tissue measurement site on the wrist of the user when the physiological monitoring device is in use"

There is no dispute that Iwamiya discloses an "annular light guide" that "annularly diffuses and irradiates the observation light." RX-0130 at 6:10-14, Fig. 4; *see* Tr. (Sarrafzadeh) at 1103:10-15; RDX-7.116C. Moreover, there is no dispute that this annular light guide is positioned between the light-emitting diodes and the user's wrist, as discussed above in the context of claim 1. *See* RIB at 193.

(iv) Element [15C]: "a light block having a circular shape"

There is no dispute that Iwamiya discloses reflection layers 13 and 15 that are light blocks, as discussed above in the context of claim 1. *See* RIB at 193-94. Figures 2 and 3 of Iwamiya show that these light blocks are arranged around the annular light guide in a circular shape. RX-0130 at 6:67-7:3, 7:45-49, Fig. 2, Fig. 3; *see* Tr. (Sarrafzadeh) at 1103:16-21; RDX-7.117C.

(v) Element [15D]: "a plurality of photodiodes configured to detect at least a portion of the light emitted from the plurality of light-emitting diodes after the light passes through the light diffusing material and a portion of the tissue measurement site encircled by the light block, wherein the plurality of photodiodes are arranged in an array having a spatial configuration corresponding to a shape of the portion of the tissue measurement site encircled by the light block"

There is no dispute that Iwamiya discloses a plurality of photodiodes configured to detect light that is reflected from a user's tissue, as discussed above in the context of claim 1. *See* RIB at 194-95. Iwamiya further describes "the plural light receiving units **9** preferably disposed on the same circumference centered on an optical axis of the scattered light taking unit **8**." RX-0130 at 14:39-41, Fig. 4; *see* Tr. (Sarrafzadeh) at 1103:22-1104:5; RDX-7.118C. Dr. Sarrafzadeh testified that he believes this limitation is indefinite but that "using Masimo's

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interpretation," this limitation is disclosed by Iwamiya. See Tr. (Sarrafzadeh) at 1103:23-5; RDX-7.118C.

Complainants argue that the disclosure in Iwamiya identified by Apple is insufficient to teach a plurality of photodiodes "arranged in an array having a spatial configuration corresponding to a shape of the portion of the tissue measurement site encircled by the light block." CIB at 232; CRB at 130-31. Complainants submit that Iwamiya only depicts a single light receiving unit. *See* Tr. (Madisetti) at 1364:7-8. Complainants further cite a statement in the prosecution history of a parent application to the '745 patent explaining that the plurality of detectors "must include sufficient detectors to represent such shapes." CX-1760 at 322; *see* Tr. (Madisetti) at 1366:13-1367:19.

In consideration of the parties' arguments, the undersigned finds that Iwamiya clearly discloses "plural light receiving units." *See* RX-0130 at 14:36-41; Tr. (Sarrafzadeh) at 1103:23-1104:5; RDX-7.118C (citing RX-0130 at 14:39-41). These plural light receiving units are further described as "disposed on the same circumference centered on an optical axis of the scattered light taking unit." *Id.* at 14:39-41; Tr. (Sarrafzadeh) at 1103:23-1104:5; RDX-7.118C. This disclosure of "plural" photodiodes that are "on the same circumference" at least renders the limitation requiring "a spatial configuration corresponding to a shape . . . encircled by the light block" to be *prima facie* obvious. *See* CRB at 131 (to meet [15D], "a plurality of photodiodes would need to be arranged in a circular-shaped array"). Iwamiya's "plural light receiving units" is a plurality,[85] and the "same circumference" corresponds to a shape encircled by the light block. *See* RX-0130 at 14:36-41.

[85] Complainants cite statements in the prosecution history of a parent application to the '745 patent where the applicant suggested that up to six detectors may be needed to represent a circular shape. *See* CX-1760

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(vi) Element [15E]: "wherein the plurality of photodiodes are further configured to output at least one signal responsive to the detected light"

There is no dispute that the photodiodes in Iwamiya are configured to output a signal responsive to the detected light, as discussed above in the context of claim 1. *See* RIB at 195.

(vii) Element [15F]: "wherein the plurality of light-emitting diodes and the plurality of photodiodes are arranged in a reflectance measurement configuration"

There is no dispute that the light-emitting diodes in Iwamiya are arranged in a reflectance measurement configuration with the photodiodes on the same side of the tissue. *See* RIB at 195; Tr. (Sarrafzadeh) at 1104:11-15; RDX-7.119C; Tr. (Madisetti) at 1359:8-1365:6.

(viii) Element [15G]: "wherein the light block is configured to optically isolate the plurality of light-emitting diodes from the plurality of photodiodes by preventing at least a portion of light emitted from the plurality of light-emitting diodes from reaching the plurality of photodiodes without first reaching the portion of the tissue measurement site"

There is no dispute that the light blocks in Iwamiya are configured to prevent light from the light-emitting diodes from reaching the photodiodes without first reaching the tissue, as discussed above in the context of claim 1. *See* RIB at 195-96.

(ix) Element [15H]: "a processor configured to receive and process the outputted at least one signal and determine a physiological parameter of the user responsive to the outputted at least one signal"

There is no dispute that Iwamiya discloses a CPU that receives and processes signals from the photodiodes and determines a physiological parameter, as discussed above in the context of claim 1. *See* RIB at 196.

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at 322. Both a "plural" and a "plurality" could include six photodiodes. *See In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003) ("In cases involving overlapping ranges, we and our predecessor courts have consistently held that even a slight overlap in range establishes a prima facie case of obviousness.").

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(x) Element [15I]: "wherein the physiological monitoring device is configured to transmit physiological parameter data to a separate processor"

Apple relies on Venkatraman in combination with Iwamiya for the limitation requiring that the physiological parameter can be transmitted to a separate processor. RIB at 196-97.[86] Venkatraman discloses a biometric device that can communicate with a secondary device (e.g., a smartphone) through a wired or wireless connection. RX-0368 at 30:66-31:35. "The biometric monitoring device may send biometric and other data to the smartphone in real-time or with some delay." *Id.* at 57:44-46. Venkatraman describes numerous benefits to using a biometric device with a smartphone app. *See id.* at 57:20-59:13. Dr. Sarrafzadeh testified that it would have been obvious to one of ordinary skill in the art to combine Iwamiya's device with the secondary device of Venkatraman because such connections were well known to enhance such devices. Tr. (Sarrafzadeh) at 1105:24-1106:7, 1108:9-18. Dr. Sarrafzadeh also testified that a person of ordinary skill in the art would have had a reasonable expectation of success, "because adding these external devices was known for quite a bit of time." *Id.* at 1106:8-11, 1108:19-23. Complainants do not dispute that the evidence shows a reason to combine Iwamiya with Venkatraman, and a reasonable expectation of success, with regard to this limitation. *See* Tr. (Madisetti) at 1359:8-1365:6.

(xi) Element [18]: "wherein the physiological parameter comprises oxygen saturation"

Claim 18 of the '745 patent depends from claim 15, "wherein the physiological parameter comprises oxygen saturation." Apple submits that the measurement of oxygen saturation is

[86] Venkatraman is U.S. Patent No. 8,998,815, which names inventors Subramaniam Venkatraman and Shelten Gee Jao Yuen, and issued on April 7, 2015. RX-0368. Accordingly, Venkatraman is prior art to the '745 patent pursuant to 35 U.S.C. § 102(a)(1).

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obvious in view of Iwamiya in combination with Sarantos. *See* RIB at 197. For the reasons discussed above in the context of claim 9, Apple not shown, clearly and convincingly, that it would have been obvious to one of ordinary skill in the art to modify the device disclosed in Iwamiya with the teachings in Sarantos to implement a measurement of oxygen saturation with a reasonable expectation of success.

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Accordingly, the evidence fails to clearly and convincingly show that claim 18 of the '745 patent is obvious in view of Iwamiya in combination with Sarantos and Venkatraman.

c. '745 Patent Claim 27

(i) Element [20 preamble]: "A system configured to measure one or more physiological parameters of a user, comprising:"

The preamble of claim 20 of the '745 patent requires "[a] system configured to measure one or more physiological parameters of a user," including "a physiological monitoring device." As discussed above in the context of the preamble of '745 patent claim 1, the evidence shows that Iwamiya discloses a "physiological monitoring device" because it contains a heart rate sensor. *See* RIB at 186, 197.

(ii) Element [20A]: "a plurality of light-emitting diodes configured to emit light in a first shape"

Claim 20 has a "plurality of light-emitting diodes" limitation that is identical to the limitation of claim 1. As discussed above in the context of claim 1, there is no dispute that Iwamiya discloses light-emitting diodes emitting light in a shape. *See* RIB at 186, 197.

(iii) Element [20B]: "a material configured to be positioned between the plurality of light-emitting diodes and tissue of the user when the physiological monitoring device is in use, the material configured to change the first shape into a second shape by which the light emitted from one or more of the

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plurality of light-emitting diodes is projected towards the tissue"

Claim 20 has a "material configured to change the first shape into a second shape" limitation that is identical to the limitation of claim 1. As discussed above in the context of claim 1, there is no dispute that Iwamiya discloses an "annular light guide unit" that is positioned between the light-emitting diodes and a user's wrist and changes the shape of the light from a first shape to a second shape. *See* RIB at 186-87, 197

(iv) Element [20C]: "a plurality of photodiodes configured to detect at least a portion of the light after the at least the portion of the light passes through the tissue, the plurality of photodiodes further configured to output at least one signal responsive to the detected light"

Claim 20 has a "plurality of photodiodes" limitation that is identical to the limitation of claim 1. As discussed above in the context of claim 1, there is no dispute that Iwamiya discloses a plurality of photodiodes that output a signal responsive to light that is reflected from a user's tissue. *See* RIB at 187-88, 197.

(v) Element [20D]: "a surface comprising a dark-colored coating, the surface configured to be positioned between the plurality of photodiodes and the tissue when the physiological monitoring device is in use, wherein an opening defined in the dark-colored coating is configured to allow at least a portion of light reflected from the tissue to pass through the surface"

Claim 20 has a "surface comprising a dark-colored coating" limitation that is identical to the limitation of claim 1. For the reasons discussed above in the context of claim 1, the undersigned finds that one of ordinary skill in the art would have had a reason to use a dark-colored coating in the device disclosed in Iwamiya and would have had a reasonable expectation of success.

(vi) Element [20E]: "a light block configured to prevent at least a portion of the light emitted from the plurality of light-emitting

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diodes from reaching the plurality of photodiodes without first reaching the tissue"

Claim 20 has a "light block" limitation that is identical to the limitation of claim 1. As discussed above in the context of claim 1, there is no dispute that Iwamiya discloses light blocks configured to prevent light from the light-emitting diodes from reaching the photodiodes without first reaching the tissue. *See* RIB at 189-90, 197.

(vii) Element [20F]: "a processor configured to receive and process the outputted at least one signal and determine a physiological parameter of the user responsive to the outputted at least one signal"

Claim 20 has a "processor" limitation that is identical to the limitation of claim 1. As discussed above in the context of claim 1, there is no dispute that Iwamiya discloses a CPU that receives and processes signals from the photodiodes to determine a physiological parameter. *See* RIB at 190-91, 197.

(viii) Element [20G]: "a processing device configured to wirelessly receive physiological parameter data from the physiological monitoring device, wherein the processing device comprises a user interface, a storage device, and a network interface configured to wirelessly communicate with the physiological monitoring device, and wherein the user interface includes a touch-screen display configured to present visual feedback responsive to the physiological parameter data"

Apple relies on Venkatraman in combination with Iwamiya for the limitation that the physiological parameter can be transmitted to a separate processing device. RIB at 197-98; Tr. (Sarrafzadeh) at 1108:1-23; RDX-7.129C. Apple identifies disclosures in Venkatraman describing a connection between a biometric monitoring device and a smartphone. *See* RX-0368 at 30:66-31:35, 57:20-59:13. Complainants argue that Apple has failed to show that Venkatraman discloses a "touch-screen display configured to present visual feedback responsive to the physiological parameter data." CRB at 132.

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In consideration of the parties' arguments, and for the reasons discussed above in the context of claim 15, the undersigned finds that one of skill in the art would have reason to connect the biometric device in Iwamiya with a smartphone as taught in Venkatraman with a reasonable expectation of success. *See* Tr. (Sarrafzadeh) at 1105:24-1106:11. The undersigned finds that one of ordinary skill in the art would have understood that a smartphone is a processing device comprising a user interface, a storage device, and a network interface. *See id.* at 1108:1-8. Moreover, Venkatraman explicitly discloses a smartphone app that displays biometric information on a touchscreen. *See* RX-0368 at 57:54-58:6 ("The user may be able to see these and other metrics on the dashboard . . . They may be able to access previous days by pressing a button or icon on a touchscreen."). Accordingly, each of the elements of the "processing device" limitation are clearly disclosed in Venkatraman, and one of ordinary skill would have reason to connect the biometric device in Iwamiya with a smartphone as taught in Venkatraman with a reasonable expectation of success.

(ix) Element [27]: "at least one of the plurality of light-emitting diodes is configured to emit light of a first wavelength and at least one of the plurality of light-emitting diodes is configured to emit light of a second wavelength, the second wavelength being different than the first wavelength"

Claim 27 of the '745 patent depends from claim 20, further requiring that "at least one of the plurality of light-emitting diodes is configured to emit light of a first wavelength and at least one of the plurality of light-emitting diodes is configured to emit light of a second wavelength, the second wavelength being different than the first wavelength." There is no dispute that Iwamiya only discloses the use of one wavelength of light. *See* Tr. (Madisettti) at 1359:22-1366:1; RX-0130 at 10:34-38. Apple contends that this limitation would have been obvious to one of ordinary skill in the art in view of Iwamiya in combination with Sarantos, which provides

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that "it may be desirable to include separate light-emitting devices that are each able to emit different wavelengths of light" to measure other physiological parameters, such as blood oxygenation levels. RX-0366 at 13:44-58. Complainants argue that Apple has failed to show that one of ordinary skill in the art would have combined Iwamiya with Sarantos with a reasonable expectation of success. CIB at 228-30; CRB at 128-30.

For the same reasons discussed above in the context of '745 patent claim 9, the undersigned finds that Apple has not shown by clear and convincing evidence that one of ordinary skill would have been able to combine Iwamiya and Sarantos to use two wavelengths of light with a reasonable expectation of success. The only specific motivation for using multiple emitters disclosed in Sarantos is for measuring oxygen saturation, *see* RX-0366 at 13:44-47, and as discussed *supra*, the evidence does not clearly and convincingly show that one of ordinary skill in the art would have had a reasonable expectation of success in modifying Iwamiya to measure oxygen saturation.

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Accordingly, the evidence fails to show that claim 27 of the '745 patent is obvious in view of Iwamiya in combination with Sarantos, because Apple has not shown, clearly and convincingly, that one of ordinary skill in the art would have had a reason to modify the device disclosed in Iwamiya with the teachings in Sarantos regarding the use of two wavelengths with a reasonable expectation of success.

3. Objective Considerations of Non-Obviousness

Complainants contend that certain objective indicia discussed above in the context of the Poeze patents support a finding of non-obviousness for the claims of '745 patent, including Apple's skepticism and failures in implementing wrist-based pulse oximetry and the commercial

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success of the Apple Watch Series 6. CIB at 233-34; CRB at 132-33. Apple disputes whether this evidence is relevant to the obviousness of the '745 patent claims. RIB at 199-201; RRB at 109-110.

For the reasons discussed above in the context of the Poeze patents, this evidence does not weigh significantly against a finding of obviousness.[87] For the reasons discussed above, however, the evidence does not provide a clear and convincing showing of obviousness for the claims of '745 patent.

H. Invalidity – Written Description and Enablement

Apple contends that the asserted claims of the '745 patent are invalid for lack of written description and/or indefiniteness pursuant to 35 U.S.C. § 112. RIB at 201-04; RRB at 110-11.

1. Written Description (Claims 1, 9, 20, 27)

Apple argues that claims 1 and 20 of the '745 patent, from which asserted claims 9 and 27 depend, are invalid for lack of written description with respect to a "surface comprising a dark-colored coating . . . wherein an opening defined in the dark-colored coating is configured to allow at least a portion of light reflected from the tissue to pass through the surface" in an embodiment where the sensors are in a reflectance configuration. RIB at 201-02. In the context of the fingertip sensor 300 depicted in Figures 3 and 4, the specification describes a "light-absorbing detector filter 306 "having a top surface coated with a "light-absorbing material" that "can be a black opaque material or coating or any other dark color or coating configured to absorb light." JX-009 at 9:31-36, Fig. 3, Fig. 4A. The specification describes a separate embodiment depicted in Figures 7A and 7B that is "a 3D reflective pulse oximetry sensor 700"

[87] The evidence of commercial success is not relevant because the Accused Products have not been shown to practice claims of the '745 patent.

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with an annular "light block 706." *Id.* at 10:40-51, Fig. 7A, Fig. 7B. Dr. Sarrafzadeh testified that "there is no description on how to combine these embodiments in the description of the patent." Tr. (Sarrafzadeh) at 1110:24-1111:2. Apple argues that the specification thus fails to describe the claimed invention "as an integrated whole" with a dark-colored coating used with a reflectance sensor. RIB at 202; RRB at 110 (citing *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1349 (Fed. Cir. 2013).

Complainants submit that the specification explicitly links the two embodiments together: "In other embodiments, for example, as describe [sic] below with respect to FIGS. 7A and 7B, the 3D sensor 300 can be arranged to detect light that is reflected by the tissue measurement site 102." JX-009 at 7:4-14. Dr. Madisetti identified a light concentrator (labeled 308 and 708 in the specification) that is common to both the Figure 3 and Figure 7 embodiments and "links all these embodiments together." Tr. (Madisetti) at 1365:7-1366:8 (citing JX-009 at 9:30-40). Complainants argue that these disclosures show that the two embodiments are not distinct but are linked together. CIB at 235-36; CRB at 133-34.

The evidence fails to show, clearly and convincingly, a lack of adequate written description support for the "dark-colored coating" limitations of claims 1 and 20. The undersigned agrees with Complainants that the specification describes common elements in the Figure 3 fingertip sensor and the Figure 7 reflectance sensor, explicitly suggesting that "the 3D sensor 300 can be arranged to detect light that is reflected by the tissue measurement site," thus supporting Dr. Madisetti's opinion that one of ordinary skill would link these embodiments. JX-009 at 7:4-14; Tr. (Madisetti) at 13:65:7-1366:8. Moreover, with respect to the light blocker 706 in the Figure 7 embodiment, the specification explicitly provides that "[t]he light blocker 706 and the cover 707 can be made of any material that optically isolates the light concentrator 708

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and the detector 710." *Id.* at 11:14-16, Fig. 7B.[88] This disclosure of "any material" for light blocking further supports Dr. Madisetti's opinion that the "light-absorbing material" described earlier in the specification in reference to Figure 4A, including "a black opaque material or coating or any other dark color or coating configured to absorb light," is linked to the Figure 7 embodiment. JX-009 at 9:31-36; Tr. (Madisetti) at 1365:7-1366:8; CDX-0012C.081. The Federal Circuit has held that "the description requirement does not demand any particular form of disclosure, or that the specification recite the claimed invention *in haec verba*." *Ariad*, 598 F.3d at 1352 (citations removed). Apple's argument that the dark-colored coating is distinct from the reflectance sensor embodiment is unconvincing in view of these disclosures in the specification.

Accordingly, based on the evidence of record, Apple has not shown clearly and convincingly that claims 1 or 20 of the '745 patent are invalid for lack of written description.

2. Indefiniteness (Claims 15, 18)

Apple argues that claim 15 of the '745 patent, from which asserted claim 18 depends, is invalid for indefiniteness with respect to the limitation requiring a plurality of photodiodes "arranged in an array having a spatial configuration corresponding to a shape of the portion of the tissue measurement site encircled by the light block." RIB at 202-04; RRB at 110-11. Dr. Sarrafzadeh testified that one of ordinary skill in the art would not have been able to determine which shape corresponds to an arrangement of photodiodes, providing an example of four photodiodes that could correspond to many different shapes. Tr. (Sarrafzadeh) at 1111:3-18; RDX-7.134C. Apple argues that this ambiguity regarding how a spatial configuration

[88] Figure 7 also appears to show shows a positioning of a surface of the light blocker 706 between the tissue and photodiode, similar to the positioning of element 306 in Fig. 3.

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corresponds to a shape renders this limitation indefinite, because one of skill in the art would not be able to determine the scope of the invention with reasonable certainty. RIB at 202-04 (citing *Nautilus, Inc. v. Biosig Instruments, Inc.*, 57 U.S. 898, 910 (2014)).

Complainants argue that Apple has not met its clear and convincing burden to prove indefiniteness. CIB at 236-38. Complainants submit that Dr. Sarrafzadeh failed to consider the surrounding claim language and other evidence in the intrinsic record defining the scope of this limitation. *Id.* at 237-38. Complainants submit that the "shape" of the configuration of photodiodes is defined by the light block, which has "a circular shape." *See* JX-009 at 16:43-52. Complainants further rely on statements in the prosecution history of the '745 patent that discuss "sufficient detectors to represent such shapes," with an example that "six or more detectors could be arranged in an annular shape and meet the recited limitation." CX-1760 at 322; *see also id.* (indicating that two or three detectors would be insufficient). Dr. Madisetti relied on these disclosures and offered his opinion that this limitation "would be understood by a person having ordinary skill in the art as requiring a sufficient number of detectors, such that when arranged together in an array can match -- have a close similarity or present the at least partially circular shape of the irradiated portion of the tissue measurement site." Tr. (Madisetti) at 1366:13-1367:19.

In consideration of the parties' arguments, the undersigned agrees with Complainants that Apple has not shown, clearly and convincingly, that the claimed arranged of photodiodes in a "spatial configuration corresponding to a shape" is indefinite. In particular, Dr. Sarrafzadeh's testimony relying on hypothetical shapes drawn through an arrangement of photodiodes fails to read this term within the context of claim 15's surrounding language. *See* CIB at 236-37. The "shape" referenced in this limitation is "a shape of the portion of the tissue measurement site

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encircled by the light block." To determine whether a device meets this limitation, one of ordinary skill in the art would not draw arbitrary shapes around the photodiodes, as Dr. Sarrafzadeh appears to suggest, but would rather assess this limitation in relation to the "tissue measurement site encircled by the light block." *See* Tr. (Madisetti) at 1366:13-1367:10. Apple has failed to show that one of ordinary skill in the art would be unable to determine whether the limitation is met by comparing the arrangement of photodiodes to the shape of the encircled tissue.[89]

Accordingly, Apple has not shown by clear and convincing evidence that claim 15 of the '745 patent is invalid for indefiniteness.

I. Prosecution Laches

Apple contends that the asserted claims of the '745 patent are unenforceable due to prosecution laches. RIB at 204-05. Apple identifies the filing dates for provisional applications and continuation applications in the family of the '745 patent and ties them to the release dates for Apple Watch products. *Id.* Apple argues that the '745 patent should be held unenforceable due to prosecution laches because the application for the '745 patent was filed nearly five years after the first provisional patent application in the family, and during this timeframe Apple invested heavily in the development of Apple Watch products and growing the market for wearable technology. *Id.*; RRB at 112.

Complainants argue that Apple has failed to show any unreasonable or unexplained delay in the prosecution of the '745 patent. CIB at 238-39. Mr. Stoll described a "continuous

[89] As discussed above in the context of the domestic industry requirement, this limitation is met by photodiodes arranged in a circular array around the light block in the '745 DI Products. As discussed above in the context of obviousness, this limitation is, at least, *prima facie* obvious in view of Iwamiya's description of "plural light receiving units" that are "disposed on the same circumference" as the light block.

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unbroken chain of patent prosecution." Tr. (Stoll) at 1415:2-10; *see* CX-1760 ('745 patent prosecution history). Complainants submit that the filing dates for applications in the '745 patent family in 2015, 2016, 2018, 2019, and 2020 demonstrate active prosecution of patents in this family. CRB at 134.

In consideration of the parties' arguments, the undersigned finds that Apple has failed to show that the '745 patent should be found unenforceable due to prosecution laches. As discussed above in the context of the Poeze patents, prosecution laches requires a showing of unreasonable and inexcusable delay, and evidence sufficient to make that showing is lacking here. The record shows continuous prosecution activity from the filing of the original provisional application in 2015 to the issuance of the '745 patent in 2020. *See* JX-009; CX-1760. Apple's arguments tying certain patent application filings to release dates for the Apple Watch is unpersuasive, and the timeline is not consistent with Apple's allegations that Masimo drafted claims to cover the Apple Watch. *See* CIB at 204-05.[90] Apple has not identified delay in the prosecution of the '745 patent that would warrant a finding of prosecution laches.

VI. U.S. PATENT NO. 7,761,127

The '127 patent is entitled "Multiple Wavelength Sensor Substrate," naming inventors Ammar Al-Ali, Mohamed Diab, Marcelo Lamego, James P. Coffin, and Yassir Abdul-Hafiz and claiming priority to a provisional application filed on March 1, 2005, and a non-provisional application filed on March 1, 2006. JX-007.

[90] As discussed above, the Apple Watch Series 0 is prior art to the '745 patent, so any claims drafted to cover this product would have been invalid as anticipated. In addition, the '745 patent issued before the release of the Apple Watch Series 6 and the other Accused Products in this investigation, so the claims of the '745 patent could not have been drafted based on any released Apple Watch with a blood oxygen feature.

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A. Specification

The specification of the '127 patent describes a physiological sensor with emitters transmitting radiation at multiple wavelengths and a thermal mass that stabilizes a bulk temperature for the emitters. JX-007 at Abstract, 10:22-26, Fig. 12. "A temperature sensor 1230 is thermally coupled to the thermal mass 1220" to measure the bulk temperature. *Id.* at 10:26-31. The specification explains that the wavelengths of the light emitters "are determinable as a function of the drive currents 1210 and the bulk temperature 1202." *Id.*

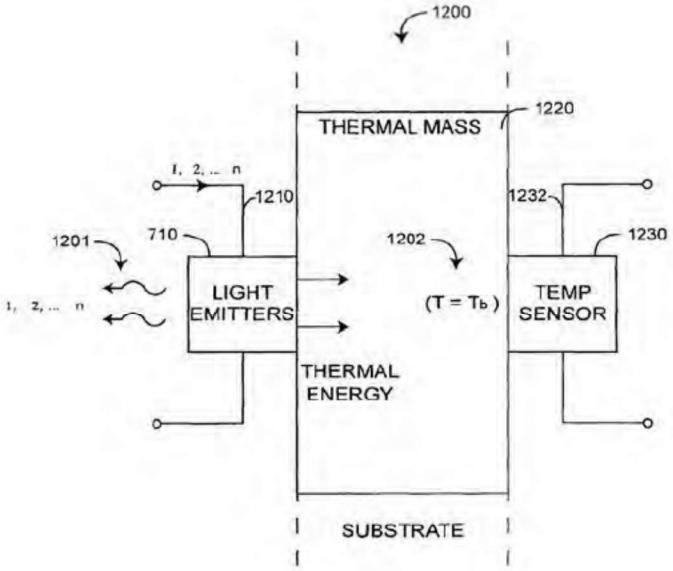


FIG. 12

Id. at Fig. 12. In particular, the operating wavelength λ_a of each light emitter is determined according to a function of the bulk temperature T_b, the drive current for the light emitter I_{drive}, and the total drive current for all light emitters ΣI_{drive}. *Id.* at 10:32-39.

The specification describes one embodiment where LEDs are mounted on a substrate, which is "configured with a relatively significant thermal mass, which stabilizes and normalizes the bulk temperature so that the thermistor measurement of bulk temperature is meaningful." *Id.*

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at 10:67-11:4. A substrate depicted in Figure 14 has "a component layer 1401, inner layers 1402-1405, and a solder layer 1406." *Id.* at 11:5-10.

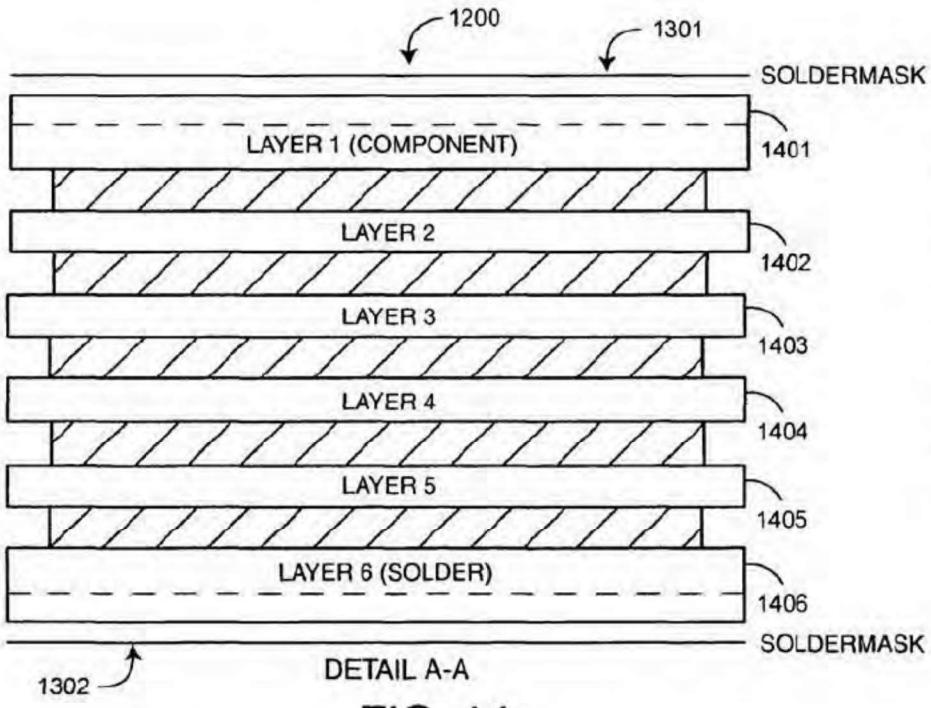


FIG. 14



FIG. 18

Id. at Fig. 14, Fig. 18. Figure 18 depicts inner layer 1402 having "substantial metallized areas 1411 that provide a thermal mass 1220 (FIG. 12) to stabilize a bulk temperature for the emitter array 700 (FIG. 12)." *Id.* at 11:10-13.

B. Claims

Complainants assert claim 9 of the '127 patent, which depends from claim 7. The limitations of these claims are recited below:

> 7. A physiological sensor capable of emitting light into tissue and producing an output signal usable to determine one or more physiological parameters of a patient, the physiological sensor comprising:
>
> a thermal mass;

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a plurality of light emitting sources, including a substrate of the plurality of light emitting sources, thermally coupled to the thermal mass, the sources having a corresponding plurality of operating wavelengths, the thermal mass disposed within the substrate;

a temperature sensor thermally coupled to the thermal mass and capable of determining a bulk temperature for the thermal mass, the operating wavelengths dependent on the bulk temperature; and

a detector capable of detecting light emitted by the light emitting sources after tissue attenuation, wherein the detector is capable of outputting a signal usable to determine one or more physiological parameters of a patient based upon the operating wavelengths.

JX-007 at 19:35-53.

9. The physiological sensor of claim 7 wherein the temperature sensor comprises a thermistor.

Id. at 19:58-59.

C. Level of Ordinary Skill in the Art

There is no dispute regarding the appropriate level of ordinary skill in the art for the '127 patent in this investigation. *See* CIB at 239; RIB at 209. Dr. Sarrafzadeh testified that a person of ordinary skill in the art would be a person with "working knowledge of physiological monitoring and thermal management technology, … a Bachelor of Science in an academic discipline emphasizing design of electrical and thermal technologies in combination with training or at least one or two years of related work experience with processing of data information, including but not limited to physiological monitoring technology" and "if somebody had a Master of Science in relevant academic discipline with less than a year of related work experience, that would qualify." Tr. (Sarrafzadeh) 1047:17-1048:4. Mr. Goldberg used this same level of ordinary skill for his analysis. *See* Tr. (Goldberg) at 1391:22-24.

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D. Claim Construction

The parties have agreed that a "plurality of wavelengths" is "two or more operating wavelengths." *See* CIB at 239; RIB at 209; Updated Joint Proposed Claim Construction Chart at 1, EDIS Doc. ID 763856 (Feb. 23, 2022).

In their post-hearing briefs, the parties dispute the construction of two terms in claim 7 of the '127 patent: "thermal mass" and "bulk temperature for the thermal mass." CIB at 239-47; RIB at 213-15; CRB at 135-41; RRB at 114-23.[91]

1. "thermal mass"

"[A] thermal mass" is the first limitation in the body of claim 7, and the term "thermal mass" also appears in the "plurality of light emitting sources" limitation, requiring a substrate of the light emitting sources to be "thermally coupled to the thermal mass," and in the "temperature sensor" limitation of claim 7, which requires "a temperature sensor thermally coupled to the thermal mass and capable of determining a bulk temperature for the thermal mass, the operating wavelengths dependent on the bulk temperature." JX-007 at 19:39-48.[92]

Apple contends that a "thermal mass" is a component that stabilizes a bulk temperature. RIB at 213-14; RRB at 116-19. Apple states that the claimed thermal mass "stabilizes a bulk

[91] Complainants argue that Apple never identified the terms "thermal mass" and "bulk temperature" during claim construction but relied on certain constructions to argue non-infringement. CIB at 239. Apple argues that Complainants' proposed claim constructions are untimely and that, "[p]rior to Complainants' initial post-hearing brief, no party requested constructions of 'thermal mass' or 'bulk temperature for the thermal mass.'" RRB at 114. Given that, *inter alia*, both parties addressed claim construction in their initial post-hearing briefs, and testimony regarding this issue was presented at the hearing without objection, the parties' claim construction arguments will be considered. *See, e.g.*, Tr. (Goldberg) at 618:9-21, 624:10-25; Tr. (Sarrafzadeh) at 1069:2-14, 1081:20-1082:8.

[92] These limitations mirror disclosures in the specification, wherein "[a] temperature sensor 130 is thermally coupled to the thermal mass 1220, wherein the temperature sensor 1232 provides a temperature sensor output 1232 responsive to the bulk temperature 1202 so that the wavelengths are determinable as a function of the drive currents 1210 and the bulk temperature 1202." JX-007 at 10:26-31.

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temperature," such that "the thermistor is then able to meaningfully measure that 'bulk temperature.'" RIB at 213. Apple argues that the term "thermal mass" does not refer simply to "the physical property of 'thermal mass' that is possessed by all objects with mass." *Id.* Apple further contends that the existence of a thermal mass cannot simply be assumed "if the sensor estimates wavelength using a temperature measurement." RRB at 117. In the context of invalidity, Apple argues that Complainants' interpretation of the "thermal mass" limitation would cover any circuit board with multiple layers. RIB at 234-35. Apple submits that the consistent disclosures in the specification of the '127 patent requires that the "thermal mass" is a component that stabilizes a bulk temperature. *Id.* at 213-14; RRB at 116-19.

Complainants propose to construe "thermal mass" to mean a "mass that provides a bulk temperature that can be used to reliably estimate the operating wavelengths of the LEDs." CIB at 240-44; CRB at 136-38. Complainants argue that the term "thermal mass" is "described in terms of the ability to estimate wavelength from the temperature measurement of the thermal mass." CIB at 243. Complainants do not specifically dispute that the "thermal mass" stabilizes a bulk temperature but argue that the temperature is not required to be constant—only sufficient to be used to reliably estimate the operating wavelengths of the LEDs. *Id.* at 234-44; CRB at 136-37. Complainants also argue that there is no basis for any requirement that the "thermal mass" have a minimum thickness. CIB at 234; CRB at 136.

Upon review of the parties' submissions, the undersigned finds that the term "thermal mass" refers to a mass that stabilizes a bulk temperature. This is consistent with the use of the term within the specification, which provides that "[a] thermal mass 1220 is disposed proximate

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to the emitters 710 so as to stabilize a bulk temperature 1202 for the emitters." *Id.* at 10:24-26.[93] The specification further describes a substrate that is "configured with a relatively significant thermal mass, which stabilizes and normalizes the bulk temperature so that the thermistor measurement of bulk temperature is meaningful." *Id.* at 10:67-11:4. In a specific embodiment, a layer of a substrate is described as having "substantial metallized areas 1411 that provide a thermal mass 1220 (FIG. 12) to stabilize a bulk temperature for the emitter array 700 (FIG. 12)." *Id.* at 11:10-13.

The specification thus clearly describes a "thermal mass" that stabilizes a bulk temperature, and the parties do not appear to dispute this fact, although only Apple's construction explicitly incorporates temperature stabilization. *See* RRB at 116-17; CIB at 240 (citing the specification's disclosures that the "thermal mass" as "disposed proximate the emitters so as to stabilize a bulk temperature for the emitters" and "relatively significant so as to stabilize and normalize the bulk temperature.").[94] Both Dr. Sarrafzadeh and Mr. Goldberg agreed that the '127 patent describes the claimed thermal mass as stabilizing a bulk temperature. *See* Tr. (Sarrafzadeh) at 1069:7-22; Tr. (Goldberg) at 643:4-12.[95]

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[93] Claims 1 and 26 include "thermal mass" limitations that mirror these specification disclosures, describing "a thermal mass disposed proximate to the emitters and within the substrate so as to stabilize a bulk temperature for the emitters." JX-007 at 19:9-11 (claim 1), 21:5-7 (claim 26).

[94] In the context of invalidity, Complainants argue that prior art references lack a "thermal mass" that "would stabilize a bulk temperature of the substrate," or a component "that functions as a thermal mass by stabilizing a bulk temperature." CIB at 279, 281.

[95] The parties also agree that the term "thermal mass," as used in the patent, does not correspond simply to a physical property possessed by any mass. *See* Tr. (Goldberg) at 639:24-640:3 (noting distinction between "thermal mass in the context of the patent or the thermal mass . . . as a scientific principle of physics"); Tr. (Sarrafzadeh) at 1071:17-21 (distinguishing between "thermal mass of the patent" and the physical property of thermal mass of "any material"); RRB at 124-25.

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While Complainants do not explicitly dispute that the claimed thermal mass stabilizes a bulk temperature, they argue that Apple's interpretation of stabilization is too narrow, requiring a minimum thickness for the thermal mass or stabilization at a constant temperature. CIB at 243; CRB at 136. Apple's proposed construction does not require a minimum thickness or a constant temperature, however. *See* RRB at 118-19. Dr. Sarrafzadeh merely offered his opinion that certain metal layers could not be a "thermal mass" where "[t]hey are not really thick enough to provide any . . . thermal stability." Tr. (Sarrafzadeh) at 1066:4-9.[96] The undersigned thus agrees with Apple that the claimed "thermal mass" is a mass that stabilizes a bulk temperature.[97]

Complainants fail to explain why their proposed construction omits any requirement for temperature stabilization, arguing only that the "thermal mass" is a "mass that provides a bulk temperature that can be used to reliably estimate the operating wavelengths of the LEDs." CIB at 240; *see* CRB at 136-38. Complainants further define "bulk temperature" to be "a single temperature used to estimate the operating wavelengths of all the LEDs." CIB at 244. Substituting this definition into Complainants' construction of "thermal mass," Complainants' proposed definition of "thermal mass" becomes "a mass that provides a single temperature used to estimate the operating wavelengths of all the LEDs, that can be used to reliably estimate the

[96] He also observed temperature variations in a circuit board, finding that it was "not at a uniform temperature through time or spatially" and that the temperature "is not stabilized." *Id.* at 1078:23-1079:9. Dr. Sarrafzadeh's analysis is consistent with Apple's proposed construction and the specification's description of "a relatively significant thermal mass, which stabilizes and normalizes the bulk temperature." JX-007 at 10:67-11:4, 11:10-13.

[97] Apple's proposed construction describes the "thermal mass" as a "component" that stabilizes a bulk temperature, RIB at 213-14, but Apple does not explain why the claim term "mass" has been replaced with the word "component," which does not appear in the claims or the relevant portions of the specification. Complainants have used the word "mass" in their proposed construction, *see* CIB at 240, and there does not appear to be any meaningful dispute regarding the meaning of the word "mass." Accordingly, the undersigned shall construe the term "thermal mass" without substituting another word for "mass."

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operating wavelengths of the LEDs" —or, effectively, "a mass that provides a single temperature used to reliably estimate the operating wavelengths of all the LEDs." Complainants also make clear that the "single temperature" required for a bulk temperature need not be a uniform temperature but is simply a "single measurement." *See* CIB at 246 ("bulk temperature" need not be a "uniform or average temperature."); *id.* at 247 (explaining that bulk temperature "is a single measurement for the thermal mass").

The intrinsic evidence fails to indicate that any mass of a non-uniform temperature, from which a single temperature measurement can be provided to estimate the operating wavelengths of all LEDs is, *ipso facto*, a "thermal mass."

First, Complainants' construction merely restates the language in the "temperature sensor" limitation of claim 7 while providing no meaning to the limitation requiring a "thermal mass." *See* JX-007 at 19:45-48 (claim 7 requiring "a temperature sensor thermally coupled to the thermal mass and capable of determining a bulk temperature for the thermal mass, the operating wavelengths dependent on the bulk temperature"). The Federal Circuit has held that "[i]t is highly disfavored to construe terms in a way that renders them void, meaningless, or superfluous." *Wasica Finance GmbH v. Continental Automotive Systems, Inc.*, 853 F.3d 1272, 1288 n.10 (Fed. Cir. 2017).

Further, the prosecution history of the '127 patent weighs against Complainants' approach. Complainants rely on the prosecution history to show that the claims of the '127 patent were distinguished from prior art without a "thermal mass," CIB at 242, CRB at 137-38, but it is clear from this record that the examiner did not understand the term "thermal mass" to only require an estimate of the operating wavelengths of the LEDs based on a single temperature measurement. In the relevant portion of the prosecution history of the '127 patent, the examiner

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considered a prior art reference, U.S. Patent No. 5,259,381 to Cheung et al. (RX-0406, "Cheung"), finding that Cheung "discloses all the elements of the current invention . . . except for the sensor comprising a thermal mass disposed proximate the emitters, wherein the thermal mass stabilizes a bulk temperature of the emitters." JX-008 at 363, 433 (MASITC_00077988, 00078058) (rejecting, *inter alia*, prosecution claim 5, which ultimately issued in amended form as claim 7).[98] When discussing the prosecution history at the hearing, Mr. Goldberg agreed that "Cheung does not have a thermal mass." Tr. (Goldberg) at 1395:13-15. Despite the lack of a "thermal mass," the examiner recognized that Cheung discloses a "temperature sensor" and a method for "determining a plurality of operating wavelengths of the light emitting sources so that one or more physiological parameters can be determined based upon the operating wavelengths." JX-008 at 362 (MASITC_00077987); *see* RX-0406 at Abstract ("[A] temperature sensor (50) is included in the sensor (12) to produce a signal indicative of sensor temperature. This signal is interpreted by the oximeter circuitry including, for example, a microcomputer (16), where the effect of temperature on wavelength is compensated for."). In response to this rejection and following an interview with the examiner, Complainants' counsel amended all of the independent claims of the '127 patent. JX-008 at 399-407.[99]

Cheung's temperature sensor measures a single temperature that is used to "accurately determine" the wavelengths of two LEDs for oxygen saturation measurements. *See* RX-0406 at

[98] Prosecution claim 5 at that time required, *inter alia*, "a temperature sensor thermally coupled to the thermal mass and capable of determining a bulk temperature for the thermal mass, the operating wavelengths dependent on the bulk temperature" and the determination of "one or more physiological parameters of a patient based upon the operating wavelengths." JX-008, at 38 (MASITC_00077663).

[99] In response to rejections based on obviousness in view of Cheung in combination with additional prior art references, including U.S. Patent No. 6,360,113 ("Dettling '113") and U.S. Patent Pub. No. 2002/0154665 ("Funabashi et al. '665), the claims were amended to specify that the thermal mass is disposed within a substrate. *See* JX-008 at 363-64, 399-407.

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13:20-32 ("[A] temperature sensor 50 . . . is employed to produce a signal that indicates the temperature of sensor assembly 48. . . . [T]his signal, when combined with information about the coding resistor 52 value, allows microcomputer 16 to accurately determine the wavelengths of the light emitted by LEDs 40 and 42 and subsequently produce an accurate determination of oxygen saturation."); RRB at 115 (quoting Cheung). Complainants' proposed construction would thus fail to distinguish claim 7's requirement for a "thermal mass" over a reference that the examiner (and Complainants' expert) recognized does not have a thermal mass. Accordingly, Complainants' proposed construction is unsupported—a "thermal mass" is not merely any mass from which a single temperature measurement can be used to estimate the operating wavelengths of the LEDs.[100]

* * *

Accordingly, "thermal mass" shall be construed to mean a mass that stabilizes a bulk temperature.

2. "bulk temperature for the thermal mass"

The "temperature sensor" limitation of claim 7 describes "a bulk temperature for the thermal mass, the operating wavelengths dependent on the bulk temperature." JX-007 at 19:45-

[100] To the extent Complainants seek to argue that their proposed construction requires, in addition, "reliably" estimating wavelength in a manner that improves over Cheung (*see* CIB at 285), such an addition is not supported by the evidence. As discussed above, the examiner viewed Cheung as meeting the claim requirements except for that of a "thermal mass" stabilizing a bulk temperature. Complainants' proposed claim construction, moreover, does not include any proviso requiring a greater degree of accuracy than Cheung. Complainants' infringement analysis also does not provide any comparison of the Accused Products to the accuracy provided in Cheung. Moreover, even if greater accuracy were shown in the Accused Products, the evidence shows that there are multiple ways to achieve greater accuracy in wavelength estimation apart from inclusion of a thermal mass, and some of these methods can be used in combination with a temperature measurement. *See* RRB at 115-16; RX-0035.0086. The existence of a thermal mass does not simply follow, as a matter of logic, from reliable wavelength estimation using, *inter alia*, a single temperature measurement. *See* RIB at 114-115.

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48. As discussed above in the context of "thermal mass," the specification provides that "[a] thermal mass 1220 is disposed proximate to the emitters 710 so as to stabilize a bulk temperature 1202 for the emitters." *Id.* at 10:24-26. The specification further provides that "[a] temperature sensor 130 is thermally coupled to the thermal mass 1220, wherein the temperature sensor 1230 provides a temperature sensor output 1232 responsive to the bulk temperature 1202 so that the wavelengths are determinable as a function of the drive currents 1210 and the bulk temperature 1202." *Id.* at 10:26-31. The specification describes two distinct methods for determining the wavelengths of the emitters, distinguishing between a method using the bulk temperature (T_b) and a method using the temperatures of individual light emitters (T_a). *Id.* at 10:32-48. In a "bulk temperature" embodiment, a thermistor is used "to determine the bulk temperature of LEDs 801 (FIG. 8) mounted on the substrate 1200," and "[t]he substrate 1200 is configured with a relatively significant thermal mass, which stabilizes and normalizes the bulk temperature so that the thermistor measurement of bulk temperature is meaningful." *Id.* at 10:67-11:4.

Apple does not propose an explicit construction for "bulk temperature" but argues that the "bulk temperature for the thermal mass" should follow the 'ordinary usage of the adjective 'bulk,' which is the majority or greater part." RIB at 215. Apple, in support, cites certain deposition testimony of one of the named inventors indicating that it is an "average" or "representative" temperature. *Id.* (citing RX-1195C (Abdul-Hafiz Dep. Tr.) at 99:1-19 ("[T]he bulk temperature means . . . I call it the representative temperature . . . a representative temperature of the whole bulk, and that's what we call bulk temperature.")) Apple also relies on a statement made by Complainants' counsel at the Markman hearing that "people understand bulk is the vast majority." Markman H'rng Tr. at 42:6-9. Apple further distinguishes a "bulk temperature" from "a local temperature" for one part of the mass. RIB at 215 ("the temperature

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sensor measures a 'bulk temperature' that is different from a regular temperature measurement by a temperature sensor, which is a local temperature measurement"); *see also* RIB at 214-15; RRB at 116-19.

Complainants argue that a "bulk temperature" is "a single temperature used to estimate the operating wavelength of all the LEDs." CIB at 244. Complainants argue that the claimed bulk temperature does not need to be an average temperature or a uniform temperature for the thermal mass, relying on the claim language describing the "bulk temperature" as a single temperature used to estimate the operating wavelengths of all the LEDs. CIB at 244-47; CRB at 138-41. Complainants argue that the "bulk temperature" is not necessarily an "average" temperature, but rather is a "single, 'representative' measurement." CIB at 244-45. Complainants rely on the testimony of Yassir Abdul-Hafiz, one of the named inventors, who described a "bulk temperature" as the "representative temperature," which is different from a "local temperature" at a "spot that we are measuring." RX-1195C (Abdul-Hafiz Dep. Tr.) at 99:1-15. He further explained that the temperature of a "thermal mass" can be "a representative temperature of the whole bulk, and that's what we call bulk temperature." *Id.* at 99:16-19. His co-inventor Mr. Diab described the "bulk temperature" as a "baseline that is defined by this substrate, and what we found in this invention is that if you measure that baseline and -- with a certain quality for the substrate, . . . you can have a very good correlation to the inside temperature of each LED." RX-1200C (Diab Dep. Tr.) at 137:12-138:8.

In consideration of the parties' arguments, the undersigned construes "bulk temperature of the thermal mass" to mean a representative temperature for the thermal mass. The parties do not appear to dispute that the "bulk temperature" claimed in the '127 patent is a representative temperature for the thermal mass, in accordance with Mr. Abdul-Hafiz's testimony. This

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construction is also consistent with the "bulk temperature" embodiment in the specification, where a thermistor is used "to determine the bulk temperature of LEDs 801 (FIG. 8) mounted on the substrate 1200," and "[t]he substrate 1200 is configured with a relatively significant thermal mass, which stabilizes and normalizes the bulk temperature so that the thermistor measurement of bulk temperature is meaningful." *Id.* at 10:67-11:4.[101] Complainants' proposed construction improperly reads out the "thermal mass" from the limitation "bulk temperature for the thermal mass." This is improper, for the same reasons discussed above in the context of the construction for "thermal mass," because it would fail to give meaning to these terms and would be inconsistent with the prosecution history. Complainants' proposed construction requiring only that the bulk temperature be used to estimate the operating wavelength of all the LEDs would be met by Cheung, which does not include a "thermal mass." *See* RX-0406 at 13:20-32.[102]

* * *

Accordingly, "bulk temperature for the thermal mass" shall be construed to mean a representative temperature for the thermal mass.

E. Infringement

Complainants allege that the Accused Products infringe claim 9 of the '127 patent, relying on the testimony of Mr. Goldberg. CIB at 248-66; CRB at 141-54; Tr. (Goldberg) at 612:9-626:16. Apple disputes whether the Accused Products meet the limitations requiring a

[101] Complainants argue that Apple's proposed interpretation of this limitation would read out the preferred embodiment in the specification using a single thermistor, CIB at 246-47, but Apple agrees that "a 'bulk temperature' could be measured by a properly positioned single thermistor if the thermal mass were stabilized at the bulk temperature." RRB at 122.

[102] Complainants' proposed construction would also be superfluous, because the subsequent language in the claim already requires "the operating wavelengths dependent on the bulk temperature." *See* JX-007 at 19:45-49.

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"thermal mass" and a temperature sensor "capable of determining a bulk temperature for the thermal mass," relying on the testimony of Dr. Sarrafzadeh. RIB at 209-24; RRB at 114-30; Tr. (Sarrafzadeh) at 1064:8-1084:5. For the reasons discussed below, the undersigned finds that the Accused Products have not been shown to infringe claim 9 of the '127 patent by a preponderance of the evidence.

1. Element [7 preamble]: "physiological sensor"

There is no dispute that the Accused Products meet the limitations of the preamble of claim 7, describing "[a] physiological sensor capable of emitting light into tissue and producing an output signal usable to determine one or more physiological parameters of a patient."[103] Complainants identify evidence that the Accused Products have LEDs capable of emitting light to a user's wrist that is reflected back to photodiodes and used to determine blood oxygen levels. CIB at 254; Tr. (Goldberg) at 616:4-16; CDX-0013C.007; CX-1724 at 3. Accordingly, the evidence shows that the Accused Products have physiological sensors that meet the preamble limitations of claim 7.

2. Element [7A]: "a thermal mass"

Mr. Goldberg identified "[redacted]" of a printed circuit board ("PCB") in the Accused Products, which Complainants identify as the claimed "thermal mass." CIB at 254-58; Tr. (Goldberg) at 617:9-618:21. Mr. Goldberg identified "[redacted]." Tr. (Goldberg) at 617:9-21.

[103] The parties have stipulated that the preambles of the asserted patents are limiting. *See* Joint Stipulation of Facts ¶ 9, EDIS Doc. ID 770692 (May 13, 2022).

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[redacted]

CDX-0013C.008 (citing CX-0193C). He further identified "[redacted]." Tr. (Goldberg) at 617:9-21.

[redacted]

CDX-0013C.008 (citing CX-0195C). Mr. Goldberg performed tests confirming that the [redacted] in the Accused Products are coupled to each other and to the LEDs and a thermistor. Tr. (Goldberg) at 20:17-021:15; CDX-0013C.013 (citing CX-0839C; CX-0840C).

Mr. Goldberg further identified an Apple document describing a "[redacted]" Tr. (Goldberg) at 622:4-18; CDX-0013C.015 (citing CX-0012C at 22). He cites another [redacted], explaining "that there's a balance in the thermal properties of the printed circuit board that needs to be maintained in order for such formulations to work." Tr. (Goldberg) at 622:22-623:7; CDX-0013C.016 (citing CX-0011C at 23). Complainants note that in this document, Apple uses the

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term "thermal mass." CX-0011C at 23. Mr. Goldberg recognized that the Accused Products use a single thermistor to measure the temperature of the PCB, and "the thermal mass is configured in a manner that the thermal coupling between the LEDs and the thermistor are such that the bulk temperature as measured by the thermistor is meaningful, and that meaningfulness has to do with being able to use that bulk temperature to determine the operating wavelengths." Tr. (Goldberg) at 624:7-25. Complainants argue that [redacted] that allows for the measurement of a single temperature that can be used to reliably estimate the wavelengths of the plurality of LEDs. CRB at 141-43, 147-48.

Apple argues that Mr. Goldberg failed to show that the Accused Products have the accused "thermal mass." RIB at 218-19. Apple cites testimony from named inventor Mohamed Diab, who agreed that "some form of experiment" would be necessary to determine whether an object stabilizes temperatures in accordance with the invention. *See* Tr. (Diab) at 238:15-19. Apple argues that Mr. Goldberg only performed tests regarding thermal conductivity, which are not sufficient to show temperature stabilization. *See* Tr. (Sarrafzadeh) at 1070:22-1071:5, 1080:11-1081:18; RDX-7.70. Apple submits that Complainants have failed to articulate what thermal properties would be sufficient to establish that a "thermal mass" stabilizes a bulk temperature. RRB at 123-24. With respect to the use of the term "thermal mass" in an Apple presentation, Dr. Mannheimer explained that the term referred to a physical property related to an object's heat capacity, and not to the "thermal mass" referenced in the '127 patent. CX-0289C (Mannheimer Dep. Tr.) at 148:8-156:1; *see also* CX-0291C (Mehra Dep. Tr.) at 180:8-182:17 ("I don't know what that refers to"); Tr. (Sarrafzadeh) at 1071:13-1072:7 ("the thermal mass here is not the thermal mass of the patent"). [redacted]

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[redacted]

[redacted] Tr. (Sarrafzadeh) at 1074:8-1078:22; RDX-7.65C; RDX-7.66C.

[redacted]

CX-0322b-C.0010.

Apple also argues that the [redacted] in the PCB of the Accused Products do not comprise a "thermal mass" because [redacted] to stabilize a bulk temperature. RIB at 215-19. Apple relies on the testimony of one of its engineers, Saahil Mehra, who testified that the

[redacted]

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[redacted]. Tr. (Sarrafzadeh) at 1065:16-1066:9; RDX-7.49. Dr. Sarrafzadeh compared the thickness of the [redacted] in the Accused Products with the thickness of Masimo's early rainbow® sensors, finding that the "rainbow sensor thickness is [redacted]" than the Accused Products. Tr. (Sarrafzadeh) at 106:10-21; RDX-7.51C. Dr. Sarrafzadeh submits that because the Accused Products have more LEDs than the rainbow sensors, thicker layers would likely be needed to provide the same level of thermal stability. Tr. (Sarrafzadeh) at 1067:4-13. He relied on testimony from Masimo engineers discussing the thickness of the rainbow sensor boards to support his opinion. *Id.* at 1068:14-25. Apple cites the testimony of Mr. Diab, who was asked whether Masimo designed the rainbow sensor circuit boards to be "as thin as possible." RX-1200C (Diab Dep. Tr.) at 108:12-15. At the hearing, Mr. Diab testified that whether a mass of [redacted] is sufficient to stabilize a bulk temperature depends on "how much heat you are pumping into the sensor, and that[] typically has to do with the number of LEDs." Tr. (Diab) at 238:9-14.

In consideration of the parties' arguments, the undersigned finds that Complainants have not shown, by a preponderance of the evidence, that [redacted] in the PCB of the Accused Products meet the "thermal mass" limitation. As discussed above, "thermal mass" has been construed to mean a mass that stabilizes a bulk temperature. Complainants have failed to show temperature stabilization in the Accused Products. [redacted]

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[redacted]

Complainants disagree with Dr. Sarrafzadeh's opinion regarding temperature stabilization, but they rely only on attorney argument to characterize [redacted] *See* CRB at 142-43. [redacted] RX-0093C.0009-10.

Mr. Goldberg admitted that he "did not do any tests that address stabilization or normalization." Tr. (Goldberg) at 649:4-11; *see also id.* at 618:1-21 (disagreeing with Apple's understanding that stabilization and normalization were required for a "thermal mass."). Complainants rely on the fact the Accused Products use a single temperature sensor to determine the wavelengths of the LEDs but as discussed above in the context of claim construction, this is insufficient to prove the existence of a "thermal mass"—during prosecution, for example, the examiner recognized that the Cheung prior art estimated such wavelengths without a "thermal mass." *See* JX-008 at 363; RX-0406 at 13:20-32. Complainants have failed to present any affirmative evidence of temperature stabilization, and accordingly, they have not met their burden to show that the Accused Products contain a "thermal mass."[104]

[104] Complainants also acknowledge that the presence of metallized layers does not show the existence of a thermal mass. *See* CRB at 162 (rejecting argument that "***any*** metallized layers in a PCB can be a thermal mass").

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There is further evidence in the record to support a finding of non-infringement with respect to the "thermal mass" limitation. Dr. Mehra testified that [redacted] of the PCB in the Accused Products [redacted] Tr. (Sarrafzadeh) at 1065:15-1066:21; RDX-7.49C; RX-0087C; RX-0338C.[105] A preponderance of the evidence does not support a finding that the Accused Products meet the "thermal mass" limitation.

3. Element [7B]: "a plurality of light emitting sources, including a substrate of the plurality of light emitting sources, thermally coupled to the thermal mass"

With respect to the "plurality of light emitting sources" limitation, Mr. Goldberg identified 4 sets of 3 LEDs in the Accused Products, which are attached to the [redacted] of the PCB with thermally conductive epoxy. Tr. (Goldberg) at 618:22-619:9; CDX-0013C.09 (citing CX-0057C; CX-0025C; CX-0198C at 17-18; CX-0199C). Mr. Goldberg further conducted testing to show that the LEDs are thermally coupled to the [redacted] of the PCB. 620:17-621:15; CDX-0013C.013 (citing CX-0839C; CX-0840C). Apple only disputes infringement with respect to the "thermal mass" within this limitation. *See* CIB at 258-59; RIB at 215-19. Accordingly, the evidence shows that the "plurality of light emitting sources" limitation is met by the Accused Products.

[105] Apple argues that the rainbow® sensors were designed to be [redacted], RRB at 126-27, citing the testimony of Mohamed Diab who stated at his deposition: "I think that was one of the requirements." RX-1200C (Diab Dep. Tr) at 108:12-15.

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4. Element [7C]: "the sources having a corresponding plurality of operating wavelengths"

With respect to the "plurality of operating wavelengths" limitation, Mr. Goldberg identified red, green, and infrared LEDs in the Accused Products. Tr. (Goldberg) at 619:10-17; CDX-0013C.010 (citing CX-0057C; CX-0025C). There is no dispute with respect to this limitation. *See* CIB at 259. Accordingly, the evidence shows that the "plurality of operating wavelengths" limitation is met by the Accused Products.

5. Element [7D]: "the thermal mass disposed within the substrate"

With respect to the "thermal mass disposed within the substrate" limitation, Mr. Goldberg identified the [redacted] within the PCB substrate of the Accused Products. Tr. (Goldberg) at 619:18-620:3; CDX-0013C.011 (citing CX-0105C; CX-0193C). Apple does not dispute that the [redacted] are disposed within the PCB substrate, but as discussed above, Complainants have not shown that these layers comprise a "thermal mass." *See* CIB at 260-61; RIB at 215-19. Accordingly, the evidence shows that the "disposed within the substrate" limitation is met by the Accused Products, but Complainants have not shown that the Accused Products have a "thermal mass."

6. Element [7E]: "a temperature sensor thermally coupled to the thermal mass"

With respect to the "temperature sensor thermally coupled to the thermal mass" limitation, Mr. Goldberg identified a thermistor near the center of the sensor board of the Accused Products. Tr. (Goldberg) at 620:4-16; CDX-0013C.012 (citing CX-0057C; CX-0025C). He performed testing to show that the thermistor is thermally coupled to the [redacted] of the PCB. Tr. (Goldberg) at 620:17-621:15; CDX-0013C.013 (citing CX-0839C; CX-0840C). As discussed above, Complainants have not shown that the [redacted] of the PCB

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comprise a "thermal mass," although Apple does not dispute that the thermistor is thermally coupled to the [redacted]. *See* CIB at 261-62; RIB at 215-19. Accordingly, the evidence shows that the "temperature sensor" limitation is met by the Accused Products, but Complainants have not shown that the Accused Products have a "thermal mass."

7. Element [7F]: the temperature sensor "capable of determining a bulk temperature for the thermal mass, the operating wavelengths dependent on the bulk temperature"

With respect to the "bulk temperature" limitation, Complainants identify the temperature measured by the thermistor in the Accused Products. CIB at 262-65. [redacted] Complainants argue that the [redacted] measured by the thermistor is the claimed "bulk temperature," because it is a single temperature

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for the thermal mass that is used to estimate the wavelengths of the LEDs. CIB at 262-65; CRB at 149-54.

[redacted]

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In consideration of the parties' arguments, the undersigned finds that Complainants have not shown, by a preponderance of the evidence, that the thermistor in the Accused Products determines a "bulk temperature for the thermal mass." As discussed above in the context of claim construction, the claimed "bulk temperature" must be a representative temperature for the thermal mass. Complainants have not shown, however, that the Accused Products have a "thermal mass" that stabilizes a bulk temperature. [redacted] Complainants disagree with Dr. Sarrafzadeh's conclusion, arguing that the observed temperature variation is "remarkably uniform" and "very stable." CRB at 145-46. But Complainants' contentions are only attorney argument, without any expert testimony. *See* RRB at 128-29. Apple documents contradict Complainants' contentions, [redacted]" RX-0093C.0009-10.

Mr. Goldberg admitted that he did not perform any tests to show whether a thermal mass stabilizes or normalizes a bulk temperature in the Accused Products. Tr. (Goldberg) at 649:4-11. His infringement analysis instead relied on the fact that the "temperature as measured by the

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thermistor is meaningful, and that meaningfulness has to do with being able to use that bulk temperature to determine the operating wavelengths." Tr. (Goldberg) at 624:7-25. This evidence may indicate that the temperature sensor in the Accused Products measures a representative temperature for the LEDs, but it does not show a representative temperature for the "thermal mass." As discussed above in the context of the "thermal mass" limitation, the fact that a temperature is used to determine the operating wavelengths of LEDs is insufficient to prove that the temperature is "a bulk temperature for the thermal mass." The determination of operating wavelengths is a separate requirement of this limitation,[106] and the examiner recognized that calculation of wavelengths using a representative temperature was known in the prior art. *See* JX-008 at 338 (MASITC_00077663), 363 (MASITC_00077988); RX-04.06 at 13:20-32. Accordingly, in addition to the failure to show that the Accused Products have a "thermal mass," Complainants have failed to show by a preponderance of the evidence that the temperature measured by the thermistor is a "bulk temperature for the thermal mass."[107]

8. Element [7G]: "a detector capable of detecting light emitted by the light emitting sources after tissue attenuation"

With respect to the "detector" limitation, Mr. Goldberg identified four photodiodes in the Accused Products. Tr. (Goldberg) at 625:1-9; CDX-0013C.018 (citing CX-0057C; CX-0025C).

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[106] [redacted]

[107] Apple separately argues in its post-hearing briefs that [redacted] and that Complainants were required to show that one of these measurements is the "bulk temperature." RIB at 224; RRB at 129-30. This non-infringement argument was not raised in Apple's pre-hearing brief, however, and accordingly, it has been waived pursuant to Ground Rule 9.2. *See* CRB at 153-54.

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Complainants further cite the testimony of Apple witnesses confirming that the photodiodes in the Accused Products detect light that is emitted by the LEDs and attenuated by the user's tissue. *See, e.g.,* CX-0281C (Block Dep. Tr.) at 86:17-87:14; CX-0289C (Mannheimer Dep. Tr.) at 133:2-134:12. There is no dispute with respect to this limitation. *See* CIB at 265; RIB at 215-19. Accordingly, the evidence shows that the "detector" limitation is met by the Accused Products.

9. Element [7H]: "wherein the detector is capable of outputting a signal usable to determine one or more physiological parameters of a patient based upon the operating wavelengths"

With respect to the "outputting a signal" limitation, Mr. Goldberg identified "PPG signals" described in Apple documents corresponding to the output of the photodiodes, which are used to determine blood oxygen saturation in combination with the wavelength estimates for the LEDs. Tr. (Goldberg) at 625:10-25; CDX-0013C.019 (citing CX-0100C at 5-8; CX-0012C at 21). Complainants further cite the testimony of Apple witnesses confirming that signals from the photodiodes are used to determine blood oxygen saturation. *See, e.g.,* CX-0281C (Block Dep. Tr.) at 72:10-73:7; CX-0289C (Mannheimer Dep. Tr.) at 134:14-138:1. There is no dispute with respect to this limitation. *See* CIB at 266; RIB at 215-19. Accordingly, the evidence shows that the "outputting a signal" limitation is met by the Accused Products.

10. Element [9]: "a thermistor"

Claim 9 further requires that the "temperature sensor" of claim 7 is a thermistor. As discussed above in the context of the "temperature sensor" limitation, there is no dispute that the Accused Products have a temperature sensor that is a thermistor. *See* Tr. (Goldberg) at 626:3-16; CDX-0013C.020 (citing CX-0057C at 1-2; CX-0025C at 31). Accordingly, the evidence shows that the "thermistor" limitation of claim 9 is met by the Accused Products.

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As discussed above, because Complainants have not shown by a preponderance of the evidence that the "thermal mass" and "bulk temperature for the thermal mass" limitations of claim 7 are met by the Accused Products, the undersigned finds that the Accused Products have not been shown to infringe claim 9 of the '127 patent.

F. Domestic Industry—Technical Prong

Complainants allege that Masimo's rainbow® sensors practice claim 9 of the '127 patent, relying on the testimony of Mr. Diab and Mr. Goldberg. CIB at 266-74; CRB at 154-60; *see* Tr. (Diab) at 216:15-226:19; Tr. (Goldberg) at 627:3-635:11. Apple disputes whether the rainbow® sensors meet the limitations requiring a "thermal mass" and a temperature sensor "capable of determining a bulk temperature for the thermal mass," relying on the testimony of Dr. Sarrafzadeh. RIB at 224-32; RRB at 130-36; Tr. (Sarrafzadeh) at 1084:6-1087:12. For the reasons discussed below, the undersigned finds that only some of Masimo's rainbow® sensors have been shown to practice claim 9 of the '127 patent.

1. Domestic Industry Products

Mr. Diab explained that there are two different LED assemblies used in Masimo's rainbow® sensors —early rainbow® sensors dating back to 2005 used [redacted] in a substrate, and current rainbow® sensors use a [redacted]. Tr. (Diab) at 216:15-219:5; *see* Tr. (Goldberg) at 627:4-13; CDX-0013C.021.Apple argues that Complainants have failed to identify the Masimo rainbow® sensors by product number and have failed to specify which products are "early" or "current" rainbow® sensors. RIB at 224-24; RRB at 130-31. Complainants submit that the rainbow® sensors have been identified on a sales spreadsheet. CRB at 9; CX-0649C. Complainants contend that "pre-2009 sales are for early rainbow®

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sensors and later sales are for current rainbow® sensors," citing the testimony of Mr. Diab. CRB at 10 (citing Tr. (Diab) at 216:15-218:1, 220:4-221:10). Mr. Diab testified at the hearing: "My understanding is that . . . we have switched to the [redacted] in around 2009." Tr. (Diab) at 233:16-20. Masimo's sales spreadsheet (CX-0649C) shows continuous sales of rainbow® sensors from 2008 through 2012, with no indication of distinct product numbers for early rainbow® sensors and current rainbow® sensors. *See* CX-0649C. The undersigned agrees with Apple that the record lacks any straightforward identification of Masimo's rainbow® sensors, but the sales data, as explained by Mr. Diab's testimony, is sufficient to infer that the design of Masimo's rainbow® sensors was changed in 2009 such that "early" rainbow® sensors before 2009 were comprised of [redacted], but all of the rainbow® sensors made and sold after 2009 are "current" rainbow® sensors with a [redacted].

2. Element [7 preamble]: "physiological sensor"

There is no dispute that the early and current rainbow® sensors meet the limitations in the preamble of claim 7, describing "[a] physiological sensor capable of emitting light into tissue and producing an output signal usable to determine one or more physiological parameters of a patient." *See* CIB at 266-67.[108] Mr. Goldberg identified evidence that the rainbow® sensors contain a photodetector that detects light emitted by LEDs and produces a signal that is used to determine "patient measurement values." Tr. (Goldberg) at 627:14-22; CDX-0013C.022 (citing CX-0430C at 5). Accordingly, the evidence shows that the preamble limitations of claim 7 are met by each of the rainbow® sensors.

[108] The parties have stipulated that the preambles of the asserted patent claims are limiting. *See* Joint Stipulation of Facts ¶ 9, EDIS Doc. ID 770692 (May 13, 2022).

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3. Element [7A]: "a thermal mass"

With respect to the "thermal mass" limitation, Complainants rely on different structures in the current rainbow® sensors and the early rainbow® sensors. CIB at 267-69. Mr. Diab described an [redacted] material that is used in the substrate of the current rainbow® sensors, "because it has very good heat conduction." Tr. (Diab) at 220:4-222:1 (citing CX-0454C; CX-0589C). Mr. Goldberg identified this [redacted] as the claimed "thermal mass" in the current rainbow® sensors, relying on Masimo documents and Mr. Diab's testimony. Tr. (Goldberg) at 627:23-628:24; CDX-0013C.023 (citing CX-0590C; CX-135C at 81, 98). With respect to the early rainbow® sensors, Mr. Diab identified [redacted], which are "connected with . . . through-holes to make sure that there is a good heat conduction throughout the system." Tr. (Diab) at 216:15-219:5 (citing CX-0397C; CX-0588C). Mr. Goldberg identified the [redacted] as the claimed "thermal mass" in the early rainbow® sensors. Tr. (Goldberg) at 628:25-629:18; CDX-0013C.024 (citing CX-0588C).

Apple argues that Complainants have failed to show that the rainbow® sensors have a "thermal mass." RIB at 226-29, 230-32. Apple submits that Complainants failed to provide any analysis of the thermal properties of the substrate in the current rainbow® sensors or the early rainbow® sensors. *Id.* at 226-279, 230-32 *see* Tr. (Sarrafzadeh) at 1084:22-1085:11 (noting the Mr. Goldberg "did not do any simulation or any other analysis"). Apple contrasts the lack of analysis for the current rainbow® sensors with Mr. Diab's extensive testing and simulation in the development of the early rainbow® sensors. RIB at 227-29. Apple further argues that Mr. Goldberg did not rely on any of Mr. Diab's testing and simulation for his opinions. RRB at 131-35.

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In consideration of the parties' arguments, the undersigned finds that Complainants have shown by a preponderance of the evidence that the early rainbow® sensors had a "thermal mass," but Complainants have failed to show that the current rainbow® sensors meet this limitation. Although Mr. Goldberg's testimony on this limitation did not rely on testing or detailed analysis of the substrates in the rainbow® sensors, his testimony is supported by other evidence in the record, including Masimo documents and Mr. Diab's testimony. In particular, Mr. Diab testified at his deposition that the early rainbow® sensors were designed to have a relatively significant thermal mass. RX-1200C (Diab Dep. Tr.) at 110:7-11. Mr. Diab also described testing and simulations that he performed in the development of the early rainbow® sensors, where he modeled the temperature of the "thermal mass" to observe the relationship between the temperature of the thermistor and the temperature of the LEDs. *Id.* at 121:4-122:3; Tr. (Diab) at 200:17-203:6 (citing CX-0342C). He observed [redacted] finding [redacted] *Id.* at 201:19-203:6. Apple argues that these simulations were only performed with a prototype design and not an actual product, RIB at 232 n.32, but Mr. Diab's description of the metal layers in his simulation matches his description of the structure of the early rainbow® sensors, and this is confirmed in the underlying documents. *Compare* Tr. (Diab) at 201:2-20 *to id.* at 216:15-218:21; CX-0342C at 6; CX-0588C. Apple argues that the rainbow® sensors have more LEDs than in Mr. Diab's simulations, but Mr. Diab explained that the amount of [redacted] was designed to account for up to 16 LEDs. RX-1200C (Diab Dep. Tr.) at 110:7-112:1. Mr. Diab further described testing on the early rainbow® sensors where he verified that the wavelength of the LEDs could be accurately determined with an equation using the measured

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temperature, confirming that the actual products work in accordance with his simulations. Tr. (Diab) at 203:7-204:11. Apple has offered no independent testing to refute Mr. Diab's testimony regarding the thermal mass in the early rainbow® sensors. *See* CRB at 156. Accordingly, the undersigned finds that Complainants have shown by a preponderance of the evidence that this limitation is met by the early rainbow® sensors.

The evidence from Mr. Diab's simulations is not applicable to the current rainbow® sensors, however. Mr. Goldberg and Mr. Diab described different structures for the alleged "thermal mass" in the current rainbow® sensors, which have a [redacted]. Tr. (Goldberg) at 627:3-13; Tr. (Diab) at 220:25-222:1. The [redacted] of the current rainbow® sensors is supplied by a [redacted] *Id.* at 221:19-222:1; CX-0598C. Mr. Diab could not find any analysis of temperature stabilization for the [redacted]. Tr. (Diab) at 240:4-11. To show the presence of a "thermal mass," Complainants merely rely on the undisputed fact that the substrate is composed of interconnected metal layers, *see* Tr. (Goldberg) at 627:23-628:13, and Mr. Diab's testimony that the current rainbow® sensors are tested to verify the accuracy of the calculation of wavelengths for the LEDs. *See* Tr. (Diab) at 246:7-19. As discussed above in the context of infringement, this is insufficient to prove that this limitation is met. Accordingly, Complainants have failed to show by a preponderance of the evidence that the current rainbow® sensors have a "thermal mass."

4. Element [7B]: "a plurality of light emitting sources, including a substrate of the plurality of light emitting sources, thermally coupled to the thermal mass"

There is no dispute that the early and current rainbow® sensors meet the "plurality of light emitting sources" limitation. *See* CIB at 269-70. Mr. Diab testified that all of Masimo's rainbow® sensors have more than two LEDs. Tr. (Diab) at 211:17-23. He described the

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placement of the LEDs in the early rainbow® sensors, *id.* at 216:15-217:8 (citing CX-0397C), and the current rainbow® sensors. *Id.* at 220:4-24 (citing CX-0454C). Mr. Goldberg identified Masimo documents showing the LEDs attached to the substrate of the rainbow® sensors using "thermally and electrically conductive epoxy." Tr. (Goldberg) at 629:19-630:12; CDX-0013C.025 (citing CX-0454C); CDX-0013C.026 (citing CX-0397C). Accordingly, the evidence shows that the "plurality of light emitting sources" limitation is met by each of the rainbow® sensors, except to the extent that the current rainbow® sensors have not been shown to have a "thermal mass."

5. Element [7C]: "the sources having a corresponding plurality of operating wavelengths"

There is no dispute that the early and current rainbow® sensors meet the "plurality of operating wavelengths" limitation. *See* CIB at 271. Mr. Goldberg cites Masimo schematics showing the multiple wavelengths of light for the LEDs in the rainbow® sensors. Tr. (Goldberg) at 630:13-24; CDX-0013C.027 (citing CX-0454C); CDX-0013C.028 (citing CX-0397C). Accordingly, the evidence shows that the "plurality of operating wavelengths" limitation is met by each of the rainbow® sensors.

6. Element [7D]: "the thermal mass disposed within the substrate"

There is no dispute that the early and current rainbow® sensors meet the "disposed within the substrate" limitation. *See* CIB at 271. Mr. Goldberg identified the [redacted] between the top and bottom of the substrate in the current rainbow® sensors. Tr. (Goldberg) at 630:25-31:6; CDX-0013C.029 (citing CX-0590C). He identified the [redacted] between the top and bottom of the substrate in the early rainbow® sensors. Tr. (Goldberg) at 631:9-16; CDX-0013C.030 (citing CX-0588C). Accordingly, the evidence shows that the "thermal mass disposed within the substrate" limitation is met by the early rainbow® sensors,

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and the [redacted] of the current rainbow® sensors are also "disposed within a substrate," although they have not been shown to be a "thermal mass."

7. Element [7E]: "a temperature sensor thermally coupled to the thermal mass"

There is no dispute that the early and current rainbow® sensors have "a temperature sensor thermally coupled to the thermal mass." *See* CIB at 271. Mr. Goldberg identified a thermistor on the substrate in the current rainbow® sensors and the early rainbow® sensors. Tr. (Goldberg) at 631:17-632:16; CDX-0013C.031 (citing CX-0454C); CDX-0013C.032 (citing CX-0397C). Accordingly, the evidence shows that the "thermally coupled" limitation is met by each of the rainbow® sensors, except to the extent that the current rainbow® sensors have not been shown to have a "thermal mass."

8. Element [7F]: the temperature sensor "capable of determining a bulk temperature for the thermal mass, the operating wavelengths dependent on the bulk temperature"

With respect to the "bulk temperature" limitation, Complainants identify the temperature measured by the thermistor in the rainbow® sensors. CIB at 271-73. Mr. Goldberg identifies Masimo documentation showing that the output from the thermistor in the rainbow® sensors is used "so that adjustments can be made to account for the temperature." Tr. (Goldberg) at 632:17-633:12; CDX-0013C.033 (citing CX-0430C). He further relies on Masimo source code that shows a calculation of wavelengths for the LEDs using the thermistor temperature. Tr. (Goldberg) at 633:13-24; CDX-0013C.034 (citing CPX-0152C; CPX-0151C). His analysis is the same for the early rainbow® sensors and the current rainbow® sensors. Tr. (Goldberg) at 633:25-634:2. Mr. Diab explained that in the development of the early rainbow® sensors, Masimo engineers developed an equation for predicting the wavelength of LEDs using a temperature measurement from a thermistor. Tr. (Diab) at 198:12-200:13. They were able to

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confirm that the equation correctly estimated the wavelengths using a spectrometer. *Id.* at 203:7-204:1. Mr. Diab explained that he wrote "[t]he original code for all of the rainbow [sensors] including the wavelength correction," and the code on the current rainbow® sensors is a "modified version." Tr. (Diab) at 212:21-213:6.

Apple argues that Complainants have not shown that the rainbow® sensors are capable of determining a "bulk temperature," because Mr. Goldberg did not perform any testing on the thermistor or the "thermal mass" in these products. RIB at 229-30; RRB at 135-36. Dr. Sarrafzadeh offered his opinion that the thermistor in the rainbow® sensors measures a "local temperature" and not a "bulk temperature." Tr. (Sarrafzadeh) at 1086:11-21. Apple further argues that Mr. Goldberg's testimony regarding the determination of operating wavelengths was conclusory. RRB at 136.

In consideration of the parties' arguments, the undersigned finds that Complainants have shown by a preponderance of the evidence that the thermistors in the early rainbow® sensors are capable of measuring a "bulk temperature" that is a representative temperature for the "thermal mass" in the substrate of these products. As discussed above in the context of the "thermal mass" limitation, Mr. Diab described "hundreds of experiments" in simulations for the design of the early rainbow® sensors. Tr. (Diab) at 199:17-200:13 (citing CX-0342C). In those simulations, he observed that [redacted] *Id.* at 201:19-203:6. Mr. Diab also described testing on the early rainbow® sensors where he verified that the wavelength of the LEDs could be accurately determined with an equation using the measured temperature. Tr. (Diab) at 203:7-204:11.

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Apple's arguments primarily rely on Complainants' alleged failure of proof for this limitation—the only affirmative evidence that Apple cites is Dr. Sarrafzadeh's opinion that the thermistor measures a "local temperature" rather than a "bulk temperature." Tr. (Sarrafzadeh) at 1086:11-21. As discussed above in the context of infringement, however, Apple concedes that "a 'bulk temperature' could be measured by a properly positioned single thermistor if the thermal mass were stabilized at the bulk temperature," RRB at 122, and the "bulk temperature" embodiment in the specification is based on a single thermistor. *See* JX-007 at 10:62-11:4, Fig. 16. Mr. Diab testified that Masimo's design of the early rainbow® sensors was based on the use of a single thermistor after recognizing that it would be difficult [redacted] Tr. (Diab) at 198:12-199:16. Mr. Diab's testimony further confirms that the bulk temperature from the thermistor in the early rainbow® sensors was used to determine the operating wavelengths of LEDs. *See* Tr. (Diab) at 203:7-204:11. Accordingly, a preponderance of the evidence shows that the early rainbow® sensors meet the limitation requiring a temperature sensor to determine a "bulk temperature" for the thermal mass, and the wavelengths of the LEDs are dependent on the bulk temperature.

As discussed above in the context of the "thermal mass" limitation, however, Complainants have not shown that the current rainbow® sensors have a "thermal mass" that stabilizes a "bulk temperature." Complainants did not present any analysis of temperature stabilization on the [redacted] of the current rainbow® sensors, and accordingly, Complainants have not shown, by a preponderance of the evidence, that the current rainbow® sensors meet the "bulk temperature" limitation.

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9. Element [7G]: "a detector capable of detecting light emitted by the light emitting sources after tissue attenuation"

There is no dispute that the early and current rainbow® sensors have "a detector capable of detecting light emitted by the light emitting sources after tissue attenuation." *See* CIB at 273-74. Mr. Goldberg identified detectors in the rainbow® sensors that detect "modulated LED light, which passes through the tissue." Tr. (Goldberg) at 634:3-635:11; CDX-0013C.035 (citing CX-0440C); CDX-0013C.03 (citing CX-0430C at 2, 5). Accordingly, the evidence shows that the "detector" limitation is met by each of the rainbow® sensors.

10. Element [7H]: "wherein the detector is capable of outputting a signal usable to determine one or more physiological parameters of a patient based upon the operating wavelengths"

There is no dispute that the detector in the rainbow® sensors outputs a signal that is used to determine physiological parameters. *See* CIB at 273-74. Complainants identify a Masimo specification describing the signal from the detectors, stating that "[t]he OEM Board uses this signal to compute patient measurement values." CX-0430C at 5; *see* Tr. (Goldberg) at 634:22-635:11; CDX-0013C.03 (citing CX-0430C at 2, 5). Accordingly, the evidence shows that the "signal usable to determine one or more physiological parameters" limitation is met by each of the rainbow® sensors.

11. Element [9]: "a thermistor"

Claim 9 further requires that the "temperature sensor" of claim 1 is a thermistor. As discussed above in the context of the "temperature sensor" limitation, and there is no dispute that the temperature sensor in the rainbow® sensors is a thermistor. Tr. (Goldberg) at 631:17-632:16; CDX-0013C.031 (citing CX-0454C); CDX-0013C.032 (citing CX-0397C). Accordingly, the evidence shows that the "thermistor" limitation of claim 9 is met by each of the rainbow® sensors.

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Accordingly, because each limitation of claims 1 and 9 is met, the undersigned finds that Complainants have shown by a preponderance of the evidence that the early rainbow® sensors practice claim 9 of the '127 patent. For the reasons discussed above in the context of the "thermal mass" and "bulk temperature" limitations, Complainants have not shown by a preponderance of the evidence that the current rainbow® sensors practice claim 9 of the '127 patent.

G. Invalidity

Apple contends that claim 9 of the '127 patent is obvious in view of several prior art references. RIB at 233-45; RRB at 136-50. Apple's contentions primarily rely on two references: an article published in 1991 by Yitzhak Mendelson (RX-0458, "Mendelson"); and a Japanese patent application published in 2004 naming inventor Yukio Yamada (RX-0381, "Yamada"). Apple relies on the testimony of Dr. Sarrafzadeh to support its invalidity contentions. Tr. (Sarrafzadeh) at 1046:14-1064:7.

1. Mendelson

Apple contends that claim 9 of the '127 patent is obvious in view of an article entitled "Invasive and Noninvasive Blood Gas Monitoring" authored by Yitzhak Mendelson and published in *Bioinstrumentation and Biosensors* in 1991 (RX-0458 "Mendelson"), in combination with the textbook *Design of Pulse Oximeters* by J.G. Webster, published in 1997 (RX-0035, "Webster"). RIB at 233-39; RRB at 140-46. Mendelson and Webster are both prior art to the '127 patent pursuant to 35 U.S.C. § 102(b).[109]

[109] The pre-AIA version of 35 U.S.C. § 102 is applicable to the '127 patent. *See* America Invents Act, 35 USCA § 100 Note, § 3(n)(1), 125 Stat. 284 (Sept. 16, 2011)

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Complainants argue that Apple has not shown claim 9 to be obvious in view of Mendelson and Webster because Mendelson does not disclose the claimed "thermal mass," "thermal mass disposed within the substrate," or a "temperature sensor." CIB at 277-78; CRB at 161-62. Complainants further argue that the combination of Mendelson and Webster fails to meet the "thermal mass" limitations and the limitations requiring a temperature sensor "thermally coupled to the thermal mass and capable of determining a bulk temperature for the thermal mass." CIB at 279-80; CRB at 162-64. Complainants argue that Webster's disclosures are cumulative of U.S. Patent No. 5,259,381 to Cheung (RX-0406, "Cheung"), a prior art patent that was considered during the prosecution of the '127 patent. CIB at 275-76.

a. Element [7 preamble]: "physiological sensor"

There is no dispute that Mendelson meets the limitations of the preamble of claim 7, describing "[a] physiological sensor capable of emitting light into tissue and producing an output signal usable to determine one or more physiological parameters of a patient." *See* CIB at 277-80; CRB at 161-64. Dr. Sarrafzadeh identified a "noninvasive reflection SaO_2 sensor" disclosed in Mendelson. Tr. (Sarrafzadeh) at 1049:9-13; RX-0458 at 266-71, Fig. 10.16. He described the operation of a pulse oximeter as depicted in Mendelson, where LEDs emit light to the tissue, "and there are a collection of photodiodes that collect the light after it has been through the tissue, and they make a determination of physiological parameters based on the optical light received by the photodiodes." Tr. (Sarrafzadeh) at 1049:14-23.

b. Element [7A]: "a thermal mass"

Apple identifies the ceramic substrate depicted in Mendelsohn as the claimed "thermal mass." RIB at 234-35. Dr. Sarrafzadeh offers his opinion that the circuit board in Mendelsohn would provide thermal connectivity and that one of ordinary skill in the art would have known to

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add a "metal core or thermal core" to provide "thermal management." Tr. (Sarrafzadeh) at 1049:24-1051:12. He references a textbook, *The Multilayer Printed Circuit Board Handbook* by J.A. Scarlett, which describes thermal cores that can be manufactured within substrates for heat conduction. RX-0397.0122 (recognizing that "the popular epoxy fiberglass substrates are notably poor heat conductors and therefore cannot provide a sufficient heat extraction," and describing "an integral heat conductor, i.e., a metal core, within the structure, to alleviate this problem"). Apple also compares Mendelsohn's disclosure of a printed circuit board with Complainants' contentions that the metal layers in the printed circuit boards of the Accused Products and the rainbow® sensors meet the "thermal mass" limitation, arguing that Mendelsohn would meet this limitation for the same reasons. CIB at 234-35; *see* Tr. (Sarrafzadeh) at 1050:25-1051:12.

Complainants argue that Mendelsohn does not disclose a "thermal mass" because there is no disclosure of thermal properties or any description of thermal coupling. CIB at 277-78. Complainants submit that Dr. Sarrafzadeh failed to provide any testing or simulations of the ceramic substrate in Mendelsohn. *Id.* at 278. Complainants argue that Apple mischaracterizes Mr. Goldberg's infringement and domestic industry analysis, which does not rely on an assumption that every multilayer circuit board contains a "thermal mass"—Complainants submit that Mr. Goldberg relied on evidence of the thermal coupling of components and the fact that the temperature of the board could be used to reliably estimate the operating wavelengths of the LEDs. *Id.* at 277-78. Complainants further argue that Apple should be precluded from relying on Scarlett as an obviousness ground, because it was not identified in Apple's invalidity contentions. *Id.* at 283-84. Even if Scarlett's disclosures were considered, Complainants submit that Apple failed to identify any reason to add a thermal core to Mendelsohn. CRB at 161.

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Dr. Goldberg testified that the problem of heat removal addressed in Scarlett is different from the use of a "thermal mass" to facilitate a bulk temperature measurement. Tr. (Goldberg) at 1398:9-1399:8.

In consideration of the parties' arguments, the undersigned finds that Apple has not shown, by clear and convincing evidence, that Mendelsohn discloses a "thermal mass." The pulse oximeter depicted in Mendelsohn has a "ceramic substrate," but there is no description of the thermal characteristics of this substrate or any components thereon. *See* RX-0458 at 269-71. Dr. Sarrafzadeh's analysis of this element also contains no description of the thermal characteristics of Mendelsohn's substrate. *See* Tr. (Sarrafzadeh) at 1049:24-1052:2. Moreover, it is not clear that the addition of a metal core designed for heat removal in Scarlett would stabilize a bulk temperature, as required for the "thermal mass" limitation—neither Scarlett nor Mendelsohn describe such stabilization. *See* Tr. (Goldberg) at 1398:9-1399:8.

Apple has also failed to identify any clear reason for one of ordinary skill in the art to modify Mendelsohn to add a "thermal mass," merely relying on Dr. Sarrafzadeh's testimony that thermal cores were "known for many years," pointing to a description of a thermal core in Scarlett.[110] *Id.* (citing RX-0397 at 122). Dr. Sarrafzadeh suggests that adding a thermal core to Mendelsohn would provide "for better management," relying on disclosures in Scarlett. Tr. (Sarrafzadeh) at 1051:1-12. In particular, Scarlett describes the problem of "heat removal from tightly packaged components" on "epoxy fiberglass substrates," which can be addressed "[w]ith

[110] Complainants argue that Apple should be precluded from relying on Scarlett because no such combination was identified in Apple's invalidity contentions. CIB at 283-84. This argument was previously rejected in the context of Complainants' motion *in limine* no. 2, however, where Apple was allowed to present evidence relying on Scarlett and other prior art references in accordance with the arguments in its prehearing brief. *See* Order No. 40 at 2 (Jun. 1, 2022). Accordingly, Apple will not be precluded from relying on Scarlett in the context of its obviousness arguments.

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an integral heat conductor, i.e., a metal core." RX-0397 at 122. It is not clear that "heat removal" is the same as temperature stabilization, however, and it is not clear that one of ordinary skill in the art would have been motivated to add a metal core to Mendelsohn for the purpose of temperature stabilization or heat removal. Dr. Sarrafzadeh's testimony that a metal core would be added for "better management" is the type of conclusory opinion that has been found to be insufficient to establish a motivation to combine. *See ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1328 (Fed. Cir. 2012) (where expert testified that a motivation to combine would have been "to build something better," the court found that "[t]his testimony is generic and . . . fails to explain why a person of ordinary skill in the art would have combined elements from specific references in the way the claimed invention does").

Accordingly, Apple has failed to show by clear and convincing evidence that one of ordinary skill in the art would have modified the device in Mendelsohn to add a "thermal mass."

c. Element [7B]: "a plurality of light emitting sources, including a substrate of the plurality of light emitting sources, thermally coupled to the thermal mass"

There is no dispute that Mendelsohn discloses a device with a plurality of LEDs thermally coupled to a circuit board. *See* RIB at 235; CIB at 277-79. Dr. Sarrafzadeh identified red and infrared LEDs shown on a circuit board in Mendelsohn. Tr. (Sarrafzadeh) at 1052:3-8; RDX-7.20.

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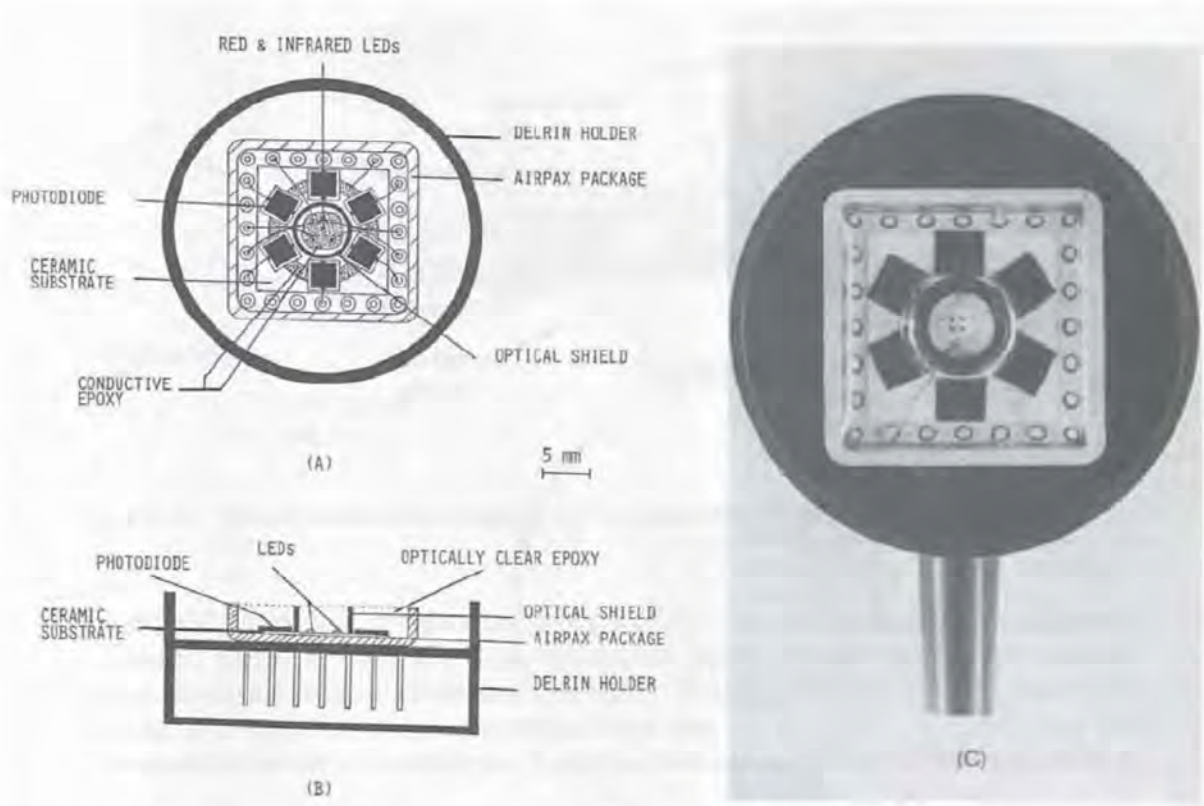


Fig. 10.16 Noninvasive reflection SaO_2 sensor.

RX-0458.0024 at Fig. 10.16; *see also* RX-0458.0022 ("The basic optical sensor of a noninvasive pulse oximeter consists of a light source (typically, a pair of red and infrared LEDs) and a photodetector mounted inside a spring-loaded clip."). Dr. Sarrafzadeh explained that "[b]ecause of electrical connection, we know that the LEDs are connected by wires to the printed circuit board, and that's the thermal connection." Tr. (Sarrafzadeh) at 1052:9-13.

d. Element [7C]: "the sources having a corresponding plurality of operating wavelengths"

There is no dispute that the LEDs in Mendelsohn have two different wavelengths. *See* RIB at 236; CIB at 277-79. Dr. Sarrafzadeh explains that Mendelsohn describes "red and infrared LEDs." Tr. (Sarrafzadeh) at 1052:18-22; RDX-7.21; RX-0458.0024 at Fig. 10.16; *see also* RX-0458.0022 (describing "a pair of red and infrared LEDs").

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e. Element [7D]: "the thermal mass disposed within the substrate"

Apple argues that the "thermal mass disposed within the substrate" limitation is obvious in view of Mendelsohn for the same reasons that as the "thermal mass" limitation. *See* RIB at 236; Tr. (Sarrafzadeh) at 1053:1-7. For the reasons discussed above in the context of the "thermal mass" limitation, the undersigned finds that Apple has not shown that "the thermal mass disposed within the substrate" is disclosed in Mendelsohn or that one of ordinary skill in the art would have modified the device in Mendelsohn to add a "thermal mass."

f. Element [7E]: "a temperature sensor thermally coupled to the thermal mass"

Mendelsohn does not disclose a temperature sensor in its pulse oximetry device, but Apple argues that it would have been obvious to incorporate a temperature sensor in this device based on disclosures in Webster. RIB at 236-37. Dr. Sarrafzadeh identifies Webster's disclosure of a temperature sensor as a way to compensate for LED temperature changes that can affect pulse oximetry measurements. Tr. (Sarrafzadeh) at 1053:8-22; RDX-7.23. Webster explicitly states: "One way to compensate for LED temperature changes is to have a temperature sensor built into the probe along with the LEDs and photodiode." RX-0035.085. Dr. Sarrafzadeh explains that such a temperature sensor would have been electrically connected and thus thermally coupled to the LEDs and the circuit board of the device in Mendelsohn. Tr. (Sarrafzadeh) at 1053:8-22. Complainants dispute the alleged obviousness of a "temperature sensor" as disclosed in Webster, but their arguments appear to be directed to the "thermal mass" limitation and the "bulk temperature" limitation. CIB at 280; CRB at 162. There does not appear to be any dispute that Webster explicitly discloses a reason for incorporating a

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temperature sensor in a pulse oximeter and that one of ordinary skill in the art would have expected success in doing so.

g. Element [7F]: the temperature sensor "capable of determining a bulk temperature for the thermal mass, the operating wavelengths dependent on the bulk temperature"

With respect to the "bulk temperature" limitation, Apple cites Webster's recognition that "a shift in LED peak wavelength due to a change in temperature can cause erroneous SpO2 readings." RX-0035.085. Webster provides a solution to this problem: "One way to compensate for LED temperature changes is to have a temperature sensor built into the probe along with the LEDs and photodiode." *Id.* Webster further explains that "[t]emperature information is fed back to the microprocessor, which then estimates how much the peak wavelength of each LED has changed from its rated value." *Id.* Although Webster only describes one temperature sensor, Dr. Sarrafzadeh suggests that "one of ordinary skill in the art would know that . . . in order to get the bulk temperature in multiple locations, you would just add multiple temperature sensors of Webster." Tr. (Sarrafzadeh) at 1053:23-1054:11. He further testifies that the relationship between wavelength and temperature described in Webster is "a fact of physics that has been known for many years." *Id.* at 1054:20-1055:3. Apple argues that the single temperature sensor in Webster is similar to the single temperature sensor in the Accused Products, and if these products measure a "bulk temperature" then this limitation should also be met by Webster. RIB at 237; *see* Tr. (Sarrafzadeh) at 1054:14-19.

Complainants argue that Webster's disclosure of a temperature sensor relies on Cheung (RX-0406), which was considered during the prosecution of the '127 patent. CIB at 280, 275-76. Complainants further argue that Mendelson does not disclose a thermal mass, and that Apple does not rely on Webster as disclosing a thermal mass. *Id.* at 279-80.

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In consideration of the parties' arguments, the undersigned finds that Apple has not shown, by clear and convincing evidence, that Webster discloses a temperature sensor capable of determining a "bulk temperature for the thermal mass." Webster does not describe a "thermal mass"—the temperature sensor is "built into the probe" and it is designed to estimate the temperature of the LEDs—not a "bulk temperature for the thermal mass." RX-0035.085.[111] Dr. Sarrafzadeh suggests that one of ordinary skill in the art would have added multiple sensors to obtain an average temperature, Tr. (Sarrafzadeh) at 1054:23-1054:7, but this opinion is not grounded in any prior art disclosure.[112] There is no clear disclosure of a measurement of a "bulk temperature for the thermal mass" in Webster.

h. Element [7G]: "a detector capable of detecting light emitted by the light emitting sources after tissue attenuation"

There is no dispute that Mendelsohn discloses photodiodes that are capable of detecting light from its LEDs after being attenuating by the user's tissue. *See* RIB at 238; CIB at 277-79. These photodiodes are depicted on Figure 10.16 in Mendelsohn. RX-0458.0024; *see* Tr. (Sarrafzadeh) at 1055:4-8.

i. Element [7H]: "wherein the detector is capable of outputting a signal usable to determine one or more physiological parameters of a patient based upon the operating wavelengths"

With respect to the "outputting a signal" limitation, Dr. Sarrafzadeh identified a block diagram (Fig. 10.12) in Mendelsohn depicting an ear oximeter that includes a processor and an output to a digital display. Tr. (Sarrafzadeh) at 1055:11-18; RX-0458.021. Complainants do not

[111] Webster notes the potential "difference between the sensed temperature and the actual temperature of the *p-n* junctions of the LEDs." RX-0035.085.

[112] Webster teaches away from the addition of multiple sensors or other components: "In addition, the sensor and additional wires needed will add cost to the probes, making a cost-benefit analysis of this method necessary before its inclusion in a pulse oximeter design." RX-0035.086.

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dispute that Mendelsohn discloses a detector meeting this limitation but argues that Dr. Sarrafzadeh incorrectly identified Mendelsohn's ear oximeter as a pulse oximeter. CIB at 278-79; CRB at 164.

j. Element [9]: "a thermistor"

Claim 9 further requires that the "temperature sensor" of claim 1 is a thermistor. Complainants argue that a thermistor is not disclosed in Mendelsohn or in Webster. CIB at 278, 280. Apple relies on Dr. Sarrafzadeh's testimony that thermistors "have been known for many years as a resistive circuit." Tr. (Sarrafzadeh) at 1055:19-1056:1. Apple cites a 2003 technical dictionary describing a "thermistor," RX-0419, and a thermistor in a pulse oximeter disclosed in Yamada. RX-0381 at ¶ [0111]. As discussed below, Yamada's disclosure shows that thermistors were known in the prior art and could be used in pulse oximeters.

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As discussed above, Apple has not shown by clear and convincing evidence that claim 9 of the '127 patent is obvious in view of Mendelsohn in combination with Webster, because these references fail to disclose a "thermal mass" or the measurement of a "bulk temperature for the thermal mass," and Apple has not shown that it would have been obvious for one of ordinary skill in the art to add these elements.

2. Yamada

Apple contends that claim 9 of the '127 patent is obvious in view of Japanese Patent Application Publication No. 2004-337605A, entitled "Light Probe, Measuring System Using the Same, and Reflected Light Detecting Method Using the Same," naming inventor Yukio Yamada (RX-0381, "Yamada"), in combination with U.S. Patent No. 5,334,916, entitled "Apparatus and Method for LED Mission Spectrum Control, naming inventor Masahiro Noguchi (RX-0353,

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"Noguchi"). RIB at 239-43; RRB at 146-48. Yamada was published on December 2, 2004, and Noguchi issued on August 2, 1994. RX-0381; RX-0353. Yamada and Noguchi are prior art to the '127 patent pursuant to 35 U.S.C. § 102(b).[113]

Complainants argue that Apple has not shown claim 9 to be obvious in view of Yamada and Noguchi because these references fail to disclose the claimed "thermal mass" and the limitations requiring a temperature sensor "thermally coupled to the thermal mass and capable of determining a bulk temperature for the thermal mass." CIB at 280-83; CRB at 164-67.

a. Element [7 preamble]: "physiological sensor"

There is no dispute that Yamada meets the limitations of the preamble of claim 7 by describing a pulse oximeter, which is "[a] physiological sensor capable of emitting light into tissue and producing an output signal usable to determine one or more physiological parameters of a patient." *See* RIB at 239; CIB at 280-82; Tr. (Sarrafzadeh) at 1058:2-7; RDX-7.33C; RX-0381 at ¶ 0041, Fig. 1, Fig. 5.

b. Element [7A]: "a thermal mass"

With respect to the "thermal mass" limitation, Dr. Sarrafzadeh identifies Yamada's disclosure of LEDs and photodetectors mounted on a printed circuit board with electrical connections, wherein "the wires provide thermal connectivity." Tr. (Sarrafzadeh) at 1058:8-19. Dr. Sarrafzadeh testified that a person of ordinary skill in the art "would know that you can readily implement this in a multilayer fashion, also add thermal cores in order to provide better thermal management in the circuit." *Id.* Apple argues that Complainants have accused a similar multilayer printed circuit board of meeting this limitation in the context of infringement. RIB at 239-40; RRB at 146-47.

[113] *See supra* n.109.

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Complainants argue that Yamada does not disclose a "thermal mass" because there is no description of the structure or thermal properties of Yamada's substrate. CIB at 281. Complainants submit that Dr. Sarrafzadeh's testimony is insufficient to show that Yamada's circuit board is a "thermal mass." *Id.* Mr. Goldberg testified that Yamada does not disclose a thermal mass "which stabilizes and normalizes in a manner that allows the bulk temperature as measured by the temperature sensor." Tr. (Goldberg) at 1396:22-1397:8. Complainants note that Yamada discloses a "thermal conductor" that "is able to adequately disperse heat from" Yamada's LED to the exterior. RX-0381 at ¶¶ 101-102. Complainants argue that this heat dispersal is different from the use of a thermal mass to stabilize a bulk temperature for measurement. CRB at 165-166; *see* Tr. (Goldberg) at 1398:9-1399:8.

In consideration of the parties' arguments, the undersigned finds that Apple has not shown, by clear and convincing evidence, that Yamada discloses a "thermal mass." For the same reasons discussed above in the context of Mendelsohn, Apple has failed to show that the circuit board in Yamada is a "thermal mass" and has failed to show that one of ordinary skill in the art would have modified Yamada to incorporate a "thermal mass." In particular, Apple has failed to identify any disclosure in Yamada that describes the stabilization of temperatures on its circuit board, and Dr. Sarrafzadeh's testimony with respect to modifying Yamada was conclusory and unsupported by disclosures in the prior art. Apple failed to identify any clear evidence that one of ordinary skill in the art would have modified Yamada to provide temperature stabilization—Yamada discloses a "thermal conductor" that "is able to adequately disperse heat," RX-0381 at ¶¶ 101-102, without any discussion of temperature stabilization and no identified need for additional thermal management.

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c. Element [7B]: "a plurality of light emitting sources, including a substrate of the plurality of light emitting sources, thermally coupled to the thermal mass"

There is no dispute that Yamada discloses a plurality of LEDs mounted on a substrate. *See* RIB at 240-41; CIB at 280-82. Dr. Sarrafzadeh identified two LEDs electrically and thermally connected to the circuit board in Yamada. Tr. (Sarrafzadeh) at 1058:20-1059:6; RDX-7.35C; RX-0381 at ¶ [0043], Fig. 5.

d. Element [7C]: "the sources having a corresponding plurality of operating wavelengths"

There is no dispute that the LEDs in Yamada have two different wavelengths. *See* RIB at 241; CIB at 280-82. Dr. Sarrafzadeh identifies disclosures in Yamada describing wavelengths of red light and infrared light. Tr. (Sarrafzadeh) at 1059:10-16; RDX-7.36C; RX-0381 at ¶ [0043] ("The light a first wavelength may be, for example, red light with a wavelength near 660 [nm]. . . The light of a second wavelength may be, for example, near infrared light with a wavelength near 880 [nm].").

e. Element [7D]: "the thermal mass disposed within the substrate"

Apple argues that the "thermal mass disposed within the substrate" limitation is obvious in view of Yamada for the same reasons that as the "thermal mass" limitation. *See* RIB at 241; Tr. (Sarrafzadeh) at 1059:18-25. For the reasons discussed above in the context of the "thermal mass" limitation, the undersigned finds that Apple has not shown that "the thermal mass disposed within the substrate" is disclosed in Yamada or that one of ordinary skill in the art would have modified Yamada to add a "thermal mass."

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f. Element [7E]: "a temperature sensor thermally coupled to the thermal mass"

With respect to the "temperature sensor" limitation, Apple points to Yamada's disclosure that "a temperature sensor maybe be attached to the light probe . . . to the surface of the substrate." RX-0381 at ¶ [0109]. Dr. Sarrafzadeh explains that this temperature sensor would be electrically attached and thus thermally coupled to the alleged "thermal mass." Tr. (Sarrafzadeh) at 1060:1-7; RDX-7.38C. Complainants dispute Yamada's disclosure of a "temperature sensor," but their arguments appear to be directed to the "thermal mass" limitation and the "bulk temperature" limitation. CIB at 281-82; CRB at 165. There does not appear to any dispute that Yamada explicitly discloses that a temperature sensor may be attached to the substrate.

g. Element [7F]: the temperature sensor "capable of determining a bulk temperature for the thermal mass, the operating wavelengths dependent on the bulk temperature"

With respect to the "bulk temperature" limitation, Apple cites Yamada's disclosure of a temperature sensor attached to the light probe on the surface of the LED substrate. RIB at 241; Tr. (Sarrafzadeh) at 1060:8-17. Apple argues that Yamada's temperature sensor meets the "bulk temperature" limitation under the same theory that Complainants have asserted for infringement of this limitation. CIB at 242. Dr. Sarrafzadeh explains that the relationship between the temperature of an LED and its wavelength is a property of physics that would have been known to persons of ordinary skill in the art, and an equation defining this relationship is explicitly described in Noguchi. Tr. (Sarrafzadeh) at 1060:25-1061:9; RDX-7.40C; RX-0353 at 2:59-68. Noguchi describes "a temperature measurement means for measuring the temperature of an LED or for measuring the temperature in the environment in which the LED is disposed," adding that "[a] plurality of LEDs and a plurality of temperature measurement means can be utilized in the present invention." RX-0353 at 1:38-50. Dr. Sarrafzadeh testified that one of ordinary skill in

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the art would have known from the teaching in Noguchi that a temperature measurement could be used to provide better wavelength estimation for the pulse oximeter in Yamada. Tr. (Sarrafzadeh) at 1061:10-1062:8. He explains that using Noguchi's wavelength estimation would have improved the functioning of Yamada's pulse oximeter and that this functionality would have been "easily added" by one of ordinary skill in the art. *Id.*

Complainants argue that the temperature sensor in Yamada does not measure a "bulk temperature." CIB at 281-82. Mr. Goldberg testified that Yamada's temperature sensor is only configured to detect "when the temperature gets too high for safety reasons," and not to measure a bulk temperature that "can be used for reliably estimating LED operating wavelengths." Tr. (Goldberg) at 1396:22-1397:8 (citing RX-0381 at ¶ [111]). Complainants note that Yamada discloses a "thermal conductor" for heat dispersal rather than to stabilize a bulk temperature for measurement. CRB at 165-166 (citing RX-0381 at ¶¶ 101-102); *see* Tr. (Goldberg) at 1398:9-1399:8. Complainants argue that Noguchi does not measure a "bulk temperature" for estimating wavelengths for multiple LEDs but merely discloses measuring the temperature of an LED to measure the wavelength for that LED. CIB at 283; CRB at 166-67; Tr. (Goldberg) at 1397:9-21. Complainants argue that Apple has failed to show a motivation to combine Yamada and Noguchi with an expectation of success. CRB at 167.

In consideration of the parties' arguments, the undersigned finds that Apple has not shown, by clear and convincing evidence, that Yamada in combination with Noguchi discloses a temperature sensor capable of determining a "bulk temperature for the thermal mass." Yamada does not disclose a measurement of temperature for a "thermal mass"—the temperature sensor is placed "to measure the temperature near the user" to "take action when the temperature gets too high, for example by sounding an alarm or halting light emission from the light-emitting

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component." RX-0381 at ¶¶ 0901-0111. Noguchi similarly fails to disclose a measurement of temperature for a "thermal mass"—similar to Webster's disclosures discussed above, Noguchi describes the relationship between an LED's temperature and its operating wavelength, *see* RX-0353 at 1:38-50, 2:58-60, but Noguchi fails to disclose the measurement of a "bulk temperature for the thermal mass." Noguchi does not describe the use of a single representative temperature for a "thermal mass" but instead suggests direct temperature measurements of individual LEDs, describing "[a] plurality of LEDs and a plurality of temperature means." RX-0353 at 1:48-50. Dr. Sarrafzadeh's suggestion to average the readings from multiple temperature sensors to generate a "bulk temperature" is conclusory and is not supported by disclosures in the prior art. *See* Tr. (Sarrafzadeh) at 1060:8-16. Apple has not shown that any measurement of a "bulk temperature" is disclosed in Yamada or Noguchi, or that such a measurement would have been known to persons of ordinary skill in the art.

h. Element [7G]: "a detector capable of detecting light emitted by the light emitting sources after tissue attenuation"

There is no dispute that Yamada discloses a detector that receives light from the LEDs after tissue attenuation. *See* RIB at 243; CIB at 280-82. Yamada explicitly discloses that "[a] portion of the light that traversed body tissue is received by the light-receiving component 12." RX-0381 at ¶ 0062; *see* Tr. (Sarrafzadeh) at 1062:9-14.

i. Element [7H]: "wherein the detector is capable of outputting a signal usable to determine one or more physiological parameters of a patient based upon the operating wavelengths"

There is no dispute that the detector in Yamada is used to determine blood oxygen saturation based on the ratio of the fluctuation ranges of red and infrared light. *See* RIB at 243; CIB at 280-82. Yamada explicitly discloses that "a strength signal for the light is sent to the analysis component 2 in the form of an electrical signal," and "analysis component 2 determines

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the range of fluctuation in the strength signal at each wavelength . . . . The CPU 23 then searches the memory component 25 for the numerical value of the oxygen concentration level corresponding to the ratio of the fluctuation ranges, and outputs the result of the search." RX-0381 at ¶ 0062, 0065; *see* Tr. (Sarrafzadeh) at 1062:15-24.

j. Element [9]: "a thermistor"

Claim 9 further requires that the "temperature sensor" of claim 1 is a thermistor. There is no dispute that Yamada discloses the use of a thermistor as its temperature sensor. *See* RIB at 243; CIB at 280-82. Yamada explicitly provides examples of temperature sensors: "it is possible to use a thermistor, a metal resistance temperature detector, or a thermocouple as the temperature sensor." RX-0381 at ¶ 0111; *see* Tr. (Sarrafzadeh) at 1062:21-25.

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For the reasons discussed above, Apple has not shown by clear and convincing evidence that claim 9 of the '127 patent is obvious in view of Yamada in combination with Noguchi , because these references fail to disclose a "thermal mass" or the measurement of a "bulk temperature for the thermal mass," and Apple has not shown that it would have been obvious for one of ordinary skill in the art to add these elements.

3. Objective Indicia of Non-Obviousness

Complainants identify evidence of commercial success and industry praise for Masimo's rainbow® sensors that support a finding of non-obviousness. CIB at 285-87. Masimo's financial records show that Masimo has earned [redacted] in revenue from the sale of rainbow® sensors practicing claim 9 of the '127 patent, with a growth rate of [redacted] from 2008 through 2014. Tr. (McGavock) at 1426:9-1427:7; CDX-0019C.0012 (citing CX-0649C). Complainants further cite evidence that the rainbow® sensors have won numerous awards,

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including the 2006 Medical Design Excellence Gold Award, the 2007 LoneStar Award for Innovation and Support, and the 2006 American Electronics Association Innovative Medical Technology Award. CX-1378 at 62-68. In connection with a 2006 award from the Society for Technology in Anesthesia, a study of a rainbow® sensor product found that the "technology represents a major advance in the monitoring of oxygenation." *Id.* at 69. Mr. Goldberg testified that the success of the rainbow® sensor products "obviously depended on them functioning to do what they were meant to do, which was to measure a variety of physiological parameters in a manner that hadn't been done before," and the patented features were [redacted] Tr. (Goldberg) at 1400:9-1401:18.[114] Apple argues that Complainants failed to show a nexus between the invention of the '127 patent and the alleged commercial success and industry praise, criticizing Mr. Goldberg's testimony as conclusory. CRB at 149.

In consideration of the parties' arguments, the undersigned finds that the evidence of commercial success and industry praise for the early rainbow® sensor products is consistent with the findings of nonobviousness with respect to claim 9 of the '127 patent, although Complainants' evidence for nexus is weak.[115] There is no explicit praise for the temperature-based wavelength correction in the early rainbow® sensor products, but Complainants did present testimony from Mr. Diab that the [redacted]

[114] Complainants also identify evidence of teaching away, CIB at 287, but this evidence has been considered in the context of the *prima facie* case for obviousness with respect to the "bulk temperature" limitation allegedly disclosed in Webster. *See supra*, n.111, n.112.

[115] These secondary considerations are only relevant with respect to the early rainbow® sensors that have been found to practice claim 9 of the '127 patent. Accordingly, any post-2009 commercial success is not relevant to obviousness.

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[redacted] Tr. (Diab) at 204:2-11. This evidence shows that there may be some nexus between the invention of the '127 patent and the commercial success and industry praise for the early rainbow® sensor products, although inventor testimony is not the type of "objective" evidence that is generally considered by the Federal Circuit. *Cf. Arkie Lures, Inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953, 957 (Fed. Cir. 1997) ("The so-called "secondary considerations" provide evidence of how the patented device is viewed by the interested public: not the inventor, but persons concerned with the product in the objective arena of the marketplace."). Accordingly, the evidence of commercial success and industry praise for the early rainbow® sensor products is not entitled to significant weight, but it is consistent with the findings of nonobviousness above with respect to claim 9 of the '127 patent.

VII. DOMESTIC INDUSTRY – ECONOMIC PRONG (MASIMO WATCH)

With respect to the Poeze patents and the '745 patent, Masimo relies on "Masimo Watch" products to satisfy the domestic industry requirement, including certain prototypes that were developed between 2019 and 2021, and a final product that was manufactured in December 2021. *See* CIB at 26-35, 288-309.

A. The "Masimo Watch" Articles

The earliest "Masimo Watch" prototype identified in this investigation is the "Circle sensor" (CPX-0021C), which "would have been built in October 2019," according to Masimo engineer Stephen Scruggs. Tr. (Scruggs) at 394:12-18. Masimo's next domestic industry product is the "Wings sensor" (CPX-0029C), which "would have been built in January of 2020." *Id.* at 395:7-15. Both the Circle sensor and Wings sensor relied on an external device to calculate oxygen saturation, but in November 2020, Masimo built the "RevA sensor" (CPX-

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0052C), "which included onboard processing." *Id.* at 396:2-13. Then in April 2021, Masimo added a display for the "RevD sensor" (CPX-0058C). *Id.* at 397:7-24. Between May and September 2021, during the time the complaint was filed, Masimo developed the "RevE sensors" (CPX-0019C, CPX-0020C, CPX-0065C), which included certain changes to the emitters and photodiodes of the "RevD sensor." Tr. (Scruggs) at 398:1-23.[116]

B. Disputed Background Issues Regarding Domestic Industry Investments

As preliminary issues, the parties dispute (1) whether the investments in "Masimo Watch" products can be aggregated for the economic prong analysis; and (2) whether Masimo's pre-2018 investments regarding wrist-worn sensors should be considered. *See* RIB at 249-50, 256-57, 267-68; RRB at 155, 164; CIB at 301-05; CRB at 179-80. Each of these disputes is addressed below.

1. Aggregation of "Masimo Watch" Expenditures

Complainants have not separately accounted for domestic industry expenditures with respect to each Masimo Watch prototype, relying on Masimo's aggregate investments because the prototypes were part of a continuous design and development effort towards a commercial product. CIB at 300-301 (citing Tr. (Muhsin) at 342:25-343:7 (describing "many iterations of wrist sensors"), 345:2-7 (describing "[m]any iterations on the watch through the design phases"); Tr. (Scruggs) at 393:12-20 ("we've designed, built, and tested many iterations of the Masimo Watch"), 402:2-12 (describing "the progression of the different sensor designs").

[116] Complainants also rely on the Masimo W1 as a domestic industry product, but for the reasons discussed *supra* in the context of the technical prong, evidence regarding this product will not be considered.

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Apple argues that it was improper for Complainants to aggregate the Masimo Watch expenditures. RIB at 256-57. Apple cites *Certain Electronic Stud Finders, Metal Detectors, And Electrical Scanners*, where the Commission held that "aggregating investments in different domestic products that practice different patents effectively precludes the Commission from quantifying the amounts of the investments in each statutory category and determining the significance" of such investments. Inv. No. 337-TA-1221, Comm'n Op. at 48, EDIS Doc. ID 765331 (Mar. 14, 2022) ("*Electronic Stud Finders*").

In consideration of the parties' arguments, the undersigned finds that Masimo's investments in the development of Masimo Watch prototypes can be aggregated for the economic prong analysis. The record shows continuous development of such prototypes at Masimo—unlike the different products at issue in *Electronic Stud Finders*, the evidence indicates that the Masimo Watch prototypes are merely "iterations" of a product design that was continuously developed in the years leading up to the filing of the complaint. *See* Tr. (Muhsin) at 342:25-343:7, 345:2-7; Tr. (Scruggs) at 393:12-20, 402:2-12; Tr. (Al-Ali) at 275:13-276:11. The Circle sensor was built in October 2019, the Wings sensor in January 2020, the RevA sensor in November 2020, the RevD sensor in April 2021, and the RevE sensors between May and September 2021. *See* Tr. (Scruggs) at 394:12-18, 395:7-15, 396:2-13, 397:7-24, 398:1-23. Within such a development timeline, there is no reasonable way to delineate between work on separate prototypes—research and development activities within the Masimo Watch project between January 2020 and November 2020 are likely to involve both improvements to the Wings sensor and development of new features for the RevA sensor. Masimo's CFO, Micah Young, explained that Masimo's financial records did not track expenditures at this level of detail. *See* Tr. (Young) at 48:22-25.

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With respect to the '745 patent, aggregation of the domestic industry expenditures is clearly appropriate because each of the identified prototypes has been found to practice claim 18 of the '745 patent.[117] Complainants have not asserted that the Circle sensor or the Wings sensor practice claims of the Poeze patents, but the record shows that the development of these prototypes led to the development of the RevA, RevD, and RevE prototypes that Complainants have asserted as domestic industry products for the Poeze patents. *See* Tr. (Scruggs) at 394:12-398:23. Accordingly, the undersigned finds that Masimo's pre-complaint investments in all of the identified prototype Masimo Watch products can also be considered as part of the domestic industry for the Poeze patents and the '745 patent. The evidence shows that Masimo's investment in the development of these prototypes occurred in the most relevant timeframe for determining whether the domestic industry requirement has been satisfied—*i.e.*., the time period leading up to the date the complaint was filed in July 2021.

2. Masimo's Pre-2018 Investments

Complainants have identified over [redacted] in investments in research and development related to "wrist-worn parameter monitoring" dating back to 2001 and continuing up to 2018. CIB at 305; CRB at 179-80. Complainants submit that these research and development activities were "foundational" to the development of the Masimo Watch. CRB at 179-80. Apple argues that these investments pre-date any of the identified Masimo Watch prototypes and cannot be reasonably attributed to the asserted domestic industry articles. RIB at 249-50, 267-68; RRB at 155, 164.

[117] Although the record is not clear as to whether the Circle sensor and Wings sensor were connected to the identified Rad-97 monitor before the filing of the complaint for satisfaction of the technical prong, there is evidence that these sensors were used with some external monitors to measure blood oxygen, *see* Tr. (Scruggs) at 403:11-404:2, and investments in these prototypes are thus "with respect to articles protected by" the '745 patent.

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In consideration of the parties' arguments, Masimo's pre-2018 expenditures will be excluded from the domestic industry analysis. There is no specific evidence in the record describing Masimo's "wrist-worn" research and development activities, and Complainants have provided no clear explanation of the relationship between these activities and the identified Masimo Watch prototypes. *See* Tr. (Kiani) at 115:1-122:21.[118] The Commission has held that merely identifying expenditures with respect to general product lines is not sufficient to account for expenditures "with respect to" domestic industry articles. *See Certain Digital Media Devices, Including Televisions, Blu-Ray Disc Players, Home Theater Systems, Tablets and Mobile Phones, Components Thereof and Associated Software*, Inv. No. 337-TA-882, Final Initial Determination at 449-51, EDIS Doc. ID 539707 (July 7, 2014) (finding that investments that "are linked to broad product categories rather than to specific products" do not "form an adequate basis for a determination that a domestic industry exists"), *not reviewed in relevant part by* Comm'n Notice, EDIS Doc. ID 541887 (Sept. 11, 2014). Accordingly, Masimo's pre-2018 expenditures will not be considered as part of the domestic industry analysis.

C. Domestic Industry Existing at the Time of the Complaint

As discussed above in the context of the technical prong of the domestic industry requirement for the Poeze patents and the '745 patent, *supra* Section IV.F.7, Section V.F.2, Complainants have shown that Masimo Watch prototypes practicing claim 12 of the '501 patent, claim 28 of the '502 patent, claims 12, 24, and 30 of the '648 patent, and claim 18 of the '745 patent existed at the time of the filing of the complaint. Complainants rely on investments with

[118] There is evidence that there were separate concurrent projects in this timeframe related to wrist-based pulse oximetry at Masimo and Cercacor. *See* Tr. (Kiani) at 119:4-8 (describing a "friendly rivalry" with Cercacor in 2018). It is unclear whether some of these projects were related to product designs that are distinct from the asserted "Masimo Watch" prototypes.

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respect to the development of "Masimo Watch" prototypes to show that a domestic industry existed at the time of the complaint. CIB at 288-309. Complainants rely on Masimo financial information that was presented in appendices to the complaint that were extracted from Masimo's records. Tr. (Young) at 485:10-488:17; CDX-0006C.002 (citing CX-0629C; CX-0635C; CX-0624C; CX-0623C; CX-0646C; CX-0632C; CX-0628C; CX-0638C); CDX-0006C.003 (citing CX-0641C; CX-0645C; CX-0644C; CX-0640C; CX-0648C; CX-0649C; CX-0642C). Complainants have separately identified investments with respect to plant and equipment and labor and capital. *See* CIB at 301-09.

1. Plant and Equipment Expenditures

Mr. Kiani described research and development on wrist-based pulse oximetry at Masimo and Cercacor in Irvine, California. Tr. (Kiani) at 119:9-12. Mr. Young, Masimo's CFO and Executive Vice President, presented certain facility expenditures between the third quarter of 2019 and the first quarter of 2021 at Masimo's Irvine headquarters and a nearby manufacturing facility. Tr. (Young) at 481:17-20, 488:18-490:16; CDX-0006C.004. Complainants do not rely on the amounts reported by Mr. Young, however, instead identifying adjusted (and lower) amounts for plant and equipment investment that were calculated by its expert, Mr. McGavock. CIB at 301-02; *see* Tr. (McGavock) at 539:16-23; CDX-0015C.006. For the 2018-2021 timeframe, Masimo identifies [redacted] in plant and equipment expenditures for Masimo Watch research and development at Masimo's headquarters (52 Discovery), and [redacted] in plant and equipment expenditures for manufacturing at the Laguna Canyon Road facility. CIB at 301-02

Mr. McGavock testified that he "followed basically the same methodology as Mr. Young did." Tr. (McGavock) at 538:4-15. Mr. Young explained that he allocated the operating expenses at Masimo headquarters using the portion of square footage of the facility that was

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dedicated to R&D and then the percentage of employee time that was spent on the Masimo Watch. Tr. (Young) at 489:22-16. With respect to the Laguna Canyon Road facility, Mr. Young allocated operating expenses based on an estimate that "about [redacted] percent of the square footage of that facility is dedicated to the Masimo Watch project." *Id.* at 489:10-16. Mr. Young explained that Masimo's operating expenses include "maintenance and utilities, property taxes, and other facility-related costs." *Id.* at 489:17-21.

Apple contends that Mr. McGavock's analysis was unreliable, arguing that it was based on Masimo financial data that has not been verified and estimates from Masimo employees without sufficient explanation. RIB at 245-48; RRB at 152-54. With respect to the allocation of Masimo's facility operating expenses, Apple argues that there is no documentary evidence to support the square footage allocations, such as floor plans. RRB at 157. Apple further identifies evidence that the portion of the Laguna Canyon Road facility designated for Masimo Watch manufacturing is shared by other projects. RIB at 251 (citing CX-0629C). A Masimo witness admitted that the allocation percentage was based on projections, without confirming that the space was used for the Masimo Watch. RX-1202C (Kaufman Dep. Tr.) at 71:12-19. With respect to allocations of employee time, Apple argues that there is no documentary evidence in the record, such as time sheets or calendar entries, to support these estimates, and the Masimo witness testimony is insufficient to explain the basis for the allocations. CRB at 152-54.

In consideration of the parties' arguments, the undersigned finds that Complainants have provided a sufficiently reliable allocation of 2018-2021 facility operating expenses for research and development at Masimo's headquarters for the Masimo Watch. The time allocations relied upon by Mr. McGavock appear to be reasonable, and the Commission has relied on similar allocations of square footage and employee time based on witness testimony. *See Certain Solid*

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State Storage Drives, Stacked Electronics Components, and Products Containing Same, Inv. No. 337-TA-1097, Comm'n Op. at 17-20, EDIS Doc. ID 649139 (June 29, 2018) (relying on a manager's estimates for allocations of square footage and employee time); *see also Certain Electrical Connectors and Cages, Components, And Products Containing the Same Thereof*, Inv. No. 337-TA-1241, Final ID at 362-66, EDIS Doc. ID 767918 (Mar. 11, 2022) (finding "good faith" estimates of employee time to be reliable), *not reviewed in relevant part by* Comm'n Notice, EDIS Doc. ID 779717 (Sept. 8, 2022). Mr. Young explained that the time allocations were prepared with Masimo's "executive team members as well as leaders of different functions and departments across the organization." Tr. (Young) at 486:16-18; *see* Tr. (Scruggs) at 436:8-12 (estimated of square footage); Tr. (Al-Ali) at 322:6-14 (estimated headcounts and percentages of time for Masimo Watch engineers); Tr. (Muhsin) at 359:12-360:5 (estimated time for executives). The allocation of manufacturing expenses at the Laguna Canyon Road facility does not appear to be reliable, however, because it is based on a projection without confirmation that any of the Masimo Watch prototypes were manufactured there. *See* RX-1202C (Kaufman Dep. Tr.) at 71:12-72:15 (explaining that the [redacted] percent allocation was based on a projection of the square footage that would be used for Masimo Watch manufacturing). Complainants cite testimony from the hearing that Masimo Watch prototypes were manufactured at Masimo's California facilities, *see* CRB at 175, but there is no evidence specifically placing any manufacturing at the Laguna Canyon Road facility. These manufacturing-related expenditures cannot be considered part of the alleged domestic industry without evidence that operations in the Laguna Canyon Road facility were "with respect to" the domestic industry articles.

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Accordingly, the qualifying plant and equipment expenditures for the Masimo Watch are limited to the [redacted] in operating expenses at Masimo's headquarters for Masimo Watch research and development from 2018-2021.[119]

2. Labor and Capital Expenditures

Complainants further rely on Masimo's employment of labor and capital with respect to the Masimo Watch. CIB at 303-05. Using a timeframe from the third quarter of 2019 to the first quarter of 2021, Mr. Young identified several categories of Masimo's labor and capital expenditures with respect to the Masimo Watch. Tr. (Young) at 488:18-496:19; CDX-0006.004. Using the projections and allocation methods described above, Mr. Young calculated [redacted] in operating expenditures for the Laguna Canyon Road manufacturing facility for the Masimo Watch at. Tr. (Young) at 489:2-21; CDX-0006C.005. Relying on estimates of square footage and employee time, Mr. Young calculated [redacted] in operating expenditures for research and development at Masimo's headquarters. Tr. (Young) at 489:22-490:15; CDX-0006C.004-.008; CX-0635C. Mr. Young calculated [redacted] in capital items expenditures related to the Masimo Watch, based on purchases of "new machinery that we used in production of the watch, as well as existing machinery that was repurchased." Tr. (Young) at 490:19-492:10; CDX-0006C.009-.010; CX-0635C; CX-0611C; CX-0835C. He also identified [redacted] spent on equipment supplies for the Masimo Watch. Tr. (Young) at 492:11-15; CDX-0006C.011. Mr. Young calculated [redacted] in labor expenditures for research and development related to the Masimo Watch, explaining that this amount was determined by using estimated time

[119] As discussed above, the most relevant timeframe for domestic industry expenditures is the period when the Masimo Watch prototypes were built between 2019 and 2021. Expenditures extending to 2018 may be less relevant, but the inclusion of this additional year in Masimo's plant and equipment investments does not affect the domestic industry analysis because, as discussed *infra*, Complainants have not identified any context for assessing the significance of these investments.

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allocations for Masimo employees. Tr. (Young) at 492:20-493:7; CDX-0006C.012-.013; CX-0635C. He also identified [redacted] in labor expenditures for [redacted] executives who worked on Masimo Watch. Tr. (Young) at 493:8-494:17; CDX-0006C.014-.015; CX-0624C. Mr. Young further identified [redacted] for clinical labor, [redacted] for regulatory and quality assurance, and [redacted] for recruiting labor for the Masimo Watch project. Tr. (Young) at 494:21-495:7; CDX-0006C.016-.018. Mr. Young calculated [redacted] in expenditures for external watch design, which were paid by Masimo to third parties [redacted] Tr. (Young) at 495:8-496:19; CX-0617C; CX-0620C.

Complainants also identify an estimated [redacted] in investments in research and development for wrist-worn technology dating back to 2001, which was calculated by taking Masimo's total R&D investments in the United States and allocating the time of Masimo employees that was related to wrist-worn technology. CIB at 305; Tr. (Young) at 497:1-20.

Apple argues that Mr. Young's estimates are unreliable, contending that the amounts are based on Masimo financial data that has not been verified and estimates from Masimo employees without sufficient explanation. RIB at 245-48. Apple argues that there is no documentary evidence in the record, such as time sheets or calendar entries, to support Complainants' estimates of employee time, and that Masimo's witness testimony is insufficient to explain the basis for these allocations. CRB at 152-54. Apple further argues that Complainants improperly rely on expenditures related to early development of products that are not asserted to practice any claim of the Poeze patents or the '745 patent. RIB at 249-50; RRB at 155. With respect to the alleged manufacturing expenditures, Apple argues that the square footage allocation is unreliable and there is no evidence that prototypes were manufactured at that facility. RIB at 250-51; RRB at 156. With respect to Masimo's R&D expenditures, Apple argues that there is insufficient

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evidence in the record describing the activities of Masimo employees or the use of Masimo facilities. RIB at 252-53, 271; RRB at 157. Apple argues that the alleged watch equipment supplies are not cognizable expenditures because there is no evidence in the record identifying the purchased supplies. RIB at 267. Apple contends that no consistent methodology was used to estimate the amount of executive labor, and it is not clear whether this includes non-cognizable expenditures, such as administrative overhead. *Id.* at 269-70. Apple further argues that there is insufficient evidence to substantiate Masimo's third-party payments for watch design or regulatory expenses. *Id.* at 271-72. Apple also argues that the estimate for recruiting labor expense is unreliable. *Id.* at 272.

In consideration of the parties' arguments, the undersigned finds that a majority of Complainants' asserted labor and capital expenditures have been reliably quantified for consideration as part of the alleged domestic industry in this investigation. As discussed above in the context of the plant and equipment expenditures, the time allocations for Masimo's employees are supported by the testimony of Masimo witnesses, which is similar to evidence that has been relied upon in other investigations. *See* Tr. (Young) at 492:20-493:7 ("We worked with our leaders of engineering, and they put together a listing of all the employees working on the watch. I think there's over [redacted] employees on the spreadsheet. They also provided the time allocation by month . . . And then we applied that to the compensation by each of those employees to come up with the allocation of R&D dollars."). Complainants have identified the names and salaries of each employee involved in the Masimo Watch project with monthly estimates of their time from 2019 to 2021. CX-0635C. Complainants provide a similar

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accounting for executive labor. CX-0624C.[120] Complainants further identify expenditures for recruiting engineers to work on the Masimo Watch. Tr. (Young) at 494:21-495:7; CDX-0006C.016-.018. Apple argues that Complainants have provided insufficient detail regarding the staffing of particular Masimo Watch projects or the specific activities of Masimo executives and employees, RIB at 269-71, but Mr. Young explained that such detailed information is not tracked in Masimo's financial records. Tr. (Young) at 484:22-25. As discussed above, Masimo engineers explained that the asserted Masimo Watch prototypes were "iterations" of a product design that was continuously developed in the years leading up to the filing of the complaint. *See* Tr. (Muhsin) at 342:25-343:7, 345:2-7; Tr. (Scruggs) at 393:12-20, 394:12-18, 395:7-15, 396:2-13, 397:7-24, 398:1-23, 402:2-12. Mr. Young further explained that with respect to the time allocations, he and other Masimo executives "were trying to also be conservative." Tr. (Young) at 493:14-494:6. With respect to Masimo's recruiting expenditures, the relevant human resources staff are identified in a spreadsheet, CX-0632C, and the allocations of time are supported by estimates made by Masimo employees. *See* RX-1202C (Kaufman Dep. Tr.) at 18:17-188:12. The Commission has held that with respect to domestic industry, "[a] precise accounting is not necessary, as most people do not document their daily affairs in contemplation of possible litigation." *Stringed Musical Instruments,* Inv. No. 337-TA-586, Comm'n Op., 2009 WL 5134139, at *17 (December 2009); *see also Certain Electronic Devices*, Inv. No. 337-TA-701, Order No. 58 at 5, EDIS Doc. ID 439031 (Nov. 18, 2010) ("[T]he Administrative Law

[120] Apple argues that the executive labor should be excluded because it may include "administrative overhead," RIB at 269-70, but the Commission's exclusion of "administrative overhead" concerns those activities "associated with importation of the domestic industry products." *Certain Bone Cements*, Inv. No. 337-TA-1153, Comm'n Op. at 22, EDIS Doc. ID 731649 (Jan. 25, 2021). Apple has not persuasively argued that administrative expenditures should be excluded for executives who are managing employees working on research and development in the United States.

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Judge declines as a matter of law to give credence to Apple's pro forma objections that Nokia has failed to give a precise accounting or failed to provide underlying documentation for sworn witness testimony."), *not reviewed by* Comm'n Notice, EDIS Doc. ID 440675 (Dec. 20, 2010). The allocations for employee and executive labor expenditures are thus reasonable, and these expenditures account for a majority of the asserted labor and capital, with [redacted] for employees engaged in Masimo Watch research and development, [redacted] for executives involved with the Masimo Watch project, and [redacted] in expenditures for recruiting. *See* CDX-0006C.012-.015, .016-.018.

With respect to the expenditures paid to outside firms for the design of the Masimo Watch, Apple argues that some of these may be foreign expenditures. RIB at 271-72. *See Certain Products Having Laminated Packaging, Laminated Packaging, and Components Thereof*, Inv. No. 337-TA-874, Comm'n Op. at 17, EDIS Doc. ID 517360 (Sept. 3, 2013) (finding that payments to vendors cannot be counted as part of the domestic industry where complainant "did not show that the . . . vendors manufacture the laminated packages in the United States"). Complainants submit that Masimo contracted with U.S.-based entities for these services, CRB at 176, but it is unclear whether the work will be conducted in the United States. The presentation from [redacted] identifies a U.S. address, but with additional addresses in Germany and China. CX-0620C at 23. The contract with [redacted] identifies a U.S. address, but the evidence is insufficient to show activities taking place in the United States before the time of the complaint. *See* CX-0617C (identifying [redacted] CX-0618C (describing design milestones extending to the end of 2021).[121] Based on this record, the

[121] Apple contends that [redacted]. RIB at 271.

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undersigned agrees with Apple that these expenditures should not be counted as part of the alleged domestic industry. In any case, these expenditures are relatively small in comparison to Masimo's R&D expenditures, *see* CIB at 304-05, and whether these additional expenditures are counted as part of the domestic industry has no impact on the determination with respect to significance, *infra*, which is based on the number of Masimo employees engaged in R&D for the Masimo Watch in the United States.

Certain of Complainants' other claimed expenditures are also insufficiently supported by evidence in the record, and whether these additional expenditures are counted as part of the domestic industry has no impact on the determination with respect to significance, *infra*, which is based on Masimo's research and development activities. As discussed above in the context of plant and equipment, the operating expenses related to manufacturing are not supported by a reliable allocation or any evidence that the domestic industry articles were manufactured at the Laguna Canyon Road facility. In addition, Complainants have not identified evidence in the record cataloguing the capital items or the supplies that correspond to the asserted expenditures—Mr. Young's testimony only identifies one piece of machinery with a "picture of the piece of equipment being used in the production of the watch," Tr. (Young) at 491:14-23 (citing CX-0611C), but even for this piece of equipment, Complainants do not explain what it does or how it is related to any Masimo Watch prototypes. The claimed labor expenses related to clinical studies and regulatory and quality assurance appear to relate to the work of a small number of Masimo employees, but Complainants do not identify the employees or explain what they do. *See* CX-0623C; CX-0646C.

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3. Significance of Investments

As discussed above, Complainants have identified approximately [redacted] in qualifying plant and equipment expenditures based on operating expenses at Masimo's headquarters, and approximately [redacted] in qualifying labor expenditures for employees, executives, and recruiting—each of these amounts relates to research and development of Masimo Watch prototype products.[122]

Complainants argue that Masimo's domestic investments are significant because 100% of the research and development activities for the Masimo Watch occur in the United States. CIB at 307; *see* Tr. (Kiani) at 321:23-322:5. Mr. McGavock testified that it was his understanding that the Masimo Watch was Masimo's [redacted] Tr. (McGavock) at 543:1-544:14. Mr. Kiani described the Masimo Watch as [redacted] Tr. (Kiani) at 126:19-23.

With respect to the labor expenditures, Complainants submit that the headcount of [redacted] employees ([redacted] full-time equivalent) in the first quarter of 2021 is significant. CIB at 307; *see* Tr. (Young) at 504:9-13; CX-0648C. Complainants submit that [redacted] percent of Masimo's R&D engineers were working on the Masimo Watch at that time. CIB at 308; *see* Tr. (McGavock) at 544:21-545:25; CDX-0015C.012.[123] For the Masimo engineers working on the Masimo Watch,

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[122] Approximately [redacted] in operating expenses is also asserted as a capital expenditure, representing the same expenditures recognized as investments in plant and equipment. Regardless of whether this amount is added to the labor expenditures under subparagraph (B), it would not affect the significance analysis below.

[123] There is a discrepancy between Mr. McGavock's testimony and his demonstrative regarding the "[redacted] percent" figure. He said: "The portion of the Masimo's R&D engineering time dedicated to the watch was [redacted] percent at the first quarter of 2021." Tr. (McGavock) at 545:12-14. His demonstrative reads: "Portion of Masimo R&D engineers dedicated to the Watch: [redacted] at Q1 2021." CDX-0015C.012. Apple does not appear to dispute that the [redacted] refers to a percentage of Masimo R&D engineer headcount, as described in the demonstrative. *See* RIB at 274.

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[redacted] of their time was spent on the Masimo Watch. CIB at 308; *see* Tr. (McGavock) at 544:21-545:25; CDX-0015C.012. Mr. Al-Ali identified a specific team of engineers that [redacted] for the Masimo Watch. Tr. (Al-Ali) at 323:18-342:21; *see also* Tr. (Muhsin) at 34:14-345:1. Mr. McGavock identified [redacted], and Complainants argue that their work was significant. CIB at 308; Tr. (McGavock) at 544:21-545:25; CDX-0015C.012. Complainants argue that Masimo's investments are significant in absolute terms. CIB at 308-09.

Apple argues that Complainants have failed to demonstrate the significance of the claimed expenditures. RIB at 253-56, 272-74. With respect to plant and equipment, Apple argues that the facility operating expenditures related to research and development for the Masimo Watch only represent about [redacted] of Masimo's total facility operating expenditures. RIB at 255. Apple submits that Masimo's R&D investments with respect to the Masimo Watch represent only [redacted] of Masimo's overall R&D investments. RIB at 273; Tr. (Thomas) at 1305:2-9. Apple argues that there is no significance to Complainants' claim that the Masimo Watch represents Masimo's [redacted] because Masimo has historically focused on clinical products. RIB at 254-55 (citing Tr. (Kiani) at 140:8-11). Apple argues that Complainants' reliance on allocation percentages to represent significance is unsupported and unreliable. RIB at 274; *see* Tr. (Thomas) at 1306:7-13 ("[U]sing percentages to arrive at a number and then circularly using those percentages to represent significance, I think, is misleading and inappropriate."). Apple argues that the employment of [redacted] does not demonstrate significance, and there is no evidence for what those engineers are doing after completion of the [redacted]. RIB at 274; Tr. (Thomas) at 1306:14-18.

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In consideration of the parties' arguments, the undersigned finds that Complainants have shown significant employment of labor with respect to Masimo's investments in research and development for the Masimo Watch. The [redacted] in labor expenditures is quantitatively significant in the context of Masimo's broader research and development efforts, because it involves [redacted] employees ([redacted] full-time equivalent) representing over [redacted] percent of Masimo's research and development engineers. *See* Tr. (Young) at 504:9-13; Tr. (McGavock) at 545:12-14; CDX-0015C.012. Apple questions the reliability of Masimo's allocations of employee time, RIB at 274, but as discussed above, the allocations are supported by reliable witness testimony. *See* Tr. (Young) at 492:20-493:7. Apple argues that the investments in the Masimo Watch are a small fraction of Masimo's overall research and development budget, RIB at 273, but the fact that Masimo invests in other products does not diminish the significance of Masimo's investments in the Masimo Watch, because "[s]ignificance is based on the marketplace conditions regarding the articles protected by the Asserted Patents," and activities regarding "other products is not pertinent to this analysis." *Certain Carburetors and Products Containing Such Carburetors*, Inv. No. 337-TA-1123, Comm'n Op. at 28, EDIS Doc. ID 692517 (Oct. 28, 2019). The significance of Masimo's investments in the Masimo Watch is corroborated by qualitative evidence that this was Masimo's [redacted] *See* Tr. (Kiani) at 12:19-2; Tr. (McGavock) at 543:1-544:14. In addition, Masimo's investments are significant because all of the research and development for the Masimo Watch has occurred in the United States. CIB at 307; *see* Tr. (Kiani) at 321:23-322:5; *see Gas Spring Nailer Prods. and Components Thereof*, Inv. No. 337-TA-1082, Comm'n Op. at 83, EDIS Doc. ID 709073 (Apr. 28, 2020) (finding quantitative significance where "all, *i.e.*, 100 percent, of Kyocera's R&D and

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engineering expenditures relating to complainant's [DI products] occurs in the United States."), *vacated and remanded on other grounds*, 22 F.4th 1369 (Fed. Cir. 2022); *Certain Shingled Solar Modules, Components Thereof, and Methods for Manufacturing the Same*, Inv. No. 337-TA-1223, Initial Determination at 60, EDIS Doc. ID 756910 (Oct. 22, 2021) (finding quantitative significance where 100% of research and development activities were based in the United States), *not reviewed in relevant party by* Comm'n Notice, EDIS Doc. ID 762554 (Feb. 4, 2022).

Complainants also submit that Masimo's investments in research and development for the Masimo Watch are qualitatively significant, because it represents [redacted] CIB at 307; Tr. (Kiani) at 121:11-123:16, 126:19-23; Tr. (McGavock) at 543:16-544:14. Complainants also point to the "custom designing and building tools and equipment" for the Masimo Watch. CIB at 307; Tr. (Scruggs) at 433:13-15; Tr. (McGavock) at 543:1-544:14. In particular, Complainants cite the design of a [redacted] CIB at 307-08; Tr. (Al-Ali_ at 323:18-324:25; Tr. (Muhsin) at 344:14-345:1. These qualitative factors demonstrate the importance of the Masimo Watch development to Masimo, and this supports the finding of quantitative significance.

Complainants have not, however, persuasively shown that Masimo's investments and plant and equipment are quantitatively significant. The floor space in Masimo's headquarters that is attributable to work on the Masimo Watch only represents about [redacted] of the facility. *See* RIB at 255; Tr. (Young) at 489:22-490:13 (allocating [redacted] percent of the floor space to R&D and between [redacted] percent of R&D to the Masimo Watch); CX-0635C. In their briefing, Complainants have not placed their plant and equipment expenditures in any appropriate context that shows significance. *See Certain Earpiece Devices and Components Thereof*, Inv. No. 337-

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TA-1121, Comm'n Op. at 19, EDIS Doc. ID 693820 (Nov. 8, 2019) (remanding a summary determination on the economic prong because complainant did "not provide context of the company's operations, the marketplace, or the industry in question necessary to understand whether the relative value of its domestic activities and investments is significant or substantial.").[124]

* * *

Accordingly, Complainants have met the economic prong of the domestic industry requirement based on the existence of a domestic industry at the time of the complaint with respect to significant investments in labor and capital for the research and development of the Masimo Watch. Complainants have thus satisfied the domestic industry requirement with respect to the Poeze patents and the '745 patent.

D. Domestic Industry in the Process of Being Established

Complainants further argue that there is a domestic industry in the process of being established based on Masimo's projected expenditures for the Masimo Watch. CIB at 305-09.[125] Mr. Young explained that at the time of the complaint, Masimo's financial department worked with engineering leaders and other Masimo employees to create a forecast of expected expenditures from the second quarter of 2021 to 2023. Tr. (Young) at 500:23-503:3; CDX-

[124] Complainants' other arguments for significance fail for the same reasons. It is unclear why the fact that engineers working on the Masimo Watch spend [redacted] of their time on the Masimo Watch should be evidence for significance. *See* CIB at 308; RIB at 274. There is evidence that the design of a [redacted] was qualitatively important to Masimo, but Complainants fail to explain why the work of these [redacted] engineers is quantitatively significant. *See* CIB at 308; RIB at 274.

[125] Masimo also relies on post-complaint evidence for the number of employees it has hired, a 2022 corporate acquisition, and a statement in Masimo's 2021 Earnings Presentation, CIB at 307-09, but this evidence will not be considered in the context of the economic prong, as discussed *supra*. Whether Complainants have shown a domestic industry in the process of being established will be determined based on the projections made by Masimo before the filing of the complaint.

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000C.030-.031. Masimo projected an increase in headcount from [redacted] to [redacted] for research and development on the Masimo Watch during this timeframe. Tr. (Young) at 502:7-18; CDX-000C.032. Masimo also projected production costs for the Masimo Watch, estimating that there would be between [redacted] and [redacted] in US-based production costs in 2022 and between [redacted] and [redacted] in US-based production costs in 2023. Tr. (Young) at 502:19-503:3; CDX-000C.033. Mr. McGavock relied on these projections to estimate that [redacted] of the cost of goods for the Masimo Watch would be incurred in the United States. Tr. (McGavock) at 545:8-9; CDX-0015C.012. Complainants further argue that Masimo's growing number of Masimo Watch personnel and the expansion of the Laguna Canyon Road manufacturing facility shows that a domestic industry is in the process of being established. CRB at 176-77; *see* Tr. (McGavock) at 542:14-20, 563:8-13, 574:25-575:2.

Apple argues that Complainants have produced no definitive timeline for the completion of the Masimo Watch, citing the absence of business plans or other documentation in the evidentiary record. RIB at 258-60, 275; RRB at 158-59, 172. Apple further argues that Masimo's projected expenditures are unsupported and unreliable. RIB at 258-60; RRB at 151, 156, 169-70.[126] Apple argues that Complainants' projections for the share of domestic expenditures in the manufacturing of future Masimo Watch products is unreliable and notes that the [redacted] for later versions of the Masimo Watch. CIB at 273 (citing CX-0629C). Apple suggests that Masimo Watch manufacturing would likely be [redacted]

[126] Apple argues that Masimo's projections for Masimo Watch manufacturing was [redacted], RIB at 258-60, RRB at 169-70, but this post-complaint evidence will not be considered in the context of the economic prong analysis.

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[redacted]. *Id.* at 273-74; *see* RX-1211C (Young Dep. Tr.) at 84:14-17; Tr. (McGavock) at 570:7-10.

In consideration of the parties' arguments, the undersigned finds that Complainants have satisfied the economic prong of the domestic industry requirement with respect to a domestic industry in the process of being established for the Masimo Watch. The Commission has held that a domestic industry is in the process of being established when (1) a complainant takes "the necessary tangible steps to establish such an industry in the United States," and (2) there is a "significant likelihood that the industry requirement will be satisfied in the future." *Certain Stringed Musical Instruments & Components Thereof*, Inv. No. 337-TA-586, Comm'n Op. at 16-17, EDIS Doc. ID 300615 (May 16, 2008). For the reasons discussed below, the evidentiary record shows that Masimo has met both requirements based on evidence of activities and investments before the filing of the complaint and projections that were made at the time of the filing of the complaint.

Masimo's design and production of Masimo Watch prototypes represent tangible steps toward the establishment of a domestic industry with respect to the Masimo Watch. As explained by Mr. Scruggs, these prototypes were designed and built from 2019 through 2021, incorporating features asserted in the claims of the Poeze patents and the '745 patent. *See* Tr. (Scruggs) at 394:12-18, 395:7-15, 396:2-13, 397:7-24, 398:1-23. Mr. Kiani explained that these prototypes were part of the ongoing project to design and manufacture the Masimo Watch. Tr. (Kiani) at 121:7-122:8, 123:17-124:4; CX-0364C; CX-0783C. As discussed above in the context of Masimo's pre-complaint investments in labor, the research and development of the Masimo Watch prototypes involved up to [redacted] Masimo employees (working the equivalent of [redacted] full-time employees). *See* Tr. (Young) at 504:9-13. There is further evidence that at the time of the filing

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of the complaint, Masimo planned to hire additional engineers to work on the Masimo Watch project, *see* Tr. (Young) at 502:7-18, CDX-000C.032, and in preparation for this expanding workforce, Masimo had taken the tangible step of hiring additional recruiting staff. *See* Tr. (Young) at 495:3-7; RX-1202C (Kaufman Dep. Tr.) at 18:17-188:12; CX-0632C. Masimo has also contracted with external design firms for work on future Masimo Watch products. *See* Tr. (Young) at 495:16-496:19; CX-0617C; CX-0618C; CX-0620C.[127] The record thus shows that Masimo was taking tangible steps towards the design and manufacture of the Masimo Watch at the time of the complaint.

As discussed above, Masimo invested [redacted] in labor expenditures in the years leading up to the complaint for research and development with respect to Masimo Watch prototypes, and this amount is both quantitatively and qualitatively significant in the context of Masimo's research and development activities. The record further shows that Masimo projected increased hiring for the Masimo Watch, and this further employment of labor would be significant for the same reasons as Masimo's past employment of labor. *See* Tr. (Young) at 494:21-495:7; CDX-0006C.016-.018. Accordingly, there is a significant likelihood that the economic prong of the domestic industry requirement will be satisfied in the future with respect to the Masimo Watch based on Masimo's past and future investments in labor for research and development.

In addition, Masimo's projected expenditures for manufacturing of the Masimo Watch are further evidence for a significant likelihood that the domestic industry requirement will be satisfied in the future. Masimo has projected that about [redacted] percent of its Laguna Canyon Road

[127] Even if this work is not conducted in the United States, *see* RIB at 271-72, the engagement of these design firms is evidence of Masimo's plans for the Masimo Watch.

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facility will be used for manufacturing the Masimo Watch. Tr. (Young) at 49:10-16; RX-1202C (Kaufman Dep. Tr.) at 71:12-72:15. Masimo has also projected that [redacted] of the manufacturing costs for the [redacted] Masimo Watch in 2021 would be domestic. Tr. (McGavock) at 545:8-9; CDX-000C.033; CX-0629C. The domestic share of manufacturing costs was projected to [redacted] to [redacted] for a [redacted] Masimo Watch in 2022 and to [redacted] for a [redacted] Masimo Watch in 2023. *See* RIB at 273; CX-0629C. Apple has identified reasons to be skeptical of the high projection for the [redacted] Masimo Watch, *see* RIB at 273-74, Tr. (Thomas) at 1305:10-19, but even the [redacted] figure would likely support a finding that the domestic industry requirement has been satisfied. *Cf. Certain Self-Anchoring Beverage Containers*, Inv. No. 337-TA-1092, Comm'n Op. at 13, EDIS Doc. ID 683010 (Jul. 4, 2019) (finding domestic investments representing 9 percent of the sales revenue for the domestic industry product to be significant). Moreover, even if Masimo's domestic contribution to manufacturing the Masimo Watch dropped in the future, the domestic industry requirement could still be satisfied based on Masimo's significant investments in research and development, as long as Masimo was continuing to make appropriate qualifying domestic investments. *See Certain Television Sets, Television Receivers, Television Tuners, and Components Thereof*, Inv. No. 337-TA-910, Comm'n Op. at 68, 2015 WL 6755093, at *36 (Oct. 30, 2015) ("Past expenditures may be considered to support a domestic industry claim so long as those investments pertain to the complainant's industry with respect to the articles protected by the asserted IP rights and the complainant is continuing to make qualifying investments at the time the complaint is filed."); *Hyosung TNS Inc. v. Int'l Trade Comm'n*, 926 F.3d 1353, 1362 (Fed. Cir. 2019) (affirming Commission's "conclusion that a past investment may, by virtue of its connection to ongoing field service and assembly expenses, support a finding that the economic prong of the domestic industry requirement is met."). Although the level of

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investment can be disputed, the record unequivocally shows that Masimo expected to continue investing in the Masimo Watch in the United States with expenditures in research and development and manufacturing. *See* Tr. (Kiani) at 123:17-124:22 (describing 2020 presentation for Masimo Watch, CX-0783C); Tr. (Young) at 500:23-503:3 (describing projections for 2021-2023 spending).

* * *

Accordingly, Complainants have identified investments and projections for investments at the time of the complaint showing, by a preponderance of the evidence, a domestic industry in the process of being established with respect to the Masimo Watch. As discussed above, Complainants have also shown that Masimo Watch products meeting the limitations of certain claims of the Poeze patents and the '745 patent were in the process of being developed at the time of the complaint. Complainants have thus satisfied the economic prong of the domestic industry requirement for the Poeze patents and the '745 patent based on an industry in the process of being established.

VIII. DOMESTIC INDUSTRY – ECONOMIC PRONG ('127 PATENT)

For the '127 patent, Complainants rely on investments with respect to research and development and manufacturing of Masimo's rainbow® sensors to satisfy the economic prong of the domestic industry requirement. *Id.* at 302-03, 309-10.

A. Domestic Industry Existing at the Time of the Complaint

As discussed above in the context of the technical prong, the domestic industry products include "early" rainbow® sensors sold before 2009, which have been shown to practice claim 9 of the '127 patent, and "current" rainbow® sensors sold after 2009, which have not been shown

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to practice claim 9 of the '127 patent.[128,129] Complainants have not allocated their domestic industry expenditures between early and current rainbow® sensors, however, and this precludes any reliable domestic industry analysis. *See Certain Subsea Telecomm. Sys. and Components Thereof*, Inv. No. 337-TA-1098, Comm'n Op. at 41, EDIS Doc. ID 691678 (Oct. 21, 2019) ("The Commission has found that complainants have not satisfied the domestic industry requirement where the complainant failed to allocate expenses to account for non-domestic industry products that do not practice the patent.").

Even if Complainants had allocated their domestic industry expenditures between the early and current rainbow® sensors, Complainants cannot satisfy the domestic industry requirement based only on investments in the early rainbow® sensors, because the record indicates that these products were discontinued in favor of the current rainbow® sensors in 2009, more than a decade before the complaint in this investigation was filed. *See* CRB at 10; Tr. (Diab) at 233:16-20. In such circumstances, the Commission has required a showing of "ongoing qualifying activities under section 337(a)(3) at the time the complaint is filed." *See Certain Television Sets, Television Receivers, Television Tuners, and Components Thereof*, Inv. No. 337-TA-910, Comm'n Op. at 68, 2015 WL 6755093, at *37 (Oct. 30, 2015); *see also*

[128] The parties dispute whether Complainants have sufficiently identified which products comprise the asserted Masimo rainbow® sensors. CIB at 36; RIB at 261; RRB at 160. As discussed above in the context of the technical prong, the undersigned finds that Complainants have sufficiently identified the asserted rainbow® sensors on a sales spreadsheet. CX-0649C.

[129] Apple argues that there are at least two models of rainbow® sensors that have not been asserted to practice the '127 patent, RRB at 160, but Complainants have acknowledged that the rainbow® sensors relevant to this investigation exclude these two models. *See* CIB at 36 n.4 (citing Tr. (Diab) at 210:13-19 ("All of rainbow sensors use wavelength correction except for a couple of them. One is an acoustic sensor, and the other one, it's called Light Set 1, but the rest of them all use temperature correction.")). There is no indication that those two models are listed in the financial spreadsheet exhibit that lists the asserted rainbow® sensors. *See* CX-0649C.

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Certain Marine Sonar Imaging Devices, Including Downscan & Sidescan Devices, Prod. Containing the Same, & Components Thereof, Inv. No. 337-TA-921, Comm'n Op. at 55-57, EDIS Doc. ID 571940 (Jan. 6, 2016) ("The Commission, thus, has found, in various investigations, a domestic industry based on a complainant's past activities relating to a discontinued product where the complainant has shown continuing qualifying investments."). There is no evidence in the record showing that Masimo has continued to invest in the early rainbow® sensors after their discontinuation. Complainants have not identified any continuing investments in warranty, customer service, or maintenance of early rainbow® sensors—the asserted domestic industry expenditures are related to research and development and manufacturing—these activities appear to have been directed to the current rainbow® sensors since 2009. CIB at 302-03, 309-10.

Accordingly, based on the present record, Complainants have failed to show that a domestic industry existed at the time of the complaint with respect to the early rainbow® sensors that have been shown to practice claim 9 of the '127 patent.

B. Domestic Industry in the Process of Being Established

Complainants also assert that there is a domestic industry in the process of being established for the rainbow® sensors, relying on projections of expenditures after the time the complaint was filed. CIB at 288, 299. These projected expenditures relate to research and development and manufacturing, CIB at 302-03, 309-10, and as discussed above, such expenditures appear to relate only to the current rainbow® sensors after 2009. Complainants have not attempted to explain how a domestic industry could be in the process of being established with respect to discontinued products. On this record, Complainants have failed to

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show that a domestic industry was in the process of being established with respect to the early rainbow® sensors.

C. Asserted Domestic Industry Expenditures

As discussed above, Complainants have improperly aggregated their domestic industry expenditures for the early rainbow® sensors and the current rainbow® sensors, and there is insufficient evidence in the record to satisfy the economic prong of the domestic industry requirement with respect to the early rainbow® sensors alone. In the event the current rainbow® sensors were found to practice the '127 patent as well, however, the undersigned addresses certain of Complainants' domestic industry expenditures below to determine whether the asserted domestic industry expenditures are significant pursuant to subparagraphs (A) and (B) of section 337(a)(3). 19 U.S.C. § 1337(a)(3).

1. Plant and Equipment

Complainants identify Cercacor, which is headquartered in Irvine, California, as the developer of Masimo's rainbow® technology.[130] CIB at 299 (citing Tr. (Kiani) at 94:8-17, 119:9-12). Complainants further submit that Masimo manufactures the LEDs for the rainbow® sensors in a facility in Hudson, New Hampshire. CIB at 299; CX-0636C. Using allocations of square footage and employee time, Mr. McGavock calculated that Masimo invested [redacted] in facility operating expenses at Masimo's headquarters for research and development of the rainbow® sensors between 2018 and the first quarter of 2021. Tr. (McGavock) at 547:6-13; CDX-0015C.014; *see* CIB at 302-03. He estimated [redacted] in allocated research and development expenditures before 2018 at that facility and added an additional [redacted] in

[130] Cercacor (formerly known as Masimo Laboratories) is a spinoff from Masimo that collaborates with Masimo on R&D for nonvital parameter monitoring. *See* Tr. (Kiani) at 93:12-94:7; *see also* CX-1612C.

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allocated research and development expenditures at an older Masimo facility. *Id.* He calculated [redacted] in operating expenditures for manufacturing rainbow® sensors at Masimo's Laguna Canyon Road facility between 2018 and the first quarter of 2021, and an additional [redacted] in expenditures before 2018. *Id.* He further calculated [redacted] in operating expenditures for manufacturing LEDs for rainbow® sensors at Masimo's New Hampshire facility between 2018 and the first quarter of 2021, and an additional [redacted] in expenditures before 2018. *Id.* As a measure of significance, Complainants submit that "[redacted] of Masimo's facility investments for rainbow® are in the U.S." CIB at 310; Tr. (McGavock) at 549:8-14; CDX-0015C.017.

Apple contends that Mr. McGavock's analysis was unreliable, arguing that it was based on Masimo financial data that has not been verified with allocations that have not been explained. RIB at 262-64; RRB at 160-62. Apple argues that Complainants have failed to offer any documents or testimony explaining how employee time was estimated for rainbow® sensor R&D. RIB at 263; RRB at 161. With respect to manufacturing expenses, Apple argues that there is no explanation for how Complainants calculated the "standard cost" for the rainbow® sensor products. RIB at 263-64; RRB at 162. Apple argues that Complainants have failed to offer any evidence that explains how the LED manufacturing in New Hampshire relates to the rainbow® sensors and questions the accuracy of certain calculations of expenditures. RIB at 264; RRB at 162. Apple further argues that Mr. McGavock's claim that Masimo's facility expenses are [redacted] domestic is not explained in the record, and it is contradicted by evidence that Masimo has significant manufacturing facilities in Mexico. RIB at 264-65; RRB at 163.

In consideration of the parties' arguments, the undersigned finds that Complainants' asserted expenditures are sufficiently reliable for the domestic industry analysis. With respect to these expenditures, Mr. McGavock explained that he "used the same methodology applied by

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Mr. Young." Tr. (McGavock) at 546:12-18. Mr. Young explained that for R&D expenditures on the rainbow® sensors, he relied on time allocations "received from our engineering leadership and teams," explaining that these allocations were "ranges anywhere from [redacted] percent over time because that was a focus project for us." Tr. (Young) at 500:8-22. For manufacturing costs, Mr. Young explained that he relied on "the U.S. standard costs," which was pulled "from our financial data warehouse." *Id.* at 498:2-10. Mr. Young confirmed that the semiconductor LEDs for the rainbow® sensors are manufactured in Hudson, New Hampshire. *Id.* at 505:12-16, 507:7-15. He further confirmed that Masimo's engineering leads estimated that [redacted] percent of the Laguna Canyon Road facility and [redacted] percent of the Hudson facility was used to manufacture rainbow® sensors. *Id.* at 508:1-22. Although Masimo's estimates may not be precise, the record shows that Mr. McGavock and Mr. Young relied upon reasonable allocations of Masimo's expenditures to attribute the investments in plant and equipment to the rainbow® sensors.

There does not appear to be reliable support in the record, however, for Complainants' assertion that [redacted] of Masimo's facility investments for rainbow® are domestic. *See* CIB at 310; Tr. (McGavock) at 549:8-14; CDX-0015C.017; RIB at 264-65; RRB at 163. Mr. McGavock's testimony with respect to this figure is conclusory, with no explanation for how the percentage was calculated. *See* Tr. (McGavock) at 549:8-14; CDX-0015C.017. Complainants cite two spreadsheets in their brief, *see* CIB at 310 (citing CX-0633C; CX-0636C), but it is not clear from these spreadsheets how the [redacted] figure was derived. This is Complainants' only basis for significance that relies on investments in plant and equipment, and because this figure is unreliable, Complainants have failed to show significant investment in plant and equipment under subparagraph (A) of section 337(a)(3).

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2. Labor or Capital

With respect to employment of labor or capital, Complainants rely on investments by Cercacor in research and development for the rainbow® sensors. CIB at 309.[131] Complainants claim that "Cercacor has employed the [redacted] to work on rainbow®." CIB at 299 (citing CDX-0015C.015 (summarizing CX-0633C)). As such, Complainants assert that Cercacor's expenditures in the employment of R&D labor or capital for the rainbow® sensors amounts to [redacted] pre-2018 and [redacted] from 2018-Q1 2021. *Id.* at 309 (citing CX-0633C at "R&D Spend History" tab; CX-0644C). In addition, Complainants state that "Cercacor has performed the [redacted] of its R&D on rainbow®, accounting for [redacted] in R&D through July of 2021." *Id.* at 310 (citing Tr. (Hammarth) at 524:25-525:5).

Apple argues that Complainants offer no corroborating documentation for these R&D expenses or explain how their calculation provides a reliable basis for allocations necessary for the economic prong requirement. RIB at 276. In addition, Apple contends that Complainants fail to show that the R&D projects identified in Cercacor's R&D expenditures are exclusively related to the rainbow® sensors, rather than to non-domestic industry products and projects. *Id.* For example, Apple asserts that Complainants' expenditures include Ember, a commercialized product sold by Cercacor that is not a domestic industry product. *Id.* (citing Tr. (Hammarth) at 532:5-13). Similarly, Apple claims that Mr. Hammarth also identified [redacted] as a [redacted]

[131] Complainants also set forth other labor or capital expenditures for the rainbow® sensors. *See* CIB at 309-10. However, because the other expenditures appear to be less reliable and are not as closely tied to Complainants' asserted bases for significance, only Cercacor's employment of R&D labor or capital is addressed herein.

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[redacted] as an [redacted]; and [redacted] as related, in part, to Ember. *Id.* (citing RX-1201C at 81:21-83:5; Tr. (Hammarth) at 527:12-528:22). Apple argues that Complainants allocate costs associated with each of these products and projects to the rainbow® sensors without any allocation for the non-domestic industry Ember product or any explanation for including R&D on [redacted] in the absence of any showing that any of the rainbow® sensors use that technology. *Id.* at 276-77.

Contrary to Apple's assertions, the undersigned finds that a preponderance of the evidence demonstrates that these R&D expenditures are reliable. According to Mr. Kiani, the chairman and CEO of Masimo and Cercacor, Cercacor developed the rainbow® technology. Tr. (Kiani) at 94:8-17. Apple does not dispute this. Mr. Jeroen Hammarth, the CFO of Cercacor, testified that for the purposes of this investigation, Cercacor exported records from its ERP system and used Excel records from various tax analysis that it had performed over the years in the normal course of business. Tr. (Hammarth) at 523:22-524:2. He also testified that he prepared a financial spreadsheet showing Cercacor's R&D spend.[132] *Id.* at 524:3-13; *see also* CX-0633C.[133] Mr. Hammarth testified that Cercacor's total R&D on the rainbow sensors though Q1 of 2021 was over [redacted]. Tr. (Hammarth) at 525:3-5. This is consistent with the data in

[132] The undersigned finds that such evidence is reasonable under the circumstances of this investigation. As the Commission has stated, "there is no need to define or quantify the industry itself in absolute mathematical terms." *Certain Stringed Musical Instruments and Components Thereof*, Inv. No. 337-TA-586, Comm'n Op. at 26 (May 16, 2008) ("A precise accounting is not necessary, as most people do not document their daily affairs in contemplation of possible litigation.")

[133] Apple refers to exhibit CX-0633C and states that it "concerns Cercacor R&D Labor, with no apparent relevance." RRB at 163. Sworn testimony demonstrates that Cercacor developed the rainbow® technology, making Cercacor's investment in R&D labor related to rainbow®, *i.e.*, the subject of CX-0633C, relevant. *See* Tr. (Kiani) at 94:8-17, 119:9-12; Tr. (Hammarth) at 524:3-13.

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the financial spreadsheet prepared by Mr. Hammarth, as well as the financial spreadsheet prepared to support Mr. Young's declaration to the complaint.[134] *See* CX-0633C; CX-0644C at Tab "Rainbow Chart" (showing that Cercacor's rainbow® R&D spend from 2007-2020 is about [redacted]); Tr. (Young) at 488:2-17. And according to Mr. Hammarth all of that R&D "was done in the U.S." Tr. (Hammarth) at 525:6-8.

Moreover, the undersigned disagrees with Apple that certain R&D projects need to be excluded from Cercacor's R&D expenditures. The undersigned finds that a preponderance of the evidence shows that Cercacor specifically allocated certain of its projects to the rainbow® sensors. *See, e.g.*, CX-0633 at Tab "Summary Calc" (showing subtotals for rainbow vs. non-rainbow). For example, Apple claims that the [redacted] project is outside the scope of the rainbow® sensors. However, Mr. Hammarth testified that the [redacted] and the rainbow® sensor measures a collection of nonvital signs, including [redacted].[135] *See* Tr. (Hammarth) at 528:1-6; *see also id.* at 528:23-529:2. Similarly, Mr. Hammarth testified that Ember is a Cercacor product that "incorporates our technologies for hemoglobin measurement, carbon monoxide measurement, and some others."[136] Tr. (Hammarth) at 532:5-13; *see also* RX-1201C at 25:10-17 ("Ember is a small device that measures a number of blood constituents noninvasively."). The evidence, including documents

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[134] As with the Masimo Watch, Complainants prepared several financial spreadsheets detailing their domestic expenditures for the rainbow® sensors. *See* CIB at 299-300. While Apple argues that these spreadsheets are unreliable as to the rainbow® sensors, Apple's arguments are unpersuasive for the same reasons as discussed above with respect to the Masimo Watch. *See* Part VII.C. *supra*.

[135] The [redacted] *See* RX-1201C (Hammarth Dep.) at 82:2-4.

[136] [redacted] is the internal project name for the Ember product. *See* RX-1201C (Hammarth Dep.) at 82:8-10.

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and sworn testimony, therefore shows that Cercacor accurately allocated certain R&D projects as related to the rainbow® sensors.

The evidence demonstrates that Cercacor's R&D investments in the rainbow® sensors are quantitatively and qualitatively significant.

Cercacor's largest project has been the rainbow® technology. For example, from 2005-2020, Cercacor spent a total net R&D expense of about [redacted], with about [redacted] of that dedicated to rainbow® technology. Tr. (Hammarth) at 524:16-525:5; CDX-0008C.002 (summarizing CX-0633C); CX-0633C. Moreover, as previously discussed, [redacted] of the investment in rainbow® technology was incurred in the U.S. Tr. (Hammarth) at 525:6-8; *see Gas Spring Nailer Prods. and Components Thereof*, Inv. No. 337-TA-1082, Comm'n Op. at 83, EDIS Doc. ID 709073 (Apr. 28, 2020) (finding quantitative significance where "all, *i.e.*, 100 percent, of Kyocera's R&D and engineering expenditures relating to complainant's [DI products] occurs in the United States."), *vacated and remanded on other grounds*, 22 F.4th 1369 (Fed. Cir. 2022); *Certain Shingled Solar Modules, Components Thereof, and Methods for Manufacturing the Same*, Inv. No. 337-TA-1223, Initial Determination at 60, EDIS Doc. ID 756910 (Oct. 22, 2021) (finding quantitative significance where 100% of research and development activities were based in the United States), *not reviewed in relevant party by* Comm'n Notice, EDIS Doc. ID 762554 (Feb. 4, 2022). Other than criticizing Complainants' other quantitative comparisons, or arguing that Complainants' expenditures are overstated and unreliable, Apple does not specifically rebut Complainants' contention that Cercacor's R&D investments are quantitatively

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significant.[137] *See, e.g.* RIB at 278; RRB at 174-75. The evidence therefore demonstrates that Cercacor's domestic investments in R&D labor for rainbow® are quantitatively significant.

Cercacor's domestic R&D investments for the rainbow® sensors are also qualitatively significant. Cercacor's R&D effort related to the rainbow technology has been a large part of its business, and again, was incurred entirely in the U.S. *See, e.g., Certain Percussive Massage Devices*, Inv. No. 337-TA-1206, Comm'n Op. at 10-15, EDIS Doc. ID 759545 (Jan. 4, 2022) (affirming finding that complainant satisfied the economic prong of the domestic industry requirement and finding qualitative significance, in part, because complainant's domestic industry products "would not exist without [its] domestic operations and spending" because it "designed and developed the DI Products in the United States"). In addition, not only has it been Cercacor's largest project in terms of R&D spend, as explained above, but over the years, Cercacor has employed the [redacted] of its employees to work on rainbow®. *See* CDX-0015C.015 (summarizing CX-0633C) (showing that Cercacor has dedicated between [redacted] and [redacted] of its employees to rainbow®); CX-0633C. In addition to Cercacor's domestic R&D labor investments, Masimo has also made domestic investments in R&D labor for rainbow®. *See* Tr. (Young) at 499:15-500:7; CX-0644C. Lastly, it is worth noting that Masimo also manufactures important components of the rainbow® sensors, semiconductor LEDs and optical packages of emitters and detectors, at its Hudson, New Hampshire facility in the U.S., distinguishing Complainants from a mere importer. *See* Tr. (Young) at 507:7-15; *see also* CX-0636C; CX-0638C; *see Certain Toner Supply Containers and Components Thereof (II)*, Inv. No. 337-TA-1260, Comm'n Op. at 11-12, EDIS Doc. ID 777011 (Aug. 3, 2022) (finding qualitative

[137] Apple's arguments disputing quantitative significance focus on Complainant's cost of goods (COGS) analysis. *See* RIB at 278. The undersigned, however, is not relying on that analysis in finding quantitative significance.

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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.

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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.

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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).

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CERTIFICATE OF SERVICE

I, Katherine M. Hiner, hereby certify that the parties listed have entered an appearance in the above captioned investigation, and a copy of the PUBLIC CERTIFICATE OF SERVICE was served upon the following parties via first class mail and air mail where necessary.

Document	Security	Document Type	Official Rec'd Date	Title
789795	Public	ID/RD - Final on Violation	02/07/2023 04:52 PM	Final Initial Determination on Violation of Section 337

Service Date: February 07, 2023

/s/

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