

**UNITED STATES DISTRICT COURT
DISTRICT OF COLUMBIA**

MASIMO CORPORATION,

Plaintiff,

v.

UNITED STATES CUSTOMS AND
BORDER PROTECTION;

KRISTI NOEM, in her official capacity as
Secretary of Homeland Security;

RODNEY SCOTT, in his official capacity as
Commissioner of U.S. Customs and Border
Protection;

ALICE KIPEL, in her official capacity as
Executive Director of Regulations and
Rulings, Office of International Trade, U.S.
Customs and Border Protection,

Defendants.

Case No.: 1:25-cv-2749

REDACTED VERSION

**COMPLAINT FOR DECLARATORY
AND INJUNCTIVE RELIEF**

INTRODUCTION

1. This action challenges an unlawful August 2025 ruling by U.S. Customs and Border Protection (“CBP”) allowing Apple Inc. (“Apple”)—via an *ex parte* process—to bypass a Limited Exclusion Order (“LEO”) from the U.S. International Trade Commission (“ITC”) that prohibits the importation of Apple Watch products that infringe Masimo Corporation’s (“Plaintiff” or “Masimo”) patents.

2. In October 2023, after a thorough investigation and full administrative process, the ITC determined that Apple’s watches infringed multiple claims of Masimo’s patents related to light-based pulse oximetry technology. The ITC accordingly issued an LEO prohibiting the

importation of Apple’s infringing products. *See Certain Light-Based Physiological Measurement Devices and Components Thereof*, Limited Exclusion Order, USITC Inv. No. 337-TA-1276 (Oct. 26, 2023), 2023 WL 7213308; *Certain Light-Based Physiological Measurement Devices and Components Thereof*, Cease and Desist Order, USITC Inv. No. 337-TA-1276 (Oct. 26, 2023), 2023 WL 7213312.

3. Following issuance of the LEO, Apple explored an established regulatory pathway to determine whether a proposed redesign would fall outside the LEO’s scope. In January 2024, CBP conducted a thorough adversarial proceeding, with full participation from both Apple and Masimo, and determined that Apple’s redesigned watches could be imported only to the extent the infringing functionality was completely disabled. *See* HQ H335304 (Jan. 12, 2024), 2024 WL 5146677.

4. [REDACTED]

5. It has now come to light that CBP thereafter reversed itself without any meaningful justification, without any material change in circumstances, and without any notice to Masimo, let alone an opportunity for Masimo to be heard. CBP changed its position on Apple’s watch-plus-iPhone redesign through an *ex parte* proceeding. Specifically, on August 1, 2025, CBP issued an

¹ “Shaffer Decl., Ex.” refers to the Exhibits attached to the Declaration of Derek L. Shaffer, attached to Plaintiff’s Motion for a Temporary Restraining Order and Preliminary Injunction.

ex parte ruling permitting Apple to import devices that, when used with iPhones already in the United States, perform the same functionality that the ITC found to infringe Masimo's patents. Masimo only discovered this ruling on Thursday, August 14, 2025, when Apple publicly announced it would be reintroducing the pulse oximetry functionality through a software update.

6. This action by CBP effectively nullified the ITC's LEO, exceeded CBP's statutory authority under the trade laws and the Administrative Procedure Act, and deprived Masimo of its due process rights. CBP's function is to enforce ITC exclusion orders, not to create loopholes that render them ineffective. By issuing its August 2025 ruling through an *ex parte* process and applying a self-imposed rule against considering indirect infringement theories, CBP has acted unlawfully and deprived Masimo of the protections of its patents.

7. Masimo seeks declaratory and injunctive relief to prevent CBP from implementing the August 2025 ruling, require CBP to enforce the ITC's exclusion order as properly interpreted in CBP's prior January 2025 decision, and ensure that all future proceedings related to the enforcement of that Order comply with CBP's own regulations and due process requirements.

PARTIES

8. Plaintiff Masimo Corporation is a Delaware corporation with its principal place of business in Irvine, California. Masimo is a leading global medical technology company that develops and manufactures innovative, noninvasive patient monitoring technologies, including light-based physiological measurement devices. Masimo is the owner of U.S. Patent Nos. 10,912,502 ("the '501 patent"), 10,912,502 ("the '502 patent"), 10,945,648 ("the '648 patent"), and 10,687,745 ("the '745 patent"), which protect Masimo's innovative pulse oximetry technology. Masimo also has rights through a cross-licensing agreement to U.S. Patent No. 7,761,127 ("the '127 patent"), owned by Cercacor Laboratories, Inc.

9. Defendant United States Customs and Border Protection is a federal agency within the Department of Homeland Security. CBP is responsible for enforcing exclusion orders issued by the ITC, including the Limited Exclusion Order at issue in this case. CBP's headquarters is located at 90 K Street NW, Washington, D.C. 20229-1177.

10. Defendant Kristi Noem is the Secretary of the Department of Homeland Security and is sued in her official capacity. As Secretary, she oversees the activities of CBP and is responsible for the actions challenged in this Complaint.

11. Defendant Rodney Scott is the Commissioner of CBP. As Commissioner, he is responsible for the administration and enforcement of customs laws and regulations, including the enforcement of ITC exclusion orders.

12. Defendant Alice Kipel is the Executive Director of Regulations and Rulings in the Office of International Trade in CBP. As Executive Director, she is responsible for overseeing the Headquarters Office charged with issuing ruling letters pertaining to the enforcement of ITC exclusion orders.

JURISDICTION AND VENUE

13. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 because Plaintiff's claims arise under the Constitution and laws of the United States, including the Administrative Procedure Act, 5 U.S.C. §§ 701-706, and the Due Process Clause of the Fifth Amendment to the United States Constitution.

14. 5 U.S.C. § 702 waives United States sovereign immunity for actions seeking declaratory and injunctive relief.

15. Venue is proper in this District because the Defendants are officers of the federal government and a substantial part of the events giving rise to this claim occurred in this District, including the challenged CBP ruling.

BACKGROUND

Plaintiff's Patents

16. Masimo owns the '502 patent and the '648 patent. The ITC concluded that Apple infringes one or more of claims 22 and 28 of the '502 patent and claims 12, 24, and 30 of the '648 patent. Both patents share a specification and relate to measuring physiological parameters of a user.

17. The '502 and '648 patents are titled “User-Worn Device for Noninvasively Measuring a Physiological Parameter of a User.” They describe non-invasive methods and devices used to analyze a user’s blood contents or “analytes,” such as the amount of oxygen in the user’s blood. '502 Patent at 2:38–46.

18. The patents measure analytes by using light-emitting diodes (“LEDs”) to emit light into a measurement site (*e.g.*, “a finger, foot, ear lobe, or the like”), photodiodes to receive the light after it has passed through the measurement site, and a processor to identify attenuated wavelengths of light in the received light signal. *Id.* at 10:40–52, 13:16–21. The underlying theory is that particular analytes, like oxygen or glucose, absorb certain light wavelengths. *See id.* at 11:45–55. By identifying wavelengths of light that appear attenuated in the received light signal, the device can determine the presence and amount of analytes that likely absorbed those “missing” wavelengths. *Id.* at 33:15–36:12.

19. For example, claim 28 of the '502 patent discloses the following:

[28pre] A user-worn device configured to non-invasively measure an oxygen saturation of a user, the user-worn device comprising:

[28a] 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;

[28b] 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;

[28c] 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 has been attenuated by tissue of the user;

[28d] a thermistor configured to provide a temperature signal;

[28e] a protrusion arranged above the interior surface, the protrusion comprising:

[28f] a convex surface;

[28g] 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

[28h] a plurality of transmissive windows, each of the transmissive windows extending across a different one of the openings;

[28i] 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;

[28j] 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;

[28k] a network interface configured to wirelessly communicate the oxygen saturation measurement to at least one of a mobile phone or an electronic network;

[28l] 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;

[28m] a storage device configured to at least temporarily store at least the measurement; and

[28n] a strap configured to position the user-worn device on the user.

20. Claim 12 of the '648 patent (which depends from claim 8) discloses the following:

[8pre] A user-worn device configured to non-invasively determine measurements of a physiological parameter of a user, the user-worn device comprising:

[8a] a 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.

The ITC Proceedings

21. On August 18, 2021, the ITC initiated an investigation in response to Plaintiff and Cercacor's complaints² alleging violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337. 86 Fed. Reg. 46275 (Aug. 18, 2021). The complaint, as amended, alleged violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain light-based physiological measurement devices and components thereof by reason of infringement of certain

² Plaintiff and Cercacor's original complaint was filed on June 30, 2021, and amended and supplemental complaints were filed on July 12 and July 19, 2021, respectively. 86 Fed. Reg. 46275 (Aug. 18, 2021).

claims of the '501 patent; the '502 patent; the '648 patent; the '745 patent; and the '127 patent. *Id.* The notice of investigation named Apple as the sole respondent. *Id.* at 46276.

22. On January 10, 2023, an administrative law judge (“ALJ”) issued a Final Initial Determination (“Final ID”), which found that Apple violated section 337 as to only claims 24 and 30 of the '648 patent, but not the remaining asserted claims. *See* Final Initial Determination on Violation of Section 337, EDIS Doc. ID 789795 (Feb. 7, 2023) (Public Version).

23. On January 24, 2023, the ALJ issued the Recommended Determination on Remedy and Bonding (“RD”), recommending that, if the Commission finds a violation, it should issue a limited exclusion order (“LEO”) directed to certain wearable electronic devices with light-based pulse oximetry functionality and components thereof that are imported, sold for importation, and/or sold after importation by Apple. *See* Recommended Determination on Remedy and Bonding, EDIS Doc. ID 790079 (Feb. 10, 2023) (Public Version).

24. Plaintiff, Cercacor, and Apple each filed a petition for review of the Final ID by the Commission. Around the same time, the United States Patent and Trademark Office (“USPTO”) denied Apple’s request for the institution of *inter partes* review proceedings (“IPRs”) as to the '501, '502, and '648 patents based on a combination of references that included the same primary reference as one of the combinations of references asserted against the asserted claims of those patents in this investigation. *See Apple Inc. v. Masimo Corp.*, IPR2022-01272 (USPTO Jan. 24, 2023) ('501 patent); *Apple Inc. v. Masimo Corp.*, IPR2022-01274 (USPTO Jan. 24, 2023) ('502 patent); *Apple Inc. v. Masimo Corp.*, IPR2022-01276 (USPTO Jan. 30, 2023) ('648 patent).

25. On May 15, 2023, the ITC determined to review the Final ID, in part. *See* 88 Fed. Reg. 32243 (May 19, 2023).

26. On October 26, 2023, the Commission determined Plaintiff and Cercacor established a violation of section 337 by Apple with respect to claims 22 and 28 of the '502 patent and claims 12, 24, and 30 of the '648 patent, but otherwise agreed with the ALJ on the other matters it reviewed. 88 Fed. Reg. 75032 (Nov. 1, 2023); *see also Certain Light-Based Physiological Measurement Devices and Components Thereof*, Commission Opinion, USITC Inv. No. 337-TA-1276 (Nov. 14, 2023), 2023 WL 8109999. The ITC issued an LEO and cease and desist order consistent with its decision. *See Certain Light-Based Physiological Measurement Devices and Components Thereof*, Limited Exclusion Order, USITC Inv. No. 337-TA-1276 (Oct. 26, 2023), 2023 WL 7213308; *Certain Light-Based Physiological Measurement Devices and Components Thereof*, Cease and Desist Order, USITC Inv. No. 337-TA-1276 (Oct. 26, 2023), 2023 WL 7213312.

27. On January 9, 2024, Apple appealed the ITC's orders to the U.S. Court of Appeals for the Federal Circuit. Oral arguments were held on July 7, 2025. *See Apple Inc. v. ITC*, No. 24-1285 (Fed. Cir. *argued* July 7, 2025). A decision remains pending.

Limited Exclusion Order

28. The ITC is authorized by statute to issue exclusion orders if, after an investigation, it determines that imports of articles “infringe a valid and enforceable United States patent,” amongst other prescribed unfair methods of competition. 19 U.S.C. § 1337(a)(1)(B)(i), (d). Exclusion orders apply only to parties before the Commission, unless the ITC determines that “general exclusion ... is necessary to prevent circumvention of an exclusion order limited to products of named persons” or “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). An LEO is an exclusion order that is limited to “named respondents that the Commission finds in violation of Section 337.” *Kyocera Wireless Corp. v. ITC*, 545 F.3d 1340, 1356 (Fed. Cir. 2008).

29. The ITC’s October 26 LEO prohibits the importation of “Light-based physiological measurement devices and components thereof that infringe one or more of claims 22 and 28 of [the ’502 patent] and claims 12, 24, and 30 of [the ’648 patent] and are manufactured abroad by, or on behalf of, or imported by or on behalf of [Apple].” Limited Exclusion Order, 2023 WL 7213308, at *1.

30. The “covered articles” barred by the LEO are described as “wearable electronic devices with light-based pulse oximetry functionality and components thereof.” *Id.* at *2.

31. The LEO applies to all imported covered articles entered into consumption after December 26, 2023, the date the United States Trade Representative, on behalf of the President, declined to overturn the ITC’s decision. *See id.*; U.S. Trade Rep., Press Release, *USTR Statement on Section 337 Review* (Dec. 26, 2023), <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2023/december/ustr-statement-section-337-review>; *see also* 19 U.S.C. § 1337(j) (providing the President authority to overturn the ITC’s decision within 60 days); 70 Fed. Reg. 43251 (July 21, 2005) (delegating the President’s authority to the U.S. Trade Representative).

32. Pursuant to the LEO, importers must report to CBP whether their articles are covered by the order. Limited Exclusion Order, 2023 WL 7213308, at *2.

CBP Administrative Rulings

33. CBP has authority to enforce ITC exclusion orders under Section 337. 19 U.S.C. § 1337(d). CBP’s authority to exclude articles is limited to the language of the ITC’s exclusion order. *Wirtgen Am., Inc. v. United States*, 447 F. Supp. 3d 1359, 1367 (Ct. Int’l Trade 2020).

34. CBP regulations authorize interested persons to request rulings from Customs as to whether certain articles are within the scope of exclusion orders. 19 C.F.R. Part 177; *see also* 19 U.S.C. § 1625 (authorizing interpretive rulings generally). Of course, CBP must follow its own regulations and directives when enforcing exclusion orders. *See Fort Stewart Schs. v. Fed. Lab.*

Rel's. Auth., 495 U.S. 641, 654 (1990) (“It is a familiar rule of administrative law that an agency must abide by its own regulations.”); *Wirtgen Am.*, 447 F. Supp. 3d at 1368.

35. CBP’s regulations provide specific procedures for obtaining an administrative ruling. Interested parties must submit ruling requests with accompanying samples, documentation, and the position of the requestor. 19 C.F.R. § 177.2. Ruling letters are issued as expeditiously as possible to those involved in the proceeding. 19 C.F.R. § 177.8. Ruling letters are immediately effective following issuance and their holdings are “binding on all Customs Service personnel in accordance with the provisions of this section until modified or revoked.” 19 C.F.R. § 177.8. CBP’s regulations require that ruling letters be published in the Federal Register within 90 days after issuance. 19 C.F.R. § 177.10; *see also* 19 U.S.C. § 1625(a).

36. Privileged or confidential information is protected by the underlying protective order from the ITC proceeding, meaning that those involved in both can confidentially share protected information. 19 C.F.R. § 177.2(b)(7); *see, e.g.*, HQ H335304 (Jan. 12, 2024), 2024 WL 5146677, at *1.

37. It is CBP’s position that, “as a general matter, the sound administration of the Customs laws for rulings regarding the enforcement or administration of Section 337 exclusion orders warrants an *inter partes* proceeding to adjudicate the admissibility question presented.” HQ H339732 (June 11, 2024), 2024 WL 5146706, at *15. CBP may conduct some exclusion order proceedings *ex parte*, but only under “exceptional circumstances.” *Id.*

38. CBP also issues what are known as “internal advice rulings” under 19 C.F.R. § 177.11 to aid field offices in enforcing exclusion orders. Field officers may request advice from the Headquarters Office (“HQ”) on their own, and importers and others may request field officers to do so on their behalf. 19 C.F.R. § 177.11(b)(1). Under the latter scenario, however, “[s]uch

advice may not be requested for the purpose of seeking reconsideration of a ruling with which the importer or other person to whom the ruling letter was issued disagrees.” 19 C.F.R. § 177.11(b)(1)(ii). Rather, the rulings are intended only to provide “[a]dvice or guidance as to the interpretation or proper application of the Customs and related laws with respect to a specific Customs transaction.” 19 C.F.R. § 177.11(a). Indeed, the purpose of these advisory rulings is to “insure the consistent application of the Customs and related laws,” not to modify those laws. *Id.* Like ruling letters, internal advice rulings represent the official position of CBP and must be published within 90 days in the Customs Bulletin. 19 C.F.R. § 177.11(b)(1)(ii).

39. Internal advice rulings under Section 177.11 can be used to review decisions holding specific articles are covered by exclusion orders, but to initiate reconsideration, the field office must formally “request that the ruling be reconsidered” and then “notify the importer or other person to whom the ruling letter was issued, in writing, that it has requested the Headquarters Office to reconsider the ruling.” 19 C.F.R. § 177.11(b)(1)(i). However, review is available “only in those cases ‘when[,] although there is evidence to support [the exclusion], [[CBP] on the *entire* evidence is left with a definite and firm conviction that a mistake has been committed.’” HQ H323683 (Mar. 17, 2022), 2022 WL 2056964, at *7 (emphasis and alterations in original) (quoting *Anderson v. Bessemer City*, 470 U.S. 564, 573 (1985)). “In any other cases, an importer whose merchandise has been excluded from entry, based on Section 337, or another interested party will need to submit a ruling request for an *inter partes* proceeding under the general provisions of 19 C.F.R. Part 177 to address the admissibility question or, in appropriate circumstances, pursue an ancillary proceeding at the Commission under 19 C.F.R. Part 210.” *Id.* (emphasis added).

40. CBP may also modify or revoke an interpretive ruling. 19 U.S.C. § 1625(c); 19 C.F.R. § 177.12. If the interpretive ruling has been in effect for less than 60 days, CBP must only

notice the parties involved. 19 C.F.R. § 177.12(b). If the interpretive ruling has been in effect for more than 60 days, Customs must publish a proposed interpretive ruling in the Customs Bulletin and give interested parties at least 30 days to comment. *Id.*; 19 U.S.C. § 1625(c). CBP must then address those comments in a final action that must be published within 30 days of the close of the comment period. 19 C.F.R. § 177.12(b); 19 U.S.C. § 1625(c).

41. Respondents in Section 337 proceedings whose imports are subject to exclusion orders have invoked these processes by redesigning their products and then seeking an administrative ruling from CBP as to whether their redesigned products fall within the scope of the exclusion order. *See, e.g., In re Koki Holdings Am., Ltd.*, 830 F. App'x 320, 321 (Fed. Cir. 2020); *Hyosung TNS Inc. v. ITC*, 926 F.3d 1353, 1355–56 (Fed. Cir. 2019).

Apple's First Administrative Ruling Request Is Granted In January 2024

42. The day after the ITC issued its decision and LEO, Apple requested an administrative ruling from CBP pursuant to 19 C.F.R. Part 177. HQ H335304 (Jan. 12, 2024), 2024 WL 5146677, at *7. Apple sought a ruling on whether its “redesigned” watch was within the scope of the LEO. *Id.* Apple also sought a stay at the ITC due, in part, to its pending ruling request with CBP, which the Commission denied as unsupported by the public interest. *Certain Light-Based Physiological Measurement Devices and Components Thereof*, Commission Opinion Denying Respondent's Motion to Stay the Remedial Orders, USITC Inv. No. 337-TA-1276 (Jan. 3, 2024), 2024 WL 80132.

43. CBP conducted the proceeding pertaining to Apple's ruling request on an *inter partes* basis with Plaintiff's full participation, consistent with its policy and practice. HQ H335304, 2024 WL 5146677, at *7. This included, as is customary, the opportunity for Plaintiff to respond to Apple's ruling request, Apple's reply and Plaintiff's sur-reply, an oral discussion of the submissions and presentations by both parties, and post oral discussion submissions by both

parties. *Id.* at *8. Plaintiff was given the source code needed to evaluate the proposed redesign and Apple made samples available for inspection. *Id.* at *7. This was consistent with CBP’s general practice in these types of proceedings.

44. The redesign ruling request focused on the Apple Watch Series 8, 9, Ultra, and Ultra 2 products. *Id.* at *1. The ITC found the Series 8 watch infringed, but made no finding with respect to the remaining products because they became available in the United States only after Plaintiff filed its complaint with the Commission. *Id.* at *8. In essence, Apple’s proposed redesign ***disabled*** the functionality of the pulse oximetry feature the ITC found infringed on Plaintiff’s patents, but still had the same pulse oximetry hardware as the legacy products found to infringe. *Id.* at *8, *18. In other words, the proposed redesign would be capable of infringing Plaintiff’s patents but for Apple disabling the functionality of the infringing features.

45. CBP ruled that the redesigned articles, as proposed, did ***not*** infringe on Plaintiff’s patents and therefore were ***not*** excluded by the LEO. *Id.* at *18, *24. Even though CBP acknowledged that the redesigned watches could infringe through modification known as “jailbreaking,” it held that the watches were neither “programmed to” infringe nor “capable of” infringing because Apple had altogether disabled the infringing functionality of the pulse oximetry feature. *Id.* at *18–24. Thus, CBP ruled that these redesigned watches could not be excluded under the LEO.

46. Upon information and belief, Apple has been importing these redesigned watches since CBP’s decision.

Apple’s Second Administrative Ruling Request Is Denied In January 2025

47. In March 2024, Apple submitted another request for an administrative ruling from CBP pursuant to 19 C.F.R. Part 177. Shaffer Decl., Ex. 1, at *9. Apple asked CBP to rule on a further “redesign” that “includes the same processors and hardware” as in the originally excluded

watch, but that moved “the processing responsible for the final calculation of a user’s blood oxygen saturation” from the watch to an iPhone. Shaffer Decl., Ex. 2 (HQ H351038 (Aug. 1, 2025)). Apple’s “redesign” appeared to be a superficial modification expressly intended to circumvent the ITC’s exclusion order; the redesigned watches contained the same infringing components and retained (at the very least) capacity to perform the same infringing steps, except Apple offloaded one of those steps to the iPhone. *Id.*

48. [REDACTED]

49. [REDACTED]

50. [REDACTED]

51. [REDACTED]

[REDACTED]

52. [REDACTED]

[REDACTED]

53. [REDACTED]

[REDACTED]

54. [REDACTED]

[REDACTED]

[REDACTED]

55. [REDACTED]

[REDACTED]

[REDACTED]

56. [REDACTED]

[REDACTED]

[REDACTED]

57. [REDACTED]

[REDACTED]

58. [REDACTED]

Apple Announces A New, Ex Parte CBP Ruling Allowing It To Circumvent The Exclusion Order

59. During the months following the denial of its second administrative ruling request, Apple announced a series of substantial investments in the United States. *See, e.g.*, Press Release, *Apple Will Spend More Than \$500 billion in the U.S. Over the Next Four Years*, Apple (Feb. 24, 2025), <https://www.apple.com/newsroom/2025/02/apple-will-spend-more-than-500-billion-usd-in-the-us-over-the-next-four-years/>. Press Release, *Apple Expands U.S. Supply Chain With \$500 Million Commitment to American Rare Earth Magnets*, Apple (July 15, 2025), <https://www.apple.com/newsroom/2025/07/apple-expands-us-supply-chain-with-500-million-usd-commitment/>; Press Release, *Apple Increases U.S. Commitment to \$600 Billion, Announces American Manufacturing Program*, Apple (Aug. 6, 2025),

<https://www.apple.com/newsroom/2025/08/apple-increases-us-commitment-to-600-billion-usd-announces-ambitious-program/>.

60. On August 14, 2025, Apple announced that it was now able to provide blood oxygen monitoring features on its Series 9, 10, and Ultra 2 Apple watches. Shaffer Decl., Ex. 3 (Press Release, *An Update on Blood Oxygen for Apple Watch in the U.S.* (Aug. 14, 2025), <https://www.apple.com/newsroom/2025/08/an-update-on-blood-oxygen-for-apple-watch-in-the-us/>). Apple stated it was able to activate the blood oxygen feature through software updates for these watches and their paired iPhones. *Id.* Apple explained that these updates would allow “sensor data from the Blood Oxygen app on Apple Watch [to] be measured and calculated on the paired iPhone, and results can be viewed in the Respiratory section of the Health app.” *Id.* Apple further stated that “[t]his update was enabled by a recent U.S. Customs ruling.” *Id.* Apple did not provide further information on this purported ruling.

61. Plaintiff was unaware of any new ruling by CBP because neither Apple nor CBP had provided Plaintiff any notice of a new CBP proceeding. Plaintiff was provided no opportunity to participate in any proceeding or process that led to this new ruling. It therefore appears that whatever proceeding led to this new ruling departed substantially from CBP’s established practice regarding LEO ruling requests.

62. As soon as Plaintiff was made aware of Apple’s announcement, counsel to Plaintiff immediately inquired with the Chief of the Exclusion Order Enforcement Branch, [REDACTED]

[REDACTED].

63. The Chief’s response was terse. He stated only that a ruling would be made available within ten business days but declined to provide specifics. When Plaintiff’s counsel inquired why the ruling was, evidently, based on *ex parte* proceedings, the Chief demurred,

pointing to CBP precedent authorizing *ex parte* proceedings in “exceptional circumstances.” HQ H339732, 2024 WL 5146706, at *15. The Chief did not explain what “exceptional circumstances” exist in this case.

Apple Discloses Redacted Version of New Ruling

64. After learning about the new ruling on August 14, 2025, Plaintiff’s counsel immediately sent Apple’s counsel a demand letter, informing Apple that it may be in violation of the ITC’s LEO and cease and desist order and that Plaintiff reserves all rights thereunder. *See* Limited Exclusion Order, 2023 WL 7213308; Cease and Desist Order, 2023 WL 7213312.

65. In response, on August 15, 2025, Apple’s counsel provided Plaintiff’s counsel with a redacted version of the new ruling that served as the basis for Apple’s announcement (the “August 2025 ruling”).³

CBP’s August 2025 Ruling Reverses Course on the Watch Plus Phone Redesign

66. CBP inexplicably reversed course in its new ruling. CBP spent a large portion of the decision merely restating its ruling from the second administrative proceeding that Apple’s redesigned watch alone does not infringe Masimo’s patents. Shaffer Decl., Ex. 2, at *10–16. Only briefly did CBP even acknowledge that it had nevertheless held that the redesigned watch was still subject to the ITC’s exclusion order because the watch plus an iPhone still infringed Masimo’s patents literally and under the doctrine of equivalents. *Id.* at *10. CBP spent the rest of its decision guarding against its own prior ruling, suggesting Apple could overcome CBP’s prior infringement analysis by simply importing its watches and iPhones separately. *See id.* at *16–18.

³ CBP released a redacted version of the August ruling yesterday, August 19, 2025. The full text of the redacted version is accessible through the official CBP rulings database at: <https://rulings.cbp.gov/ruling/H351038>.

67. For this proposition, CBP relied on a prior decision concluding that the articles in that case—an ink container and an adapter for a printer—“contained in the same shipment fall within the scope of the [exclusion order].” *Id.* at *18 (emphasis omitted) (alteration in original) (quoting Shaffer Decl., Ex. 4, at *22–25 (*Certain Ink Cartridges and Components Thereof*, USITC Inv. No. 337-TA-565, CBP HQ Protest Decision H025822 (Nov. 23, 2009))). CBP appeared to employ the logical fallacy of “denying the antecedent” to make its point, incorrectly concluding that a decision holding “if the articles are in the same shipment, then they are excluded” meant that “if the articles are not in the same shipment, then they are not excluded.” CBP also failed to explain the basis for interpreting this case-specific decision about printer components to mean that infringers could circumvent ITC decisions by merely sending infringing components in different shipments.

68. Finally, CBP considered whether the redesigned watch plus an iPhone might *indirectly* infringe Masimo’s patents. *Id.* at *19–21. Why CBP decided to *sua sponte* raise indirect infringement is unclear, [REDACTED]

[REDACTED]. CBP appeared to raise indirect infringement to suggest that adjudicating the watch-plus-iPhone combination had somehow traveled beyond its jurisdiction ([REDACTED]

[REDACTED]).

According to CBP, “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 it would not do so at this junction. *Id.* at *20. CBP therefore released the redesigned watches, effectively reversing its second administrative decision and endorsing a direct violation of the ITC’s exclusion order. *Id.* at *21.

CLAIMS

COUNT 1

VIOLATION OF ADMINISTRATIVE PROCEDURE ACT — ARBITRARY AND CAPRICIOUS

69. Plaintiff incorporates by reference all allegations contained in the preceding paragraphs.

70. The APA requires this Court to “hold unlawful and set aside” agency action that is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A).

71. Agency action is arbitrary and capricious when the agency “has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

72. CBP’s August 2025 ruling is arbitrary and capricious for multiple reasons. [REDACTED]

[REDACTED]

[REDACTED]

73. *Second*, CBP adopted a self-imposed rule against considering indirect infringement theories without adequate justification. This effectively creates a loophole in the enforcement of the ITC’s Exclusion Order by addressing only the narrow question of direct infringement of watches imported alone—even when those watches are being imported for the express purpose of being paired with separately shipped or already-imported phones to carry out the function barred by the ITC’s Order [REDACTED].

74. *Third*, and relatedly, CBP failed to consider the impact on Plaintiff's patent rights, which were specifically protected by the ITC's LEO. Consequently, CBP issued a ruling that effectively modified the LEO.

75. Courts have recognized that agency action based on pretext or improper considerations violates the APA. *See, e.g., Dep't of Com. v. New York*, 588 U.S. 752, 766 (2019) (holding that agency action may be set aside as arbitrary and capricious when the agency's stated rationale is pretextual).

76. For these reasons, CBP's August 2025 ruling is arbitrary, capricious, and contrary to law, and should be set aside under 5 U.S.C. § 706(2)(A).

COUNT 2

VIOLATION OF ADMINISTRATIVE PROCEDURE ACT — IN EXCESS OF STATUTORY AUTHORITY AND ULTRA VIRES

77. Plaintiff incorporates by reference all allegations contained in the preceding paragraphs.

78. The Administrative Procedure Act requires this Court to “hold unlawful and set aside” agency action that is “in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.” 5 U.S.C. § 706(2)(C).

79. Under 19 U.S.C. § 1337, the ITC has exclusive authority to determine whether imported articles infringe valid and enforceable U.S. patents and to issue exclusion orders prohibiting the importation of infringing products. CBP's role is to enforce the ITC's exclusion orders, not to re-examine or effectively overturn the ITC's substantive determinations regarding patent infringement.

80. The ITC properly exercised its statutory authority by conducting a full investigation, including an evidentiary hearing before an ALJ, and determined that Apple's

watches infringed Plaintiff's patents. The ITC then issued an LEO directing CBP to exclude the infringing products from entry into the United States.

81. Apple has appealed the ITC's determination to the Federal Circuit, but that appeal remains pending. *See Apple Inc. v. ITC*, No. 24-1285 (Fed. Cir. *argued* July 7, 2025). Unless and until the Federal Circuit reverses or modifies the ITC's determination, it remains binding on CBP.

82. CBP's August 2025 ruling expressly acknowledges 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." H351038 at 21-22.

83. Despite this acknowledgement, the CBP's August 2025 ruling improperly narrows the scope of its analysis to exclude consideration of indirect infringement theories that would prevent circumvention of the ITC's Exclusion Order.

84. CBP's August 2025 ruling further states that it has an "agency practice" against applying indirect infringement theories when enforcing exclusion orders. H351038 at 20. However, nothing in 19 U.S.C. § 1337 or CBP's implementing regulations justifies this limitation, which effectively allows importers to circumvent exclusion orders by imposing components of infringing products separately.

85. By artificially restricting its analysis to direct infringement only and refusing to consider that Apple's stated intention in importing the watches was to allow those watches to be used with phones already in or separately shipped to the United States for the function that is barred by the ITC's Exclusion Order, CBP has exceeded its statutory authority and impermissibly

encroached on the ITC's exclusive jurisdiction to determine patent infringement and issue exclusion orders.

86. CBP lacks the statutory authority to impose self-limiting rules that have the effect of nullifying the ITC's exclusion orders. Its statutory role is limited to enforcing the ITC's orders, not creating loopholes that render them ineffective.

87. CBP's August 2025 ruling thus represents an *ultra vires* attempt to exercise authority reserved to the ITC and the Federal Circuit. By effectively permitting Apple to import products that, when used as intended with phones already in the United States, would infringe on Plaintiff's patents as determined by the ITC, CBP has acted in excess of its statutory authority and contrary to its statutory duties.

88. For these reasons, CBP's August 2025 ruling should be set aside under 5 U.S.C. § 706(2)(C).

COUNT 3

VIOLATION OF THE DUE PROCESS CLAUSE OF THE FIFTH AMENDMENT

89. Plaintiff incorporates by reference all allegations contained in the preceding paragraphs.

90. The Due Process Clause of the Fifth Amendment provides that "[n]o person shall ... be deprived of life, liberty, or property, without due process of law." U.S. Const. amend. V.

91. Plaintiff has a protected property interest in its patents and in the enforcement of the ITC's Limited Exclusion Order prohibiting the importation of products that infringe those patents. This property interest is protected by the Due Process Clause of the Fifth Amendment. *See Florida Prepaid Postsecondary Educ. Expense Bd. v. College Savings Bank*, 527 U.S. 627, 642 (1999) ("Patents ... have long been considered a species of property As such, they are surely

included within the ‘property’ of which no person may be deprived ... without due process of law.”).

92. The ITC’s issuance of an LEO in Plaintiff’s favor following a full adjudicatory proceeding created a legitimate expectation of enforcement that is protected by due process. *See Spansion, Inc. v. Int’l Trade Comm’n*, 629 F.3d 1331, 1359-60 (Fed. Cir. 2010) (recognizing the special statutory significance of ITC exclusion orders and the strong expectation of enforcement that accompanies them).

93. The Supreme Court has established that procedural due process requires notice and a meaningful opportunity to be heard. *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976); *see also LaChance v. Erickson*, 522 U.S. 262, 266 (1998) (“The core of due process is the right to notice and a meaningful opportunity to be heard.”).

94. In *Mathews*, the Court established a three-factor test to determine what process is due: (1) the private interest affected; (2) the risk of erroneous deprivation and the probable value of additional procedural safeguards; and (3) the government’s interest, including the fiscal and administrative burdens of additional procedures. 424 U.S. at 335.

95. Under this test, Plaintiff was entitled to substantial procedural protections before CBP could issue a ruling that effectively nullifies the protection provided by the ITC’s Limited Exclusion Order: (1) the private interest affected—Plaintiff’s patent rights and the competitive advantage protected by the ITC’s Exclusion Order—is substantial; (2) the risk of erroneous deprivation is severe given that CBP employed an *ex parte* process that wholly excluded the participation and technical expertise of Plaintiff; and (3) the government’s interest in proceeding *ex parte* is minimal—CBP has established procedures for *inter partes* proceedings that it regularly utilizes, [REDACTED]

██████████. Including Plaintiff would have imposed no significant administrative burden and implicated no confidentiality concerns that could not be addressed through existing protective order mechanisms. Any modest delay resulting from Plaintiff's participation would have been reasonable and proportional given the substantial property interests at stake and CBP's statutory obligation to properly enforce the ITC's Exclusion Order.

96. Defendants violated Plaintiff's due process right by: (1) failing to provide any notice to Plaintiff that CBP was considering a ruling that would reverse its own prior ruling and effectively nullify the ITC's Limited Exclusion Order; (2) conducting *ex parte* proceedings, despite Plaintiff being a directly affected party; and (3) issuing a ruling with immediate effect before Plaintiff had any opportunity to review or challenge it.

97. For these reasons, Defendants' actions violate the Due Process Clause of the Fifth Amendment and must be vacated and set aside.

PRAYER FOR RELIEF

For these reasons, Plaintiff respectfully requests an order:

1. temporarily restraining Defendants, their agents, and all persons acting in concert or participation with Defendants from implementing, maintaining, or giving effect to the August 2025 ruling;
2. preliminarily enjoining Defendants, their agents, and all persons acting in concert or participation with Defendants from implementing, maintaining, or giving effect to the August 2025 ruling;
3. postponing the effectiveness of the August 2025 ruling;
4. directing the Defendants to file the administrative record expeditiously;
5. declaring that Defendants' actions are unlawful;

6. permanently enjoining Defendants, their agents, and all persons acting in concert or participation with Defendants from implementing, maintaining, or giving effect to the August 2025 ruling;
7. entering judgment in favor of Plaintiff;
8. awarding Plaintiff its costs and attorney's fees and expenses pursuant to applicable law, including but not limited to 42 U.S.C. § 1988; and
9. issuing any and all other such relief as the Court deems just and proper.

Dated: August 20, 2025

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