "user-worn." Apply Reply at 9-18. These arguments are addressed below.

1. The Intrinsic Evidence From The Asserted Patents

As a preliminary matter, to the extent the parties dispute the meaning of any claim limitations in the asserted patents, including "user-worn device," they do not offer any express constructions for such limitations.[4] See Masimo Sur-Reply at 13. Accordingly, in reviewing the parties' specific arguments and responses thereto in this context, the claim limitations will be given their plain and ordinary meaning to one skilled in the art. See Thorner v. Sony Computer Entm't Am. LLC, 669 F.3d 1362 (Fed. Cir. 2012). As Thorner made clear, "[t]he words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history." Id. at 1365 (citing Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). Significantly, as "[i]t is the claims that define the metes and bounds of the patentee's invention," a "patentee is free to

[4] The Commission did not provide an express construction for the claim limitations at issue as there was no dispute between the parties on these grounds with respect to the legacy products in the underlying investigation and therefore a detailed analysis on claim construction was not necessary to find infringement. See FID at 26-33.

choose a broad term and expect to obtain the full scope of its plain and ordinary meaning unless the patentee explicitly redefines the term or disavows its full scope." Id. at 1367. There are only two exceptions to the general rule above that words of a claim are given their ordinary and customary meaning: (1) "when a patentee sets out a definition and acts as his own lexicographer" and (2) "when the patentee disavows the full scope of a claim term either in the specification or during prosecution." Id. at 1365 (citing Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1580 (Fed. Cir. 1996)).

"To act as its own lexicographer, a patentee must 'clearly set forth a definition of the disputed claim term' other than its plain and ordinary meaning." Thorner at 1365 (quoting CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002). "It is not enough for a patentee to simply disclose a single embodiment or use a word in the same manner in all embodiments, the patentee must 'clearly express an intent' to redefine the term." Id. (quoting Helmsderfer v. Bobrick Washroom Equip., Inc., 527 F.3d 1379, 1381 (Fed. Cir. 2008)). For example, as Thorner noted, the Federal Circuit has "held that [a] patentee acted as its own lexicographer when the specification stated: 'Multiple embossed' means two or more embossing patterns are superimposed on the web to create a complex pattern of differing depths of embossing.'" Id. at 1366 (quoting 3M Innovative Properties Co. v. Avery Dennison Corp., 350 F.3d 1365, 1369, 1371 (Fed. Cir. 2004).

With respect to the standard for disavowal of claim scope, as noted previously, that standard is "exacting." Thorner at 1366; see also Poly-America, L.P. v. API Indus., Inc., 839 F.3d 1131, 1136 (Fed. Cir. 2016) ("[T]he standard for disavowal is exacting, requiring clear and unequivocal evidence that the claimed invention includes or does not include a particular feature."). "Where the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question." Scimed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1341 (Fed. Cir. 2001). "The patentee may demonstrate intent to deviate from the ordinary and accustomed meaning of a claim term by including in the specification expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1325 (Fed. Cir. 2002). However, "[m]ere criticism of a particular embodiment encompassed in the plain meaning of a claim term is not sufficient to rise to the level of clear disavowal." Thorner at 1366 (citing Epistar Corp. v. Int'l Trade Comm'n, 566 F.3d 1321, 1335 (Fed. Cir. 2009) (holding that even a direct criticism of a particular technique did not rise to the level of clear disavowal)). And, as highlighted above, any disclaimer must be "clear and unmistakable." Thorner at 1367.

Apple does not cite Thorner in this *inter partes* proceeding or argue that either of the two exceptions from above apply in this context. Accordingly, as Apple has not argued, with respect to "user-worn device," that Masimo set out a specific definition and acted as its own lexicographer or disavowed the full claim scope for this term, this limitation will receive its plain and ordinary meaning to one skilled in the art when read in the context of the specification and prosecution history and the EOE Branch will determine whether such a plain and ordinary meaning limits the asserted claims to a single device.

As the primary basis for its view that the asserted claims only cover a ***single*** "user-worn device," Apple argues that Masimo's theory of infringement is unsupportable because Masimo's position "that the adjudicated patent claims cover the combination of the Redesign 2 Watch and Redesigned iPhone is ***contrary to the intrinsic evidence***." Apple Reply at 9 (emphasis added). The starting point for Apple's analysis is a recitation of each independent claim that refers to "a" user-worn device and the respective preambles and the dependent claims that refer back to "the" user-worn device. See Apple Reply at 9-12. In quoting this claim language, Apple observes that "all adjudicated patent claims refer to 'a user-worn device' and 'the user-worn device.'" Apple Reply at 12. But Apple makes this observation without a citation to, or analysis of, any patent case law on claim construction or providing the reasons that it believes such claim drafting carries particular significance. Instead, Apple recites the claim language as self-evident support for its view that the usage of the indefinite article "a" followed by the definite article "the" means this must be a ***single*** "user-worn device." Notably, this recitation argument is not repeated in Apple's Post-Oral Discussion submission, which instead focuses primarily, if not exclusively, on Masimo's statements in *Apple I* as support for its argument that "***a*** user-worn device' refer[s] only to a singular device (e.g., a watch)." Apple Post-Oral Discussion Submission at 7.

As the EOE Branch already held in this ruling, Masimo's statements from *Apple I* do not constitute a "clear and unmistakable" disclaimer of claim scope. Furthermore, Apple's arguments that merely recite the claim language do not form a sufficient basis to conclude that the term "user-worn device" is limited to a single device. This is especially the case when, as noted above, Masimo has not acted as its own lexicographer to define "user-worn device" to mean a single device or disavowed any claim scope. Accordingly, Apple has not demonstrated how the plain and ordinary meaning of this claim term forecloses an interpretation that covers a user-worn device consisting of separate housings with processors on each. Conversely, Masimo has cited evidence supporting such a finding. See Masimo Response at 25 ("[A] 'programmed to' construction does not require locating all of the recited processors in a single housing or device. … The specification provides examples that a POSITA would understand to show such distributed processing. For example, the specification describes a monitoring device 200B that includes a finger clip sensor 201b connected to a monitor 209b via a cable. '502 Patent at 17:27-30, FIG. 2B."). Masimo's argument based on the specification explains that the monitor and sensor can be wirelessly coupled. Id. (citing '502 Patent at 17:51-55 ("[t]he sensor 201b and the monitor 209b can be coupled together via a wireless communication link, such as an infrared link, radio frequency channel, or any other wireless communication protocol and channel.")). Moreover, this argument demonstrates that, by communicating with wireless communication protocols, "a POSITA would understand that such a separate sensor and monitor would each have some processing capability." Id.; see also Attachment 1 to Masimo Response ("Madisetti Declaration") at ¶¶ 105. The above supports a finding that "[t]he *processor in the **sensor** and the processor in the **monitor*** are examples of the claimed 'one or more processors'" and that they do not have to be located on the same housing or device. Id. (emphasis added).

Most importantly, Masimo counters Apple's argument concerning the intrinsic evidence by demonstrating how "[t]he specification of the '502 and '648 Patents confirms that 'a user-worn device' in the claims could be a sensor that is ***physically separate*** from a monitor that performs the ultimate calculation." Masimo Response at 26 (emphasis added). The EOE Branch agrees with Masimo that "the specification describes multiple embodiments of 'a monitoring device'

comprising a sensor for PPG measurements and a monitor for computing physiological parameter measurements based on the sensor-measured PPGs." Id. Masimo further notes that "the specification describes a monitoring device 200B comprising a user-worn monitor and a finger-clip sensor. Specifically, the monitoring device 200B 'includes a finger clip sensor 201b connected to a monitor 209b via a cable.' '502 Patent at 17:27-30, FIG. 2B. The monitor 209b can include the processing used to compute the measurement of one or more physiological parameters. Id. at 17:32-40. The monitor 209b 'can be attached to the patient' using a 'belt clip or straps (see, *e.g.*, FIG. 2C) that facilitate attachment to a patient's belt, arm, leg, or the like.'" Masimo Response at 26 (citing '502 Patent, Col. 17:56-59).

The embodiments from the specification are depicted below and, contrary to Apple's position, they support a finding that the intrinsic evidence, consistent with the description above, shows the claims are not limited to a ***single*** "user-worn device."

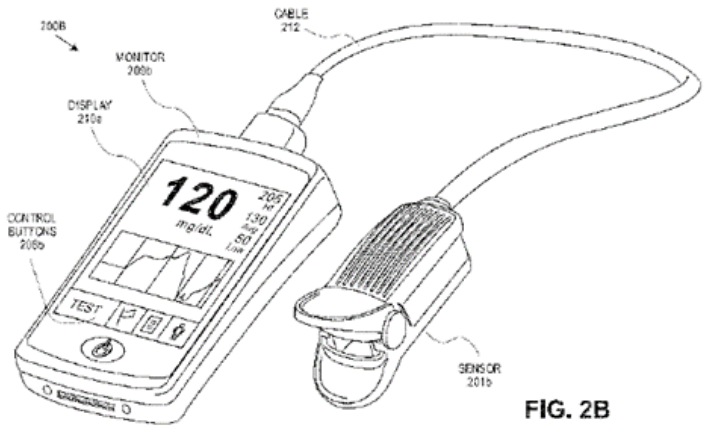


FIG. 2B

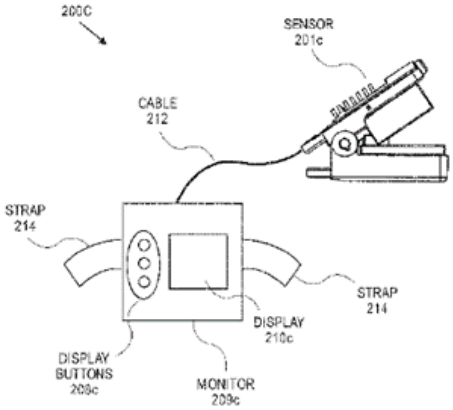


FIG. 2C

Furthermore, as Masimo explains with respect to Figure 1 in the specification:

> Regarding the sensor, the *specification teaches that "[t]he data collection system 100 can include a sensor 101 (or multiple sensors) that is coupled to a processing device or physiological monitor 109"* ***such that "the sensor 101 and monitor 109 are integrated into a single unit" or "the sensor 101 and the monitor 109 are separate from each other and communicate one with another in any suitable manner, such as via a wired or wireless connection***." Id. at 11:56-63. Figure 2C shows such a separate sensor 201c that communicates with a monitor 209c through a cable 212, and the specification explains the separate sensor 201c and monitor 209c can be coupled via "wireless communication." Id. at FIG. 2C, 17:51-55.

Apple did not respond to this point during the oral discussion or its post-oral discussion submissions and therefore this intrinsic evidence remains unrebutted as support for a finding that

the claimed "user-worn device" is not limited to a single device. Apple instead argues that the "context of the claims illustrates that all requirements, including the necessary processing, must occur within a single device." Apple Reply at 12. Apple points to Claim 28 of the '502 patent, which "requires 'a strap configured to position the user-worn device on the user' and claim 12 of the '648 patent requires 'a housing' and 'a strap configured to position the housing proximate tissue of the user when the device is worn.'" In Apple's view, this not only confirms "that 'a user-worn device' is a singular device" but that Masimo has "fail[ed] to explain how a multi-device system could meet these requirements that are clearly directed to a single device." Id.

However, Masimo's sur-reply indicates:

> Apple [has] ignored that the specification uses these same terms to describe embodiments with separate sensors connected by cable or wirelessly to monitors. For example, Figure 2C shows a monitor 209c that is separate from sensor 201c[.] The specification describes that "[t]he monitor 209b can be attached to the patient." '502 Patent at 17:56-62. For example, it explains that 'the monitor 209b can include a belt clip or straps (see, e.g., FIG. 2C) that facilitate attachment to a patient's belt, arm, leg, or the like." Id. Figure 2C (above) shows monitor 209c with its strap 214. As the specification explains, '[t]he monitor 209c shown also includes straps 214c that allow the monitor 209c to be attached to a patient's limb or the like.'" Id. at 18:17-19.

Masimo Sur-Reply at 13-14.

Based on the above, Masimo has shown that the specification provides support for finding "a user-worn device" can encompass two physically separate devices and that Apple has not shown, under the claim term's plain and ordinary meaning, that user-worn device should be limited to a single device.

As an ancillary argument, Apple contends that the use of the term "mobile phone" in claim 24 of the '502 patent, which like claim 22 depends from claim 19, shows that "'the user-worn device' in independent claim 19 cannot encompass a mobile phone like the iPhone because 'the user-worn device' is expressly required, in dependent Claim 24, to transmit the oxygen saturation measurements 'to . . . a mobile phone.'" The language of Claim 24 of the '502 patent is provided below:

> ***The user-worn device*** of claim 19 ***further comprising***:
> ***a network interface configured to wirelessly communicate at least the measurements of oxygen saturation to at least one of: a mobile phone or a computer network***;
> a user interface comprising a touch-screen display, wherein the user interface is configured to display indicia responsive to the measurements of oxygen saturation; and
> a memory device configured to at least temporarily store at least the measurements of oxygen saturation.

'502 Patent, col. 46:22-44.

While not expressly stated, it appears that Apple's legal theory with respect to this argument is based on claim differentiation because dependent claim 24 includes a reference to a "mobile phone" that is not recited in independent claim 19. Under the doctrine of claim differentiation, "different words or phrases used in separate claims are presumed to indicate that the claims have different meanings and scope." Andersen Corp. v. Fiber Composites, LLC, 474 F.3d 1361, 1369 (Fed. Cir. 2007) (quoting Karlin Tech. Inc. v. Surgical Dynamics, Inc., 177 F.3d 968, 971-72 (Fed. Cir. 1999)). However, Apple's resort to claim differentiation does not support its view given that the scope of dependent claim 24 is already narrowed by the requirement that the invention practice the claimed "network interface" and the term "mobile phone[,]" as used in the claim, could refer to an additional mobile phone as Masimo notes. Specifically, as explained by Masimo, dependent claim 24 could be satisfied "by either (1) a device configured to send to a computer network without the mobile phone or (2) a device configured to send to a different mobile phone." Masimo Sur-Reply at 15. The presumption of claim differentiation is strongest in cases where "the limitation in dispute is the only meaningful difference between an independent and dependent claim." InterDigital Communs., LLC v. ITC, 690 F.3d 1318, 1325 (Fed. Cir. 2012). This strong presumption of claim differentiation is not applicable in the present case because the scope of dependent claim 24, as noted above, is already different since it requires the addition of the "network interface." See Andersen Corp. v. Fiber Composites, LLC, 474 F.3d 1361, 1370 (Fed. Cir. 2007) (declining to apply claim differentiation where "there are numerous other differences varying the scope of the claimed subject matter").

The Federal Circuit has routinely held that "the language of a dependent claim cannot change the scope of an independent claim whose meaning is clear on its face." Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp., 831 F.3d 1350, 1360 (Fed. Cir. 2016) ("[w]hile it is true that dependent claims can aid in interpreting the scope of claims from which they depend, they are only an aid to interpretation and are not conclusive. The dependent claim tail cannot wag the independent claim dog.") (quoting N. Am. Vaccine, Inc. v. Am. Cyanamid Co., 7 F.3d 1571, 1577 (Fed. Cir. 1993))). For these reasons, the EOE Branch finds that Apple has not shown that claim differentiation requires that the claimed "user-worn device" be limited to a single device. And most significantly, it has not rebutted the plain and ordinary meaning analysis from above.

Finally, Apple argues that Masimo is "mistaken that the adjudicated claims must cover the multi-device embodiments." Apple Reply at 15. Apple points out that "the Federal Circuit has repeatedly held [] it is '***not necessary*** for each claim to cover every embodiment of the patent.'" Id. (quoting Baran v. Med. Device Techs., Inc., 616 F.3d 1309, 1312 (Fed. Cir. 2010)) (emphasis added). While Apple cites Federal Circuit precedent as support for the general proposition that every claim is not required to cover each embodiment disclosed in the corresponding specification, it does not demonstrate how this proposition applies specifically with respect to the '502 and '648 patents and the embodiments disclosed therein. Moreover, "the claims of a patent are ***always*** to be read or interpreted in light of its specifications." Phillips, 415 F.3d at 1316 (quoting Schriber-Schroth Co. v. Cleveland Trust Co., 311 U.S. 211, 217 (1940)) (emphasis added). And while "the specification often describes very specific embodiments of the invention, [the Federal Circuit has] repeatedly warned against confining the claims to those embodiments." Id. at 1323. Therefore, it is improper to import limitations from the specification into the claims but in the other direction it

is likewise improper to consider an embodiment disclosed in the specification to be outside the claims without a sufficient basis. The Federal Circuit has confirmed that it "normally do[es] not interpret claim terms in a way that excludes embodiments disclosed in the specification." Google LLC v. Ecofactor, Inc., 92 F.4th 1049, 1058 (Fed. Cir. 2024) (quoting Oatey Co. v. IPS Corp., 514 F.3d 1271, 1276 (Fed. Cir. 2008)). Moreover, "[a]t leas[t] where claims can ***reasonably*** [be] interpreted to include a specific embodiment, it is incorrect to construe the claims to exclude that embodiment, ***absent probative evidence [to] the contrary***." SIMO Holdings, Inc. v. H.K. uCloudlink Network Tech., Ltd., 983 F.3d 1367, 1378 (Fed. Cir. 2021) (quoting Oatey, 514 F.3d at 1276, 1277) (emphases added). As noted above, Apple has not demonstrated why the embodiments disclosed in the specifications are not covered by the claims and, therefore, has not provided the "probative evidence to the contrary" needed for such a finding.

2. Apple's Position That The Asserted Patent Claims Are Limited to A "Single" User-Worn Device

Apple argues that the asserted patent claims "***require a single device to perform all requirements, including the necessary processing functions***." Apple Reply at 9 (emphasis added). Apple's support for this position is that each of the independent claims is directed to "***a*** user-worn device" and the preambles in those claims, or the claims that depend from those claims, refer back to "***the*** user-worn device." According to Apple, such drafting within the "context of the [asserted] claims illustrates that all requirements, including the necessary processing, must occur within a single device." As further evidence, Apple points to claim 19 of the '502 patent and the limitation requiring that the four photodiodes be "arranged within the user-worn device." Apple Reply at 12.

However, in raising an argument about the significance of the claim drafting and in particular the use of indefinite and definite articles, such as "***a*** user-worn device" and "***the*** user-worn device," Apple does not contend with the Baldwin line of cases. In such cases, applying what is described as a "general rule," the Federal Circuit:

> has repeatedly emphasized that an indefinite article "a" or "an" in patent parlance carries the meaning of "one or more" in open-ended claims containing the transitional phrase "comprising." KCJ Corp. v. Kinetic Concepts, Inc., 223 F.3d 1351, 1356 (Fed. Cir. 2000). That "a" or "an" can mean "one or more" is best described as a rule, rather than merely as a presumption or even a convention. The exceptions to this rule are extremely limited: a patentee must "evince[] a clear intent" to limit "a" or "an" to "one." Id. The subsequent use of definite articles "the" or "said" in a claim to refer back to the same claim term does not change the general plural rule, but simply reinvokes that non-singular meaning. An exception to the general rule that "a" or "an" means more than one only arises where the language of the claims themselves, the specification, or the prosecution history necessitate a departure from the rule.

Baldwin Graphic Sys., Inc. v. Siebert, Inc., 512 F.3d 1338, 1342-1343 (Fed. Cir. 2008) (emphasis added).

As Apple has not discussed the "general rule" from Baldwin despite raising its arguments concerning the indefinite and definite articles in the claim drafting, this cannot be considered an instance where the exception to the rule would apply, especially given that such exceptions are "extremely limited" in the first place. For the reasons already noted above in connection with the parties' respective arguments regarding the intrinsic evidence, Apple has not shown that language of the claims themselves, the specification, or the prosecution history necessitate a departure from the rule. And the above is consistent with the EOE Branch's determination that the claim term "user-worn device" should receive its plain and ordinary meaning. Accordingly, like in Baldwin itself, the administrative record "does not contain a clear indication that [Masimo] departed from the general rule for the article 'a' [since] [n]othing in the claim language, specification, or prosecution history compels [such] an exceptional reading" that would limit the claims to a single "user-worn device." Baldwin Graphic, 512 F.3d at 1343.

Perhaps even more significant is that, in arguing whether the patent claims "***require a single device to perform all requirements, including the necessary processing functions***," neither party – but particularly Apple given its position on the issue – has not raised Finjan LLC v. SonicWall, Inc., 84 F.4th 963 (Fed. Cir. 2023) or Salazar v. AT&T Mobility LLC, 64 F.4th 1311 (Fed. Cir. 2023). In Finjan, the patent owner (Finjan) argued "that the district court erred in determining that [the accused infringer] SonicWall's Capture ATP technology ***in combination with*** SonicWall's Gateways and/or ES products cannot infringe the asserted claims of the ARB Patent and requiring each recited step be performed by 'a single, standalone computer.'" Finjan, 84 F.4th at 973 (emphasis in the original). Finjan argued that the asserted patent requires "'a computer'—subsequently referred to as 'the computer'—to perform certain steps, where the use of 'a' indicates that 'one or more' computers can perform the various steps of the claim." Id. (quoting Baldwin Graphic, 512 F.3d at 1342).

In response, SonicWall did not dispute "that its Capture ATP and Gateway products are performed by different computers [and] challen[ed] only whether the claims required the 'same computer' to perform the claim limitations." Id. Specifically, SonicWall argued "that even if the reference to 'a computer' may mean 'one or more computers,' the subsequent references to 'the computer' can only be satisfied by the same 'one or more computers' that satisfied the first limitation." Id. at 974.

The Federal Circuit agreed with SonicWall, relying on Salazar (referenced above) and Traxcell Techs., LLC v. Nokia Sols. & Networks Oy, 15 F.4th 1136, 1143-44 (Fed. Cir. 2021). In Nokia, the Federal Circuit explained that "[a]s a matter of plain language, reciting 'a computer' (or a 'first computer') that performs a function, ***and then further reciting that 'the computer' (or 'said first computer') performs multiple additional functions, suggests that such 'computer' must be tied to all those functions***." Id. (emphasis added). Similarly, in Salazar, the Federal Circuit agreed that "the claim term 'a microprocessor' [did] not require there be only one microprocessor [but] ***the subsequent limitations referring back to 'said microprocessor' require[d] that at least one microprocessor be capable of performing each of the claimed functions***." Salazar, 64 F.4th at 1317 (emphasis added). Moreover, in Salazar, the Federal Circuit confirmed that it "did not hold in Baldwin that using an indefinite article somehow displaces the antecedent basis rule, as to require 'said fabric roll' to refer to something other than the same earlier referenced 'pre-soaked fabric roll.'" Salazar at 1316. Significantly, as the Federal Circuit

recognized in Finjan, there is "no inconsistency between the holdings in Salazar and Nokia and the principles outlined in Baldwin. [T]he indefinite article a means one or more in open-ended claims containing the transitional phrase comprising. ***But that is a separate issue from whether the claims require the same component to perform multiple functions or satisfy multiple limitations of a claim***." Finjan at 974 (emphasis added) (internal quotations and citations omitted).

Despite the direct relevance that this case law appears to have for the issue under consideration, as noted above, neither party has cited it, even though Apple in particular is taking the position that asserted the patent claims "***require a single device to perform all requirements, including the necessary processing functions***[.]" Apple Reply at 9 (emphasis added). Since Apple has not cited or analyzed this case law, Apple has not articulated a basis why the EOE Branch should not apply the "general rule" that "a" or "an" can mean "one or more" and conclude that the limitation "user-worn device" is not limited to a single device that must perform all the requirements recited in the asserted claims. Additionally, by not citing or analyzing this case law as the framework to consider this issue, Apple has not shown why the holdings of Nokia, Salazar, and Finjan apply in this *inter partes* proceeding, such that the asserted claims only cover a single device and one that must be capable of performing each of the claimed functions.

The holdings in Nokia, Salazar, and Finjan make clear that the key is the claim drafting and, specifically, the inclusion of subsequent limitations that refer back to a feature or functionality by using the definite article "the" or "such." Although Apple does not cite any of the case law, it does make an argument about a subsequent limitation referring back to a previous limitation. However, it is notable that Apple points to claim 19 of the '502 patent as requiring "four photodiodes arranged within ***the*** user-worn device." Apple Reply at 12 (emphasis added). This is especially notable because Apple does not mention that the primary limitation in claim 19, requiring "***one or more processors*** configured to receive one or more signals from at least one of the four photodiodes and output measurements responsive to the one or more signals, the measurements indicative of the oxygen saturation of the user" does not include a reference back to "such" user-worn device or "the" user-worn device. The implication is that, while the specific "four photodiodes" in claim 19 must be "arranged within the user-worn device," the "one or more processors" are not thusly limited. At the very least, Apple has not raised this case law to support its position and show why Nokia, Salazar, and Finjan apply instead of Baldwin.

Lastly, in Finjan, the Federal Circuit addressed another case where "the parties disputed whether the 'location facility' software 'must be contained ***entirely on a single*** locator server computer . . . or whether it may be ***distributed*** among multiple locator server computers.'" Finjan at 974 (quoting 01 Communique Laboratory, Inc. v. LogMeIn, Inc., 687 F.3d 1292, 1296 (Fed. Cir. 2012)). The Federal Circuit explained that, in that case, "the use of 'a,' 'its,' and 'the' in the claims did ***not*** require the locator server computer to be a single computer, especially where the patent disclosed that 'the locator server computer may comprise multiple computers.'" Id. at 974-75. This seems applicable for the "user-worn device" in the asserted patents since they claim multiple ("one or more") processors and their specifications discloses embodiments that are not limited to a single device. Moreover, without Apple pointing to this case law or any instance with subsequent claim limitations requiring processors that refer back to the user-worn device, there is no basis for the EOE Branch to apply Finjan or Salazar instead of the "general rule" in Baldwin and approach in 01 Communique Laboratory.

3. Apple's Position That Masimo's "Distributed Processing" Theory Is Estopped Based Its Response To Apple's Invalidity Arguments During Underlying Investigation

Apple argues that Masimo is "estopped from arguing that distributed processing satisfies the claims because Masimo argued that the prior art reference Lumidigm did not meet the claims for this same reason" during the 1276 investigation. Apple Reply at 16. According to Apple, Masimo "argued that Lumidigm did not invalidate the claims because it lacked blood oxygen processing" and the ALJ adopted this position. Id. Masimo disagrees and argues that "Apple never argued that Lumidigm had some form of distributed processing from its wristwatch to a separate device" in the 1276 investigation or "identified [anything] in the ALJ's analysis about distributed processing." Masimo Sur-Reply at 18.

The FID shows that the ALJ's findings with respect to Lumidigm and the limitations from claim 19 of the '502 patent were based on the view within the art about measuring blood oxygen at the wrist rather than anything having to do with distributed processing. Specifically, the ALJ emphasized the following:

> In rebuttal to Lumidigm's blood oxygen disclosure, Complainants have presented persuasive evidence that persons of ordinary skill in the art ***would not have expected to successfully measure blood oxygen in a wristwatch at the time of the Poeze patents***. … Complainants have also cited testimony from numerous Apple engineers describing the significant ***difficulty of performing pulse oximetry at the wrist***. See Tr. (Mannheimer) at 1012:12-1013:6 (admitting that in 2014, he believed that ***pulse oximetry at the wrist would be a challenge***, that he "did not know if it could be done," that "the ***wrist is just enormously different from the physiological perspective***," and that the ***signal at the wrist is "enormously weak***"); ... CX-0299C (Waydo Dep. Tr.) at 166:4-167:5 ("The ***wrist is one of the most difficult places on the body to do almost every physiological measurement***"); CX-0295C (Shui Dep. Tr.) at 108:13-21 ("[[ ]] The watch is worn on the wrist, and the ***wrist is well known for its lack of signal***."). The blood oxygen measurement described in Lumidigm is characterized as ***relying on "spectrographic changes that may be detected" by its biometric sensor***, which are "correlated with oxygenation and/or hemoglobin levels." RX-0411 at 19:22-26. The testimony of Apple engineers shows the ***difficulty in calculating blood oxygen from such spectra if obtained at the wrist***, [[ ]].") ... Apple counters this evidence with Dr. Warren's testimony describing pulse oximetry experiments at Kansas State University in 2002-05, RRB at 52-53, but there is little evidence that ***wrist-based*** blood oxygen levels were successfully measured in a

> watch-type environment. … Apple also does not identify measurements of oxygen saturation at the wrist in the corroborating documents provided by Dr. Warren. … Apple also argues that methods for pulse oximetry were well-known at the time of the Poeze patents, RRB at 51, ***but Apple's evidence for prior art blood oxygen measurements relies on measurements at other locations on the body—not at the wrist.***
>
> ***
>
> As discussed above in the context of the preamble limitations, the evidence indicates that one of skill in the art would not have been enabled to use the Lumidigm wristwatch embodiment to measure oxygen saturation. In particular, Lumidigm only discloses that spectroscopic changes correlated with oxygenation "may be detected according to the methods described above." RX-0411 at 19:22-26. ***Complainants have presented credible evidence that one of ordinary skill in the art would not have been able to successfully implement this detection in a wristwatch at the time of the Poeze patents***. See CIB at 126-29; CRB at 44-46. Accordingly, for the same reasons discussed above in the context of the preamble, Apple has not shown by clear and convincing evidence that the "one or more processors" limitation of '502 patent claim 19 is met by Lumidigm.

FID at 115-117, 124.

The above shows that the ALJ's findings "that one of skill in the art would not have been enabled to use the Lumidigm wristwatch embodiment to measure oxygen saturation" was due to the perceived difficulty of performing pulse oximetry at the wrist and Complainants credible evidence on these grounds rather than a discussion of distributed processing as the basis for why the claim was not met by the prior art reference.

4. Apple's Argument That The Redesigned iPhone, As A Factual Matter, Is Not A "User-Worn Device"

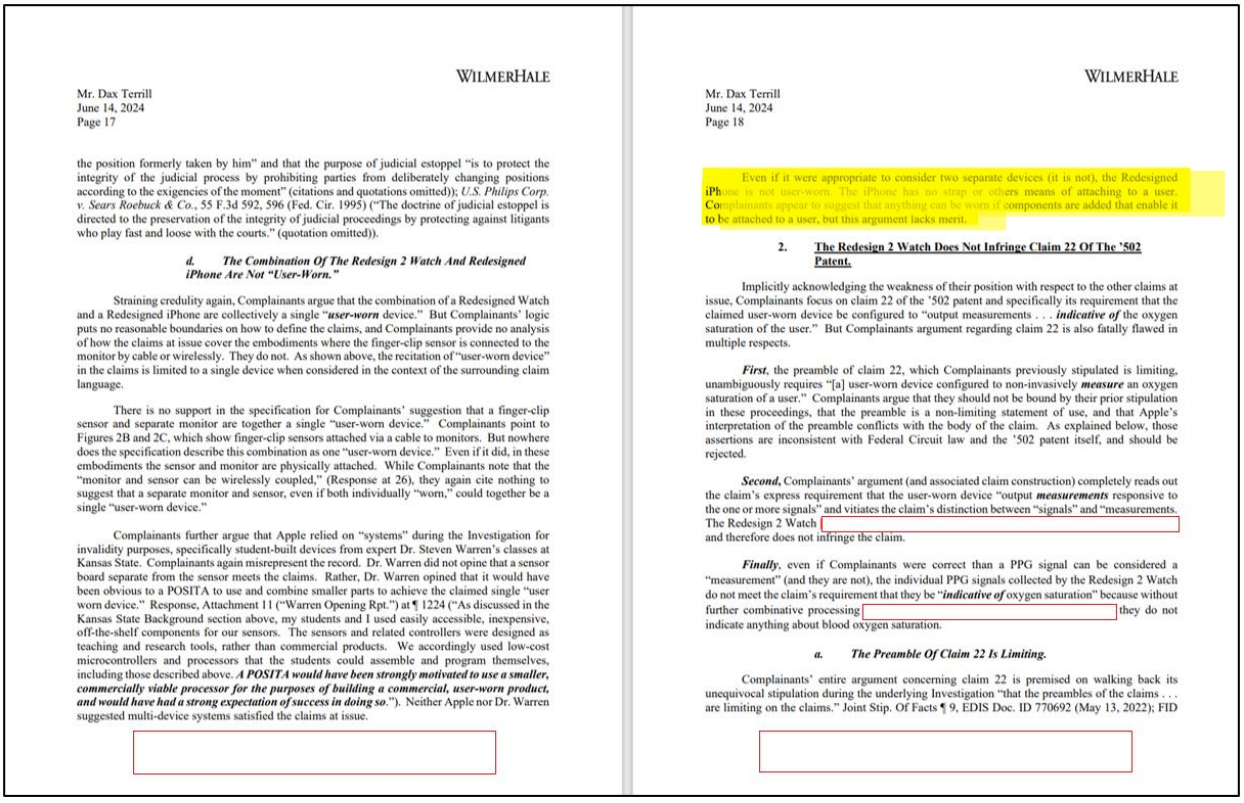
As an initial point, neither party in this *inter partes* proceeding suggests that there is a meaningful difference between a "wearable electronic device" as referenced in the exclusion order's definition of "covered articles" and a "user-worn device" as recited in the claim limitations of the asserted patents. The EOE Branch recognizes that, as discussed above, the former defines the scope of the investigation and the latter applies for purposes of the second step in the patent infringement analysis that involves determining, as a factual matter, whether the claim limitation reads onto the articles at issue. However, consistent with the framework in Thorner and the EOE Branch's determination to give "user-worn device" its plain and ordinary meaning, there is no reason that the same dictionary definitions from above for "wearable" are not equally applicable to "user-worn" and no party has argued against this or offered a different construction. Accordingly, the EOE Branch will consider whether Apple has carried its burden to establish that the Redesigned iPhone is not "capable of being worn" and "fit or suitable to be worn." 20 Oxford English Dictionary 49 (2d ed. 1989); see also Merriam-Webster Online Dictionary, https://www.merriam-webster.com/dictionary/wearable (last visited January 7, 2025). As detailed

below, Apple has not carried its burden to establish admissibility since it has not submitted ***any*** record evidence to support its position that the Redesigned iPhone is not "user-worn." Moreover, the ***only*** record evidence in this *inter partes* proceeding is that which Masimo has submitted in the form of its expert declaration. And lastly, Masimo's evidence identifies an instance where Apple has referred to a user's ability to "wear" the iPhone. For these reasons, the EOE Branch finds that Apple has not carried its burden on this factual question to show the Redesigned iPhone is not "capable of being worn" and "fit or suitable to be worn."

As the "would-be importer" of the articles at issue, and "as a condition [for their] entry, the burden of establishing noninfringement" is on Apple. Hyundai Elecs. Indus. Co. v. ITC, 899 F.2d at 1210. Accordingly, for purposes of the exclusion order issued under Section 337, Apple has the burden of proof to establish that the articles at issue are noninfringing and therefore admissible into the United States.

"For many years the term '***burden of proof***' was ambiguous because the term was used to describe two distinct concepts." Dir. v. Greenwich Collieries, 512 U.S. 267, 272 (1994). "Historically, the term has encompassed two separate burdens: the '***burden of persuasion***' (*specifying which party loses if the evidence is balanced*), as well as the '***burden of production***' (*specifying which party must come forward with evidence at various stages in the litigation*). Microsoft Corp. v. i4i Ltd. P'ship, 564 U.S. 91, 100, FN 4 (2011) (emphasis added). More recently, the Federal Circuit has noted that, as "two distinct burdens of proof" for a party to carry, "the burden of persuasion is the ultimate burden assigned to a party who must prove something to a specified degree of certainty, such as by a preponderance of the evidence or by clear and convincing evidence" and the distinct "burden of production may entail producing additional evidence and presenting persuasive argument based on new evidence or evidence already of record." In re Magnum Oil Tools Int'l, Ltd., 829 F.3d 1364, 1375 (Fed. Cir. 2016) (internal quotations and citations omitted). Significantly, when Hyundai places the "burden" on the "would-be importer," that is understood to encompass both the "burden of persuasion" and the "burden of production" such that Apple must produce sufficient record evidence that proves to the requisite degree of certainty the relevant question of fact. This approach is generally consistent with application of the Customs laws in other contexts. See Shamrock Bldg. Materials, Inc. v. United States, 119 F.4th 1346, 1352 (Fed. Cir. 2024) ("[T]the importer must produce evidence (the burden of production portion of the burden of proof) that demonstrates by a preponderance (the burden of persuasion portion of the burden of proof) that Customs' classification decision is incorrect.") (citing Universal Electronics Inc. v. United States, 112 F.3d 488, 492 (Fed. Cir. 1997); Timber Products Co. v. United States, 515 F.3d 1213, 1219 (Fed. Cir. 2008); and Libas, Ltd. v. United States, 193 F.3d 1361, 1365 (Fed. Cir. 1999)).

The full extent of Apple's factual arguments and support for its position that the Redesigned iPhone is not "user-worn" is highlighted below.



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the position formerly taken by him" and that the purpose of judicial estoppel "is to protect the integrity of the judicial process by prohibiting parties from deliberately changing positions according to the exigencies of the moment" (citations and quotations omitted)); *U.S. Philips Corp. v. Sears Roebuck & Co.*, 55 F.3d 592, 596 (Fed. Cir. 1995) ("The doctrine of judicial estoppel is directed to the preservation of the integrity of judicial proceedings by protecting against litigants who play fast and loose with the courts." (quotation omitted)).

d. The Combination Of The Redesign 2 Watch And Redesigned iPhone Are Not "User-Worn."

Straining credulity again, Complainants argue that the combination of a Redesigned Watch and a Redesigned iPhone are collectively a single "***user-worn*** device." But Complainants' logic puts no reasonable boundaries on how to define the claims, and Complainants provide no analysis of how the claims at issue cover the embodiments where the finger-clip sensor is connected to the monitor by cable or wirelessly. They do not. As shown above, the recitation of "user-worn device" in the claims is limited to a single device when considered in the context of the surrounding claim language.

There is no support in the specification for Complainants' suggestion that a finger-clip sensor and separate monitor are together a single "user-worn device." Complainants point to Figures 2B and 2C, which show finger-clip sensors attached via a cable to monitors. But nowhere does the specification describe this combination as one "user-worn device." Even if it did, in these embodiments the sensor and monitor are physically attached. While Complainants note that the "monitor and sensor can be wirelessly coupled," (Response at 26), they again cite nothing to suggest that a separate monitor and sensor, even if both individually "worn," could together be a single "user-worn device."

Complainants further argue that Apple relied on "systems" during the Investigation for invalidity purposes, specifically student-built devices from expert Dr. Steven Warren's classes at Kansas State. Complainants again misrepresent the record. Dr. Warren did not opine that a sensor board separate from the sensor meets the claims. Rather, Dr. Warren opined that it would have been obvious to a POSITA to use and combine smaller parts to achieve the claimed single "user worn device." Response, Attachment 11 ("Warren Opening Rpt.") at ¶ 1224 ("As discussed in the Kansas State Background section above, my students and I used easily accessible, inexpensive, off-the-shelf components for our sensors. The sensors and related controllers were designed as teaching and research tools, rather than commercial products. We accordingly used low-cost microcontrollers and processors that the students could assemble and program themselves, including those described above. ***A POSITA would have been strongly motivated to use a smaller, commercially viable processor for the purposes of building a commercial, user-worn product, and would have had a strong expectation of success in doing so***."). Neither Apple nor Dr. Warren suggested multi-device systems satisfied the claims at issue.

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Even if it were appropriate to consider two separate devices (it is not), the Redesigned iPhone is not user-worn. The iPhone has no strap or others means of attaching to a user. Complainants appear to suggest that anything can be worn if components are added that enable it to be attached to a user, but this argument lacks merit.

2. The Redesign 2 Watch Does Not Infringe Claim 22 Of The '502 Patent.

Implicitly acknowledging the weakness of their position with respect to the other claims at issue, Complainants focus on claim 22 of the '502 patent and specifically its requirement that the claimed user-worn device be configured to "output measurements . . . ***indicative of*** the oxygen saturation of the user." But Complainants argument regarding claim 22 is also fatally flawed in multiple respects.

First, the preamble of claim 22, which Complainants previously stipulated is limiting, unambiguously requires "[a] user-worn device configured to non-invasively ***measure*** an oxygen saturation of a user." Complainants argue that they should not be bound by their prior stipulation in these proceedings, that the preamble is a non-limiting statement of use, and that Apple's interpretation of the preamble conflicts with the body of the claim. As explained below, those assertions are inconsistent with Federal Circuit law and the '502 patent itself, and should be rejected.

Second, Complainants' argument (and associated claim construction) completely reads out the claim's express requirement that the user-worn device "output ***measurements*** responsive to the one or more signals" and vitiates the claim's distinction between "signals" and "measurements." The Redesign 2 Watch and therefore does not infringe the claim.

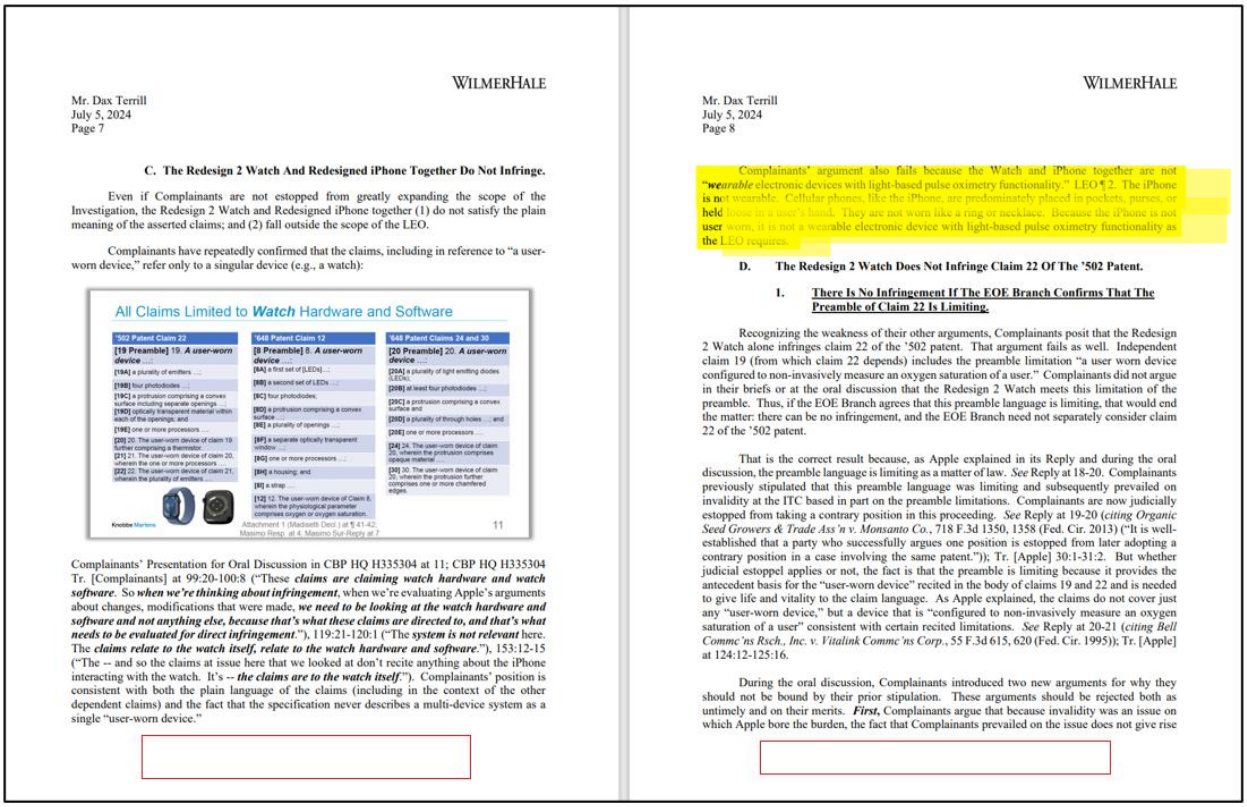
Finally, even if Complainants were correct than a PPG signal can be considered a "measurement" (and they are not), the individual PPG signals collected by the Redesign 2 Watch do not meet the claim's requirement that they be "***indicative of*** oxygen saturation" because without further combinative processing they do not indicate anything about blood oxygen saturation.

a. The Preamble Of Claim 22 Is Limiting.

Complainants' entire argument concerning claim 22 is premised on walking back its unequivocal stipulation during the underlying Investigation "that the preambles of the claims . . . are limiting on the claims." Joint Stip. Of Facts ¶ 9, EDIS Doc. ID 770692 (May 13, 2022); FID

> Even if it were appropriate to consider two separate devices (it is not), the Redesigned iPhone is not user-worn. The iPhone has no strap or others means of attaching to a user. Complainants appear to suggest that anything can be worn if components are added that enable it to be attached to a user, but this argument lacks merit.

Apple Reply at 18.



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C. The Redesign 2 Watch And Redesigned iPhone Together Do Not Infringe.

Even if Complainants are not estopped from greatly expanding the scope of the Investigation, the Redesign 2 Watch and Redesigned iPhone together (1) do not satisfy the plain meaning of the asserted claims; and (2) fall outside the scope of the LEO.

Complainants have repeatedly confirmed that the claims, including in reference to "a user-worn device," refer only to a singular device (e.g., a watch):

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.	

Knobbe Martens — Attachment 1 (Macbeth Decl.) at ¶ 41-42; Masimo Resp. at 4; Masimo Sur-Reply at 7 — 11

Complainants' Presentation for Oral Discussion in CBP HQ H335304 at 11; CBP HQ H335304 Tr. [Complainants] at 99:20-100:8 ("These ***claims are claiming watch hardware and watch software***. So ***when we're thinking about infringement***, when we're evaluating Apple's arguments about changes, modifications that were made, ***we need to be looking at the watch hardware and software and not anything else, because that's what these claims are directed to, and that's what needs to be evaluated for direct infringement***."), 119:21-120:1 ("The ***system is not relevant*** here. The ***claims relate to the watch itself, relate to the watch hardware and software***."), 153:12-15 ("The -- and so the claims at issue here that we looked at don't recite anything about the iPhone interacting with the watch. It's -- ***the claims are to the watch itself***."). Complainants' position is consistent with both the plain language of the claims (including in the context of the other dependent claims) and the fact that the specification never describes a multi-device system as a single "user-worn device."

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Complainants' argument also fails because the Watch and iPhone together are not "***wearable*** electronic devices with light-based pulse oximetry functionality." LEO ¶ 2. The iPhone is not wearable. Cellular phones, like the iPhone, are predominately placed in pockets, purses, or held loose in a user's hand. They are not worn like a ring or necklace. Because the iPhone is not user worn, it is not a wearable electronic device with light-based pulse oximetry functionality as the LEO requires.

D. The Redesign 2 Watch Does Not Infringe Claim 22 Of The '502 Patent.

1. There Is No Infringement If The EOE Branch Confirms That The Preamble of Claim 22 Is Limiting.

Recognizing the weakness of their other arguments, Complainants posit that the Redesign 2 Watch alone infringes claim 22 of the '502 patent. That argument fails as well. Independent claim 19 (from which claim 22 depends) includes the preamble limitation "a user worn device configured to non-invasively measure an oxygen saturation of a user." Complainants did not argue in their briefs or at the oral discussion that the Redesign 2 Watch meets this limitation of the preamble. Thus, if the EOE Branch agrees that this preamble language is limiting, that would end the matter: there can be no infringement, and the EOE Branch need not separately consider claim 22 of the '502 patent.

That is the correct result because, as Apple explained in its Reply and during the oral discussion, the preamble language is limiting as a matter of law. *See* Reply at 18-20. Complainants previously stipulated that this preamble language was limiting and subsequently prevailed on invalidity at the ITC based in part on the preamble limitations. Complainants are now judicially estopped from taking a contrary position in this proceeding. *See* Reply at 19-20 (*citing Organic Seed Growers & Trade Ass'n v. Monsanto Co.*, 718 F.3d 1350, 1358 (Fed. Cir. 2013) ("It is well-established that a party who successfully argues one position is estopped from later adopting a contrary position in a case involving the same patent.")); Tr. [Apple] 30:1-31:2. But whether judicial estoppel applies or not, the fact is that the preamble is limiting because it provides the antecedent basis for the "user-worn device" recited in the body of claims 19 and 22 and is needed to give life and vitality to the claim language. As Apple explained, the claims do not cover just any "user-worn device," but a device that is "configured to non-invasively measure an oxygen saturation of a user" consistent with certain recited limitations. *See* Reply at 20-21 (*citing Bell Commc'ns Rsch., Inc. v. Vitalink Commc'ns Corp.*, 55 F.3d 615, 620 (Fed. Cir. 1995)); Tr. [Apple] at 124:12-125:16.

During the oral discussion, Complainants introduced two new arguments for why they should not be bound by their prior stipulation. These arguments should be rejected both as untimely and on their merits. ***First,*** Complainants argue that because invalidity was an issue on which Apple bore the burden, the fact that Complainants prevailed on the issue does not give rise

Complainants' argument also fails because the Watch and iPhone together are not "***wearable*** electronic devices with light-based pulse oximetry functionality." LEO ¶ 2. The iPhone is not wearable. Cellular phones, like the iPhone, are predominately placed in pockets, purses, or held loose in a user's hand. They are not worn like a ring or necklace. Because the iPhone is not user worn, it is not a wearable electronic device with light-based pulse oximetry functionality as the LEO requires.

Apple Post-Oral Discussion Submission at 8.

As reflected above, Apple does not cite anything to support its position. Instead, these statements are attorney argument, rather than record evidence, and relying on such assertions would be improper. See Enzo Biochem, Inc. v. Gen-Probe, Inc., 424 F.3d 1276, 1284 (Fed. Cir. 2005) ("***Attorney argument is no substitute for evidence***.") (emphasis added); see also Wasica Fin. GmbH v. Cont'l Auto. Sys., 853 F.3d 1272, 1284 (Fed. Cir. 2017) ("That finding is supported by record evidence, and Schrader did not adduce any evidence to the contrary. We thus think it was reasonable for the Board to accept Wasica's expert testimony over Schrader's bare attorney argument."). In the absence of this evidence, Apple cannot be found to have carried its burden to establish admissibility when it has not come forward with any evidence, let alone sufficient record evidence, that proves the Redesigned iPhone is not capable or suitable of being worn.

On the other hand, Masimo's argument that the iPhone is a "user-worn device" is supported with record evidence in the form of an expert declaration with opinions and support for those views. See Masimo Response at 28. In particular, Masimo's expert provided the following explanation in support of its conclusion that "Apple designs and intends the iPhone to be a user-worn device."

> 111. In my opinion, Apple's marketing materials show that the iPhone is also "a user-worn device," which Apple designs to be "worn" by users for assorted health-related features and purposes. Apple explains that "as you walk with iPhone in your pocket or ***wear [iPhone] near your waist***, these [mobility] metrics [tracked by iPhone] are used to calculate and record your walking steadiness." Attachment 9. Apple's marketing materials show that it designs the iPhone to be worn by users, such as in an armband or waistband, while those users are also wearing the Apple Watch. For example, Apple explains that "[y]our iPhone GPS allows your Apple Watch to achieve even more distance accuracy. For example, if you carry your iPhone while using the Workout app on a run, your Apple Watch uses the iPhone GPS to calibrate your stride." Attachment 10.
>
> 112. Therefore, based on the evidence discussed above, it is my opinion that Apple designs and intends the iPhone to be a user-worn device. While I recognize that there are scenarios where the iPhone and Apple Watch can be used without being worn, such as when either device is used while resting on a table or other surface during charging, a POSITA would understand that such situations do not change that the iPhone and Apple Watch are designed to be user-worn devices and often are user-worn. Further, I understand that accused devices are still infringing if they only infringe some of the time. Therefore, in my opinion, both the LW/A 2 Watch and paired iPhone are user-worn devices.

Attachment 1 to Masimo Response ("Madisetti Declaration") at ¶¶ 111-112.

The opinions above, including with regard to one's ability to use the Redesigned iPhone with an armband or waistband, are consistent with the meaning of "wearable" and "user-worn" when defined as "capable of being worn" and "fit or suitable to be worn." Put another way, the Redesigned iPhone is "user-worn" because it is capable of being worn with, for example, an armband. Moreover, given that Apple bears the "burden of persuasion" that specifies it would lose if the evidence produced from both sides was balanced, this is further cemented in this *inter partes* proceeding where only Masimo has produced record evidence to support a finding. See Gemtron Corp. v. Saint-Gobain Corp., 572 F.3d 1371, 1380 (Fed. Cir. 2009) (a party's "unsworn attorney argument . . . is not evidence" and cannot rebut record evidence).

Furthermore, Masimo's expert relied not only on its own opinions but representations from Apple's marketing materials. Masimo's expert points to Apple's "iPhone User Guide," which states that a user can "walk with [the] iPhone in your pocket or ***wear it*** near your waist[.]" Attachment 1 to Masimo Response ("Madisetti Declaration") at ¶¶ 111 (emphasis in original declaration). This reference to Apple's "iPhone User Guide" is found on Apple's own website, as depicted below.

> • *Mobility data:* iPhone stores important mobility metrics such as walking asymmetry, double support time, and more. Over time, as you walk with iPhone in your pocket or wear it near your waist, these metrics are used to calculate and record your walking steadiness. You can browse this data in the Mobility category. You can also receive a notification and share your notification with others if your steadiness becomes low enough to put you at increased risk of falling in the next 12 months.

Attachment 9 to Masimo Response at 2 (referencing the iPhone User Guide: Intro to Health Data on iPhone, available at https://support.apple.com/guide/iphone/intro-to-health-data-iphbb8259c61/17.0/ios/17.0 (last visited January 7, 2025).

Finally, it is significant to note that the Commission found that the asserted patent claims apply to "any" user-worn device and that this category expressly is not limited to devices that are located at the wrist. See Comm'n Op. at 44 ("the asserted claims apply to ***any 'user-worn device,' including user-worn devices that are not worn on the wrist.***") (emphasis added); see also FID at 150. This shows that the asserted patents and the exclusion order extend beyond smartwatches to other articles that are capable or suitable of being worn. In addition to not meeting its burden of production, Apple has not carried its burden of persuasion since it has not identified where the line of user-worn devices that are not worn on the wrist stops and why the Redesigned iPhone is outside that line. And this applies with greater force when the only record evidence produced in this *inter partes* proceeding is contrary to the view Apple has advanced.

Accordingly, the EOE Branch finds that Apple has not carried its burden to establish that the Redesigned iPhone is not "user-worn."

5. Apple Has Failed To Show That The Combination Of The Redesign 2 Watch and Redesigned iPhone Does Not Meet Any Limitation From the Asserted Patents

Since the EOE Branch has found that Apple has **not** shown (i) that, under its plain and ordinary meaning, the claimed "user-worn device" is limited to a single device; (ii) that the Redesigned iPhone is not a "user-worn;" and (iii) that Redesigned iPhone is not subject to the scope of the 1276 LEO, the only remaining question is whether Redesign 2 Watch and Redesigned iPhone, when considered in combination, satisfy each of the limitations from the asserted claims such that they infringe the relevant patents from the exclusion order. Other than the Apple's arguments recited above, which have been rejected, Apple does not contest that the Redesign 2 Watch and Redesigned iPhone, when considered in combination, satisfy all of the limitations in the asserted patent claims. See Ruling Request at 2 ("[[

]] that processing ***functionality required by the adjudicated patent claims to be performed by the iPhone instead*** of Apple Watch, *i.e.*, the claimed 'user worn device.'") (emphasis added). Accordingly, the EOE Branch finds that Apple has failed to show that the Redesign 2 Watch and Redesigned iPhone, in combination as the articles at issue, do not satisfy any of the claim limitations from the asserted patents and, therefore, has as not carried its burden to establish noninfringement in response to Masimo's theory of literal infringement.

D. Admissibility Question Regarding Infringement Under the Doctrine of Equivalents

Masimo first argues that "Apple fail[ed] to show a prima facie case that the doctrine of equivalents does not apply" because "Apple never [addressed] infringement under the doctrine of equivalents" in its initial Ruling Request. Masimo Response at 30. However, a respondent in an *inter partes* proceeding under 19 C.F.R. Part 177 does not immediately waive its ability to present non-infringement arguments under the doctrine of equivalents by failing to present them in the first instance as part of the initial ruling request. While a respondent is encouraged to raises all legal and factual arguments or defenses that support its noninfringement position, a respondent can raise its arguments related to the doctrine of equivalents in a subsequent submission, before any oral discussion, in reply to the complainant's theory of infringement under the doctrine. That said, the EOE Branch may, in its discretion, consider a complainant, as the other interested party participating in an *inter partes* proceeding under 19 C.F.R. Part 177, to have waived its ability to present a theory of infringement under the doctrine if it is not raised in the first submission responding to the ruling request.

Masimo next argues that "[b]ecause Apple's attempted work-around (the LW/A 2 Watch and iPhone) includes only unimportant and insubstantial changes from the claimed devices, it also infringes Claim 22 of the '502 Patent and Claims 12, 24, and 30 of the '648 Patent under the doctrine of equivalents." Masimo Response at 14. Specifically, according to Masimo, "Apple failed to show that [the] insubstantial change [in the Redesign 2 Watch] avoids infringement under the doctrine of equivalents" because "the difference [] between the claims and Apple's new approach is insubstantial—pieces of Apple's oxygen saturation computation take place on the

iPhone[.]" Masimo Response at 29-30. Masimo continues that "Apple bore the burden" and failed "to show why the doctrine of equivalents did not apply to its attempted work-around under the 'function-way-result' and 'insubstantial differences' tests." Masimo Sur-Reply at 18. Masimo further argues that "Apple never provided the element-by-element comparison required for a doctrine of equivalents analysis." Masimo Sur-Reply at 20.

In response to Masimo's theory of infringement under the doctrine of equivalents, Apple argues that the Apple Watch 2 "is a fundamentally different approach with meaningful differences from the adjudicated claims [and] [t]here is no equivalence under either the function-way-result test or the insubstantial difference test." Apple Reply at 27. Additionally, Apple argues that "[f]inding equivalence here would eliminate the requirement for the user-worn device to include the necessary processing capabilities." Apple Reply at 27.

In CBP HQ Ruling H284032 (dated April 4, 2017), CBP established the standard for applying the doctrine of equivalents when administering an exclusion order under Section 337:

> **CBP will *not* extend the doctrine of equivalents when administering an exclusion order pursuant to section 337 *except in two instances***. The first is where the Commission found a violation of section 337, during the underlying investigation, through infringement under the doctrine. The second is, in those cases when the Commission has found only literal infringement of the asserted patents, where a respondent identified in an exclusion order fails to show a prima facie case that the doctrine does not apply to its new or modified article under the "function-way-result" or "insubstantial differences" test based on the administrative record before CBP.

CBP HQ Ruling H284032 at 26 (emphasis added). Accordingly, as confirmed above, the default rule is that CBP will ***not*** extend the doctrine of equivalents except in limited circumstances and then only when a respondent fails to make a *prima facie* showing. This approach not only furthers the sound administration of the Customs law but is consistent with the Federal Circuit's recognition that "[t]he doctrine of equivalents provides a ***limited exception*** to the principle that claim meaning defines the scope of the exclusivity right in our patent system[.]" VLSI Tech. LLC v. Intel. Corp., 87 F.4th 1332, 1341 (Fed. Cir. 2023) (emphasis added). Moreover, the Federal Circuit has "explained that liability under the doctrine is '***exceptional'*** [and] 'emphasized . . . ***that the doctrine of equivalents is the exception, however, not the rule***[.]'" Id. at 1342 (quoting Honeywell International, Inc. v. Hamilton Sundstrand Corp., 523 F.3d 1304, 1313 (Fed. Cir. 2008) for the former point and quoting Eli Lilly & Co. v. Hospira, Inc., 933 F.3d 1320, 1330 (Fed. Cir. 2019) for the latter) (emphasis added).

As such, "[t]he ***exceptional character*** of the doctrine's use is maintained by closely related demands that ***restrict the availability*** of liability under the doctrine." VLSI, 87 F.4th at 1342 (emphasis added). These demands that restrict extension of the doctrine include the following:

> ***First***, proof of equivalents must be limitation specific, not focused only on the claim as a whole, though the limitation-specific inquiry of equivalence may be informed by the "role played by each element in the context of the specific patent claim."

> Warner-Jenkinson, 520 U.S. at 40; see DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., 469 F.3d 1005, 1017 (Fed. Cir. 2006); Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp., 149 F.3d 1309, 1315 (Fed. Cir. 1998); Dawn Equipment Co. v. Kentucky Farms Inc., 140 F.3d 1009, 1015 (Fed. Cir. 1998).
>
> ***Second***, for the determination of whether a substitute element is only insubstantially different from a claimed element and hence an equivalent, a traditional formulation . . . asks "whether a substitute element matches the function, way, and result of the claimed element." Warner-Jenkinson, 520 U.S. at 40. *Such matching requires that each of function, way, and result be "substantially the same,"* see Spectrum Pharmaceuticals, Inc. v. Sandoz Inc.*, 802 F.3d 1326, 1337 (Fed. Cir. 2015),* ***with the "way" requirement of particular importance, as a practical matter, in keeping the doctrine properly limited***. See Warner-Jenkinson, 520 U.S. at 35, 39; Union Paper-Bag Machine Co. v. Murphy, 97 U.S. 120, 125, 24 L. Ed. 935, 1878 Dec. Comm'r Pat. 199 (1877) (stressing the crucial importance of "way"); Advanced Steel Recovery, LLC v. X-Body Equipment, Inc., 808 F.3d 1313, 1320 (Fed. Cir. 2015) (similar); Zygo Corp. v. Wyko Corp., 79 F.3d 1563, 1569 (Fed. Cir. 1996) (similar); Slimfold Manufacturing Co. v. Kinkead Industries, Inc., 932 F.2d 1453, 1457-58 (Fed. Cir. 1991) (similar).
>
> ***Third***, we have long demanded specificity and completeness of proof as crucial to enforcing the limits on the doctrine: The patentee must provide "particularized testimony and linking argument as to the insubstantiality of the differences between the claimed invention and the accused device." Akzo Nobel Coatings, Inc. v. Dow Chemical Co., 811 F.3d 1334, 1342 (Fed. Cir. 2016) (internal quotation marks omitted); see Gemalto S.A. v. HTC Corp., 754 F.3d 1364, 1374 (Fed. Cir. 2014); Texas Instruments Inc. v. Cypress Semiconductor Corp., 90 F.3d 1558, 1566-67 (Fed. Cir. 1996); Lear Siegler, Inc. v. Sealy Mattress Co. of Michigan, 873 F.2d 1422, 1426 (Fed. Cir. 1989).

VLSI Tech. LLC, 87 F.4th at 1342 (emphasis added). Accordingly, the Federal Circuit has placed special emphasis on the "***way***" requirement in the function-way-result test.

Additionally, "both the Supreme Court and this court have made clear that the evidence of equivalents must be from the perspective of someone skilled in the art, for example through testimony of experts or others versed in the technology; by documents, including texts and treatises; and, of course, by the disclosures of the prior art." Nexstep, Inc. v. Comcast Cable Commc'ns, LLC, 119 F.4th 1355, 1371 (Fed. Cir. 2024) (quoting AquaTex Indus., Inc. v. Techniche Sols., 479 F.3d 1320, 1329 (Fed. Cir. 2007) (cleaned up)). "'[W]hen the patent holder relies on the doctrine of equivalents,' [the Federal Circuit] 'require[s] that evidence be presented to the jury or other fact-finder through the ***particularized testimony*** of a person of ordinary skill in the art, typically a qualified expert." Id. (emphasis added).

And finally, the Federal Circuit has "'long demanded specificity and completeness of proof as crucial to enforcing the limits on the doctrine: The patentee must provide ***particularized testimony and linking argument*** as to the insubstantiality of the differences between the claimed

invention and the accused device." Nexstep, 119 F.4th at 1371 (quoting VLSI, 87 F.4th at 1343) (emphasis added). "Generalized testimony as to the overall similarity between the claims and the accused infringer's product or process will not suffice." Id. (quoting Texas Instruments, Inc. v. Cypress Semiconductor Corp., 90 F.3d 1558, 1567 (Fed. Cir. 1996)). "Rather, the patentee must provide a 'meaningful explanation of why' the element or elements from the accused product or process are equivalent to the claimed limitation." Id. (quoting VLSI, 87 F.4th at 1344). However, for purposes of Section 337, as the burden to establish admissibility based on noninfringement is shifted to the would-be importer, it is that party that must provide the "particularized testimony" and "meaningful explanation" described above. As such, Apple is required to provide "the evidence to establish what the function, way, and result of both the claimed device and the accused device are, and why those functions, ways, and results are [***not***] substantially the same." Nexstep, 119 F.4th at 1371 (quoting Malta v. Schulmerich Carillons, Inc., 952 F.2d 1320, 1327 n.5 (Fed. Cir. 1991)).

For a respondent to make a *prima facie* showing in this context to defeat the "limited exception" when CBP will extend the doctrine of equivalents, it is not required to reach "a conclusion on the ultimate issue." Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc., 699 F.3d 1340, 1348 (Fed. Cir. 2012); see also CBP HQ Ruling H326593 (dated September 30, 2022) at 38. Instead, the party with such a burden must simply "present evidence 'sufficient to establish a fact or raise a presumption [regarding the relevant issue].'" Transocean Offshore Deepwater Drilling Inc., 669 F.3d at 1348 (quoting Black's Law Dictionary (9th ed 2009)). Sufficient evidence in this context includes that which the EOE Branch may rely upon to determine that no reasonable factfinder "could conclude that an element of an accused device is equivalent to an element called for in the claim, or that the theory of equivalence to support the conclusion of infringement otherwise lacks legal sufficiency." CBP HQ Ruling H329729 (dated December 1, 2023) at 13-14 (quoting U.S. Philips Corp. v. Iwasaki Elec. Co., 505 F.3d 1371, 1378-79 (Fed. Cir. 2007)).

The parties agree that, during the underlying investigation, the Commission found only literal infringement of the asserted patents. Masimo Response at 30 ("The Commission did not address the doctrine of equivalents for the infringing Apple Watches because the Commission found literal infringement for the Watches then at issue."); see also Apple Reply at 26. Thus, the EOE Branch will address the second of the limited instances in which the doctrine may be extended in CBP's administration of Section 337, namely, whether Apple has failed to make a *prima facie* showing that the doctrine does not apply to the articles at issue under the function-way-result or insubstantial differences test, taking into consideration the framework outlined above.

1. The Function-Way-Result Test

The function-way-result test asks "whether the substitute element matches the function, way, and result of the claimed element." Tronzo v. Biomet, Inc., 156 F.3d 1154, 1160 (Fed. Cir. 1998) (quoting Warner-Jenkinson v. Hilton Davis Chem. Co., 520 U.S. 17, 40 (1997)). For the function-way-result test, analysis should be provided "on an element-by-element basis" to determine whether "the accused product performs substantially the same function in substantially the same way with substantially the same result as each claim limitation of the patented product." Intendis GmbH, 822 F.3d 1355, 1360 (Fed. Cir. 2016) (quoting Crown Packaging Tech., Inc. v.

Rexam Beverage Can Co., 559 F.3d 1308, 1312 (Fed. Cir. 2009)). Furthermore, "[e]ach prong of the function-way-result test is a factual determination." Id.

The Federal Circuit has held that discussion of the doctrine of equivalents under either the function-way-result test or the insubstantial differences test should not be based in broad, conclusory statements. See Akzo Nobel Coatings Inc. v. Dow Chem. Co., 811 F.3d 1334 (Fed. Cir. 2016). In Akzo, for example, the Federal Circuit found the following function-way-result test argument to be "broad and scant:"

> Dow's and Michelman's piping and heat exchangers perform the same function (maintain the pressure) and achieve the same result (maintaining sufficient pressure to prevent boiling of the aqueous medium) in substantially the same way (by collecting the dispersed material in a contained volume) as the vessel used by the inventors in Examples 2 and 3 of the patent.

Id. at 1343. The Federal Circuit determined that "[s]uch ambiguity and generality cannot create a genuine issue of material fact," noting the statement's "failure to articulate how Dow's accused process operates in substantially the same way" or "how the differences between the two processes are insubstantial." Id.

Apple provides the following arguments for noninfringement under the function-way-result test:

> ***Different Function***: Apple's Redesign 2 Watch is not "configured to" or "programmed to" output, calculate, measure, or determine a user's blood oxygen saturation. Apple's redesign achieves pulse oximetry functionality by relocating the required processing functions to the Redesigned iPhone. The Redesign 2 Watch transmits the recorded PPG signals to the Redesigned iPhone without performing any processing capable of measuring a user's blood oxygen saturation. The Redesign 2 Watch does not perform the claimed processing functions at all, and therefore, cannot be considered as performing a function equivalent to the processing recited in the claims.
>
> ***Different Wa***y: Apple's redesign presents a fundamentally different way of providing pulse oximetry functionality. The Redesign 2 Watch does not provide any blood oxygen measurements. Instead, the Watch records the PPG signals and transmits them to the Redesigned iPhone for processing. The Watch instructs the user to refer to their Redesigned iPhone for blood oxygen results because that processing is now exclusive to the Redesigned iPhone. There is no way for the Redesign 2 Watch to provide blood oxygen processing or measurements, and therefore, it is not equivalent to the way blood oxygen processing is captured by the adjudicated claims.
>
> ***Different Result***: Apple's Redesign 2 Watch provides a different result than that contemplated by the adjudicated patent claims. [T]he Redesign 2 Watch does not

> provide any blood oxygen measurements and instead directs a user to their Redesigned iPhone for results[.]

Apple Reply at 28 (emphasis in original).

In response to Apple's arguments, Masimo argues that Apple has failed to show a *prima facie* case that the Redesign 2 Watch does not infringes under the function-way-result test for the following reasons:

> [The Redesign 2 Watch] performs the [same] claimed functions [because] the LW/A 2 Watch outputs PPG signals and that collectively, the Watch and iPhone measure oxygen saturation.... [D]istribut[ing] that functionality across two devices in no way changes that functionality.
>
> [The Redesign 2 Watch] performs the claimed function in substantially the same way. The only purported difference between Apple's attempted work-around and the claimed devices is that some of the claimed processing now occurs on iPhone processors. But all the measured data still comes from the LW/A 2 Watch. The only functional aspect "relocated" to the iPhone is the computation of the oxygen saturation value. The iPhone's processors now use the Watch-measured PPGs to compute those numerical values. Moving some processing from the Watch to the iPhone is an insubstantial and trivial difference from the claimed devices.... Relocating functionality from one device to another is insufficient to avoid infringement. Federal Circuit precedent is clear that the accused feature need not be in the exact same location specified by the claim to infringe under the doctrine of equivalents.
>
> [The Redesign 2 Watch] achieves substantially the same result ... [because] the LW/A 2 Watch and iPhone collectively compute the user's oxygen saturation based on PPG signals measured by the Watch ... [and] provide[s] consumers and medical researchers access to the blood oxygen functionality.

Masimo Response at 31-32 (citations omitted).

As confirmed above, Apple has the burden to "present evidence 'sufficient to establish a fact or raise a presumption [regarding the relevant issue].'" Transocean Offshore Deepwater Drilling, Inc., 699 F.3d at 1348 (quoting Black's Law Dictionary (9th ed 2009)). The evidence it presents must "establish what the function, way, and result of both the claimed device and the accused device are, and why those functions, ways, and results are [***not***] substantially the same." Nexstep, 119 F.4th at 1371 (quoting Malta v. Schulmerich Carillons, Inc., 952 F.2d 1320, 1327 n.5 (Fed. Cir. 1991)). And it must do this with "***particularized testimony and linking argument*** as to the insubstantiality of the differences between the claimed invention and the accused device" that serves as the "meaningful explanation of why the element or elements from the accused product or process are [***not***] equivalent to the claimed limitation." Nexstep, 119 F.4th at 1371 (quoting VLSI, 87 F.4th at 1343) (emphasis added).

Apple has failed to provide a sufficient basis given that the only difference it identifies is that some processing functionality that was previously performed on the Apple Watch is now performed on a separate device. Apple's argument is too narrowly focused on the Redesign 2 Watch and what it can perform without considering, for purposes of the doctrine of equivalents, the functionality of the Redesign 2 Watch and the Redesigned iPhone in combination. For instance, it does not address the way in which the processors distributed across the separate devices are not substantially the same as the relevant claim limitations. This is especially significant given that Apple does not contend there is a material difference in the way the processors on the legacy Apple Watches, that were found to infringe during the underlying investigation, performed the final calculation of blood oxygen saturation and those that have been moved to the Redesigned iPhone and are under consideration perform that calculation. In other words, Apple's primarily, if not exclusively argues about the location of the processors responsible for this functionality rather than the way they perform that functionality. And it does so without adequate particularized testimony and linking argument that would be adequate to carry its burden. Apple's entire analysis under the function-way-result test is recited above. Significantly, the only record evidence Apple submits with respect to application of this test is found in one paragraph from its expert's reply declaration. See Apple Reply at 29; see also Attachment J to Apple Reply ("Sarrafzadeh Reply Declaration") at ¶ 20. However, that declaration makes clear that it found there was "no equivalence between the Redesign 2 Watch and the required limitations of the Asserted Claims" but does not address as a factual matter whether the Redesign 2 Watch and Redesigned iPhone, in combination, are substantially the same as the relevant claim limitations. Id. As such, this evidence lacks particularized testimony and linking argument and is not sufficient for Apple to present a *prima facie* case that the doctrine does not apply.

Foundationally, Apple's noninfringment argument with respect to the doctrine of equivalents largely rests on its view that "Complainants' allegations lack merit because they rely on the Redesigned iPhone, a product unquestionably outside the scope of the 1276 LEO." Apple Reply at 26. For the various reasons set forth above in this ruling, that argument is without merit and, in particular, because the EOE Branch concluded that the claimed "user-worn device" is not limited a single device. And Apple's arguments that it has provided a sufficient basis because "[t]he Watch instructs the user to refer to their Redesigned iPhone for blood oxygen results" and "does not provide any blood oxygen measurements and instead directs a user to their Redesigned iPhone for results" are not persuasive because such changes are unrelated to the claim limitations. The Federal Circuit has routinely held that "the function-way-result test [requires] one [to] consider[] whether the ***element of the accused device*** at issue performs substantially the same function, in substantially the same way, to achieve substantially the same result, ***as the limitation at issue in the claim.***" Dawn Equip. Co. v. Kentucky Farms Inc., 140 F.3d 1009, 1016 (Fed. Cir. 1998) (emphasis added); see also Intendis GmbH, 822 F.3d at 1360. Significantly, the features identified by Apple (*i.e.*, the Redesign 2 Watch not displaying the blood oxygen measurements and instructing the user to view results on the Redesigned iPhone) are unrelated to the "configured to non-invasively measure an oxygen saturation of a user" and the "one or more processors" limitations in the relevant claims of the asserted patents.

For the reasons discussed above, the EOE Branch finds that Apple has failed to present a *prima facie* case under the function-way-result test that the articles at issue do not satisfy the relevant claim limitations when viewed on an element-by-element basis.

2. The Insubstantial Differences Test

With respect to the interplay between the function-way-result and insubstantial differences tests, the Federal Circuit has "recognized that the function, way, result test [has] often sufficed to show the substantiality of the differences." Texas Instruments, 90 F.3d at 1566 (internal citation omitted). Accordingly, the EOE Branch underscores that, for CBP's administration of Section 337 as it relates to the doctrine of equivalents, if either the function-way-result test or the insubstantial differences test is not met, it is unlikely that the articles at issue would be covered under the other. The same would be true in the case where a party has not carried its burden to show that one of the tests does not apply to the articles at issue. "'Different linguistic frameworks may be more suitable to different cases, depending on their particular facts,' but these formulations all aim to investigate the same 'essential inquiry.'" Nexstep, 119 F.4th at 1370 (quoting Warner-Jenkinson, 520 U.S. at 40).

Regarding the insubstantial differences test, the analysis asks whether "the substitution . . . is a change of such substance as to make the doctrine of equivalents inapplicable." Graver Tank v. Mfg. Co. v. Linde Air Products Co., 339 U.S. 605, 610 (1950). For this test, "an important factor is whether persons reasonably skilled in the art would have known of the interchangeability of an ingredient not contained in the patent with one that was." Id. at 609. Under the insubstantial differences test, Apple argues that "[t]here are substantial differences between the claimed processing requirements and Apple's Redesign 2 Watch" because "the Redesign 2 Watch lacks the necessary processing functionality for achieving a blood oxygen measurement" and "[a] POSITA would not understand that relocating necessary processing functionality to an entirely separate device would infringe the adjudicated claims." Apple Reply at 29; see also Attachment J to Apple Reply ("Sarrafzadeh Reply Declaration") at ¶ 20.

In response to Apple's arguments, Masimo argues that "[t]he insubstantial differences test [] demonstrates that [the Redesign 2 Watch] would infringe under the doctrine of equivalents" because "[a] POSITA understands that whether the PPG signals measured by the user-worn device are processed to 'determine' or 'output' the claimed measurements on the user-worn device itself or on a wirelessly connected companion device is an insubstantial and unimportant difference." Masimo Response at 32; see also Attachment 1 to Masimo Response ("Madisetti Declaration") at ¶¶ 123-124.

Despite Apple's arguments regarding insubstantial differences, the EOE Branch finds that Apple has failed to present a *prima facie* case that the articles at issue do not satisfy this test. Specifically, to the extent Apple's position on insubstantial differences reiterates its view that the claimed "user-worn device" must be a single device, that argument was rejected above, such that Apple's arguments regarding the relocation of processing functionality to the Redesigned iPhone do not constitute a substantial difference from the claim limitations of the asserted patents. Moreover, the Redesign 2 Watch and the Redesigned iPhone can work in tandem to achieve the same functionality claimed by the limitations in the asserted patents in a manner that is not materially different from those found to infringe in the legacy products in the underlying investigation at the Commission. For the reasons discussed above, the EOE Branch finds that Apple has failed to present a *prima facie* case under the insubstantial differences test that the

articles at issue do not satisfy the relevant claim limitations when viewed on an element-by-element basis.

3. Claim Vitiation

"If a theory of equivalence would vitiate a claim limitation, however, then there can be no infringement under the doctrine of equivalents as a matter of law." Tronzo, 156 F.3d at 1159. "A party establishing vitiation in an *inter partes* proceeding under 19 C.F.R. Part 177 would carry its burden to show a *prima facie* case." CBP HQ Ruling H329729 at 17. The Federal Circuit has confirmed that "[v]itiation is 'not an exception to the doctrine of equivalents, but instead a legal determination that the evidence is such that no reasonable [fact finder] could determine two elements to be equivalent.'" Ring & Pinion Serv. Inc. v. ARB Corp. Ltd., 743 F.3d 831, 836 (Fed. Cir. 2014) (quoting Deere & Co. v. Bush Hog, LLC, 703 F.3d 1349, 1356 (Fed. Cir. 2012)).

Further, "[t]he vitiation test cannot be satisfied by simply noting that an element is missing from the claimed structure or process because the doctrine of equivalents, by definition, recognizes that an element is missing that must be supplied by the equivalent substitute." Deere, 703 F.3d at 1356. "The vitiation test cannot be satisfied merely by noting that the equivalent substitute is outside the claimed limitation's literal scope." Brilliant Instruments, Inc. v. GuidTech, LLC, 707 F.3d 1342, 1347 (Fed. Cir. 2013). As explained by the Federal Circuit:

> Rather, vitiation applies when one of skill in the art would understand that the literal and substitute limitations are not interchangeable, not insubstantially different, and when they do not perform substantially the same function in substantially the same way, to accomplish substantially the same result. In short, saying that a claim element would be vitiated is akin to saying that there is no equivalent to the claim element in the accused device based on the well-established "function-way-result" or "insubstantial differences" tests.

Id.

Apple argues that "[f]inding equivalence here would eliminate the requirement for the user-worn device to include the necessary processing capabilities." Apple Reply at 27. Masimo disagrees and argues that "merely focus[ing] on missing features is an improper application of the vitiation doctrine because it would render the doctrine of equivalents nothing more than a repeat of literal infringement[.]" Masimo Sur-Reply at 20; see also Epos Techs. Ltd. v. Pegasus Techs. Ltd., 766 F.3d 1338, 1348 (Fed. Cir. 2014) ("Courts should be cautious not to shortcut this inquiry by identifying a 'binary' choice in which an element is either present or 'not present.'"). Apple's claim vitiations argument fails because, as discussed above, the claims do not require the functionality to be on a single device and Apple's argument to the contrary have been rejected. Therefore, the relocation of some processing to a second device does not vitiate the "user worn device" claim limitation.

Accordingly, Apple's arguments regarding claim vitiation, the function-way-result, and the insubstantial differences tests, fail to present a *prima facie* case that the articles at issue do not satisfy the relevant claim limitations when viewed on an element-by-element basis. Consequently,

the EOE Branch finds that Apple, the party with the burden under the standard established in CBP HQ Ruling H284032, has failed to present a *prima facie* case that the doctrine of equivalents does not apply to the articles at issue.

V. HOLDING

We find that Apple has not met it burden to establish that the articles at issue do not infringe the relevant claims of the asserted patents. Accordingly, we find that the articles at issue are subject to the limited exclusion order issued as a result of Inv. No. 337-TA-1276. However, nothing in this ruling modifies, revokes, or otherwise changes the admissibility determination in *Apple I*. As such, Apple may continue to enter the articles at issue, including its redesigned Apple Watch that was adjudicated in the previous *inter partes* proceeding. See CBP HQ Ruling H335304 (dated January 12, 2024).

The decision is limited to the specific facts set forth herein. If articles differ in any material way from the articles at issue described above, or if future importations vary from the facts stipulated to herein, this decision shall not be binding on CBP as provided for in 19 C.F.R. §§ 177.2(b)(1), (2), (4), and 177.9(b)(1) and (2).

Sincerely,

Dax Terrill
Chief, Exclusion Order Enforcement Branch

CC: Ms. Sheila N. Swaroop
Knobbe Martens
2040 Main St., 14th Fl.
Irvine, CA 92614
Sheila.Swaroop@knobbe.com

EXHIBIT 2

90 K Street NE – 10th Floor
Washington, DC 20229-1177

U.S. Customs and Border Protection

HQ H351038

August 1, 2025

OT:RR:BSTC:EOE H351038

CATEGORY: 19 U.S.C. § 1337; Unfair Competition

Center Director
Electronics Center of Excellence and Expertise
U.S. Customs and Border Protection
301 E. Ocean Blvd., Suite 900
Long Beach, California 90802

Attn: John Gerber, Supervisory Import Specialist

VIA EMAIL: john.p.gerber@cbp.dhs.gov

RE: Internal Advice Request; U.S. International Trade Commission; Limited Exclusion Order; Investigation No. 337-TA-1276; Certain Light-Based Physiological Measurement Devices and Components Thereof

Dear Center Director:

Pursuant to 19 C.F.R. § 177.11, the Exclusion Order Enforcement ("EOE") Branch, Regulations and Rulings, U.S. Customs and Border Protection ("CBP") issues this internal advice ruling based on your request (dated July 8, 2025) regarding the entry for consumption of five (5) Apple Watches that Apple Inc. ("Apple") imported at the Port of Chicago under Entry Number SCS-20982810 and related to AWB 014-23379381-YYZ00011437 (H). The Apple Watches, as described in more detail below, have been detained based on the limited exclusion order that the U.S. International Trade Commission ("ITC" or "Commission") issued resulting from ITC Investigation No. 337-TA-1276 ("the 1276 investigation" or "underlying investigation) under section 337 of the Tariff of 1930, as amended, 19 U.S.C. § 1337 ("Section 337"). See CBP Detention Notice (dated July 07, 2025) for Detention No. 1751555713390. The Apple Watches were presented for examination on July 2, 2025. See Email to the EOE Branch from the Port of Chicago (dated July 9, 2025); see also 19 U.S.C. § 1499(c)(5), as implemented by 19 C.F.R. § 151.16(b) ("For purposes of this section, merchandise will be considered to be presented for CBP examination when it is in a condition to be viewed and examined by a CBP officer."); see also Blink Design, Inc. v. United States, 986 F. Supp. 2d 1348, 38 C.I.T. 746, 749-754 (Ct. Int'l Trade, 2014) ("In light of this regulation, Defendant contends that Customs considers merchandise 'presented for examination' when 'it is in a condition to be examined by a Customs official.' … When Customs requests that merchandise be delivered to a container examination station ('CES')

for inspection, as occurred in the present action, Defendant specifies that 'Customs routinely considers the date on which merchandise is presented for examination as being the date that the last requested container is delivered to the CES, its contents have been unloaded by the private contractor, and Customs has received the pertinent documents that it needs to perform the examination. … ***By treating the date when (1) the last requested container arrives at a CES and is unloaded and (2) Customs has the relevant explanatory documents, as the date on which merchandise is presented for examination, Customs ensures that the actual merchandise and relevant accompanying information are before its officials so that an examination may proceed***.") (emphasis added).

Specifically, you have requested the EOE Branch's admissibility determination regarding the proper administration of the limited exclusion order and, in particular, the applicability of an administrative ruling the EOE Branch issued on January 7, 2025, resulting from an *inter partes* proceeding under 19 C.F.R. § 177, to the importation of these Apple Watches. See CBP HQ Ruling H338254 (dated January 7, 2025) ("*Apple II* Ruling"). Familiarity with the EOE Branch's administrative rulings related to the 1276 investigation is presumed and recited below are those facts necessary to address the issues presented by this entry for consumption.

The EOE Branch further notes that determinations of the Commission resulting from the underlying investigation or a related proceeding under 19 C.F.R. Part 210 are binding authority on CBP and, in the case of conflict, will by operation of law modify or revoke any contrary CBP ruling or decision pertaining to Section 337 exclusion orders. A "related proceeding" is defined as, *inter alia*, "proceedings to ***enforce***, ***modify***, or ***revoke*** a remedial or consent order, or ***advisory opinion proceedings***." 19 C.F.R. § 210.3 (emphasis added). A determination from these proceedings represents binding authority, as noted above, and Commission action that directs CBP accordingly. Moreover, the Commission may "investigate any alleged violation of this section on complaint under oath ***or upon its initiative***." 19 U.S.C. § 1337(b) (emphasis added); see also Certain Road Construction Machines and Components Thereof Notice of Commission Determination To Institute a Modification Proceeding; Request for Written Submissions, 85 Fed. Reg. 3944, 3945 (Jan. 23, 2020) ("[T]he Commission has determined that institution of a modification proceeding is also warranted based on the Commission's authority, *sua sponte*, to institute a modification proceeding. Commission Rule 210.76(a)(1), 19 CFR 210.76(a)(1) ('The Commission may also in its own initiative consider such action' to modify its remedial orders.).").

Lastly, before publication of this internal advice ruling pursuant to 19 U.S.C. § 1625, as implemented by 19 C.F.R. § 177.10, Apple is to be given an opportunity to identify any confidential information, including any information subject to the administrative protective order from the underlying investigation. See 19 C.F.R. §§ 177.2, 177.8. Consistent with the above, Apple is directed upon receiving this internal advice ruling to identify any confidential information with [[red brackets]] that indicate such information should be redacted from the public version of the ruling that will be published in accordance with 19 C.F.R. § 177.10. Apple is to contact the EOE Branch within ten (10) business days of the date of this internal advice ruling to identify such information with the brackets noted above. See, e.g., 19 C.F.R. § 177.8(a)(3).

To confirm, disclosure and redaction of information related to administrative rulings under 19 C.F.R. Part 177 is governed by, for example, 6 C.F.R. Part 5, 31 C.F.R. Part 1, 19 C.F.R. Part

103, and 19 C.F.R. § 177.8(a)(3). See, e.g., 19 C.F.R. § 177.10(a). In addition, CBP is guided by the laws relating to confidentiality and disclosure, such as the Freedom of Information Act ("FOIA"), as amended (5 U.S.C. § 552), the Trade Secrets Act (18 U.S.C. § 1905), and the Privacy Act of 1974, as amended (5 U.S.C. § 552a). A request for confidential treatment of information submitted in connection with a ruling requested under 19 C.F.R. Part 177 faces a strong presumption in favor of disclosure. See, e.g., 19 C.F.R. § 177.8(a)(3). The person seeking this treatment must overcome that presumption with a request that is appropriately tailored and supported by evidence establishing that: the information in question is customarily kept private or closely-held and either that the government provided an express or implied assurance of confidentiality when the information was shared with the government or there were no express or implied indications at the time the information was submitted that the government would publicly disclose the information. See Food Marketing Institute v. Argus Leader Media, 139 S. Ct. 2356, 2366 (2019) (concluding that "[a]t least where commercial or financial information is both customarily and actually treated as private by its owner and provided to the government under an assurance of privacy, the information is 'confidential' within the meaning of exemption 4."); see also U.S. Department of Justice, Office of Information Policy (OIP): Step-by-Step Guide for Determining if Commercial or Financial Information Obtained from a Person is Confidential Under Exemption 4 of the FOIA (updated 10/7/2019); see also OIP Guidance: Exemption 4 after the Supreme Court's Ruling in Food Marketing Institute v. Argus Leader Media (updated 10/4/2019).

I. BACKGROUND

A. The Limited Exclusion Order and Asserted Patents From ITC Investigation No. 337-TA-1276

The limited exclusion order from the 1276 investigation prohibits the unlicensed entry for consumption of light-based physiological devices and components thereof that infringe one or more of claims 22 and 28 of U.S. Patent No. 10,912,502 ("the '502 patent") and claims 12, 24 and 30 of U.S. Patent Nos. 10,945,648 ("the '648 patent"). See Certain Light-Based Physiological Measurement Devices and Components Thereof, Inv. No. 337-TA-1276, EDIS Doc. ID 2011470, Limited Exclusion Order (Oct. 26, 2023) at 2, ¶ 1. The Commission described the asserted patents as covering "non-invasive physiological sensors for measuring blood constituents or analytes using multi-stream spectroscopy." *Apple II* Ruling at 3. The "sensors use an emitter that [] uses optical radiation at different wavelengths to measure blood analytes like glucose, hemoglobin, or oxygen saturation." Id. "The sensors are connected to handheld or portable monitoring devices that can be attached to a patient's body." Id.

B. *Inter Partes* Proceedings Under 19 C.F.R. Part 177 Related To The Limited Exclusion Order From ITC Investigation No. 337-TA-1276

1. Apple's First Ruling Request ("*Apple I*")

On October 27, 2023, Apple requested an administrative ruling under 19 C.F.R. Part 177 that its redesigned Apple Watches were not subject to the limited exclusion order from the 1276 investigation because they did not infringe any claims of the '502 and '648 patents. See CBP HQ

Ruling H335304 (dated January 12, 2024) at 8. In its ruling request, Apple stated that as redesigned the Apple Watches in question were no longer reasonably capable of satisfying the claim limitations at issue in the limited exclusion order. Id. at 1. Specifically, Apple's argument was based on the pairing process between the redesigned Apple Watch and an unmodified iPhone such that the pulse oximetry functionality was disabled. Id. at 11. Nonetheless, Masimo argued that an ability existed that allowed the redesigned Apple Watch to practice the claim limitations at issue. Id. at 13. Specifically, Masimo attempted to show that the infringing pulse oximetry functionality from the legacy devices at issue in the underlying investigation, while disabled, could nonetheless be enabled "after (1) jailbreaking the iPhones used for pairing with the Redesigned Watches that is needed to activate the Watches and put them into operation; and (2) installing third-party software[.]" Id. at 29. Relying on the relevant caselaw, the EOE Branch concluded that "the products designed and manufactured by Apple cannot infringe without modification—the modification of jailbreaking the iPhones that is needed for pairing with the Redesigned Watches for their operation and the installation of the software." Id. at 28. Accordingly, the EOE Branch concluded that the redesigned Apple Watches in *Apple I* did not infringe the '502 and '648 patents and were not subject to the limited exclusion order.

2. Apple's Second Ruling Request ("*Apple II*")

On March 26, 2024, Apple submitted another request an administrative ruling pursuant to 19 C.F.R. Part 177. This time, Apple's request concerned its "Redesign 2 Watch" that "include[d] the same processors and hardware" at issue in the *Apple I* but with the processing responsible for the final calculation of a user's blood oxygen saturation moved from the Apple Watch to the iPhone. *Apple II* Ruling at 9. Apple referred to the Apple Watches at issue in this second administrative ruling request as the "Redesign 2 Watch" and the iPhone at issue as the "Redesigned iPhone." Id.

As Masimo explained with respect the redesigned functionality, "the LW/A 2 Watch[1] emits red and infrared light, detects light with four photodetectors, processes the detected light signals to separate them into red and infrared PPGs, and further processes those two PPGs before sending them to the iPhone." *Apple II*, Masimo Post-Oral Discussion Submission at 10. Masimo provides the following chart explaining how the pulse oximetry functionality and processing is divided between the Redesign 2 Watch and the Redesigned iPhone:

[1] The parties in this *inter partes* proceeding at times referred to the Redesign 2 Watch as the LW/A 2 Watch.

[[ ]]

Apple II, Masimo Oral Discussion Slides at 21.

In Apple's redesign, the PPG measurements for both wavelengths (*i.e.*, PPG for red light and PPG for infrared light) are done on the LW/A 2 Watch. *Apple II*, Attachment 1 to Masimo Response ("Madisetti Declaration") at ¶¶ 50-52; see also *Apple II*, Masimo Post Oral Discussion Submission at 11; see also Apple Reply at 22 ("The individual red and infrared PPG signals [are] recorded by the Redesign 2 Watch[.]"). Using those PPGs, the Redesigned iPhone computes the ratio of ratios and the user's oxygen saturation value. Id.; see also *Apple II*, Masimo Post Oral Discussion Submission at 11; see also *Apple II*, Apple Reply at 3 ("[Complainant] acknowledges that the relevant functionality has been relocated to the Redesigned iPhone [and] processors of the LW/A 2 Watch are configured to output PPG signals with information that can be used, and is used, by the iPhone to compute the user's oxygen saturation measurement.").

C. Apple Watches Imported Under Entry Number SCS-20982810

The entry documents Apple submitted in connection with this importation confirm that the shipment contains five Apple Watches and no other products. See CBP Form 7501 for Entry Number SCS-20982810. The model numbers for the imported Apple Watches from this shipment, as identified in the commercial invoice, are depicted below. Moreover, Apple has confirmed that, for this specific shipment, the imported Apple Watches implement the functionality from the *Apple II* Ruling. See Apple Certification (executed on April 16, 2025) (providing that Apple will enter for consumption one shipment containing five Apple Watches that "implement the redesign that was at issue in CBP HQ Ruling H338254 (dated January 7, 2025) (the 'Redesign 2 Watches').").

[[ ]]

II. ISSUE

Whether the redesigned Apple Watches at issue in the *Apple II* Ruling, that were found to infringe claim 22 of the '502 patent or claims 12, 24, or 30 of the '648 patent only when considered in combination with the redesigned iPhone, are subject to exclusion from entry when imported alone.

III. LEGAL FRAMEWORK

A. Section 337 Exclusion Order Administration

The Commission shall investigate any alleged violation of section 337 to determine, with respect to each investigation conducted by it under this section, whether there is a violation of this section. See 19 U.S.C. § 1337(b)(1) and (c). If the Commission determines, as a result of an investigation under this section, that there is a violation of this section, it shall direct that the articles concerned, imported by any person violating the provision of this section, be excluded from entry into the United States unless the Commission finds based on consideration of the public interest that such articles should not be excluded from entry. See 19 U.S.C. § 1337(d)(1).

When the Commission determines that there is a violation of Section 337, it generally issues one of two types of exclusion orders: (1) a limited exclusion order or (2) a general exclusion order. See Fuji Photo Film Co., Ltd. v. ITC, 474 F.3d 1281, 1286 (Fed. Cir. 2007). Both types of orders direct CBP to bar infringing products from entering the country. See Yingbin-Nature (Guangdong) Wood Indus. Co. v. ITC, 535 F.3d 1322, 1330 (Fed Cir. 2008). "A limited exclusion order is 'limited' in that it only applies to the specific parties before the Commission in the investigation. In contrast, a general exclusion order bars the importation of infringing products by everyone, regardless of whether they were respondents in the Commission's investigation." Id. A general exclusion order is appropriate only if two exceptional circumstances apply. See Kyocera Wireless Corp. v. ITC, 545 F.3d 1340, 1356 (Fed. Cir. 2008). A general exclusion order may only be issued if (1) "necessary to prevent circumvention of a limited exclusion order," or (2) "there is a pattern of violation of this section and it is difficult to Identify the source of infringing products." 19 U.S.C. § 1337(d)(2); see Kyocera, 545 F.3d at 1356 ("If a complainant wishes to obtain an exclusion order operative against articles of non-respondents, it must seek a GEO [general exclusion order] by satisfying the heightened burdens of §§ 1337(d)(2)(A) and (B).").

In addition to the action taken above, the Commission may issue an order under 19 U.S.C. § 1337(i) directing CBP to seize and forfeit articles attempting entry in violation of an exclusion order if their owner, importer, or consignee previously had articles denied entry on the basis of that exclusion order and received notice that seizure and forfeiture would result from any future attempt to enter articles subject to the same. An exclusion order under § 1337(d)—either limited or general—and a seizure and forfeiture order under § 1337(i) apply at the border only and are operative against articles presented for customs examination or articles conditionally released from customs custody but still subject to a timely demand for redelivery. See 19 U.S.C. §§ 1337(d)(1) ("The Commission shall notify the Secretary of the Treasury of its action under this subsection directing such exclusion from entry, and upon receipt of such notice, the Secretary shall, through the proper officers, refuse such entry."); id. at (i)(3) ("Upon the attempted entry of ***articles*** subject to an order issued under this subsection, the Secretary of the Treasury shall immediately notify all ports of entry of the attempted importation and shall identify the persons notified under paragraph (1)(C).") (emphasis added).

Significantly, unlike district court injunctions, the Commission can issue a general exclusion order that broadly prohibits entry of articles that violate section 337 of the Tariff Act of 1930 without regard to whether the persons importing such articles were parties to, or were related to parties to, the investigation that led to issuance of the general exclusion order. See Vastfame Camera, Ltd. v. ITC, 386 F.3d 1108, 1114 (Fed. Cir. 2004). The Commission also has recognized that even limited exclusion orders have broader applicability beyond just the parties found to infringe during an investigation. See Certain GPS Devices and Products Containing Same, Inv. No. 337-TA-602, Comm'n Op. at 17, n.6, Doc ID 317981 (Jan. 2009) ("We do not view the Court's opinion in Kyocera as affecting the issuance of LEOs [limited exclusion orders] that exclude infringing products made by respondents found to be violating Section 337, but imported by another entity. The exclusionary language in this regard that is traditionally included in LEOs is consistent with 19 U.S.C. § 1337(a)(1)(B)-(D) and 19 U.S.C. § 1337(d)(1).").

Moreover, "[t]he Commission has consistently issued exclusion orders ***coextensive with the violation*** of section 337 found to exist." See Certain Erasable Programmable Read Only

Memories, Inv. No. 337-TA-276, Enforcement Proceeding, Comm'n Op. at 11, Doc ID 43536 (Aug. 1991) (emphasis added). "[W]hile individual models may be evaluated to determine importation and [violation], the Commission's jurisdiction extends to all models of [violative] products that are imported at the time of the Commission's determination and to all such products that will be imported during the life of the remedial orders." See Certain Optical Disk Controller Chips and Chipsets, Inv. No. 337-TA-506, Comm'n Op. at 56-57, USITC Pub. 3935, Doc ID 287263 (July 2007).

Lastly, despite the well-established principle that "the burden of proving infringement generally rests upon the patentee [or plaintiff]," Medtronic, Inc. v. Mirowski Family Ventures, LLC, 571 U.S. 191 (2014), the Commission has held that Medtronic is not controlling precedent and does not overturn its longstanding practice of placing the burden of proof on the party who, in light of the issued exclusion order, is seeking to have an article entered for consumption. See Certain Sleep-Disordered Breathing Treatment Systems and Components Thereof, Inv. No. 337-TA-879, Advisory Opinion at 6-11. In particular, the Commission has noted that the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") "has upheld a Commission remedy which effectively shifted the burden of proof on infringement issues to require a company seeking to import goods to prove that its product does ***not*** infringe, despite the fact that, in general, the burden of proof is on the patentee to prove, by a preponderance of the evidence, that a given article ***does*** infringe[.]" Certain Integrated Circuit Telecommunication Chips, Inv. No. 337-TA-337, Comm'n Op. at 21, n.14, USITC Pub. 2670, Doc ID 217024 (Aug. 1993) (emphasis in original) (citing Sealed Air Corp. v. ITC, 645 F.2d 976, 988-89 (C.C.P.A. 1981)).

This approach is supported by Federal Circuit precedent. See Hyundai Elecs. Indus. Co. v. ITC, 899 F.2d 1204, 1210 (Fed. Cir. 1990) ("Indeed, we have recognized, and Hyundai does not dispute, that in an appropriate case the Commission can impose a general exclusion order that binds parties and non-parties alike and ***effectively shifts to would-be importers of potentially infringing articles, as a condition of entry, the burden of establishing noninfringement***. The rationale underlying the issuance of general exclusion orders—placing the risk of unfairness associated with a prophylactic order upon potential importers rather than American manufacturers that, vis-a-vis at least some foreign manufacturers and importers, have demonstrated their entitlement to protection from unfair trade practices—applies here [in regard to a limited exclusion order] with increased force.") (emphasis added) (internal citation omitted).

B. Patent Infringement

Determining patent infringement requires two steps. Advanced Steel Recovery, LLC v. X-Body Equip., Inc., 808 F.3d 1313, 1316 (2015). The first is to construe the limitations of the asserted claims and the second is to compare the properly construed claims to the accused product. Id. To establish literal infringement, every limitation recited in a claim must be found in the accused product whereas, under the doctrine of equivalents, infringement occurs when there is equivalence between the elements of the accused product and the claimed elements of the patented invention. Microsoft Corp. v. GeoTag, Inc., 817 F.3d 1305, 1313 (Fed. Cir. 2016). One way to establish equivalence is by showing, on an element-by-element basis, that the accused product performs substantially the same function in substantially the same way with substantially the same result as each claim limitation of the patented invention, which is often referred to as the function-

way-result test. See Intendis GmbH v. Glenmark Pharms., Inc., 822 F.3d 1355, 1361 (Fed. Cir. 2016).

As for the first step above, "claim construction is a matter of law." SIMO Holdings, Inc. v. H.K. uCloudlink Network Tech., Ltd., 983 F.3d 1367, 1374 (Fed. Cir. 2021). Moreover, the ultimate construction of a claim limitation is a legal conclusion, as are interpretations of the patent's intrinsic evidence (the patent claims, specifications, and prosecution history). UltimatePointer, L.L.C. v. Nintendo Co., 816 F.3d 816, 822 (Fed. Cir. 2016) (citing Teva Pharms. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831, 841, 190 L. Ed. 2d 719 (2015).[2] "Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). "In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges." Id. at 1314. In others, courts look to public sources such as "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." Id.

"To begin with, the context in which a term is used in the asserted claim can be highly instructive." Phillips, 415 F.3d at 1314 ("To take a simple example, the claim in this case refers to 'steel baffles,' which strongly implies that the term 'baffles' does not inherently mean objects made of steel."). The context in which a claim term is used also includes the full chain of dependence as well as the remaining suite of claims and the written description. See Inline Plastics Corp. v. EasyPak, LLC, 799 F.3d 1364, 1371 (Fed. Cir. 2015) ("Since the specification explicitly mentions the 'alternative' . . . there can be no debate concerning the application of the doctrine of claim differentiation.").

The second step to establish infringement involves a comparison of the claims, as properly construed, to the accused product, which is a question of fact. Apple Inc. v. Samsung Elecs. Co., Ltd., 839 F.3d 1034, 1040 (Fed. Cir. 2016) (en banc).

In addition to direct infringement, a party can indirectly infringe a patent through active inducement, which occurs if the party knew of the patent and that the induced acts constitute patent infringement. See Commil USA, LLC v. Cisco Sys., Inc., 575 U.S. 632 (2015); see also 35 U.S.C. § 271(b) ("Whoever actively induces infringement of a patent shall be liable as an infringer."). For a finding of induced infringement, the infringer must possess a specific intent to encourage another's infringement. See i4i Ltd. Partnership v. Microsoft Corp., 598 F.3d 831, 851 (Fed. Cir. 2010), aff'd, 564 U.S. 91 (2011). Furthermore, induced infringement requires a showing that the accused inducer took an affirmative act to encourage infringement. See Microsoft Crop. v. Datatern, Inc., 755 F.3d 899, 904 (Fed. Cir. 2013).

"[I]nduced infringement under § 271(b) requires knowledge that the induced acts constitute patent infringement." Global-Tech Appliances, Inc. v. SEB S.A., 563 U.S. 754, 766 (2011). In requiring proof that the party knew that the induced acts were infringing, the Supreme Court has

[2] Although claim construction is a question of law, the consideration of extrinsic evidence may constitute a subsidiary finding of fact. Teva, 135 S. Ct. at 841, 190 L. Ed. 2d at 733.

held that a party cannot be liable for induced infringement if that party maintains a reasonable non-infringement position. Commil, 575 U.S. at 642 ("[T]he Global-Tech rationale is sound. Qualifying or limiting its holding . . . would lead to the conclusion, both in inducement and contributory infringement cases, that a person, or entity, could be liable even though he did not know the acts were infringing. In other words, even if the defendant reads the patent's claims differently from the plaintiff, and that reading is reasonable, he would still be liable because he knew the acts might infringe. Global-Tech requires more. It requires proof that the defendant knew the acts were infringing. And the Court's opinion was clear in rejecting any lesser mental state as the standard.") (internal citations omitted); see also Warsaw Orthopedic, Inc. v. NuVasive, Inc., 824 F.3d 1344, 1351 n.2 (Fed. Cir. 2016) ("To show the intent to induce infringement, it is sufficient that the plaintiff establish that defendant's asserted belief in non-infringement was unreasonable."). This requirement can be satisfied by a finding of willful blindness as to infringement, which requires that the accused subjectively believed that there was a high risk of infringement and took deliberate actions to avoid confirming infringement, as opposed to deliberate indifference to a known risk of infringement. Global-Tech., 563 U.S. at 769-70. Further, the Federal Circuit has emphasized that "[t]he Supreme Court's Global-Tech Appliances and Commil decisions require a showing of the accused infringer's *subjective knowledge* as to the underlying direct infringement." Unwired Planet, LLC v. Apple Inc., 829 F.3d 1353, 1364 (Fed. Cir. 2016) (emphasis added).

IV. LAW AND ANALYSIS

A. The *Apple II* Ruling Only Found The Redesigned Apple Watch To Infringe When Considered In Combination With The Redesigned iPhone But Not When Considered Alone

During the *inter partes* proceeding in *Apple II*, the EOE Branch addressed are whether Apple had established that: **(1)** the Apple Watch, as redesigned, is not a "covered article" as defined by the limited exclusion order and for purposes of the 1276 investigation; **(2)** the Apple Watch, as redesigned, when considered alone, does not infringe claim 22 of the '502 patent; **(3)** the Apple Watch and iPhone, as redesigned, when considered in combination, do not infringe claim 22 of the '502 patent or claims 12, 24, or 30 of the '648 patent; and **(4)** the Apple Watch and iPhone, as redesigned, when considered in combination, do not infringe claim 22 of the '502 patent or claims 12, 24, or 30 of the '648 patent under the doctrine of equivalents as applied by CBP. Of these four arguments regarding admissibility, the only one where Apple prevailed is the second: that the redesigned Apple Watch, when considered alone, does not infringe claim 22 of the '502 patent, which is the only patent claim from the limited exclusion order that Masimo asserted against the Apple Watch by itself.

1. The Respective Positions From The Parties On The Second Argument In *Apple II* Whether The Redesign Apple Watch Infringes When Considered Alone

Masimo's theory of infringement with respect to the second argument from above was that the Redesign 2 Watch, when considered alone, literally infringes Claim 22 of the '502 patent. *Apple II* Ruling at 30. The basis for its contention was centered on Masimo's view that "the LW/A 2 Watch-measured PPGs are 'indicative of' oxygen saturation[.]" *Apple II*, Masimo Post Oral

Discussion Submission at 13. Apple disagreed with Masimo and made two arguments. First, Apple argued that the Redesign 2 Watch alone did not infringe claim 22 of the '502 patent because "the preamble is limiting" and, as such, the Redesign 2 Watch cannot infringe as it is not a user-worn device "configured to non-invasively measure an oxygen saturation of a user" as required by the preamble in claim 19 and from which claim 22 depends. *Apple II*, Apple Reply at 2. Second, Apple argued that "even if the preamble was not limiting[], the Redesign 2 Watch does not satisfy the other limitations of claim 22 because the Watch itself cannot output 'measurements' responsive to the recorded PPG signals, and the individual PPG signals themselves are not 'indicative of' oxygen saturation." Id.

The parties agreed that the phrase "user-worn device" recited in the preamble is limiting but disagreed whether the remainder of the preamble reciting "configured to non-invasively measure an oxygen saturation" is limiting as well. See *Apple II*, Apple Reply at 20; see also *Apple II*, Masimo Response at 17. Apple argued that the preamble is limiting for two reasons. First, Apple argued that Masimo should be "judicially estopped" from adopting a position that the "configured to" language in the preamble of Claim 22 is not limiting because the "[t]he parties [] stipulated that all preambles of all asserted claims are limiting" during the underlying investigation and Masimo has "benefited from that position[.]" *Apple II*, Apple Reply at 18-19; see also *Apple II*, Apple Post-Oral Discussion Submission at 8. Masimo disagreed and argued that the stipulation should not apply in this *inter partes* proceeding because "the parties expressly limited the stipulation to the 'Investigation only.'" *Apple II*, Masimo Sur-Reply at 5. Masimo further argued that "there is nothing 'clearly inconsistent' in Masimo's positions" because the Commission also found "that [the prior art reference] Lumidigm did not satisfy 'several other Limitations' of Claim 22" in addition to not satisfying the preamble. *Apple II*, Masimo Sur-Reply at 7. Second, Apple argued that that the "the 'configured to' language in the preamble … is limiting [based on Federal Circuit precedent] because it states a 'necessary and defining aspect of the claimed invention.'" *Apple II*, Apple Reply at 20 (citing On Demand Mach. Corp. v. Ingram Indus., 442 F.3d 1331, 1343 (Fed. Cir. 2006)). Masimo disagreed and argues that "the preamble's 'configured to' clause is non-limiting statement of use." *Apple II*, Masimo Sur-Reply at 5.

2. The EOE Branch's Request For Confirmation Or Clarification From The Commission

In reviewing the parties' respective positions, the EOE Branch recognized that the Commission may have already addressed the answer to this issue during the underlying investigation and, in such a case, would have reached a determination that, under 19 C.F.R. Part 210, is binding on CBP and must be applied. As such, the EOE Branch requested that the Commission confirm whether it found or determined that the preamble of claim 19 of the '502 patent (from which claim 22 depends, as noted above) was limiting. Specifically, the EOE Branch made the following request to the Commission:

> It is our understanding that in the underlying investigation the Commission found a violation of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, based on infringement of claims 22 and 28 of U.S. Patent No. 10,912,502 ("the '502 patent") and claims 12, 24, and 30 of U.S. Patent No. 10,945,648 ("the '648 patent") by Apple, Inc. ("Apple"). During the underlying investigation, the parties

> stipulated[[
>]].” Certain Light-Based Physiological Measurement Devices and Components Thereof, Inv. No. 337-TA-1276, EDIS Doc. ID 770692, Joint Stipulation of Facts (May 13, 2022) (confidential) at 2. In determining whether the accused wearable electronic devices (i.e., Apple Watch products) infringed claim 22 of the ’502 patent, the Administrative Law Judge noted “[t]here is no dispute that the Accused Products meet the limitations of the preamble of ’502 patent claim 19, which requires ‘[a] user-worn device configured to non-invasively measure an oxygen saturation of a user.’” Certain Light-Based Physiological Measurement Devices and Components Thereof, Inv. No. 337-TA-1276, EDIS Doc. ID 1950712, Final Initial Determination (January 10, 2023) (“FID”) (public) at 40. Moreover, in discussing Apple’s invalidity arguments for the relevant claims in the ’502 patent, the Administrative Law Judge found that claim 22 was not rendered obvious by Lumidigm, alone or in combination with other prior art, because “Apple has not shown that the preamble limitations of ’502 patent claim 19 are met by Lumidigm.” FID at 118. See also FID at 114 (“In consideration of the parties’ arguments, the undersigned finds that the evidence of record fails to show that one of ordinary skill would have been enabled to measure oxygen saturation in the Lumidigm wristwatch.”).
>
> In the context of a request for an administrative ruling under 19 C.F.R. Part 177, an issue has arisen with respect to the Commission’s findings during the underlying investigation. Specifically, the EOE Branch is seeking confirmation or clarification whether the Commission found or determined that the preamble of claim 19 of the ’502 patent (from which claim 22 depends) was limiting. If the Commission found or determined the preamble to be limiting, we request the Commission’s confirmation or clarification regarding whether it found the preamble to be limiting in its entirety or only found certain parts of the preamble to be limiting and, if so, which parts (e.g., “a user worn device” or “configured to” or “non-invasively measure an oxygen saturation of a user” or a combination thereof).

EOE Branch Request to ITC for Confirmation or Clarification (dated September 13, 2024).

The Commission replied with a letter to the EOE Branch and confirmed that it found the preamble in claim 19 of the ’502 patent to be limiting ***in its entirety***. Specifically, the ITC stated:

> Thank you for your letter of September 13, 2024, seeking clarification as to the proceedings in the above-referenced investigation, Certain Light-Based Physiological Measurement Devices and Components Thereof, Inv. No. 337-TA-1276. Specifically, you seek confirmation or clarification regarding whether and to what extent the Commission found or determined that the preamble is limiting in claim 19 of U.S. Patent No. 10,912,502 (“the ’502 patent”). In sum, the Commission considered the entirety of the preamble of claim 19 of the ’502 patent to be limiting.

In the above-referenced investigation, the Commission found a violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, based on infringement of claims 22 and 28 of the '502 patent, among others, by Respondent Apple Inc. ("Apple"). See 88 Fed. Reg. 74032-33 (Nov. 1, 2023). Complainants Masimo Corporation and Cercacor Laboratories, Inc. (collectively "Masimo") asserted several other patents in the investigation, including U.S. Patent No. 10,912,501 ("the '501 patent"), which is relevant to this issue and is in the same patent family as the '502 patent. Id.

In the '502 patent, claim 22 depends from claim 19, which includes preamble language describing "[a] user-worn device configured to non-invasively measure an oxygen saturation of a user." See Light-Based Physiological Measurement Devices, Commission Opinion ("Comm'n Op.") at 8-10, EDIS Doc. ID 808521 (Public Version) (Nov. 14, 2023).

As you have recognized, the parties filed a joint stipulation wherein Masimo stipulated that "[f]or purposes of this Investigation only, Masimo does not contest that the preambles of the claims of the '501 patent, the '502 patent, [among others,] are limiting on the claims." Light-Based Physiological Measurement Devices, Joint Stipulation of Facts ¶ 9, EDIS Doc. ID 770692 (Confidential) (May 13, 2022). This stipulation was cited in the Final Initial Determination in the context of infringement for claim 1 of the '501 patent, which contains similar language to claim 19 of the '502 patent. Light-Based Physiological Measurement Devices, Final Initial Determination ("Final ID") at 34 n.8, EDIS Doc. ID 789795 (Public Version) (Jan. 10, 2023).

When addressing infringement of claims 19 and 22 of the '502 patent, the Final ID recognized that "[t]here is no dispute that the Accused Products meet the limitations of the preamble of '502 patent claim 19." Id. at 40. The Final ID cited evidence, first discussed in the context of the '501 patent, showing that "the Accused Products are watches configured to measure blood oxygen saturation." Id. at 34. The Commission determined not to review the Final ID's findings with respect to infringement regarding the '501 patent and the '502 patent. See 88 Fed. Reg. 32243-46 (May 19, 2023).

In the context of the technical prong of the domestic industry requirement, the Final ID found that certain prototype devices met the limitations of claim 28 of the '502 patent, which has the same preamble language as claim 19. Final ID at 68-69. The Final ID referenced an earlier discussion of similar preamble language in the '501 patent, finding that the prototype devices measured blood oxygen saturation and met the "user-worn" limitation. Id. (citing Id. at 60-63). The Commission determined to review the Final ID's domestic industry findings and affirmed the existence of a domestic industry with respect to the '502 patent without modifying the Final ID's technical prong analysis. Comm'n Op. at 66-68.

> In the context of invalidity, the Final ID found that a prior art reference, U.S. Patent No. 7,620,212 (RX-0411, "Lumidigm"), did not meet the preamble limitations of claim 19 of the '502 patent, because Lumidigm did not enable the measurement of oxygen saturation in its only user-worn embodiment, which was a wristwatch. Final ID at 113-118. The Final ID further found that claim 22 of the '502 patent was not shown to be obvious in view of Lumidigm based on the failure to meet these preamble limitations and other limitations in the claims. Id. at 113-27. The Commission determined to review the Final ID's obviousness findings and affirmed the Final ID's analysis of the preamble language of claim 19 of the '502 patent. Comm'n Op. at 22-23. The Commission also affirmed, with modified reasoning, the Final ID's determination that claim 22 of the '502 patent was not shown to be obvious in view of Lumidigm. Id. at 21-49.
>
> In accordance with the foregoing, we confirm that the Commission found the preamble of claim 19 of the '502 patent to be limiting. The Commission explicitly discussed the preamble language of claim 19 in the context of infringement and invalidity. See Final ID at 34, 40, 115-118; Comm'n Op. at 22-23. With respect to the specific preamble phrases identified in your letter, the Commission's infringement and invalidity analysis explicitly considered "a user-worn device," "configured to," and "non-invasively measure an oxygen saturation of a user" as claim limitations. See Final ID at 34, 40, 115-118; Comm'n Op. at 22-23. The Commission also relied on identical preamble language in claim 28 of the '502 patent with respect to the technical prong of the domestic industry requirement. See Final ID at 60-63, 68-69. Accordingly, the Commission considered the entirety of the preamble of claim 19 of the '502 patent to be limiting.

Certain Light-Based Physiological Measurement Devices and Components Thereof, Inv. No. 337-TA-1276, EDIS Doc. ID 833876, Response to Letter of Clarification (Public) (Oct. 2, 2024).

3. The EOE Branch's Conclusion In Light Of The Commission's Confirmation or Clarification Response

The parties did not dispute that Apple based its non-infringement position for the Redesign 2 Watch – in reply to Masimo's "watch only" theory of infringement for purposes of claim 22 of the '502 patent – on the device not satisfying every clause in the preamble and specifically that the limitations in the preamble require a device to be "configured to non-invasively measure an oxygen saturation of a user." See *Apple II*, Ruling Request at 30; see also *Apple II*, Apply Reply at 21. Apple's argument was that the "measure an oxygen saturation of a user" recitation in the preamble, ***if limiting***, requires that an accused device perform the final calculation or at least be programmed to perform that calculation under relevant claim construction for the "configured to" limitation at issue in the *inter partes* proceeding.

As indicated in its response, Masimo recognized that Apple had presented such a non-infringement argument with respect to the entirety of the preamble text. See *Apple II*, Masimo Response at 13 (reproduced below).

B. Apple Argues Non-Infringement Based Only On The "Configured To" Limitations

Apple and its expert argue non-infringement based only on the following claim language:

'502 Patent Element 19[Pre]	"a user-worn device configured to non-invasively measure an oxygen saturation of a user"
'502 Patent Element 19[E]	"one or more processors configured to … output measurements … indicative of the oxygen saturation of the user"
'502 Patent Element 28[Pre]	"a user-worn device configured to non-invasively measure an oxygen saturation of a user"
'502 Patent Element 28[I]	"one or more processors configured to … calculate an oxygen saturation measurement of the user"
'502 Patent Element 28[J]	"a network interface configured to wirelessly communicate the oxygen saturation measurement"
'502 Patent Element 28[K]	"user interface [] configured to display indicia responsive to the oxygen saturation measurement."
'648 Patent Element 8[Pre]	"a user-worn device configured to non-invasively determine measurements of a physiological parameter"
'648 Patent Element 12	"one or more processors configured to receive one or more signals from at least one of the photodiodes and output measurements of a physiological parameter of a user" and "wherein the physiological parameter comprises oxygen or oxygen saturation"
'648 Patent Element 20[E]	"one or more processors configured to receive one or more signals from at least one of the photodiodes and determine measurements of oxygen saturation of the user"

Nevertheless, Masimo did not present a theory of infringement regarding how this aspect of the claim is satisfied if the preamble, in its entirety, was found to be limiting. Instead, Masimo relied solely on its argument that it would be improper, for the reasons articulated in its submissions, to find this clause in the preamble to be limiting. Therefore, in light of the Commission's confirmation or clarification, and due to the lack of an infringement contention from Masimo that the Redesign 2 Watch, by itself, satisfied the entirety of the preamble in claim 19 of the '502 patent (specifically the limitation "configured to non-invasively measure an oxygen saturation of a user"), the EOE Branch found that Masimo did not present a complete theory of infringement with respect to all limitations.

Given the lack of a complete infringement contention, the EOE Branch found that Masimo's theory of infringement for the Redesign 2 Watch, when considered ***alone*** for purposes of claim 22 of the '502 patent, was "***not a basis to refuse the article's entry pursuant to the***" limited exclusion order from the 1276 investigation. *Apple II* Ruling at 35 (citing Greenlaw v. United States, 554 U.S. 237, 243 (2008) ("In our adversary system, in both civil and criminal cases, in the first instance and on appeal, *we follow the principle of party presentation.* ***That is, we rely on the parties to frame the issues for decision and assign to courts the role of neutral arbiter of matters the parties present***.")) (emphasis added); see also Astellas Pharma, Inc. v. Sandoz Inc., 2024 U.S. App. LEXIS 23669, at *12 (Fed. Cir. 2024) ("It is for the parties—not the court—to chart the course of the litigation."); see also Certain Robotic Floor Cleaning Devices and Components Thereof, Inv. No. 337-TA-1252, Initial Determination on Violation of Section 337 and Recommended Determination on Remedy and Bonding, EDIS Doc. ID 783814 (Public)

(October 7, 2022) at 10, FN 16 ("***Given that [complainant] did not dispute that the [relevant] products in this category are non-infringing, this Initial Determination finds no reason to conclude otherwise***.") (emphasis added), aff'd, Notice of Commission Final Determination Finding a Violation of Section 337, EDIS Doc. ID 792838 (Public) (March 21, 2023) ("All findings in the FID that are not inconsistent with the Commission's determination are affirmed."); see also CBP HQ Ruling HQ H340844 (dated September 27, 2024) at 6-7.

Accordingly, Apple prevailed on this argument and the EOE Branch did not find the Apple Watches ***by themselves*** to infringe. But more than this, the EOE Branch concluded in *Apple II* that the redesign Apple Watch, when considered alone, was "not a basis to refuse the article's entry pursuant to the" limited exclusion order from the 1276 investigation. As such, if imported alone, there is no basis to exclude the Apple Watches from entry because, as noted above and in light of the EOE Branch's findings, they do not directly infringe the asserted patents in the limited exclusion order from ITC Inv. No. 337-TA-1276. In other words, if imported alone, the redesigned Apple Watches are not subject to exclusion from entry and, for purposes of Section 337 administration, they are to be released since, by themselves, they do not satisfy all of the relevant claim limitations and therefore cannot directly infringe the asserted patent claims. For these reasons, the redesigned Apple Watches at the Port of Chicago under Detention No. 1751555713390 are to be released.

B. Binding CBP Precedent Regarding Exclusion Order Administration Confirms This Position

In CBP HQ Protest Decision H025822 (dated November 23, 2009), the legacy Intellectual Property Rights ("IPR") Branch (*i.e.*, the predecessor of the EOE Branch), addressed an exclusion from entry based on the general exclusion order in ITC Inv. No. 337-TA-545 (*Certain Ink Cartridges and Components Thereof*). The articles at issue in this Protest Decision were identified as the R-Series product, "a two-piece device consisting of a 'cartridge' and an 'adapter.'" Protest Decision at 2. According to the Protestant, the "R-Series cartridges are designed to fit within printers in which an R-Series adapter has been installed. [Specifically,] the R-Series adapte[r] is affixed within the printer before the cartridge is inserted. When the R-Series cartridge runs out of ink and requires replacement, the R-Series adapter remains fixed within the printer and only the cartridge is replaced. *The R-Series adapter and R-Series cartridge are supplied* ***as separate products*** *and do not engage each other to form a unitary assembly*." Id. at 3 (emphasis added). However, the Protest Decision made reference to "[i]mages of a sample R-Series 'cartridge' and 'adapter' *that were part of the* ***same shipment*** *excluded from entry*." Id.

Moreover, in this Protest Decision, the IPR Branch addressed Protestant's "final argument regarding why the R-Series product [fell] outside the scope of the 565 GEO." Id. at 22. Protestant pointed to the language of the 565 GEO itself, which stated that "[i]nk cartridges covered by [the relevant patents] are excluded from entry … for the remaining term of the patents, except under license of the patent owner or as provided by law." Id. Based on this language, Protestant argued that "the scope of the 565 GEO does not extend to components of ink cartridges." Id. The IPR Branch responded with the following:

The determination above has found that the R-Series "ink container" satisfies the "ink cartridge" limitation of claim 1 from the '917 patent when used in combination with the R-series "adapter." Furthermore, in this instance, the R-Series "ink containers" have been imported along with the "adapters" in the same shipment that was excluded from entry. See Ninestar Image International Ltd. Commercial Invoice (dated May 11, 2009) (indicating the shipment in question contains "ink tank" products and "adapter" products). Since the two products, when used in combination, were determined to infringe claim 1 of the '917 patent and, in this instance, were attempting to make entry in the same shipment, the determination here is they qualify as an "ink cartridge" that is subject to the 565 GEO and were properly excluded from entry. A contrary reading of the exclusion order's language would mean the entry for consumption of a two-piece ink cartridge found to infringe at the ITC, such as representative cartridge 8, would not violate the 565 GEO if the ink cartridge was disassembled into its two pieces and ***imported together in the same shipment***. See [Commission Opinion] at 36 (for depictions of representative cartridge 8 from CPX-103). The determination here is that such a reading is untenable in light of the infringement analysis above and the commingled nature of this entry. The fact that the ITC did not extend the 565 GEO to cover "components" does not mean unassembled ink cartridges likewise do not fall within the order's scope.

Moreover, for purposes of the U.S. General Rules of Interpretation ("GRI") of the Harmonized Tariff Schedule, unassembled products are treated as assembled products for entry and classification purposes. See GRI 2(a), 19 U.S.C. § 1202 ("Any reference in a heading to an article shall be taken to include a reference to that article incomplete or unfinished, provided that, as entered, the incomplete or unfinished article has the essential character of the complete or finished article. It shall also include a reference to that article complete or finished (or falling to be classified as complete or finished by virtue of this rule), entered unassembled or disassembled."). Furthermore, the Court of International Trade has interpreted GRI 2(a) thusly:

> According to the relevant Explanatory Notes, for purposes of GRI 2(a), "'articles presented unassembled or disassembled' means articles the components of which are to be assembled either by means of fixing devices (screws, nuts, bolts, etc.) or by riveting or welding, for example, provided only assembly operations are involved." See Explanatory Note 2(a)(VII).
>
> That is not to say that assembly of an imported article ***must*** involve "fixing devices (screws, nuts, bolts, etc.) or…riveting or welding" to fall within the definition of an "unassembled or disassembled" article for purposes of GRI 2(a). Articles involving even simpler assembly are also covered. See, e.g., HQ 965440 (Aug. 7, 2002) (ruling that "Swiffer Wet Jet" (a manual floor mop with an internal, hand-operated sprayer, used to wet-mop hard surface floors), which

> is imported unassembled in three basic pieces that "snap together for ease of assembly by the ultimate consumer," is properly classified under heading 8509 "at [the level of] GRI 1 and GRI 2(a) (because the Wet Jet is imported unassembled)"). Indeed, the Explanatory Notes themselves state that "[n]o account is to be taken…of the complexity of the assembly method." See Explanatory Note 2(a)(VII).
>
> Pomeroy Collection, Ltd. v. United States, 559 F. Supp. 2d 1374, 1386, FN 13 (Ct. Int'l Trade 2008) (emphasis in original). Accordingly, since unassembled products are considered assembled for entry purposes, the determination here is that the R-Series products were *properly excluded from entry when the "ink container" and "adapter" were* ***contained in the same shipment***.
>
> ***
>
> Therefore, based on the entire analysis above, the entered "ink container" and "adapter" articles that were ***contained in the same shipment fall within the scope of the [exclusion order]***.

Id. at 23-25 (emphasis added in last two paragraphs). Accordingly, CBP has upheld the exclusion from entry of articles, even those characterized as "separate products," in cases where they are imported in the same shipment and where, having been considered in combination, they directly infringe the relevant patents because the articles at issue satisfy all of the limitations in a claim from the asserted patents in the exclusion order. Significantly, given that a Customs ruling (including a Protest Decision) represents the official position of the agency under 19 C.F.R. § 177.9(a) with respect to the particular transaction or issue described therein, it is binding on all CBP officials and must be applied until modified or revoked. See CBP HQ Ruling H339732 (dated June 11, 2024) at 20; see also Int'l Custom Prods. v. United States, 748 F.3d 1182, 1185-86, 1187 ("Section 1625(c) requires Customs to undergo notice and comment procedures before it may issue 'a proposed *interpretive ruling or decision* which would — (1) *modify . . . or revoke* a prior interpretive ruling or decision which has been in effect for at least 60 days.'" (emphasis in original) . . . "Once Customs issued the Ruling Letter, [plaintiff] *and other importers* were entitled 'to expect certainty' that Customs 'w[ould] not unilaterally change' [its position] 'without providing proper notice and an opportunity for comment.'" (emphasis added) (internal citations omitted)). As such, the enforcement position regarding articles entered "in the same shipment" applies with equal force with respect to the importation at issue in this internal advice ruling.

For the reasons above, the entry of the redesigned Apple Watches, by themselves and without the redesigned iPhones at issue in the *Apple II* Ruling, cannot satisfy all of the claim limitations in the asserted patents and, therefore, cannot be excluded from entry under a theory of direct infringement. Moreover, the EOE Branch specifically found that, the redesign Apple Watch, when considered alone, such as the importation at issue here, was "not a basis to refuse the article's entry pursuant to the" limited exclusion order from the 1276 investigation. Accordingly, as noted above, the Apple Watches at the Port of Chicago under Detention No. 1751555713390 are to be released.

C. CBP Exclusion Order Administration And Application Of Indirect Patent Infringement

As recognized in the *Apple II*, the Commission's long-established practice "does not limit [an exclusion order] to covered products that were actually adjudicated to infringe [during the underlying investigation]." *Apple II* Ruling at 20 (quoting Certain Movable Barrier Operator Systems and Components Thereof, Inv. No. 337-TA-1118, EDIS Doc. ID 839790, Remand Commission Opinion at 48 (Public) (December 20, 2024). "Consistent with [that] long-standing practice, the scope of [exclusion orders] includes all [ ] infringing [devices subject to the scope of the investigation], *whether they have been adjudicated in the investigation or were later introduced*." Certain Road Construction Machines and Components Thereof, Inv. No. 337-TA-1088 (Modification), Commission Opinion, Doc. ID 719534 (Sept. 14, 2020) at 12-13 (emphasis added). "This coverage is to ensure that the exclusion order affords the complainant 'complete relief' and cannot be 'easily circumvented.'" Certain Movable Barrier Operator Systems and Components Thereof, Inv. No. 337-TA-1118, EDIS Doc. ID 839790, Remand Commission Opinion at 48 (Public) (December 20, 2024) (citing Certain Graphics Systems, Components Thereof, and Consumer Products Containing Same, Inv. No. 337-TA-1044, Comm'n Op. at 66 (Sept. 18, 2018); see also Certain Human Milk Oligosaccharides and Methods of Producing Same, Comm'n Op. at 19-20, 2020 WL 3073788 at *11 (June 20, 2020) (redesigned products may still fall within the scope of the remedial orders even if they were not adjudicated for infringement in the original investigation), aff'd, Jennewein Biotechnologie GmbH v. Int'l Trade Comm'n, 2021 WL 4250784 (Fed. Cir. Sept. 17, 2021) (unpublished)).

In applying the Commission's precedent concerning its remedial orders under Section 337, the EOE Branch has recognized that "an infringement analysis is required and remains the test to determine admissibility under Section 337 absent specific direction from the Commission, such as in an exclusion order with express indication in any Commission Opinion from the underlying investigation." CBP HQ Ruling H325119 (dated November 30, 2023) at 20. As the EOE Branch further explained:

> The scope of the exclusion order, however, is best understood to encompass articles "covered by" the relevant patent claims, the infringement of which formed the basis of the violation of Section 337 in the underlying investigation and resulted in the issuance of the exclusion order. As [the Commission] has repeatedly confirmed: "The Commission's long-standing practice is to direct its remedial orders to all products ***covered by the patent claims*** as to which a violation has been found, rather than limiting its orders only to those specific models selected for the infringement analysis[.] [W]hile individual models may be evaluated to determine importation and infringement, the Commission's jurisdiction extends to all models of ***infringing products*** that are imported at the time of the Commission's determination ***and to all such products that will be imported during the life of the remedial orders.***" Certain Road Construction Machines and Components Thereof, Inv. No. 337-TA-1088 (Modification), Commission Opinion, Doc. ID 719534 (Sept. 14, 2020) at 13 (emphasis added) (quoting Optical Disk Controller Chips and Chipsets and Products Containing Same, including DVD Players and PC Optical

> Storage Devices, Inv. No. 337-TA-506, Comm'n Op. at 56-57 (Sept. 28, 2005) (that quoted Certain Hardware Logic Emulation Systems & Components Thereof, Inv. No. 337-TA-383, Comm'n Op., 1998 WL 307240, *9 (Mar. 31, 1998))).

CBP HQ Ruling H325119 at 20-21.

As indicated above, "both Commission and EOE Branch precedent makes clear that the traditional test for patent infringement remains the touchstone for CBP when administering a Section 337 exclusion order." *Apple II* Ruling at 30. "Accordingly, the test that the EOE Branch must apply requires an analysis whether an unadjudicated article that falls within the scope of the underlying investigation ***infringes any claims from the patents at issue based on the traditional two-step approach noted above***." Id. (emphasis added). However, this "traditional two-step approach" only concerns ***direct*** patent infringement when determining whether all the limitations in the asserted patents are satisfied by the article at issue, such that it would be subject to an exclusion order.

Consequently, the question remains whether the terms "covered by" the patent claims or "that infringe" the patent claims, as used in the Commission's remedial orders – including the limited exclusion order from the 1276 investigation – require CBP to apply indirect infringement when enforcing exclusion orders. For the reasons below, the EOE Branch concludes that it does not and, as such, declines to apply this an approach with respect to active inducement infringement under 35 U.S.C. § 271(b).[3]

The Federal Circuit has upheld the Commission's statutory authority to issue exclusion orders under Section 337 for violations based on a theory of indirect infringement. See Suprema, Inc. v. Int'l Trade Comm'n, 796 F.3d 1338 (Fed. Cir. 2015); see also Comcast Corp. v. Int'l Trade Comm'n, 951 F.3d 1301 (Fed. Cir. 2020). To confirm, nothing in this internal advice ruling applies to such exclusion orders where the Commission finds a violation of Section 337 based on indirect infringement and directs CBP to refuse entry to the legacy products found to infringe. Conversely, nothing in the Federal Circuit cases cited above indicates that CBP must extend exclusion orders that are based only on violations under direct infringement theories and, in such cases, apply indirect infringement where the Commission has not, in the first instance, made such a finding.

It is notable in this regard that, as an agency practice, CBP has never applied a theory of indirect infringement to find that an article is subject to a Section 337 exclusion order and, on these grounds, must be denied entry. A reason for this is likely that parties appearing before the EOE

[3] Notwithstanding this position regarding active inducement infringement under 35 U.S.C. § 271(b), the EOE Branch acknowledges that contributory infringement under 35 U.S.C. § 271(c) may present a different question. For example, the Commission frequently includes "components thereof" in the operative paragraph of its exclusion orders and this inclusion may align with the "***component***" reference in 35 U.S.C. § 271(c). In fact, the same Protest Decision referred to above notes that, "on September 11, 2008, the ITC modified [the seizure and forfeiture order in question] to delete the phrase 'component parts thereof'" and that this carried significance because, in deleting that phrase, the ITC confirmed "[t]he general exclusion order [as originally issued did] not in fact cover components of ink cartridges." CBP HQ Protest Decision H025822 at 23. In other words, the Commission's statements in that investigation suggest that, when it intends for CBP to apply 35 U.S.C. § 271(c) and refuse entry to "components thereof" that infringe, it includes this phrase in its remedial orders.

Branch in *inter partes* proceedings under 19 C.F.R. Part 177 rarely present theories of indirect infringement. In fact, Masimo did not present a theory of indirect infringement in *Apple II*. This is telling, not only in demonstrating the reluctance of a party to raise theories of indirect infringement before the EOE Branch but, more significantly, as Masimo did not raise such an argument, it has waived its ability to do so before CBP in connection with this limited exclusion order. Of course, this would not preclude Masimo from presenting such an argument in a related proceeding at the Commission.

Additionally, it is far from clear that the Commission has directed, or would even want, CBP to refuse entry to imported articles based on a theory of indirect infringement when the Commission has not, in the first instance, found such infringement during an underlying investigation. The EOE Branch is not aware of any Section 337 precedent that instructs CBP to take such action and, as already noted above, the precedent that is available focuses on CBP enforcing exclusion orders against new or modified products by applying theories of direct infringement. This seems even more appropriate when considering that, for indirect infringement through active inducement, not only must a party have known of the patent and that the induced acts constitute patent infringement, but that the infringer also possess a specific intent to encourage another's infringement. See i4i Ltd. Partnership v. Microsoft Corp., 598 F.3d 831, 851 (Fed. Cir. 2010), aff'd, 564 U.S. 91 (2011). The EOE Branch concludes that such determinations are better suited for related proceedings at the Commission rather than the border enforcement operations at CBP. As such, the EOE Branch finds that infringement questions such as these should return to the Commission in the first instance for a related proceeding because the Commission is the ultimate arbiter of its remedial orders and is the agency that issues final determinations that are subject to direct appeal at the Federal Circuit by any person adversely affected by such a final determination. See 19 U.S.C. § 1337(c).

Accordingly, for the reasons above, CBP will not apply indirect infringement under a theory of active inducement when administering an exclusion order under Section 337 ***except*** when the Commission finds a violation of Section 337 based on indirect infringement during an underlying investigation or when CBP is instructed to do so by the Commission, either as a general instruction that would have the effect of modifying or revoking this ruling by operation of law, see 19 C.F.R. § 177.12(d) ("The publication and issuance requirements set forth in paragraphs (b) and (c) of this section are inapplicable in circumstances in which ***a Customs position is modified, revoked or otherwise materially affected by operation of law or by publication pursuant to other legal authority or by other appropriate action taken by Customs in furtherance of an order, instruction or other policy decision of another governmental agency*** or entity pursuant to statutory or delegated authority.") (emphasis added), or with an instruction on an exclusion order-by-exclusion order basis.

V. HOLDING

For the reasons above, the redesigned Apple Watches at the Port of Chicago under Detention No. 1751555713390 are to be released.

The EOE Branch reiterates that determinations of the Commission resulting from the underlying investigation or a related proceeding under 19 C.F.R. Part 210 are binding authority on

CBP and, in the case of conflict, will by operation of law modify or revoke any contrary CBP ruling or decision pertaining to Section 337 exclusion orders. Moreover, the Commission may modify or revoke this position, as noted above, or provide investigation-specific directions when issuing exclusion orders in the future and directing CBP accordingly.

Please send this internal advice ruling to Apple and confirm its transmission once that is complete. As noted above, Apple is directed upon receiving this internal advice ruling to identify any confidential information with [[red brackets]] that indicate such information should be redacted from the public version of the ruling that will be published in accordance with 19 C.F.R. § 177.10. Apple is to contact the EOE Branch within ten (10) business days of the date of this internal advice ruling to identify such information with the brackets noted above.

Sincerely,

Dax Terrill
Chief, Exclusion Order Enforcement Branch

EXHIBIT 3

QUICK READ • August 14, 2025

An update on Blood Oxygen for Apple Watch in the U.S.

Apple will introduce a redesigned Blood Oxygen feature for some Apple Watch Series 9, Series 10, and Apple Watch Ultra 2 users through an iPhone and Apple Watch software update coming later today.

Users with these models in the U.S. who currently do not have the Blood Oxygen feature will have access to the redesigned Blood Oxygen feature by updating their paired iPhone to iOS 18.6.1 and their Apple Watch to watchOS 11.6.1. Following this update, sensor data from the Blood Oxygen app on Apple Watch will be measured and calculated on the paired iPhone, and results can be viewed in the Respiratory section of the Health app. This update was enabled by a recent U.S. Customs ruling.

There will be no impact to Apple Watch units previously purchased that include the original Blood Oxygen feature, nor to Apple Watch units purchased outside of the U.S.

Apple's teams work tirelessly to create products and services that empower users with industry-leading health, wellness, and safety features that are grounded in science and have privacy at the core. Apple Watch Series 9, Series 10, and Apple Watch Ultra 2 also offer users irregular rhythm notifications, the ECG app, Sleep Apnea Notifications, Fall Detection, sleep tracking, wrist temperature sensing, the Vitals app, the Noise app, the Medications app, and the Mindfulness app, among many other helpful tools, helping users live a healthier life.

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EXHIBIT 4

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

RESPONDENT APPLE INC.'S RESPONSE TO MASIMO'S REQUEST FOR CLARIFICATION, OR IN THE ALTERNATIVE, PETITION FOR MODIFICATION AND REQUEST FOR EXPEDITED TREATMENT

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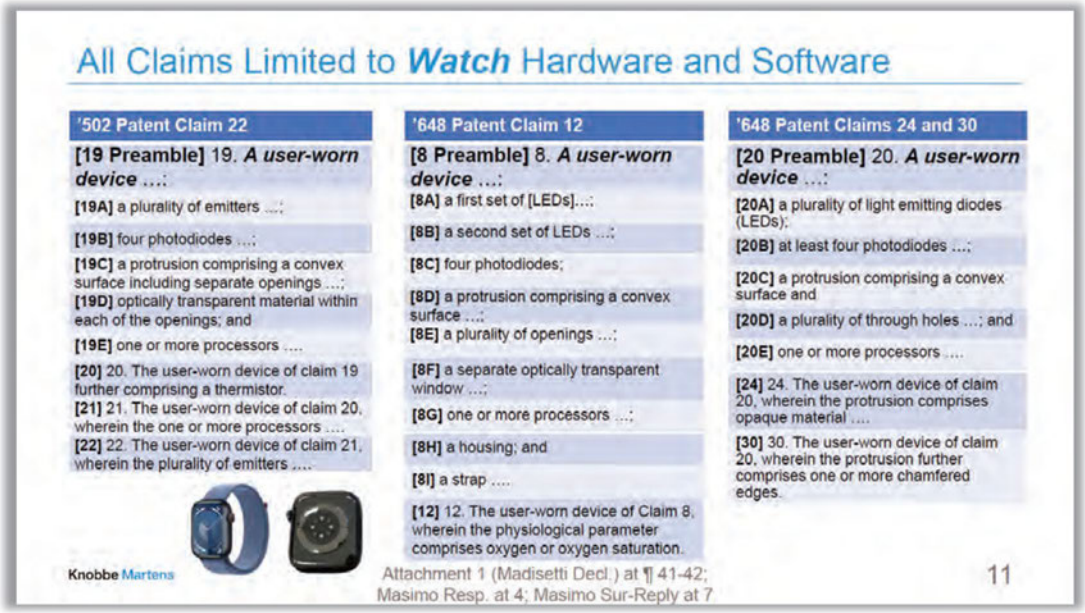
slide, which emphasizes that "All Claims [Are] Limited to ***Watch*** Hardware and Software" because each preamble recites "***A user-worn device***" (Masimo's emphasis):



Masimo expressly represented that the claimed functionality must be performed on Watch without regard to any processing that may occur on the iPhone, explaining "[t]he system is not relevant here. The claims relate to the watch itself, relate to the watch hardware and software." Ex. 2 [Dec. 28, 2023 Oral Discussion Tr.] at 119:15–120:1.

For all these reasons, the adjudicated patents demonstrate the claimed "a user-worn device" must be limited to a single device. There is no merit to Masimo's argument that the Redesign 2 Watch in combination with the iPhone practices the adjudicated patents.

B. The Commission Lacks Jurisdiction To "Modify" The Remedial Orders In The Manner Masimo Requests

1. The Federal Circuit Presently Has Jurisdiction Over Issues Implicated In This Proceeding

The Commission cannot rule on Masimo's request for modification because it implicates issues presently under the Federal Circuit's jurisdiction. *Gilda Indus. v. United States*, 511 F.3d

1348, 1350 (Fed. Cir. 2008) ("Ordinarily, the act of filing a notice of appeal confers jurisdiction on an appellate court and divests the trial court of jurisdiction over matters related to the appeal." (*citing Griggs v. Provident*, 459 U.S. 59 (1982)). Specifically, the appeal from the underlying investigation directly implicates the meaning of the term "user worn device," the meaning of which is relevant to at least two issues pending on appeal: (1) whether Masimo's alleged domestic industry devices satisfied the "user worn device" limitation; and (2) whether the Lumidigm prior art reference—RX-0411 [U.S. Patent No. 7,620,212] ("Lumidigm")—taught the "user-worn device" limitation and renders the relevant asserted claims invalid. *See* Appellant's Brief, *Apple v. ITC,* No. 24-1285 at 33-34, 36-37 (Fed. Cir. Apr. 28, 2024); Brief of Appellee International Trade Commission, *Apple v. ITC,* No. 24-1285 at 10-11 (Fed. Cir. Jun. 28, 2024) ("ITC's Federal Circuit Brief") ("The Commission's non-obviousness conclusion is supported on two independent grounds relevant to all claims subject to appeal: (1) Apple failed to show that the prior art teaches or suggests the **"*user-worn device*"** configured to measure "oxygen saturation" limitations"); *id.* at 20-21 (arguing that domestic industry devices were user-worn).

Notably, Masimo's petition now equates "user-worn" with "wearable," a new term that does not appear in any claims nor even in the shared specification of the '502 and '648 patents.[3] Pet. at 16-17. Masimo construes the term "wearable"—even though "wearable" devices are not what is claimed—using dictionary definitions to mean "suitable for being worn" or "merely capable of being worn." Masimo then urges the Commission to find under that construction that

[3] The word "wearable" only appears in the titles of certain prior art references cited on the face of the patents.

the iPhone is "user-worn" even though it cannot be "worn" without modification. Pet. at 16-17.[4] Masimo's interpretation renders the "user-worn" limitation meaningless, as anything could be hypothetically modified to allow it to be attached to a person.

Neither Masimo nor the Commission identified that construction to the Federal Circuit for purposes of evaluating the domestic industry or invalidity issues on appeal. Moreover, Masimo's theory that the iPhone is "user-worn," despite being strapless, is inconsistent with the manner in which the Commission itself argued to the Federal Circuit that Masimo's domestic industry devices allegedly met the "user-worn" limitation. *See* ITC's Federal Circuit Brief at 20-21 (arguing Masimo's devices were "user-worn" because they had a "mechanism for attaching a strap" and also "had [a strap] at one point in time"); Brief of Intervenors Masimo and Cercacor, *Apple v. ITC,* No. 24-1285 at 35 (Fed. Cir. June 28, 2024) (similar).

Although the Commission has previously held that it retains the ability to enforce its remedial orders while its final determination is on appeal, *see Certain Marine Sonar Imaging Devices*, USITC Inv. No. 337-TA-921, Comm'n Op. (Aug. 29, 2016), the present case is

[4] Masimo's new claim revision and construction are improper for a host of reasons. For one, it is erroneous to rewrite the claim language by substituting "wearable" for "user-worn." The Federal Circuit has rejected attempts to re-draft claim language in such a manner. *See In re Shafovaloff*, 2025 WL 1779173, at *2 (Fed. Cir. June 27, 2025) ("'It is not our function to rewrite claims …' and construing 'bent' as 'bend***able***' would rewrite the claim language to include what is foreclosed by the plain meaning" (citation omitted)). Additionally, Masimo's revision would materially broaden the "user-worn device" claims into claims drawn to mere capability—even though claims 22 and 28 of the '502 patent and claims 22 and 28 of the '648 patent do not use the word "capable of" (or wear***able***) and instead use the term "***configured to***." *E.g.*, '502 patent, cl. 19 ("A user-worn device configured to"); '648 patent, claim 8 (same); *Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1349 (Fed. Cir. 2012) (explaining that claims drawn to "capable of" are "broader" than "configured to"/"designed to"). Masimo's claim construction approach is also erroneous because it relies on extrinsic, dictionary definitions (Petition at 17) instead of the intrinsic record. *See Intel Corp. v. VIA Techs., Inc*., 319 F.3d 1357, 1367 (Fed. Cir. 2003) (use of extrinsic evidence improper when intrinsic evidence unambiguous); *see also Phillips v. AWH Corp*., 415 F.3d 1303, 1321-22 (Fed. Cir. 2005) (en banc) (holding that claim construction does not start with the dictionary definitions of a word).

distinguishable. In *Marine Sonar*, the Commission expressly acknowledged that the modification proceeding would not "affect the Commission's findings concerning indirect infringement, which are at issue in Navico's appeal." *Id*. at 6. By contrast, the Commission's applied scope of "user-worn device" is directly at issue in these proceedings in the two ways outlined above. Although styled as a request for "modification" or "clarification," Masimo's request asks the ITC to adopt a significantly broader scope of "user-worn device," arguing that it should cover not only a single wristwatch, but also a pair of two devices, including a mobile phone that is not even user-worn. *See* Pet. at 16 ("The question in this proceeding is whether a combination of the Redesign 2 Watch and a paired iPhone meets [the user-worn device limitation]."). Adopting that sweeping new claim scope would go far beyond what is permissible during an appeal—i.e., "preserving the status quo or otherwise supervising compliance." *See Washington Metro. Area Transit Comm'n v. Reliable Limousine Serv., LLC,* 985 F. Supp. 2d 23, 30 (D.D.C. 2013). Masimo's petition asks the Commission to fundamentally change the meaning of a disputed claim term (an issue which the Federal Circuit reviews *de novo*) and apply it to a new product at a time when the parties have already briefed and argued the issues under the original claim scope the Commission applied in the underlying Investigation. Granting Masimo's petition would therefore improperly impinge upon the Federal Circuit's jurisdiction. *Newton v. Consol. Gas Co. of New York*, 258 U.S. 165, 177 (1922) (during pendency of appeal, trial court "may not finally adjudicate substantial rights directly involved in the appeal"). The proper course of action is for the Commission to defer ruling on Masimo's petition until after the Federal Circuit has issued its opinion and resulting mandate.[5]

[5] Delaying resolution of Masimo's petition would also conserve Commission resources in the event that the Federal Circuit overturns any portion of the Commission's Final Determination.

EXHIBIT 5

[redacted]

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)**

JOINT PROPOSED LIST OF UNDISPUTED FACTS, DISPUTED FACTS, AND DISPUTED CLAIM TERMS FOR SEPTEMBER 22, 2025 SUBMISSION

[redacted]

DISPUTED CLAIM TERMS

Claim Term	Apple's Preliminary Proposed Meaning	Complainants' Proposed Construction
"the . . . device comprising"	plain and ordinary meaning— i.e., a single device that comprises all of the recited claim elements	plain and ordinary meaning—the claim is not limited to a single device, as Apple proposes
"user-worn device"	plain and ordinary meaning—i.e., a device that is, without modification, worn by a user	plain and ordinary meaning—"user-worn" means born or carried on the person. *See, e.g.* Merriam-Webster Dictionary.

[redacted]

DATED: September 22, 2025

Respectfully submitted,

/s/ Steven Cherny
Steven Cherny
Michael Swartz
Matthew Traupman
QUINN EMANUEL URQUHART & SULLIVAN, LLP
295 5th Avenue, 9th Floor
New York, New York 10016
Tel.: (212) 849-7000

S. Alex Lasher
Derek Shaffer
Jared Newton
QUINN EMANUEL URQUHART & SULLIVAN, LLP
1300 I Street, NW, Suite 900
Washington, D.C. 20005
Tel.: (202) 538-8000

Stephen C. Jensen
Joseph R. Re
Sheila N. Swaroop
Ted. M. Cannon
Alan G. Laquer
Kendall M. Loebbaka
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street
Fourteenth Floor
Irvine, CA 92614

William R. Zimmerman
Jonathan E. Bachand
KNOBBE, MARTENS, OLSON & BEAR, LLP
1717 Pennsylvania Avenue N.W., Suite 900
Washington, DC 20006

Brian C. Horne
KNOBBE, MARTENS, OLSON & BEAR, LLP
1925 Century Park East
Suite 600
Los Angeles, CA 90067

Karl W. Kowalis
Matthew S. Friedrichs
KNOBBE, MARTENS, OLSON & BEAR, LLP
1155 Avenue of the Americas, 24th Floor

[redacted]

New York, NY 10036

Counsel for Complainant Masimo Corp.

CERTAIN LIGHT-BASED PHYSIOLOGICAL MEASUREMENT DEVICES AND COMPONENTS THEREOF

Inv. No. 337-TA-1276

CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing document was caused to be served upon the following parties, as indicated on September 22, 2025:

The Honorable Lisa R. Barton **Secretary to the Commission** **U.S. International Trade Commission** 500 E Street, SW – Room 112 Washington, DC 20436	[ ] Via Hand Delivery [ ] Via Overnight/UPS Delivery [ ] Via First Class Mail [X] Via Electronic Filing (EDIS) [ ] Via Email
Michael Esch David Cavanaugh **WILMER CUTLER PICKERING HALE AND DORR LLP** 1875 Pennsylvania Avenue, NW Washington, DC 20006 Mark Selwyn **WILMER CUTLER PICKERING HALE AND DORR LLP** 2600 El Camino Real Suite 400 Palo Alto, California 94306 Joseph Mueller Richard Goldenberg Sarah Frazier **WILMER CUTLER PICKERING HALE AND DORR LLP** 60 State Street Boston, Massachusetts 02109 *Counsel for Respondent Apple Inc.*	[ ] Via Hand Delivery [ ] Via Overnight/UPS Delivery [ ] Via First Class Mail [ ] Via Electronic Filing (EDIS) [X] Via Email: WHApple-Masimo1276servicelist@wilmerhale.com

Dated: September 22, 2025

/s/ Michael Labas
Michael Labas