



**U.S. Customs and
Border Protection**

HQ H351038

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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 Watch¹ 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.

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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’).”).

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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 Corp. v. Datatarn, 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