UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

In the Matter of Certain Light-Based Physiological Measurement Devices and Components Thereof	Investigation No. 337-TA-_____

COMPLAINT UNDER SECTION 337 OF
THE TARIFF ACT OF 1930, AS AMENDED

Complainants:

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

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

Respondent:

Apple Inc.
One Apple Park Way
Cupertino, CA 95014
Telephone: 408-996-1010

Counsel for Complainants:

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

Jonathan E. Bachand
KNOBBE MARTENS OLSON & BEAR, LLP
1717 Pennsylvania Ave NW, Suite 900
Washington DC, 20006
Telephone: (202) 640-6400

APPLE 1012

TABLE OF CONTENTS

Page No.

I. INTRODUCTION 1

II. COMPLAINANTS 3

III. PROPOSED RESPONDENT 7

IV. PRODUCTS AND TECHNOLOGY AT ISSUE 8

A. Complainants' Technology 8

B. Apple's Copying of Complainants' Technology 11

C. The Accused Products 13

V. THE ASSERTED PATENTS 14

A. U.S. Patent No. 10,912,501 14

1. Identification of the Patent and Ownership by Masimo Corporation 14

2. Foreign Counterparts to the '501 Patent 17

3. Non-Technical Description of the '501 Patent 17

B. U.S. Patent No. 10,912,502 18

1. Identification of the Patent and Ownership by Masimo Corporation 18

2. Foreign Counterparts to the '502 Patent 20

3. Non-Technical Description of the '502 Patent 20

C. U.S. Patent No. 10,945,648 21

1. Identification of the Patent and Ownership by Masimo Corporation 21

2. Foreign Counterparts to the '648 Patent 24

3. Non-Technical Description of the '648 Patent 24

D. U.S. Patent No. 10,687,745 25

1. Identification of the Patent and Ownership by Masimo Corporation 25

2. Foreign Counterparts to the ’745 Patent 26

3. Non-Technical Description of the ’745 Patent 26

E. U.S. Patent No. 7,761,127..... 27

1. Identification of the Patent and Ownership by Cercacor 27

2. Foreign Counterparts to the ’127 Patent 28

3. Non-Technical Description of the ’127 Patent 28

F. Licensees..... 29

VI. UNLAWFUL AND UNFAIR ACTS OF PROPOSED RESPONDENT..... 29

VII. THE DOMESTIC INDUSTRY Related to Asserted Patents..... 37

A. Technical Prong 38

B. Economic Prong..... 39

VIII. SPECIFIC INSTANCES OF UNFAIR IMPORTATION AND SALE 40

IX. CLASSIFICATION OF THE INFRINGING PRODUCTS UNDER THE HARMONIZED TARIFF SCHEDULE OF THE UNITED STATES 41

X. RELATED LITIGATION..... 41

XI. REQUESTED RELIEF 42

LIST OF EXHIBITS

Exhibit No.	Description
1	Certified Copy of U.S. Patent No. 10,912,501
2	Certified Copy of U.S. Patent No. 10,912,502
3	Certified Copy of U.S. Patent No. 10,945,648
4	Certified Copy of U.S. Patent No. 10,687,745
5	Certified Copy of U.S. Patent No. 7,761,127
6	Certified Assignment Documents for U.S. Patent No. 10,912,501
7	Certified Assignment Documents for U.S. Patent No. 10,912,502
8	Certified Assignment Documents for U.S. Patent No. 10,945,648
9	Certified Assignment Documents for U.S. Patent No. 10,687,745
10	Certified Assignment Documents for U.S. Patent No. 7,761,127
11	CONFIDENTIAL EXHIBIT: Amended and Restated Cross-Licensing Agreement between Masimo Laboratories and Masimo Corporation Effective January 1, 2007
12	Listing of All Foreign Patents and All Foreign Patent Applications Corresponding to Asserted Patents
13	Representative Photos of Representative Apple Watch Series 6 (Model No. 109.627 shown)
14	Product Literature Regarding the Apple Watch Series 6
15	CONFIDENTIAL EXHIBIT: Claim Chart Comparing Claims of the '501 Patent to an Apple Watch Series 6
16	CONFIDENTIAL EXHIBIT: Claim Chart Comparing Claims of the '502 Patent to an Apple Watch Series 6
17	CONFIDENTIAL EXHIBIT: Claim Chart Comparing Claims of the '648 Patent to an Apple Watch Series 6
18	CONFIDENTIAL EXHIBIT: Claim Chart Comparing Claims of the '745 Patent to an Apple Watch Series 6
19	CONFIDENTIAL EXHIBIT: Claim Chart Comparing Claims of the '127 Patent to an Apple Watch Series 6
20	CONFIDENTIAL EXHIBIT Drawings, Photographs, or Other Visual Representations of Masimo's rainbow® Sensors
21	CONFIDENTIAL EXHIBIT: Drawings, Photographs, or Other Visual Representations of Masimo's Confidential Domestic Industry Product
22	CONFIDENTIAL EXHIBIT: Claim Chart Comparing Exemplary Claims of the '501 Patent to Masimo's Domestic Industry Product
23	CONFIDENTIAL EXHIBIT: Claim Chart Comparing Exemplary Claims of the '502 Patent to Masimo's Domestic Industry Product
24	CONFIDENTIAL EXHIBIT: Claim Chart Comparing Exemplary Claims of the '648 Patent to Masimo's Domestic Industry Product

Exhibit No.	Description
25	CONFIDENTIAL EXHIBIT: Claim Chart Comparing Exemplary Claims of the '745 Patent to Masimo's Domestic Industry Product
26	CONFIDENTIAL EXHIBIT: Claim Chart Comparing Exemplary Claims of the '127 Patent to Masimo's Domestic Industry Products
27	CONFIDENTIAL EXHIBIT: Confidential Declaration of Bilal Muhsin
28	CONFIDENTIAL EXHIBIT: Confidential Declaration of Micah Young
29	September 15, 2020 Press Release
30	CONFIDENTIAL EXHIBIT: Invoice dated April 19, 2021
31	Photographs of Product Packaging of the Apple Watch Series 6
32	January 28, 2021 Apple 10K Filing with SEC
33	Fowler, Geoffrey, "The new Apple Watch says my lungs may be sick. Or perfect. It can't decide." *Washington Post*, September 23, 2020.
34	Masimo Form 10-K, dated February 23, 2021
35	"The Apple Watch's blood oxygen sensor is less accurate than you think"
36	"Can the Apple Watch Series 6 Keep the Doctor Away?"
37	"Apple Watch Series 6 review – Minute Improvements"
38	"The New Apple Watch 6 May Have a Problem. Oddly Enough, That's OK"
39	"Apple Watch Series 6 and SE Review – Watch Out for the Upsell"
40	Provisional Application No. 60/367,428

LIST OF APPENDICES

Appendix	Description
A	File History for U.S. Patent No. 10,912,501
B	Relevant Technical References Cited in File History for U.S. Patent Nos. 10,912,501, 10,912,502, and 10,945,648
C	File History for U.S. Patent No. 10,912,502
D	File History for U.S. Patent No. 10,945,648
E	Certified File History for U.S. Patent No. 10,687,745
F	Relevant Technical References Cited in File History for U.S. Patent No. 10,687,745
G	Certified File History for U.S. Patent No. 7,761,127
H	Relevant Technical References Cited in File History for U.S. Patent No. 7,761,127

I. INTRODUCTION

1. Masimo Corporation and Cercacor Laboratories, Inc. (collectively, "Masimo" or "Complainants") request that the United States International Trade Commission ("Commission") institute an investigation into violations of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 ("Section 337") committed by Respondent Apple Inc. ("Apple") ("Apple" or "Respondent").

2. This Complaint is based on Respondent's unlawful and unauthorized importation into the United States, sale for importation, and/or sale within the United States after importation of certain light-based physiological measurement devices and components thereof. Respondent's products, including, but not limited to, the "Apple Watch Series 6," or "Series 6" ("Accused Products") infringe at least one claim of U.S. Patent No. 10,912,501, titled "User-Worn Device for Noninvasively Measuring a Physiological Parameter of a User," ("the '501 Patent"), U.S. Patent No. 10,912,502, titled "User-Worn Device for Noninvasively Measuring a Physiological Parameter of a User," ("the '502 Patent"), U.S. Patent No. 10,945,648, titled "User-Worn Device for Noninvasively Measuring a Physiological Parameter of a User," ("the '648 Patent"), U.S. Patent No. 10,687,745, titled "Physiological Measurement Devices, Systems, and Methods," ("the '745 Patent"), and U.S. Patent No. 7,761,127, titled "Multiple Wavelength Sensor Substrate," ("the '127 Patent") (collectively, "the Asserted Patents"), either literally or under the doctrine of equivalents.

3. The Accused Products directly infringe and/or induce the infringement of, literally or under the doctrine of equivalents, at least the following claims (collectively, "the Asserted Claims") of the Asserted Patents:

U.S. Patent	Asserted Claims[1]
'501 Patent	**1**-9, 11-18, **19**-25 and **26**-30
'502 Patent	**1**-2, 4-6, 8-12, 14-18, **19**-22, 24-26, and **28**-30
'648 Patent	**1**-5, **6**-17, 19, and **20**-30
'745 Patent	**1**-6, 8-9, 11, 14, **20**-24, and 26-27
'127 Patent	**7**-9

Further discovery may reveal that Respondent infringes additional claims.

4. Certified copies of the '501 Patent, '502 Patent, '648 Patent, '745 Patent, and '127 Patent are attached hereto as **Exhibits 1, 2, 3, 4, and 5**, respectively. Masimo Corp. owns by assignment the entire right, title, and interest in and to the '501 Patent, '502 Patent, '648 Patent, and '745 Patent (collectively, "the Masimo Patents"). Certified copies of the recorded assignments of the Masimo Patents are attached hereto as **Exhibits 6, 7, 8, and 9**, respectively. Masimo Corp. exclusively licenses certain rights to the Masimo Patents to Cercacor. A copy of the Amended and Re-Stated Cross-Licensing Agreement between Masimo Corp. and Cercacor (formerly known as Masimo Laboratories) granting the license to Cercacor is attached hereto as **Confidential Exhibit 11**. Cercacor owns by assignment the entire right, title, and interest in and to the '127 Patent ("the Cercacor Patent"). Certified copies of the recorded assignment of the Cercacor Patent are attached hereto as **Exhibit 9**. Masimo is a licensee of certain exclusive rights to the Cercacor Patents, as reflected in **Confidential Exhibit 11.**

5. Respondent's activities with respect to the importation into the United States, the

[1] Independent claims are noted in **BOLD**.

sale for importation into the United Sates, and/or the sale within the United States after importation of certain light-based physiological measurement devices and components thereof, described more fully *infra*, are unlawful under 19 U.S.C. § 1337(a)(1)(B)(i) in that they constitute infringement of the valid and enforceable Asserted Patents.

6. As required by Section 337(a)(2) and defined by Section 337(a)(3), industries exist in the United States relating to articles covered by the Asserted Patents or alternatively such industries relating to articles protected by the Asserted Patents are in the process of being established.

7. Complainants seek relief from the Commission in the form of a permanent limited exclusion order, pursuant to Section 337(d), excluding from entry into the United States the Accused Products that infringe one or more claims of the Asserted Patents. Complainants also seek a permanent cease and desist order, pursuant to Section 337(f), directing Respondent to immediately cease and desist from importing, marketing, advertising, demonstrating, warehousing inventory for distribution, distributing, offering for sale, selling, or using in the United States the certain light-based physiological measurement devices and components thereof that infringe one or more claims of the Asserted Patents.

8. Complainants further seek as relief a bond, for the 60-day Presidential review period pursuant to Section 337(j), for the importation of the certain light-based physiological measurement devices and components thereof that infringe one or more claims of the Asserted Patents.

II. COMPLAINANTS

9. Complainant Masimo Corporation is a Delaware corporation having its principal place of business at 52 Discovery, Irvine, California 92618. Masimo owns the Masimo Patents and has certain exclusive rights to the Cercacor Patent. (*See* **Exhibits 1-4, 6-9, Confidential**

Exhibit 11). Complainant Cercacor is a Delaware corporation having its principal place of business at 15750 Alton Pkwy, Irvine, CA 92618. Cercacor is the owner of the Cercacor Patent and has certain exclusive rights to the Masimo Patents. (*See* **Exhibits 5 and 10, Confidential Exhibit 11**).

10. Masimo is a global medical technology company that has revolutionized non-invasive monitoring of physiological parameters, such as pulse rate, arterial oxygen saturation and many others. These innovations have been repeatedly recognized by Federal courts. *See Mallinckrodt, Inc. v. Masimo Corp.*, Case No. 2:00-CV-06506 (C.D. Cal. Apr. 5, 2004), ECF No. 588; *Mallinckrodt, Inc. v. Masimo Corp.*, Case No. 2:00-CV-06506 (C.D. Cal. July 12, 2004), ECF No. 622; *Mallinckrodt, Inc. v. Masimo Corp.*, Case No. 2:00-CV-06506 (C.D. Cal. Aug. 4, 2004), ECF No. 632, *aff'd in part and rev'd in part*, 147 F. App'x 158 (Fed. Cir. 2005); *Mallinckrodt, Inc. v. Masimo Corp.*, 147 F. App'x 158 (Fed. Cir. 2005); *Masimo Corp. v. Philips Elec. N. Am. Corp.*, Case No. 1:09-CV-00080 (D. Del. Oct. 17, 2014), ECF No. 919; *Masimo Corp. v. Philips Elec. N. Am. Corp.*, Case No. 1:09-CV-00080 (D. Del. May 18, 2015), ECF No. 997; *Masimo Corp. v. Philips Elec. N. Am. Corp.*, Case No. 1:09-CV-00080 (D. Del. May 18, 2015), ECF No. 998.

11. Masimo develops, manufactures, and markets a variety of noninvasive patient monitoring technologies and hospital automation solutions as part of its mission to improve patient outcomes and reduce the cost of patient care. Masimo's patient monitoring solutions are systems that generally incorporate a monitor or circuit board, proprietary single-patient use or reusable sensors, software and/or cables. Masimo primarily sells its products to professional caregivers, such as hospitals, emergency medical service providers, home care providers,

physician offices, veterinarians, long term care facilities and also to consumers, through its direct sales force, online, distributors, and original equipment manufacturer (OEM) partners.

12. Masimo has rapidly expanded its workforce despite the COVID-19 Pandemic. As of December 28, 2019, Masimo had approximately 1,600 full-time employees and approximately 3,700 dedicated contract personnel worldwide. **Exhibit 34** (Masimo Form 10k) at 34. By January 2, 2021, Masimo had grown to 2,000 full-time employees and approximately 4,200 dedicated contract personnel worldwide.

13. Masimo's core business is referred to as Masimo SET® pulse oximetry. Pulse oximetry allows for the noninvasive measurement of the oxygen saturation level of arterial blood, which delivers oxygen to the body's tissues. Pulse oximetry also allows for the measurement of pulse rate. "SET" refers to Masimo's Signal Extraction Technology, a technology invented by Masimo that, for the first time, allowed pulse oximeters to provide accurate measurements of oxygen saturation even during patient motion and low perfusion (i.e., decreased arterial blood flow) conditions.

14. Over the years, Masimo's product offerings have expanded significantly to also include rainbow® Pulse CO-Oximetry, with its unique ability to allow for real-time non-invasive monitoring of additional physiological measurements, including carboxyhemoglobin (SpCO®), methemoglobin (SpMet®), total hemoglobin concentration (SpHb®) and fractional arterial oxygen saturation (SpfO2™). Rainbow® Pulse CO-oximetry also has the ability to measure pulse rate, perfusion index (Pi), Pleth Variability Index (PVi®) and respiration rate from the pleth (RRp®). The rainbow SET® platform also allows for the calculation of Oxygen Content (SpOC™) and Oxygen Reserve Index (ORi™).

15. Masimo's current technology offerings also include remote patient monitoring, connectivity, and hospital automation solutions, including Masimo Patient SafetyNet™, Masimo Patient SafetyNet™ Surveillance, Replica™, Iris®, MyView®, UniView™ and Trace™. Masimo's technologies are supported by a substantial intellectual property portfolio.

16. Masimo invests significantly in its research and development efforts, and currently spends about 10% of its sales revenue on research and development activities. For the year ending January 2, 2021, Masimo spent approximately $118,689,000 for research and development activities. **Exhibit 34** (Masimo Form 10k) at 66. The majority of these activities take place in the United States. **Exhibit 34** (Masimo Form 10k) at 62. As a result of these efforts, Masimo has been awarded numerous patents in the United States and around the world. As of January 2, 2021, Masimo had approximately 800 issued patents and approximately 500 pending applications in the U.S., Europe, Japan, Australia, Canada and other countries throughout the world. **Exhibit 34** (Masimo Form 10k) at 32.

17. Masimo owns two facilities in Irvine, California, with combined square footage of approximately 314,400, housing its corporate headquarters and the majority of its U.S. research and development activities. Masimo also owns approximately 86,500 square feet of property in Hudson, New Hampshire, which is used to develop and manufacture advanced light emitting diodes and other advanced component-level technologies, as well as warehousing and administrative operations.

18. Masimo also leases and occupies approximately 105,800 square feet of additional building space in Irvine, California for product manufacturing and warehousing. Masimo also leases or owns an additional 61,000 square feet at various locations throughout the United States, that provide centers for distribution of Masimo's products directly to its customers, and is in the

[redacted]

process of establishing distribution centers throughout the United States, [redacted]

19. Complainant Cercacor is a health and wellness innovator based in Irvine, California. In 1998, Masimo spun certain technology off into a new company, Masimo Laboratories, Inc. or "Masimo Labs," to further research and develop the technologies. The name of the company was later changed to "Cercacor." Cercacor and Masimo have a license agreement between them to facilitate collaboration between the companies.

20. Like Masimo, Cercacor is an innovator of non-invasive monitoring technologies. Cercacor is on the frontline of understanding how measuring, tracking, and analyzing physiological parameters can impact pre-diabetic and diabetic patients, endurance sports training and performance, and overall health and wellness. Cercacor continued the development that started at Masimo on numerous non-invasive parameters. Leading hospitals around the world use Cercacor technology licensed to Masimo and sold under the name Masimo rainbow SET®. This technology was the first, and remains the only, noninvasive monitoring technology that can measure carbon monoxide, methemoglobin, and total hemoglobin in the blood.

III. PROPOSED RESPONDENT

21. Respondent Apple Inc. ("Apple") is a California corporation having a principal place of business at One Apple Park Way, Cupertino, California 95014. Apple unlawfully sells for importation, imports, and/or sells after importation into the United States certain light-based physiological measurement devices and components thereof, including the Apple Watch Series 6, that infringe the '501 Patent, the '502 Patent, the '648 Patent, the '745 Patent, and the '127 Patent, either literally or under the doctrine of equivalents.

22. Apple is in the business of designing, manufacturing, and marketing smartphones, personal computers, tablets, wearables, and accessories, and sells a variety of related services.

Apple's wearables include certain light-based physiological measurement devices and components thereof, including the Apple Watch Series 6.

IV. PRODUCTS AND TECHNOLOGY AT ISSUE

A. Complainants' Technology

23. Products that practice one or more claims of the Asserted Patents—including the Accused Products and Masimo's Domestic Industry products—are light-based physiological measurement devices and components thereof. These physiological measurement devices typically rely on light that is transmitted through the body tissue. The received light, that has been attenuated by the various components of the body tissue, including the pulsing arterial blood, is known in the industry as a photoplethysmography or "PPG." The transmission and receipt of this light is typically accomplished through a sensor that is applied to a body part such as a finger, arm, toes, forehead or ear.

24. Before Masimo, non-invasive measurements from the PPG were plagued by unreliability, often when the measurement was needed most, due to the person moving or having low peripheral blood flow (known as "low perfusion"). The industry had essentially given up on solving these problems, concluding they were largely unsolvable. In the medical context, clinicians had to live with the results—patient monitors gave excessive false alarms, froze their measurements for prolonged periods of time despite potential changes in the physiological parameter (e.g., oxygen saturation or pulse rate), delayed notification of alarms due to long averaging times of sensor data, produced inaccurate measurements, or were unable to obtain data on the most critical patients and babies who cannot be instructed to stay still. Masimo's pioneering Masimo SET® technology, solves this problem and dramatically improved the reliability of monitoring and reporting physiological signals derived from the PPG.

[redacted]

25. Following its initial success with Masimo SET® technology, Masimo invested heavily in developing additional breakthrough measurement technologies, such as non-invasively measuring total hemoglobin, carboxyhemoglobin, and methemoglobin. Masimo has continued to innovate, succeeding where others have consistently failed. Masimo was the first, and remains the only, company delivering these game-changing technologies to hospitals in the United States. Use of Masimo's technology in the clinical setting has been proven to reduce blindness in premature infants, detect congenital heart disease in infants, save lives on the general care floor and post-surgery, and improve transfusion management, while also saving substantial money for the hospitals providing care.

26. Masimo's investment in its technology and research and development has included significant investments in wrist-worn devices for measurements of physiological parameters. Masimo's patent filings as early as 2002 disclose wrist-worn devices for measuring physiological parameters that wirelessly connected to monitors. *See* **Exhibit 40** (Provisional Application No. 60/367,428 filed on March 25, 2002).

27. One of Masimo's commercially marketed wrist-worn device for measuring physiological parameters, the Radius PPG, was cleared by the FDA in May of 2019. The Radius PPG eliminated the need for a cabled connection to a pulse oximetry monitor, allowing patients to move freely and comfortably while still being continuously monitored reliably and accurately. The device communicated with monitors via a wireless connection allowing patients to benefit from mobility.

28. [redacted]

[redacted]

29. Given its success selling medical-grade devices for non-invasively measuring physiological parameters, Complainants decided to leverage these clinical grade products for sale directly to consumers where allowable. Masimo noticed that there has been many devices sold to consumers purporting to provide physiological measurements, but could identify none that provided clinical grade measurement. The devices available to consumers were more like toys. In 2013, Masimo first began selling its pulse oximetry products to the consumer market. After Masimo began selling directly to consumers, it also increased its investment in direct-to-consumer advertising, including being a premium sponsor of the BNP Paribas Open Tennis Tournament in Palm Springs, CA.

30. Notably, despite the acute awareness of pulse oximetry created by the COVID-19 pandemic, the large multitude of so-called pulse oximeters offered to consumers are prohibited for medical purposes. Unfortunately, the consumers do not recognize this, which puts their health at risk.

31. The Asserted Patents claim devices and/or components of devices used in the non-invasive measurement of physiological parameters such as oxygen saturation. For example, the four Masimo Patents claim devices containing multiple optical sources that emit light at different wavelengths and numerous light detectors. The light detectors are configured to detect the optical radiation from the tissue and output a respective signal stream responsive to this detection. The devices are configured in specific ways which improve the successful detection of the signal while minimizing the effects of light-piping. The Cercacor Patent also claims novel technologies assisting in the non-invasive measurement of physiological parameters. The ’127

Patent claims a sensor using a thermal mass within a substrate to measure and account for effects on measurements from temperature changes.

B. Apple's Copying of Complainants' Technology

32. In 2013, Apple contacted Masimo and asked to meet regarding a potential collaboration. Apple told Masimo that Apple would like to understand more about Masimo's technology to potentially integrate that technology into Apple's products. Apple and Masimo later entered into a confidentiality agreement, and Masimo's management met with Apple. The meetings included confidential discussions of Masimo's technology. After what seemed to Masimo to have been productive meetings, Apple quickly began hiring Masimo's employees, including engineers and key management.

33. Masimo employed Michael O'Reilly as its Chief Medical Officer and Executive Vice President for Medical Affairs beginning in January 2008. As part of the Masimo executive team, O'Reilly was privy to extremely sensitive information, including information about mobile medical products and applications, wellness applications, clinical data gathering and analytics, and other technology of Masimo. Upon information and belief, Apple employed O'Reilly in July 2013, shortly after the meetings with Masimo, to assist in wellness and mobile applications that include non-invasive measurement of physiological parameters. Not long after, by December of 2013, O'Reilly was already meeting with the FDA on behalf of Apple to discuss medical applications and discuss medical products that non-invasively measures blood constituents.

34. Apple systematically recruited other key Masimo personnel, such as Marcelo Lamego (a named inventor on many of the Asserted Patents), who was the former Chief Technical Officer of Cercacor and a former Research Scientist at Masimo. Lamego was a

Masimo employee during 2000-2001 and 2003-2006, and the Cercacor Chief Technical Officer during 2006-2014.

35. Lamego had unfettered access to Complainants' technical information. He was trained and mentored at Masimo by the most skilled engineers and scientists, and was taught about the keys to effective non-invasive monitoring, something he was not involved in prior to Masimo. Masimo engineers and scientists including, among others, Ammar Al-Ali, Mohamed Diab, and Walter Weber, exposed Lamego to all of Masimo's technology on non-invasive monitoring. The Masimo engineers, including Al-Ali, Diab, and Weber, were Masimo employees at all relevant times. Lamego also had access to and learned guarded secrets regarding Complainants' mobile medical products, including key technology and advance plans for future products.

36. When Lamego left Cercacor, he assured Complainants that he would not violate his agreements with Complainants and volunteered that he would not work on technology similar to Complainants' technology. On January 24, 2014, Complainants sent a letter to Apple explaining that Lamego possessed Complainants' confidential proprietary information and warning Apple to respect Complainants' rights in such information. The letter stated, "we trust that Apple will employ Mr. Lamego in an area that does not involved healthcare technology, including mobile health applications and the measurement of physiological information." The letter also asked that "Apple refrain from inducing Mr. Lamego to take actions that would violate the Agreement while he performs services for Apple" and asked Apple to "direct Mr. Lamego to honor his obligations to all of his prior employers." Based on Complainants' conversations with Lamego, Complainants' letter to Apple, and Complainants' confidentiality agreement with Apple, Complainants' reasonably believed that Lamego would not use or disclose Complainants'

confidential information and that Apple would not induce Lamego to do so or itself use Complainants' confidential information.

37. Unbeknownst to Complainants at the time, it now appears that, shortly after joining Apple in January 2014, Lamego began pursuing on behalf of Apple numerous patent applications directed toward technologies he worked on at Complainants, and with which he had no prior experience or knowledge.

38. Apple announced the first version of its watch in September 2014 and began shipping its watch in April 2015. On information and belief, Apple began incorporating Masimo's technology in later versions of its watch. Ultimately with the launch of the Apple Watch Series 6 in September 2020, Apple for the first time purported to have incorporated the ability to measure blood oxygen saturation (pulse oximetry) into its watches—technology, which as described in more detail below, infringes the Asserted Claims. Unfortunately for U.S. consumers, the Apple Watch Series 6 differs from Masimo's medical grade technology in that Apple's Accused Products do not reliably measure blood oxygen concentrations, as described in **Exhibits 33 and 35-39**.

C. <u>The Accused Products</u>

39. Pursuant to 19 C.F.R. § 210.12(a)(12), the category of the Accused Products may be plainly described as wearable electronic devices with light-based pulse oximetry functionality, including various devices made by Apple, including, but not limited to, various models of the Apple Watch Series 6. The Apple Watch Series 6 is an electronic smartwatch, which purportedly includes pulse oximetry functionality. Relevant here, the Accused Products contain LEDs, photodiodes, and other features within the scope of the Masimo Patents to measure the oxygen saturation of the user. The Accused Products also contain the thermal mass technology

claimed in the ’127 Patent. The infringing products—including their associated systems, and components thereof—are further described in **Exhibits 15, 16, 17, 18, and 19**, which include claim charts comparing the Asserted Claims to the Apple Watch Series 6. The Apple Watch Series 6 either infringes these claims upon importation or Apple induces consumers to infringe these claims through its sale of the Apple Watch Series 6 and its recommendation, encouragement, and/or instruction to users to use the Apple Watch Series 6 in connection with an iPhone.

40. The Apple Watch Series 6 is imported into and sold within the United States by or on behalf of Apple. On information and belief, commercially significant volumes of infringing products are maintained in inventory by Apple in the United States.

41. The identification of exemplary Accused Products is intended purely for illustration and is not intended to limit the scope of the investigation. Any remedy should extend to all present and future infringing products of Apple, regardless of model number, name, or type of product.

V. THE ASSERTED PATENTS

A. U.S. Patent No. 10,912,501

1. Identification of the Patent and Ownership by Masimo Corporation

42. Masimo Corporation owns by assignment the entire right, title, and interest in the ’501 Patent, entitled “User-Worn Device for Noninvasively Measuring a Physiological Parameter of a User,” which issued on February 9, 2021. **Exhibit 1**. The ’501 Patent issued from U.S. Patent Application Serial No. 17/031,356, filed on September 24, 2020. The ’501 Patent is a continuation of U.S. Patent Application No. 16/834,538, filed March 30, 2020, which is a continuation of U.S. Patent Application No. 16/725,292, filed December 23, 2019, which is a

continuation of U.S. Patent Application No. 16/534,949, filed August 7, 2019, which is a continuation of U.S. Patent Application No. 16/409,515, filed May 10, 2019, which is a continuation of U.S. Patent Application No. 16/261,326, filed January 29, 2019, which is a continuation of U.S. Patent Application No. 16/212,537, filed December 6, 2018, which is a continuation of U.S. Patent Application No. 14/981,290 filed December 28, 2015, which is a continuation of U.S. Patent Application No. 12/829,352 filed July 1, 2010, which is a continuation of U.S. Patent Application No. 12/534,827 filed August 3, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed August 4, 2008, 61/086,108 filed August 4, 2008, 61/086,063 filed August 4, 2008, 61/086,057 filed August 4, 2008, and 61/091,732 filed August 25, 2008. U.S. Patent Application No. 12/829,352 is also a continuation-in-part of U.S. Patent Application No. 12/497,528 filed July 2, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed August 4, 2008, 61/086,108 filed August 4, 2008, 61/086,063 filed August 4, 2008, 61/086,057 filed August 4, 2008, 61/078,228 filed July 3, 2008, 61/078,207 filed July 3, 2008, and 61/091,732 filed August 25, 2008. U.S. Patent Application No. 12/497,528 also claims the benefit of priority under 35 U.S.C. § 120 as a continuation-in-part of the following U.S. Design Patent Application Nos. 29/323,409 filed August 25, 2008 and 29/323,408 filed August 25, 2008. U.S. Patent Application No. 12/829,352 is also a continuation-in-part of U.S. Patent Application No. 12/497,523 filed July 2, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed August 4, 2008, 61/086,108 filed August 4, 2008, 61/086,063 filed August 4, 2008, 61/086,057 filed August 4, 2008, 61/078,228 filed July 3, 2008, 61/078,207 filed July 3, 2008, and 61/091,732 filed August

25, 2008. U.S. Patent Application No. 12/497,523 also claims the benefit of priority under 35 U.S.C. § 120 as a continuation-in-part of the following U.S. Design Patent Application Nos. 29/323,409 filed August 25, 2008 and 29/323,408 filed August 25, 2008. A certificate of correction issued on the '501 Patent on April 6, 2021. Pursuant to Commission Rule 210.12(a)(9)(xi) the expiration date of the '501 Patent is August 25, 2028.

43. The inventors of the '501 Patent, Jeroen Poeze, Marcelo Lamego, Sean Merritt, Cristiano Dalvi, Hung Vo, Johannes Bruinsma, Ferdyan Lesmana, Massi Joe E. Kiani, and Greg Olsen, assigned to Masimo Laboratories, Inc. the entire right, title, and interest throughout the world in, to and under said improvements in the invention described and claimed in U.S. Patent Application No. 12/534,827 and all divisions and continuations thereof, which includes the '501 Patent. **Exhibit 9**. On August 2, 2010, Masimo Laboratories Inc. changed its name to Cercacor Laboratories, Inc. **Exhibit 9**. On July 29, 2019, Cercacor assigned to Masimo Corporation, the entire right, title and interest to U.S. Application No. 16/212537 and all continuations thereof, which includes the '501 Patent. **Exhibit 9**. Cercacor is the licensee of certain exclusive rights to the '501 Patent. **Confidential Exhibit 17**. The '501 Patent is valid, enforceable, and is currently in full force and effect.

44. Pursuant to Rule 210.12(c) of the Commission's Rules of Practice and Procedure, this Complaint is accompanied by: 1) an electronic copy of the prosecution history of the '501 Patent[2]; and 2) an electronic copy of each patent and applicable pages of each technical reference

[2] Due to USPTO errors, Complainants submitted certificates of correction to correct typographical errors in U.S. Patent Nos. 10,912,501, 10,912,502, and 10,945,648 as originally issued. Although these certificates of correction have been approved, and certificates of correction have been issued for both U.S. Patent Nos. 10,912,501 and 10,945,648, the certificate of correction for U.S. Patent No. 10,912,502 has not yet issued. Additionally, Complainants have not yet received certified copies of the prosecution histories which contain the information related to the certificates of correction for U.S. Patent Nos. 10,912,501, 10,912,502, and 10,945,648. Accordingly, Complainants are submitting uncertified copies of the

mentioned in the prosecution history. These materials are included in Appendices A and B, respectively.

2. Foreign Counterparts to the ’501 Patent

45. Pursuant to Commission Rule 210.12(a)(9)(v), Complainants submit the attached list of foreign patents, foreign patent applications (not already issued as a patent), and each foreign patent application that has been denied, abandoned, or withdrawn corresponding to the ’501 Patent. **Exhibit 12**. No other foreign patents or patent applications corresponding to the ’501 Patent are known to Masimo Corporation.

3. Non-Technical Description of the ’501 Patent

46. The ’501 Patent involves devices for the non-invasive measurement of physiological parameters such as blood oxygen saturation and pulse rate. The devices include multiple optical sources that emit light at different wavelengths and numerous light detectors. The light detectors are configured to detect the optical radiation from the tissue and output a respective signal stream responsive to this detection. This data is then processed by a processing device which outputs a measurement of the physiological parameter. The ’501 Patent includes limitations to novel architecture features to implement the required measurement while limiting any light noise that could impact the accuracy of measurements. The ’501 Patent also includes limitations to novel arrangements of light sources and photodetectors. The ’501 Patent also contains limitations to processors, network devices, and user interfaces, allowing the device to be easily used by consumers.

---

prosecution histories of U.S. Patent Nos. 10,912,501, 10,912,502, and 10,945,648, and will submit certified copies once received.

[redacted]

47. In sum, the invention of the ’501 Patent provides a novel combination of features allowing for the measurement of a user’s physiological parameters. [redacted].

48. The foregoing non-technical description of the patented technology is not intended to limit, define, or otherwise affect the scope of the claimed inventions, nor is the non-technical description in any way intended to construe or define any word, phrase, term, or limitation recited in any claim of the ’501 Patent.

B. U.S. Patent No. 10,912,502

1. Identification of the Patent and Ownership by Masimo Corporation

49. Masimo Corporation owns by assignment the entire right, title, and interest in the ’502 Patent, entitled “User-Worn Device for Noninvasively Measuring a Physiological Parameter of a User,” which issued on February 9, 2021. **Exhibit 2**. The ’502 Patent issued from U.S. Patent Application Serial No. 17/031,407, filed on September 24, 2020. The ’502 Patent is a continuation of a continuation of U.S. Patent Application No. 16/834,538, filed March 30, 2020, which is a continuation of U.S. Patent Application No. 16/725,292, filed December 23, 2019, which is a continuation of U.S. Patent Application No. 16/534,949, filed August 7, 2019, which is a continuation of U.S. Patent Application No. 16/409,515, filed May 10, 2019, which is a continuation of U.S. Patent Application No. 16/261,326, filed January 29, 2019, which is a continuation of U.S. Patent Application No. 16/212,537, filed December 6, 2018, which is a continuation of U.S. Patent Application No. 14/981,290 filed December 28, 2015, which is a continuation of U.S. Patent Application No. 12/829,352 filed July 1, 2010, which is a continuation of U.S. Patent Application No. 12/534,827 filed August 3, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application

Nos. 61/086,060 filed August 4, 2008, 61/086,108 filed August 4, 2008, 61/086,063 filed August 4, 2008, 61/086,057 filed August 4, 2008, and 61/091,732 filed August 25, 2008. U.S. Patent Application No. 12/829,352 is also a continuation-in-part of U.S. Patent Application No. 12/497,528 filed July 2, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed August 4, 2008, 61/086,108 filed August 4, 2008, 61/086,063 filed August 4, 2008, 61/086,057 filed August 4, 2008, 61/078,228 filed July 3, 2008, 61/078,207 filed July 3, 2008, and 61/091,732 filed August 25, 2008. U.S. Patent Application No. 12/497,528 also claims the benefit of priority under 35 U.S.C. § 120 as a continuation-in-part of the following U.S. Design Patent Application Nos. 29/323,409 filed August 25, 2008 and 29/323,408 filed August 25, 2008. U.S. Patent Application No. 12/829,352 is also a continuation-in-part of U.S. Patent Application No. 12/497,523 filed July 2, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed August 4, 2008, 61/086,108 filed August 4, 2008, 61/086,063 filed August 4, 2008, 61/086,057 filed August 4, 2008, 61/078,228 filed July 3, 2008, 61/078,207 filed July 3, 2008, and 61/091,732 filed August 25, 2008. U.S. Patent Application No. 12/497,523 also claims the benefit of priority under 35 U.S.C. § 120 as a continuation-in-part of the following U.S. Design Patent Application Nos. 29/323,409 filed August 25, 2008 and 29/323,408 filed August 25, 2008. On May 25, 2021, the PTO approved a certification of correction for the ’502 patent, which has not yet issued. Pursuant to Commission Rule 210.12(a)(9)(xi) the expiration date of the ’502 Patent is August 25, 2028.

50. The inventors of the ’502 Patent, Jeroen Poeze, Marcelo Lamego, Sean Merritt, Cristiano Dalvi, Hung Vo, Johannes Bruinsma, Ferdyan Lesmana, Massi Joe E. Kiani, and Greg

Olsen, assigned to Masimo Laboratories, Inc. the entire right, title, and interest throughout the world in, to and under said improvements in the invention described and claimed in U.S. Patent Application No. 12/534,827 and all divisions and continuations thereof, which includes the ’502 Patent. **Exhibit 7**. On August 2, 2010, Masimo Laboratories Inc. changed its name to Cercacor Laboratories, Inc. **Exhibit 7**. On July 29, 2019, Cercacor assigned to Masimo Corporation, the entire right, title and interest to U.S. Application No. 16/212537 and all continuations thereof, which includes the ’502 Patent. **Exhibit 7**. Cercacor is the licensee of certain exclusive rights to the ’502 Patent. **Confidential Exhibit 11**. The ’502 Patent is valid, enforceable, and is currently in full force and effect.

51. Pursuant to Rule 210.12(c) of the Commission’s Rules of Practice and Procedure, this Complaint is accompanied by: 1) an electronic copy of the prosecution history of the ’502 Patent; and 2) a electronic copy of each patent and applicable pages of each technical reference mentioned in the prosecution history. These materials are included in Appendices C and B, respectively. Because the ’501 Patent, ’502 Patent, and ’648 Patent are related, there is a substantial overlap of the patents and applicable pages of each technical reference mentioned in the prosecution histories and the copies are provided together in Appendix B.

2. Foreign Counterparts to the ’502 Patent

52. Pursuant to Commission Rule 210.12(a)(9)(v), Complainants submit the attached list of foreign patents, foreign patent applications (not already issued as a patent), and each foreign patent application that has been denied, abandoned, or withdrawn corresponding to the ’502 Patent. **Exhibit 12**. No other foreign patents or patent applications corresponding to the ’502 Patent are known to Masimo Corporation.

3. Non-Technical Description of the ’502 Patent

53. Like the '501 Patent, the '502 Patent involves devices for the non-invasive measurement of physiological parameters such as blood oxygen saturation and pulse rate. The devices include multiple optical sources that emit light at different wavelengths and numerous light detectors. The light detectors are configured to detect the optical radiation from the tissue and output a respective signal stream responsive to this detection. This data is then processed by a processing device which outputs a measurement of the physiological parameter. The '502 Patent includes limitations to novel architecture features to implement the required measurement while limiting any light noise that could impact the accuracy of measurements. The '502 Patent also includes limitations to novel arrangements of light sources and photodetectors. The '502 Patent also contains limitations to processors, network devices, and user interfaces, allowing the device to be easily used by consumers.

54. In sum, the invention of the '502 Patent provides a novel combination of features allowing for the measurement of a user's physiological parameters. .

55. The foregoing non-technical description of the patented technology is not intended to limit, define, or otherwise affect the scope of the claimed inventions, nor is the non-technical description in any way intended to construe or define any word, phrase, term, or limitation recited in any claim of the '502 Patent.

C. U.S. Patent No. 10,945,648

1. Identification of the Patent and Ownership by Masimo Corporation

56. Masimo Corporation owns by assignment the entire right, title, and interest in the '648 Patent, entitled "User-Worn Device for Noninvasively Measuring a Physiological Parameter of a User," which issued on March 16, 2021. (*See* **Exhibit 3**). The '648 Patent issued

from U.S. Patent Application Serial No. 17/031,316, filed on September 24, 2020. The ’648 Patent is a continuation of is a continuation of U.S. Patent Application No. 16/834,538, filed March 30, 2020, which is a continuation of U.S. Patent Application No. 16/725,292, filed December 23, 2019, which is a continuation of U.S. Patent Application No. 16/534,949, filed August 7, 2019, which is a continuation of U.S. Patent Application No. 16/409,515, filed May 10, 2019, which is a continuation of U.S. Patent Application No. 16/261,326, filed January 29, 2019, which is a continuation of U.S. Patent Application No. 16/212,537, filed December 6, 2018, which is a continuation of U.S. Patent Application No. 14/981,290 filed December 28, 2015, which is a continuation of U.S. Patent Application No. 12/829,352 filed July 1, 2010, which is a continuation of U.S. Patent Application No. 12/534,827 filed August 3, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed August 4, 2008, 61/086,108 filed August 4, 2008, 61/086,063 filed August 4, 2008, 61/086,057 filed August 4, 2008, and 61/091,732 filed August 25, 2008. U.S. Patent Application No. 12/829,352 is also a continuation-in-part of U.S. Patent Application No. 12/497,528 filed July 2, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed August 4, 2008, 61/086,108 filed August 4, 2008, 61/086,063 filed August 4, 2008, 61/086,057 filed August 4, 2008, 61/078,228 filed July 3, 2008, 61/078,207 filed July 3, 2008, and 61/091,732 filed August 25, 2008. U.S. Patent Application No. 12/497,528 also claims the benefit of priority under 35 U.S.C. § 120 as a continuation-in-part of the following U.S. Design Patent Application Nos. 29/323,409 filed August 25, 2008 and 29/323,408 filed August 25, 2008. U.S. Patent Application No. 12/829,352 is also a continuation-in-part of U.S. Patent Application No. 12/497,523 filed July 2, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of

the following U.S. Provisional Patent Application Nos. 61/086,060 filed August 4, 2008, 61/086,108 filed August 4, 2008, 61/086,063 filed August 4, 2008, 61/086,057 filed August 4, 2008, 61/078,228 filed July 3, 2008, 61/078,207 filed July 3, 2008, and 61/091,732 filed August 25, 2008. U.S. Patent Application No. 12/497,523 also claims the benefit of priority under 35 U.S.C. § 120 as a continuation-in-part of the following U.S. Design Patent Application Nos. 29/323,409 filed August 25, 2008 and 29/323,408 filed August 25, 2008. A certificate of correction issued on the '648 Patent on April 20, 2021. Pursuant to Commission Rule 210.12(a)(9)(xi) the expiration date of the '648 Patent is August 25, 2028.

57. The inventors of the '648 Patent, Jeroen Poeze, Marcelo Lamego, Sean Merritt, Cristiano Dalvi, Hung Vo, Johannes Bruinsma, Ferdyan Lesmana, Massi Joe E. Kiani, and Greg Olsen, assigned to Masimo Laboratories, Inc. the entire right, title, and interest throughout the world in, to and under said improvements in the invention described and claimed in U.S. Patent Application No. 12/534,827 and all divisions and continuations thereof, which includes the '648 Patent. **Exhibit 8**. On August 2, 2010, Masimo Laboratories Inc. changed its name to Cercacor Laboratories, Inc. **Exhibit 8**. On July 29, 2019, Cercacor assigned to Masimo Corporation, the entire right, title and interest to U.S. Application No. 16/212537 and all continuations thereof, which includes the '648 Patent. **Exhibit 8**. Cercacor is the licensee of certain exclusive rights to the '648 Patent. **Confidential Exhibit 11**. The '648 Patent is valid, enforceable, and is currently in full force and effect.

58. Pursuant to Rule 210.12(c) of the Commission's Rules of Practice and Procedure, this Complaint is accompanied by: 1) an electronic copy of the prosecution history of the '648 Patent; and 2) a electronic copy of each patent and applicable pages of each technical reference mentioned in the prosecution history. These materials are included in Appendices D and B,

[redacted]

respectively. Because the ’501 Patent, ’502 Patent, and ’648 Patent are related, there is a substantial overlap of the patents and applicable pages of each technical reference mentioned in the prosecution histories and the copies are provided together in Appendix B.

2. Foreign Counterparts to the ’648 Patent

59. Pursuant to Commission Rule 210.12(a)(9)(v), Complainants submit the attached list of foreign patents, foreign patent applications (not already issued as a patent), and each foreign patent application that has been denied, abandoned, or withdrawn corresponding to the ’648 Patent. **Exhibit 12**. No other foreign patents or patent applications corresponding to the ’648 Patent are known to Masimo Corporation.

3. Non-Technical Description of the ’648 Patent

60. Like the ’501 and ’502 Patents, the ’648 Patent involves devices for the non-invasive measurement of physiological parameters such as blood oxygen saturation and pulse rate. The devices include multiple optical sources that emit light at different wavelengths and numerous light detectors. The light detectors are configured to detect the optical radiation from the tissue and output a respective signal stream responsive to this detection. This data is then processed by a processing device which outputs a measurement of the physiological parameter. The ’648 Patent includes limitations to novel architecture features to implement the required measurement while limiting any light noise that could impact the accuracy of measurements. The ’648 Patent also includes limitations to novel arrangements of light sources and photodetectors. The ’648 Patent also contains limitations to processors, network devices, and user interfaces, allowing the device to be easily used by consumers.

61. In sum, the invention of the ’648 Patent provides a novel combination of features allowing for the measurement of a user’s physiological parameters. [redacted].

62. The foregoing non-technical description of the patented technology is not intended to limit, define, or otherwise affect the scope of the claimed inventions, nor is the non-technical description in any way intended to construe or define any word, phrase, term, or limitation recited in any claim of the ’648 Patent.

D. U.S. Patent No. 10,687,745

1. Identification of the Patent and Ownership by Masimo Corporation

63. Masimo Corporation owns by assignment the entire right, title, and interest in the ’745 Patent, entitled “Physiological Monitoring Devices, Systems, and Methods,” which issued on June 23, 2020. (*See* **Exhibit 4**). The ’745 Patent issued from U.S. Patent Application Serial No. 16/835,772, filed on March 31, 2020. The ’745 Patent is a continuation of U.S. Patent Application No. 16/791,963, filed February 14, 2020, which is a continuation of U.S. Patent Application No. 16/532,065 filed August 5, 2019, which is a continuation of U.S. Patent Application No. 16/226,249 filed December 19, 2018, which is a continuation of U.S. Patent Application No. 15/195,199 filed June 28, 2016, which claims priority benefit under 35 U.S.C. § 119(e) from U.S. Provisional Application No. 62/188,430, filed July 2, 2015. A certificate of correction issued on the ’745 Patent on September 22, 2020. Pursuant to Commission Rule 210.12(a)(9)(xi) the expiration date of the ’745 Patent is June 28, 2029.

64. The inventor of the ’745 Patent, Ammar Al-Ali, assigned to Masimo Corporation the entire right, title, and interest in in U.S. Patent Application No. 15/195199, and all divisions and continuations thereof, which includes the ’745 Patent. **Exhibit 9**. Cercacor is the licensee of certain exclusive rights to the ’745 Patent. **Confidential Exhibit 11**. The ’745 Patent is valid, enforceable, and is currently in full force and effect.

65. Pursuant to Rule 210.12(c) of the Commission's Rules of Practice and Procedure, this Complaint is accompanied by: 1) an electronic copy of the certified prosecution history of the '745 Patent; and 2) an electronic copy of each patent and applicable pages of each technical reference mentioned in the prosecution history. These materials are included in Appendices E and F, respectively.

2. Foreign Counterparts to the '745 Patent

66. Pursuant to Commission Rule 210.12(a)(9)(v), Complainants submit the attached list of foreign patents, foreign patent applications (not already issued as a patent), and each foreign patent application that has been denied, abandoned, or withdrawn corresponding to the '745 Patent. *See* **Exhibit 12**. No other foreign patents or patent applications corresponding to the '745 Patent are known to Masimo Corporation.

3. Non-Technical Description of the '745 Patent

67. The '745 Patent involves devices for the non-invasive measurement of physiological parameters such as blood oxygen saturation and pulse rate. The devices include multiple optical sources that emit light at different wavelengths and numerous light detectors. The devices also include optical transmission materials configured to change the shape of the emitted light or diffusers to spread the light. The devices also contain light blocks to inhibit light from the optical sources from reaching the detectors before being attenuated by the user's skin. The light detectors are configured to detect the optical radiation from the tissue and output a respective signal stream responsive to this detection. This data is then processed by a processing device which outputs a measurement of the physiological parameter. The '745 Patent includes limitations to novel architecture features to implement the required measurement while limiting any light noise that could impact the accuracy of measurements. The '745 Patent also includes limitations to novel arrangements of light sources and photodetectors.

[redacted]

68. In sum, the invention of the ’745 Patent provides a novel combination of features allowing for the measurement of a user’s physiological parameters. [redacted].

69. The foregoing non-technical description of the patented technology is not intended to limit, define, or otherwise affect the scope of the claimed inventions, nor is the non-technical description in any way intended to construe or define any word, phrase, term, or limitation recited in any claim of the ’745 Patent.

E. U.S. Patent No. 7,761,127

1. Identification of the Patent and Ownership by Cercacor

70. Cercacor owns by assignment the entire right, title, and interest in the ’127 Patent, entitled “Multiple Wavelength Sensor Substrate,” which issued on July 20, 2010. **Exhibit 5**. The ’127 Patent issued from U.S. Patent Application Serial No. 11/366,209, filed on March 1, 2006. The ’127 Patent claims priority to Provisional Application No. 60/657,596, filed on March 1, 2005, Provisional Application No. 60/657,281, filed on March 1, 2005, Provisional Application No. 60/657,268, filed on March 1, 2005, and Provisional Application No. 60/657,759, filed on March 1, 2005. Certificates of correction issued on the ’127 Patent on January 4, 2011 and February 1, 2011. Pursuant to Commission Rule 210.12(a)(9)(xi) the expiration date of the ’127 Patent is April 28, 2029.

71. The inventors of the ’127 Patent, Ammar Al-Ali, Mohamed Diab, Marcelo Lamego, James Coffin, and Yassir Abdul-Hafiz, assigned to Masimo Laboratories, Inc. the entire right, title, and interest in U.S. Patent Application No. 11/366,209, and all patents granted thereof, which includes the ’127 Patent. **Exhibit 10**. On August 2, 2010, Masimo Laboratories, Inc. changed its name to Cercacor Laboratories, Inc. **Exhibit 10**. Masimo is a licensee of

certain exclusive rights to the ’127 Patent. **Confidential Exhibit 11**. The ’127 Patent is valid, enforceable, and is currently in full force and effect.

72. Pursuant to Rule 210.12(c) of the Commission’s Rules of Practice and Procedure, this Complaint is accompanied by: 1) an electronic copy of the certified prosecution history of the ’127 Patent; and 2) an electronic copy of each patent and applicable pages of each technical reference mentioned in the prosecution history. These materials are included in Appendices G and H, respectively.

2. Foreign Counterparts to the ’127 Patent

73. Pursuant to Commission Rule 210.12(a)(9)(v), Complainants submit the attached list of foreign patents, foreign patent applications (not already issued as a patent), and each foreign patent application that has been denied, abandoned, or withdrawn corresponding to the ’127 Patent. **Exhibit 12**. No other foreign patents or patent applications corresponding to the ’127 Patent are known to Masimo Corporation.

3. Non-Technical Description of the ’127 Patent

74. The ’127 Patent discloses and involves a physiological sensor for the non-invasive measurement of physiological parameters such as blood oxygen saturation and pulse rate. The sensor includes a thermal mass, a plurality of light emitting sources operating at a plurality of wavelengths thermally coupled to the thermal mass, a temperature sensor to determine the bulk temperature of the thermal mass, and a detector capable of detecting light emitted from the light emitting sources after attenuation by the user’s skin. Based on the bulk temperature of the thermal mass, the sensor is able to compensate for shifts in the LED wavelengths due to temperature.

75. In sum, the ’127 Patent provides a novel combination of features allowing for the measurement of a user’s physiological parameters. Confidential samples of rainbow® sensors that embody the claims of the ’127 Patent are available upon request.

76. The foregoing non-technical description of the patented technology is not intended to limit, define, or otherwise affect the scope of the claimed inventions, nor is the non-technical description in any way intended to construe or define any word, phrase, term, or limitation recited in any claim of the ’127 Patent.

F. Licensees

77. Masimo has licensed certain exclusive rights to the Masimo Patents to Cercacor. **Confidential Exhibit 11**. Cercacor has licensed certain exclusive rights to the Cercacor Patent to Masimo. **Confidential Exhibit 11**. There are no other licensees to the Asserted Patents.

VI. UNLAWFUL AND UNFAIR ACTS OF PROPOSED RESPONDENT

78. Respondent manufactures, markets, sells for importation, imports and/or sells after importation into the United States products that directly infringe the ’501 Patent, the ’502 Patent, the ’648 Patent, the ’745 Patent, and the ’127 Patent, either literally or under the doctrine of equivalents. Apple also induces the infringement of claims 20-24 and 26-27 of the ’745 Patent by recommending, encouraging, and/or suggesting that consumers use their Apple Watch Series 6 with the consumer’s iPhone in an infringing manner. On information and belief, Apple has knowledge of the ’745 Patent because it monitors Masimo’s patent filings. Apple will also have knowledge of the ’745 Patent before the issuance of any requested relief in this Investigation, from the filing of this lawsuit itself and service of this complaint.

79. Respondent’s Apple Watch Series 6 are sold under the below model names and numbers.

Model Name	Model Number
Apple Watch Series 6 (GPS) 40 mm case	A2291
Apple Watch Series 6 (GPS) 44 mm case	A2292
Apple Watch Nike (GPS) 40 mm case	A2291
Apple Watch Nike (GPS) 44 mm case	A2292
Apple Watch Series 6 (GPS + Cellular) Aluminum 40 mm case	A2293
Apple Watch Series 6 (GPS + Cellular) Aluminum 44 mm case	A2294
Apple Watch Nike (GPS + Cellular) 40 mm case	A2293
Apple Watch Nike (GPS + Cellular) 44 mm case	A2294
Apple Watch Series 6 (GPS + Cellular) Stainless Steel 44 mm case	A2293
Apple Watch Series 6 (GPS + Cellular) Stainless Steel 44 mm case	A2294
Apple Watch Hermes (GPS + Cellular) 40 mm case	A2293
Apple Watch Hermes (GPS + Cellular) 44 mm case	A2294
Apple Watch Edition (GPS + Cellular) Titanium 40 mm case	A2293
Apple Watch Edition (GPS + Cellular) Titanium 44 mm case	A2294

80. Photographs of a representative Apple Watch Series 6 (specifically Model No. 2291) are attached to this Complaint as **Exhibit 13**. A copy of information regarding the Apple Watch Series 6 from Apple's website is attached hereto as **Exhibit 14**. Samples of the Apple Watch Series 6 can be made available upon request.

81. On information and belief, Respondent and others on its behalf manufacture the Accused Products at least in China, and then import them into the United States, sell them for importation into the United States, and/or sell them within the United States after importation.

[redacted]

82. These acts of Respondent constitute infringement of the Asserted Patents.

83. Claim charts demonstrating how a representative Apple Watch Series 6 infringes the ’501 Patent, the ’502 Patent, the ’648 Patent,’745 Patent, and the ’127 Patent are attached as **Confidential Exhibits 15, 16, 17, 18, and 19**, respectively. While a representative Apple Watch Series 6 is shown in the claim charts in **Confidential Exhibits 15, 16, 17, 18, and 19**, Respondent does not distinguish in any relevant manner between other model numbers of the Apple Watch Series 6 in their marketing or promotional materials, and Masimo alleges that all of Respondent’s Apple Watch Series 6 identified in ¶79 above infringe at least one Asserted Claim of the Asserted Patents.

84. Masimo has not licensed or otherwise authorized Respondent to make, use, sell, offer to sell, or import the Accused Products.

85. Respondent has sought to capitalize on Masimo’s extensive research and development efforts.

VII. THE DOMESTIC INDUSTRY RELATED TO ASSERTED PATENTS

86. A domestic industry exists or is in the process of being established as defined by 19 U.S.C. §§ 1337(a)(2)–(3) relating to Masimo’s significant investment in plant and equipment; significant employment of labor or capital; research and development activities; and substantial investment in exploitation of the patents, including engineering with respect to Masimo’s physiological measurement devices and monitors. With respect to the ’501 Patent, the ’502 Patent, the ’648 Patent, and the ’745 Patent, Masimo’s activities in the United States with respect to [redacted]—constitute a domestic industry for purposes of Section 337. To the extent it is determined that a domestic industry does not currently exist with respect to the ’501 Patent, the ’502 Patent, the ’648 Patent, and/or the ’745 Patent, Masimo is in the process of establishing a domestic industry [redacted]

37

[redacted] is protected by one or more claims of each of the ’501 Patent, the ’502 Patent, the ’648 Patent, and the ’745 Patent.

87. With respect to the ’127 Patent, Masimo’s activities in the United States with respect to at least its rainbow® sensor technology constitute a domestic industry for purposes of Section 337. Masimo’s rainbow® sensors—including the, RD rainbow® Set-2, rainbow® R1, rainbow® R25, rainbow® R20, rainbow® DCI SC 200, rainbow® DCI SC 400, rainbow® DCI SC 1000, rainbow® DCI mini SC-200, rainbow® DCI mini SC-400, rainbow® DCI mini SC-1000, rainbow® Super DCI mini SC-200, rainbow® Super DCI mini SC-400, rainbow® Super DCI mini-SC-1000, rainbow® DCI, rainbow® DCI-dc, RD rainbow® 8 λ SpCO Adhesive Sensor, LNCS-II™ rainbow® DCI® 8λ SpHb, LNCS-II™ rainbow® DCIP® 8λ SpHb, LNCS-II™ rainbow® DCI® 8λ SpCO, and LNCS-II™ rainbow® DCIP® 8λ SpCO—are protected by at least one claim of the ’127 Patent.

A. <u>Technical Prong</u>

88. Masimo has designed and developed its domestic industry products through its extensive research and development efforts based almost entirely in the United States. Moreover, Masimo [redacted] in the United States and manufactures a material amount of the components of its rainbow® sensors in the United States. As set forth in more detail herein, Masimo’s domestic industry products incorporate the inventions claimed in one or more claims of the Asserted Patents.

89. Drawings, photographs, or other visual representations of representative Masimo domestic industry products (specifically, [redacted] and certain rainbow® sensors) are

38

attached hereto as **Confidential Exhibit 20 and Confidential Exhibit 21**. Claim charts showing how a representative Masimo domestic industry product practices exemplary claims of the ’501 Patent, the ’502 Patent, the ’648 Patent, the ’745 Patent, and the ’127 Patent are attached hereto as **Confidential Exhibits 15, 16, 17, 18 and 19**, respectively. Additional information regarding the domestic industry products is found in the Declaration of Bilal Muhsin, attached hereto as **Confidential Exhibit 27**.

B. <u>Economic Prong</u>

90. The domestic industry in this case is based on significant investments Masimo has made and/or plans to make and activities Masimo has undertaken and/or plans to undertake in the United States relating to products protected by one or more claims of the Asserted Patents. These investments and activities include research and development, manufacturing, testing, and engineering for the Masimo domestic industry products. Specific, non-limiting examples of Masimo’s substantial investments and activities related to the Asserted Patents are set forth in the confidential declaration of Micah Young, attached to this complaint as **Confidential Exhibit 28**.

91. Masimo employs a significant number of employees in its U.S facilities in Irvine, California. These employees devote substantial personnel-hours toward the research and development, testing and engineering for the Masimo domestic industry products. The confidential declaration of Micah Young sets forth details regarding the investments it has made in these U.S. employees.

92. Masimo also invests capital toward manufacturing and research and development for products protected by the Asserted Patents. The confidential declaration of Micah Young provides additional details regarding Masimo’s capital investments.

39

[redacted]

93. In addition, Masimo has made substantial investments in plant and equipment in the United States. Masimo's facilities in Irvine, California, houses activities for research and development, manufacturing, testing and engineering for the Masimo domestic industry products. Masimo also owns a facility in New Hampshire where manufacturing activities for its rainbow® sensors take place. The confidential declaration of Micah Young includes further non-limiting examples of Masimo's investments in this category.

94. To the extent it is determined that a domestic industry does not currently exist, Masimo is in the process of establishing a domestic industry with respect to the Masimo Patents because it is actively engaged in the steps leading to the exploitation of its intellectual property rights, and there is a significant likelihood that an industry will be established in the United States in the future [redacted]. Further, non limiting examples regarding the active steps taken by Masimo to establish a domestic industry are included in the confidential declaration of Micah Young filed herewith as **Confidential Exhibit 28**.

VIII. SPECIFIC INSTANCES OF UNFAIR IMPORTATION AND SALE

95. Respondent, and/or others on its behalf, manufactures the Accused Products at least in China, and then imports them into the United States, sells them for importation into the United States, and/or sells them after importation into the United States. Respondent sells and offers for sale the Accused Products directly to customers in the United States. Respondent stated in a press release dated September 15, 2020, that it was introducing the Series 6 in the United States for sale starting on September 18, 2020. **Exhibit 29**

96. Prior to filing this Complaint, a representative Apple Watch Series 6 product was purchased on April 19, 2021, in the United States. A copy of the invoice of this purchase is

40

attached hereto as **Confidential Exhibit 30**. The packaging of this Accused Product indicates that it was made outside the United States. Photographs of the product packaging for this Apple Watch product, showing that it was made in China, are attached hereto as **Exhibit 31**.

97. In addition, Apple's 10K filed with the SEC on January 28, 2021 states that "[s]ubstantially all of the Company's hardware products are manufactured by outsourcing partners that are located primarily in Asia, with some Mac computers manufactured in the U.S. and Ireland." **Exhibit 32**.

IX. CLASSIFICATION OF THE INFRINGING PRODUCTS UNDER THE HARMONIZED TARIFF SCHEDULE OF THE UNITED STATES

98. Upon information and belief, the Accused Products may be classified under at least the following heading of the Harmonized Tariff Schedules of the United States: 8517.62.0090. This HTS identification is illustrative and not exhaustive. The identification is not intended to limit the scope of the Investigation, nor is it intended to restrict the scope of any exclusion order or other remedy ordered by the Commission.

X. RELATED LITIGATION

99. On January 9, 2020, Masimo Corp. and Cercacor filed suit in the United States District Court for the Central District of California, Case No. 8:20-cv-00048. In that case, Complainants assert that Respondent Apple has, *inter alia*, engaged in trade secret misappropriation and has infringed patents not asserted in this complaint by the sale of the certain products, including the Apple Watch Series 6. Complainants also seek a declaration of ownership of several patents and applications filed by Apple. That case is currently pending before the district court, but Complainants' patent infringement claims are stayed pending resolution of the below referenced *inter partes* review proceedings.

41

100. Respondent has filed numerous petitions for *inter partes* review of the patents involved in Case No. 8:20-cv-0048, none of which are asserted in this complaint: IPR2020-01520 (Instituted March 2, 2021); IPR2021-00208 (Instituted June 3, 2021); IPR2020-01521 (Instituted April 14, 2021); IPR2021-00193 (Instituted June 3, 2021); IPR2021-00195 (Instituted June 3, 2021); IPR2021-00209 (Instituted June 3, 2021); IPR2020-01524 (Instituted April 16, 2021); IPR2020-01722 (Instituted May 12, 2021); IPR2020-01723 (Institution denied May 12, 2021); IPR2020-01536 (Instituted March 2, 2021); IPR2020-01537 (Instituted March 2, 2021); IPR2020-01538 (Instituted March 2, 2021); IPR2020-01539 (Instituted March 2, 2021); IPR2020-01526 (Instituted April 16, 2021); and IPR2020-01523 (Instituted April 14, 2021).

101. There have been no other foreign or domestic court or agency litigations involving any of the Asserted Patents.

XI. REQUESTED RELIEF

102. WHEREFORE, by reason of the foregoing, Complainants request that the United States International Trade Commission:

a) institute an immediate investigation pursuant to 19 U.S.C. § 1337 into the violations of that section based on Respondent's unlawful importation into the United States, sale for importation into the United States, and/or sale in the United States after importation of certain light-based physiological measurement devices and components thereof that infringe one or more claims of U.S. Patent Nos. 10,912,501, 10,912,502, 10,945,648, 10,687,745, and/or 7,761,127;

b) schedule and conduct a hearing pursuant to Section 337(c), for the purposes of receiving evidence and hearing argument concerning whether there has been a violation of Section 337;

42

c) determine that there has been a violation of Section 337 by Respondent;

d) issue a permanent exclusion order, pursuant to 19 U.S.C. § 1337(d), excluding from entry into the United States all of Respondent's light-based physiological measurement devices and components thereof, including Apple Watch Series 6, that infringe one or more claims of U.S. Patent Nos. 10,912,501, 10,912,502, 10,945,648, 10,687,745, and/or 7,761,127;

e) issue a permanent cease and desist order, pursuant to 19 U.S.C. § 1337(f), directing Respondent to cease and desist from importing, marketing, advertising, demonstrating, warehousing of inventory for distribution, sale, or use of certain light-based physiological measurement devices and components thereof that infringe one or more claims of U.S. Patent Nos. 10,912,501, 10,912,502, 10,945,648, 10,687,745, and/or 7,761,127;

f) impose a bond upon Respondent should Respondent continue to import infringing articles during the 60-day Presidential Review period pursuant to 19 U.S.C. § 1337(j); and

g) grant such other and further relief as the Commission deems appropriate and just under the law, based on the facts complained of herein and determined by the investigation.

Respectfully submitted,

Dated: June 29, 2021

By: /s/ *Jonathan E. Bachand*

Jonathan E. Bachand
KNOBBE, MARTENS, OLSON & BEAR, LLP
1717 Pennsylvania Ave NW STE 900
Washington, DC 20006
Telephone: 202-640-6400

43

Facsimile: 949-760-9502

Stephen C. Jensen
Joseph R. Re
Sheila N. Swaroop
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street, 14th Floor
Irvine, CA 92614
Telephone: (949) 760-0404
Facsimile: (949) 760-9502

44

VERIFICATION OF COMPLAINT

I, Jonathan E. Bachand, declare, in accordance with 19 C.F.R. §§ 210.4 and 210.12(a), under penalty of perjury, that the following statements are true:

1. I am Counsel for Complainants Masimo Corporation and Cercacor Laboratories, Inc. and I am duly authorized to sign the Complaint on behalf of Complainants;

2. I have read the foregoing Complaint;

3. To the best of my knowledge, information, and belief, based upon reasonable inquiry, the foregoing Complaint is well-founded in fact and is warranted by existing law or by a non-frivolous argument for the extension, modification, or reversal of existing law, or the establishment of new law;

4. The allegations and other factual contentions have evidentiary support or are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery; and

5. The foregoing Complaint is not being filed for an improper purpose, such as to harass or cause unnecessary delay or needless increase in the cost of litigation.

Executed this 29th day of June, 2021.

/s/ *Jonathan E. Bachand*
Jonathan E. Bachand
Counsel for Complainants
Masimo Corporation and Cercacor
Laboratories, Inc.