

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of

**CERTAIN LIGHT-BASED
PHYSIOLOGICAL MEASUREMENT
DEVICES AND COMPONENTS THEREOF**

Inv. No. 337-TA-1276

FINAL INITIAL DETERMINATION ON VIOLATION OF SECTION 337

Administrative Law Judge Monica Bhattacharyya

(January 10, 2023)

Appearances:

For Complainants Masimo Corporation and Cercacor Laboratories, Inc.:

Stephen C. Jensen, Joseph R. Re, Irfan A. Lateef, Sheila N. Swaroop, Ted M. Cannon, Brian C. Claassen, Alan G. Laquer, Kendall M. Loebbaka, Daniel C. Kiang, and Douglas B. Wentzel of Knobbe, Martens, Olson & Bear, LLP in Irvine, CA; William R. Zimmerman and Jonathan E. Bachand of Knobbe, Martens, Olson & Bear, LLP in Washington, DC; Carol Pitzel Cruz of Knobbe, Martens, Olson & Bear, LLP in Seattle, WA; and Karl W. Kowallis and Matthew S. Friedrichs of Knobbe, Martens, Olson & Bear in New York, NY.

For Respondent Apple Inc.:

Mark D. Selwyn of Wilmer Cutler Pickering Hale and Dorr LLP in Palo Alto, CA; Joseph J. Mueller, Richard Goldenberg, and Sarah R. Frazier of Wilmer Cutler Pickering Hale and Dorr LLP in Boston, MA; and Michael D. Esch and David Cavanaugh of Wilmer Cutler Pickering Hale and Dorr LLP in Washington, DC.

C. Asserted Patents

The '501 patent, '502 patent, and '648 patent share a common specification, claiming priority to an application filed on July 3, 2008. JX-0001; JX-0002; JX-0003. These patents are entitled “User-Worn Device for Noninvasively Measuring a Physiological Parameter of a User,” naming inventors Jeroen Poeze *et al.*, and are referenced herein as the “Poeze patents.” *Id.*

The '745 patent is entitled “Physiological Monitoring Devices, Systems, and Methods,” and claims priority to an application filed on June 28, 2016, naming inventor Ammar Al-Ali. JX-0009.

The '127 patent is entitled “Multiple Wavelength Sensor Substrate” and issued from an application filed on March 1, 2006, naming inventors Ammar Al-Ali *et al.* JX-0007.

D. Products at Issue

The products at issue are “wearable electronic devices with light-based pulse oximetry functionality and components thereof.” Notice of Investigation at 2.

1. Accused Products

Complainants accuse Apple Watch products of infringing the asserted patents, including the Apple Watch Series 6, the Apple Watch Series 7, and certain prototype Apple Watch products [REDACTED] (“Next Generation Apple Watches”). CIB at 37-39. Apple has stipulated to the importation of the Apple Watch Series 6, Apple Watch Series 7, and Next Generation Apple Watches (collectively, the “Accused Products”). *See* CX-0128C (Stipulation Regarding Importation and Inventory) at ¶¶ 2-4; CX-1259C (Stipulation Relating to Next-Generation Watches) at ¶¶ 5-6. The parties have stipulated that the Accused Products are materially identical for the purposes of infringement in this investigation. *See* Joint Stipulation of Facts at ¶¶ 11-13, EDIS Doc. ID 770692 (May 13, 2022); CX-1259C at ¶¶ 7-8.

- c. **Element [19B]: “four photodiodes arranged within the user-worn device and configured to receive light after at least a portion of the light has been attenuated by tissue of the user”**

There is no dispute that each of the Accused Products contains four photodiodes configured to receive light that has been attenuated by tissue of the user. *See* CIB at 68. The relevant evidence was discussed above in the context of the “photodiodes” limitation of ’501 patent claim 1. The evidence of record shows that this limitation is met.

- d. **Element [19C]: “a protrusion comprising a convex surface including separate openings extending through the protrusion and lined with opaque material, each opening positioned over a different one associated with each of the four photodiodes, the opaque material configured to reduce an amount of light reaching the photodiodes without being attenuated by the tissue”**

There is no dispute that each of the Accused Products contains a protrusion comprising a convex surface, as discussed above in the context of the “protrusion” limitation of ’501 patent claim 1. *See* CIB at 66. With respect to the ’502 patent claim 19 limitation requiring “openings extending through the protrusion,” Complainants identify the same “openings” that are discussed above in the context of the “plurality of openings” limitation of ’501 patent claim 1. *See* CIB at 66-67. Complainants further identify the same [REDACTED] discussed above in the context of the “opaque lateral surfaces” limitation of ’501 patent claim 1. *Id.*

Apple disputes infringement of this limitation based on its erroneous proposed constructions of the claim terms “over” and “openings.” *See* RIB at 26-39; RRB at 21-34. These arguments have been rejected, however, as discussed above in the context of the “plurality of openings” limitation of ’501 patent claim 1 and in the claim construction analysis above. *See* Part IV.D, *supra*. Accordingly, the undersigned finds that the Accused Products meet the limitation in ’502 patent claim 19 requiring a “protrusion” including “openings extending

Accordingly, because each limitation of claims 19, 20, 21, and 22 are satisfied, the undersigned finds that the Accused Products infringe claim 22 of the '502 patent.

3. '502 Patent Claim 28

- a. Element [28 preamble]: “A user-worn device configured to non-invasively measure an oxygen saturation of a user, the user worn device comprising:”**

There is no dispute that the Accused Products meet the limitations of the preamble of '502 patent claim 28, which requires “[a] user-worn device configured to non-invasively measure an oxygen saturation of a user.” *See* CIB at 72. The relevant evidence was discussed above in the context of the preamble of '501 patent claim 1. The evidence of record shows that this limitation is met.

- b. Element [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”**

There is no dispute that each of the Accused Products contains four sets of LEDs, with each set containing three LEDs emitting light at different wavelengths. *See* CIB at 72. The relevant evidence was discussed above in the context of the “LEDs” limitation of '501 patent claim 1. The evidence of record shows that this limitation is met.

- c. Element [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”**

There is no dispute that each of the Accused Products contains four sets of LEDs, with each set containing three LEDs emitting light at different wavelengths. *See* CIB at 72. The relevant evidence was discussed above in the context of the “LEDs” limitation of '501 patent claim 1, and Dr. Block confirmed that the wavelengths in each of the LED groups is the same--

5. '648 Patent Claim 24¹¹

- a. **Element [20 preamble]: “A user-worn device configured to non-invasively determine measurements of a user’s tissue, the user-worn device comprising:”**

There is no dispute that the Accused Products meet the limitations of the preamble of '648 patent claim 20, which requires “[a] user-worn device configured to non-invasively determine measurements of a user’s tissue.” *See* CIB at 81. The relevant evidence was discussed above in the context of the preamble of '501 patent claim 1. The evidence of record shows that this limitation is met.

- b. **Element [20A]: “a plurality of light emitting diodes (LEDs)”**

There is no dispute that each of the Accused Products has LEDs. *See* CIB at 82. The relevant evidence was discussed above in the context of the “LEDs” limitation of '501 patent claim 1. The evidence of record shows that this limitation is met.

- c. **Element [20B]: “at least four photodiodes configured to receive light emitted by the LEDs, the four photodiodes being arranged to capture light at different quadrants of tissue of a user”**

There is no dispute that each of the Accused Products contains four photodiodes arranged in quadrants. *See* CIB at 82. The relevant evidence was discussed above in the context of the “photodiodes” limitation of '501 patent claim 1 and the “photodiodes” limitation of '502 patent claim 28. The evidence of record shows that this limitation is met.

- d. **Element [20C]: “a protrusion comprising a convex surface”**

There is no dispute that each of the Accused Products contains a protrusion comprising a convex surface. *See* CIB at 80-81. The relevant evidence was discussed above in the context of

¹¹ Because claim 24 of the '648 patent depends from claim 20, the infringement, technical prong and invalidity analyses address the limitations of claims 20 and 24. *See* CIB at xxix.

that the identified protrusion in the Accused Products has a coating and ink that is configured to prevent light piping, as discussed above in the context of the “opaque lateral surface” limitation of ’501 patent claim 1. *See* CIB at 82. The evidence of record shows that this limitation is met.

Accordingly, because each of the limitations of claims 20 and 24 are satisfied, the undersigned finds that the Accused Products infringe claim 24 of the ’648 patent.

6. ’648 Patent Claim 30

Claim 30 of the ’648 patent depends from claim 20, further requiring that “the protrusion further comprises one or more chamfered edges.” There is no dispute that the identified protrusion in the Accused Products has chamfered edges. *See* CIB at 82-83. Dr. Madisetti identified chamfered edges on engineering drawings for the Accused Products. Tr. (Madisetti) at 699:4-19; CX-0063C (Apple Watch Series 7 Engineering Drawings) at 2; *see also* CX-1548C (Apple Watch Series 7 Photographs) at 3; CX-0070C (Apple Watch Series 7 Engineering Drawings) at 1. The evidence of record shows that this limitation is met.

Accordingly, because each of the limitations of claims 20 and 30 are satisfied, the undersigned finds that the Accused Products infringe claim 30 of the ’648 patent.

F. Domestic Industry—Technical prong

The domestic industry products that Complainants rely on for the Poeze patents are the RevA sensor (CPX-0052C), the RevD sensor (CPX-0058C), the RevE sensors (CPX-0019C, CPX-0020C, CPX-0065C), and the Masimo W1 (CPX-0146C). CIB at 26-35. Complainants allege that the RevA, RevD, RevE, and Masimo W1 devices practice claim 12 of the ’501 patent and claims 12, 24, and 30 of the ’648 patent; and that the RevD, RevE, and Masimo W1 devices

significance where a domestic industry is based on “core manufacturing activities,” affirming an initial determination finding that “[s]uch activities have long been recognized as a domestic industry within the meaning of section 337.”).

In opposition, Apple argues that “Complainants ignore that rainbow® product revenues generally comprise only [REDACTED] of Masimo’s total product revenues in 2020.” *See* RIB at 278. Apple, however, fails to explain why this would be a more appropriate comparison under these circumstances. *See, e.g., Certain Carburetors and Prods. Containing Such Carburetors, Inv. No. 337-TA-1123, Comm’n Op. at 28 (Oct. 28, 2019)* (“Significance is based on the marketplace conditions regarding the articles protected by the Asserted Patents. The fact that a complainant may have substantial sales of other products is not pertinent to this analysis.”).

Accordingly, the undersigned finds that Complainants have demonstrated significant employment of labor or capital with respect to the rainbow® sensors. As discussed above, however, Complainants have not satisfied the domestic industry requirement with respect to the ’127 patent because the current rainbow® sensors have not been shown to practice any claim of the ’127 patent.

IX. CONCLUSIONS OF LAW

Based on the foregoing, and the record as a whole, it is the undersigned’s final initial determination that there has been a violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in the importation into the United States, the sale for importation, and/or the sale within the United States after importation of certain wearable electronic devices with light-based pulse oximetry functionality and components thereof by reason of infringement of claims 24 and 30 of the ’648 patent. There has been no violation of the statute with respect to the asserted claims of the ’501 patent, the ’502 patent, the ’745 patent, or the ’127 patent.

This determination is based on the following conclusions of law:

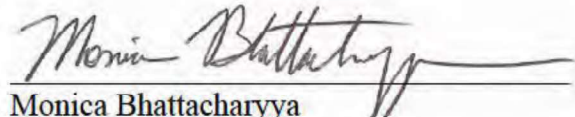
1. The Commission has subject matter jurisdiction over this investigation.
2. The Accused Products have been imported into the United States, sold for importation, and/or sold within the United States after importation.
3. The Commission has *in rem* jurisdiction over the Accused Products.
4. The Accused Products infringe claim 12 of the '501 patent, claims 22 and 28 of the '502 patent, and claims 12, 24, and 30 of the '648 patent.
5. The technical prong of the domestic industry requirement has been satisfied for claim 12 of the '501 patent, claim 28 of the '502 patent, and claims 12, 24, and 30 of the '648 patent.
6. Claim 12 of the '501 patent, claim 28 of the '502 patent, and claim 12 of the '648 patent are invalid.
7. The '501 patent, '502 patent, and '648 patent have not been shown to be unenforceable.
8. The economic prong of the domestic industry requirement has been satisfied with respect to the '501 patent, the '502 patent, and the '648 patent.
9. The Accused Products have not been shown to infringe claims 9 or 27 of the '745 patent.
10. The technical prong of the domestic industry requirement has been satisfied for claim 18 of the '745 patent.
11. Claims 9, 18, and 27 of the '745 patent have not been shown to be invalid.
12. The '745 patent has not been shown to be unenforceable.
13. The economic prong of the domestic industry requirement has been satisfied with respect to the '745 patent.
14. The Accused Products have not been shown to infringe claim 9 of the '127 patent.
15. The technical prong of the domestic industry requirement has been satisfied for claim 9 of the '127 patent.
16. Claim 9 of the '127 patent has not been shown to be invalid.
17. The economic prong of the domestic industry requirement has not been satisfied with respect to the '127 patent.

The undersigned hereby certifies the record in this investigation to the Commission with the undersigned's final initial determination. Pursuant to Commission Rule 210.38, the record further comprises the complaint and exhibits thereto, and the exhibits attached to the parties' summary determination motions and the responses thereto. 19 C.F.R. § 210.38(a).

Pursuant to Commission Rule 210.42(h)(2), this initial determination shall become the determination of the Commission 60 days after the service thereof, unless a party files a petition for review pursuant to Commission Rule 210.43(a), the Commission orders its own review pursuant to Commission Rule 210.44. 19 C.F.R. § 210.42(h)(2).

This initial determination is being issued with a confidential designation pursuant to Commission Rule 210.5 and the protective order in this investigation. Within 10 days of the date of this document, the parties shall submit a joint statement as to whether or not they seek to have any portion of this document deleted from the public version. If the parties do seek to have portions of this document deleted from the public version, they must submit a single proposed public version of this final initial determination with any proposed redactions consistent with the manner specified by Ground Rule 1.9.¹³⁸ The submission shall be made by email to Bhattacharyya337@usitc.gov and need not be filed with the Commission Secretary.

SO ORDERED.


Monica Bhattacharyya
Administrative Law Judge

¹³⁸ Redactions should be limited to avoid obscuring the reasoning underlying the decision. Parties who submit excessive redactions may be required to provide an additional written statement, supported by declarations from individuals with personal knowledge, explaining why each proposed redaction meets the definition for confidential business information in 19 C.F.R. § 201.6(a).