

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.,
Petitioner

v.

WILLOW LABORATORIES, INC.,
Patent Owner

Case IPR2024-00296
Patent 10,984,911

PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE

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EXHIBITS

APPLE-1001	U.S. Patent No. 10,984,911 to Smith et al. (“the ’911 patent”)
APPLE-1002	Excerpts from the Prosecution History of the ’911 patent
APPLE-1003	Declaration of Dr. Thomas Kenny
APPLE-1004	U.S. Patent Application Publication No. 2004/0039272 to Abdul-Hafiz et al. (“Abdul-Hafiz”)
APPLE-1005	U.S. Patent No. 6,014,576 to Raley (“Raley”)
APPLE-1006	U.S. Patent No. 5,188,108 to Secker (“Secker”)
APPLE-1007	U.S. Patent No. 5,983,122 to Jarman et al. (“Jarman”)
APPLE-1008	U.S. Patent No. 5,413,100 to Barthelemy et al.
APPLE-1009	U.S. Patent No. 6,721,585 to Parker (“Parker”)
APPLE-1010	U.S. Patent No. 5,720,284 to Aoyagi et al. (“Aoyagi”)
APPLE-1011	Excerpts from Webster, Design of Pulse Oximeters, Institution of Physics Publishing (1997) (“Webster”)
APPLE-1012	U.S. Patent No. 5,692,503 to Kuenstner (“Kuenstner”)
APPLE-1013-1059 RESERVED	
APPLE-1060	Combined Civil and Criminal Federal Court Management Statistics (Sep. 30, 2023) United States Courts (uscourts.gov), available at: https://www.uscourts.gov/sites/default/files/fcms_na_distprofile0930.2023.pdf
APPLE-1061	Memorandum, Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation (USPTO June 21, 2022)(“Director’s Guidance”)

APPLE-1062	Apple's Complaint for Patent Infringement (Design), <i>Apple Inc., v. Masimo Corporation, et al.</i> , Case No. 1-22-cv-01377 (D. Del. Oct. 20, 2022)
APPLE-1063	Apple's Complaint for Patent Infringement (Utility), <i>Apple Inc., v. Masimo Corporation, et al.</i> , Case No. 1-22-cv-01378 (D. Del. Oct. 20, 2022)
APPLE-1064	Defendant Masimo Corporation's Answer to Complaint and Counterclaims, <i>Apple Inc., v. Masimo Corporation, et al.</i> , Case No. 1-22-cv-01378 (D. Del. Dec. 12, 2022)
APPLE-1065	Order Granting Joint Motion to Amend the Case Schedule, <i>Apple Inc., v. Masimo Corporation, et al.</i> , Case No. 1-22-cv-01378 (D. Del. Sep. 21, 2023)
APPLE-1066	Stipulation by Apple Inc.
APPLE-1067	Email Identifying Masimo's District Court Invalidity Grounds (Nov. 16, 2023)
APPLE-1068	Excerpt of Apple's District Court Expert Invalidity Report, <i>Apple Inc., v. Masimo Corporation, et al.</i> , Case No. 1-22-cv-01378 (Nov. 22, 2023)
APPLE-1069	Order Granting Unopposed Motion to Stay Certain Patent Counterclaims, <i>Apple Inc., v. Masimo Corporation, et al.</i> , Case No. 1-22-cv-01378 (Jan. 10, 2023)
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APPLE-1075	Joint Letter for March 20, 2024 Case Management Conference, <i>Apple Inc., v. Masimo Corporation, et al.</i> , Case No. 1-22-cv-01378 (Mar. 16, 2024)
APPLE-1076	Combined Civil and Criminal Federal Court Management Statistics (Dec. 31, 2023) United States Courts (uscourts.gov), available at: https://www.uscourts.gov/sites/default/files/fcms_na_distprofile_1231.2023_0.pdf

APPLE-1077	Median Time to Disposition in Cases Terminated After Hearing or Submission United States Court of Appeals for the Federal Circuit (Sep. 30, 2023), available at: MedDispTimeMERITS-Table-FY23.pdf (uscourts.gov)
APPLE-1078	<i>Sotera</i> Stipulation by Apple Inc.
APPLE-1079	Supplemental Declaration of Dr. Thomas Kenny
APPLE-1080	U.S. Patent Application Publication No. 2004/0054291 to Schulz et al. (“Schulz”)
APPLE-1081	U.S. Patent No. 6,608,562 to Kimura et al. (“Kimura”)
APPLE-1082	Excerpts from Rebuttal Expert Report of Vijay K. Madisetti, Ph.D. Regarding Validity of U.S. Patent No. 10,984,911, <i>Apple Inc., v. Masimo Corporation, et al.</i> , Case No. 1-22-cv-01378 (Dec. 15, 2023)
APPLE-1083	Transcript of Deposition of Dr. Vijay Madisetti
APPLE-1084	International Patent Application Publication No. WO2000002294A2
APPLE-1085	U.S. Patent No. 4,412,255 to Kuhlman et al.
APPLE-1086	U.S. Patent Application Publication No. 2002/0165440 to Mason et al.
APPLE-1087	DuPont CB028 Silver Conductor Technical Data Sheet (03/2013)

As explained in the Petition and addressed below, the prior art renders obvious the Challenged Claims. The Board should find the Challenged Claims unpatentable.

I. Dr. Kenny has the knowledge and capability of a POSITA.

Masimo mischaracterizes Dr. Kenny’s testimony regarding a POSITA’s understanding and capabilities. POR, 11. Dr. Kenny clarified during his deposition that a POSITA would not have had to already develop a system such as described by Abdul-Hafiz. EX2080, 92:16-93:16, 22:7-20; APPLE-1079, ¶¶5-7. Further, Dr. Kenny provides corroborating evidence and factual analysis in support of his conclusions. *Cf. Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9 (PTAB Aug. 24, 2022) (Precedential).

II. Masimo’s claim construction arguments fail.

Masimo recycles its arguments from the POPR that Apple presents inconsistent claim constructions. *Compare* POPR, 9-11, *with* POR, 14-17. The Board correctly dismissed them in the Institution Decision. ID, 19-20. Masimo has not provided any arguments that would change the Board’s conclusion.

III. Raley teaches a “cavity.”

Based on Masimo’s recycled arguments from the POPR (*compare* POPR, 11-13, *with* POR, 17-18), the Board correctly concluded that Raley teaches a “cavity.” ID, 20, 35-36. Masimo further argues that Raley “does not disclose

whether its LEDs are placed into a ‘pre-existing’ cavity or mounted on a flat substrate.” POR, 19. As Dr. Kenny explains, Raley’s LEDs are “recessed into” a pre-existing cavity. APPLE-1079, ¶¶9-11; APPLE-1005, 6:61-7:5, 7:16-20, FIGS. 1, 3. Raley’s FIG. 3 shows that a circular opening 26 accommodates the LED assembly. Opening 26 has a vertical depth and is a cavity in the interconnect cable segment within which the LED assembly is recessed and set back into. Dr. Kenny confirmed during his deposition that a POSITA would have interpreted Raley’s disclosure to describe LEDs that are recessed into a cavity defined by the circular opening 26 in order to not be destroyed during the assembly of the interconnect cable segment 20 into the connector 17 and to protect the patient from excess heat. EX2080, 74:12-20, 101:8-11, 102:13-103:7.

IV. Abdul-Hafiz teaches “a top.”

Based on Masimo’s recycled arguments from the POPR (*compare* POPR, 13, *with* POR, 19-20), the Board correctly concluded that Abdul-Hafiz discloses “a top.” ID, 36-37. Masimo has not provided any additional arguments that would change the Board’s conclusion. Here, it is irrelevant that the ’911 patent and Abdul-Hafiz use different terms for the uppermost portion. APPLE-1079, ¶12; APPLE-1004, FIG. 6A. A “reference need not satisfy an *ipsissimis verbis* test” in order to satisfy a claim element. *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009); *Whitserve, LLC v. Comput. Packages, Inc.*, 694 F.3d 10, 21 (Fed. Cir. 2012)

V. Abdul-Hafiz teaches a light block with “only one opening.”

Masimo accuses Apple and the Board of ignoring the presence of an EMI shield. POR, 2, 23-25. Apple is not ignoring the presence of the EMI shield nor proposing to remove the EMI shield. Rather, Apple relies on Abdul-Hafiz’s low noise optical housing 400, not fixed shield 1005, for disclosing the recited light block. Pet. 35 (citing APPLE-1003, ¶¶85–87); APPLE-1004, FIGS. 4A-4C. In Abdul-Hafiz, light passes through the single aperture 470 in low noise optical housing 400 to detector 820. *Id.* at 42 (citing APPLE-1003, ¶96; APPLE-1004, Abstract, ¶¶5–7). Thus, the low noise optical housing 400 with the single aperture 470 is a light block with “only one opening.” APPLE-1079, ¶14.

A POSITA would not have understood that Abdul-Hafiz’s EMI shield is a light block. APPLE-1079, ¶13. Abdul-Hafiz never describes that the EMI shield blocks light nor describes that the EMI shield is made of optically opaque material like copper. Dr. Kenny also explained during his deposition that there are examples of EMI shields that would still allow some light transmission and may not provide adequate ambient and piped light reduction. EX2080, 158:15-160:21, 106:13-20; APPLE-1084 (EMI shields that “permit high visible light transmissivity”); APPLE-1085 (a “transparent electromagnetic shield”); APPLE-1086, [0036] (“DUPONT CB028 silver-filled thermoplastic screenable ink”); APPLE-1087.

Abdul-Hafiz is similar to the '911 patent. APPLE-1001, FIGS. 32A-32B. If the '911 patent's EMI shield were considered a light block, then the '911 patent provides no support for this claimed element because the '911 patent's EMI shield has a grid with multiple openings, as shown in FIGS. 24 and 46 below. APPLE-1001, 13:38-54, 15:14-23, 19:15-16, FIGS. 24, 46; APPLE-1079, ¶15; APPLE-1082, ¶907.

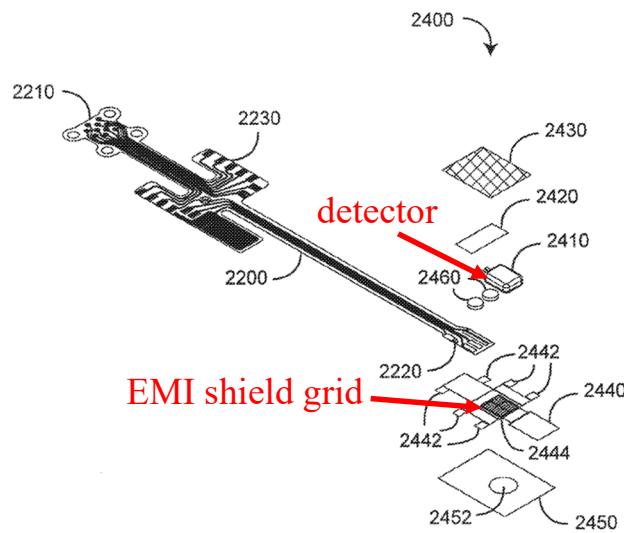


FIG. 24

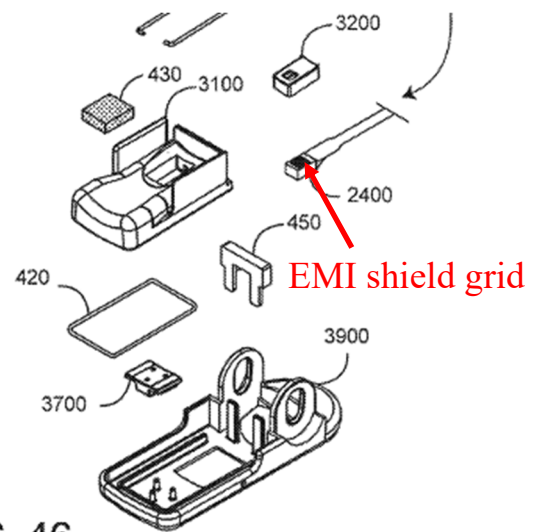


FIG. 46

Masimo's reliance on *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1332 (Fed. Cir. 2019) and *St. Jude Med., LLC v. Snyders Heart Valve LLC*, 977 F.3d 1232, 1243 (Fed. Cir. 2020) is misplaced, as they are directed to determining whether there is a motivation to combine references.

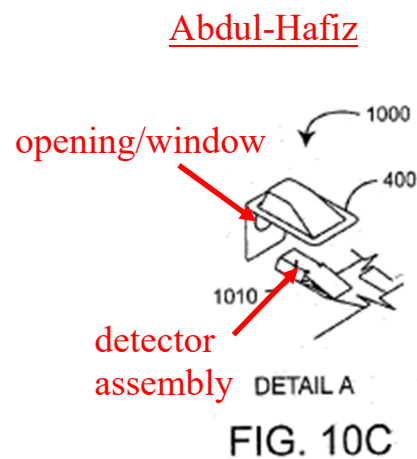
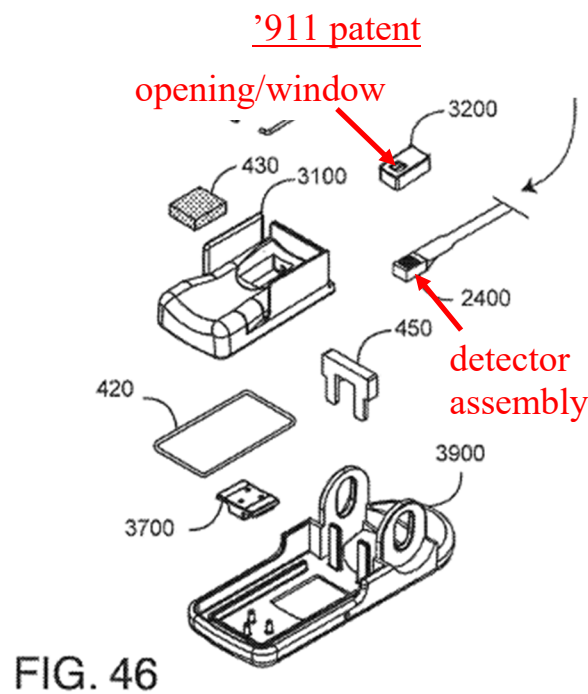
VI. Abdul-Hafiz discloses an opening/window with an area smaller than the detector's detection surface area at least as well as the '911 patent itself discloses this element.

Masimo takes issue with Apple's reliance on Abdul-Hafiz's figures as teaching this element. POR, 3, 25-26, 28-29. But Masimo improperly seeks to hold the prior art to a higher standard of disclosure than the '911 patent itself. APPLE-1079, ¶¶22-23; APPLE-1082, ¶¶924-941; APPLE-1083, 33:18-34:21. Masimo should not be able to rely on the '911 patent's figures as providing support for this element while complaining that Apple cannot rely on Abdul-Hafiz's figures for satisfying this element. *In re Epstein*, 32 F.3d 1559, 1568 (Fed. Cir. 1994).

The '911 patent's detailed description provides no description of this feature, never mentions the terms "opening" or "detection surface area," uses the term "window" only once, and never describes the opening/window as having an area smaller than a detection surface area of the detector. APPLE-1001, 6:42-47, 15:4-9, 15:14-23; APPLE-1079, ¶16. As such, Apple must rely on the figures of the '911 patent to interpret this claim limitation. The only plausible support for this element appears to be FIG. 46 which shows the detector assembly 2400 and the shoe box 3200 with the window 3210 in the same figure. APPLE-1079, ¶17. The '911 patent FIG. 46 allegedly shows that the opening/window has an area smaller than the entire surface area of one side of the detector. Thus, FIG. 46 indicates to a POSITA that the "detection surface area" recited in the claims would be the

surface area of the light-detecting side of the detector. APPLE-1082, ¶911.

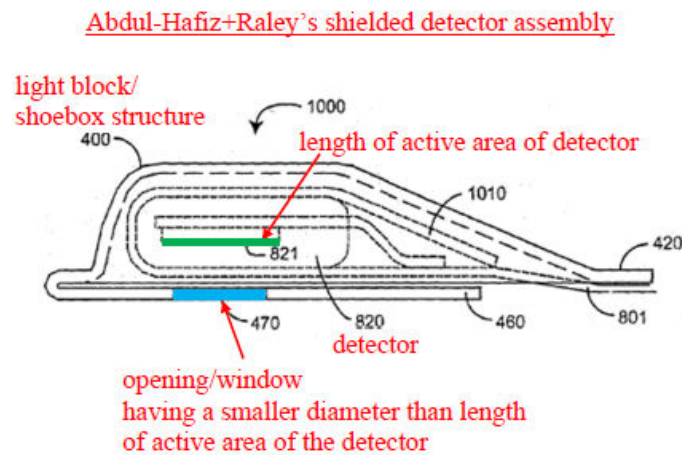
Abdul-Hafiz's specification and figures are at least as, if not more, detailed than the '911 patent's specification and figures supporting this element. APPLE-1079, ¶18. As such, Abdul-Hafiz satisfies this element in the same way as the '911 patent, i.e., from its figures. A visual inspection of the '911 patent's FIG. 46 (below, left) and Abdul-Hafiz's FIG. 10C (below, right) shows the same relationship between the detector and the opening/window with respect to this element.



In addition to Abdul-Hafiz's FIG. 10C, Abdul-Hafiz's FIGS. 6A, 3, and 11B show the opening/window smaller than the detector's detection surface area.

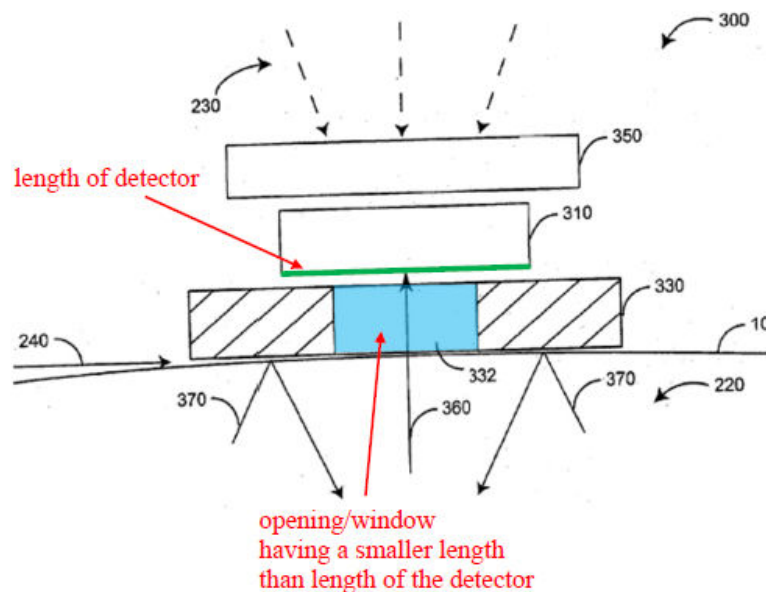
APPLE-1079, ¶¶19-21; APPLE-1004, [0004], [0033], [0037]. Abdul-Hafiz's FIG.

6A shows that the length of the light-detecting side of Abdul-Hafiz's detector 820 is longer than the diameter of Abdul-Hafiz's aperture 470. Pet., 47.



APPLE-1004, FIG. 6A

Abdul-Hafiz's FIG. 3 similarly shows that the length of the light-detecting side of Abdul-Hafiz's detector 310 is longer than the diameter of Abdul-Hafiz's aperture 332. Pet., 48; APPLE-1003, ¶102; POR, 29; EX2079, ¶86; APPLE-1083, 50:8-52:3.



APPLE-1004, FIG. 3

Abdul-Hafiz's FIG. 11B reveals that the width of the light-detecting side of Abdul-Hafiz's detector is at least as wide as the diameter of Abdul-Hafiz's aperture. As Masimo acknowledges, FIG. 11B shows that Abdul-Hafiz's aperture (470) includes a fixed EMI shield (1005, red). POR, 30. The surface area of the EMI shield (1005, red) is representative of the surface area of the light-detecting side of Abdul-Hafiz's detector, just like the '911 patent FIG. 46. Because the EMI shield (1005, red) spans at least the entire area of the aperture (470), the aperture (470) has an area smaller than the surface area of the EMI shield (1005, red), and thus the aperture (470) has an area smaller than the light-detecting side of Abdul-Hafiz's detector, just like the '911 patent FIG. 46. From Abdul-Hafiz's FIG. 11B, the surface area of the light-detecting side of Abdul-Hafiz's detector must be bigger than the circle otherwise the boundary of the detector would be visible in the circle. The diameter of the circle is at least as wide as the smallest dimension of the detector because no detector edges are shown. Abdul-Hafiz's FIG. 11B would have been understood to reveal that the width is at least as wide as the diameter of the circular aperture and, given that the length is known from FIGS. 6A and 3 to be longer than the diameter of the circular aperture, the detection surface area is larger than the surface area of the aperture, as illustrated by the red boundary outline of the detection surface area in FIG. 11B below. EX2080, 114:8-14 ("outer boundaries of the detector are not shown").

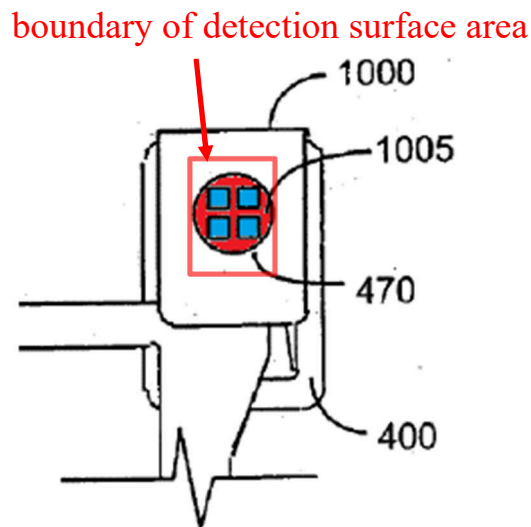


FIG. 11B

APPLE-1004, FIG. 11B (annotated according to Abdul-Hafiz's teachings)

Masimo points to no support in the '911 patent for its construction of detection surface area being "the four blue areas" where light reaches the detector/photodiode (820/821) of Abdul-Hafiz. POR, 31-32; APPLE-1083, 27:4-29:20; APPLE-1079, ¶24. Rather, as Dr. Kenny explained during his deposition, the light can come in at oblique angles and reach portions of the detector/photodiode (820/821) that are under the fixed shield (1005). EX2080, 114:15-115:2; APPLE-1079, ¶25.

Masimo takes issue with Apple's explanation that Abdul-Hafiz's detector is "square or rectangular." POR, 33-36. Regardless, Abdul-Hafiz's FIG. 11B would have been understood to reveal that the width is at least as wide as or wider than the diameter of the circular aperture and, given that the length is known from

FIGS. 6A and 3 to be longer than the diameter of the circular aperture, the detection surface area is larger than the surface area of the aperture, as illustrated by two examples of the red boundary outline of the detection surface area in FIG. 11B below. APPLE-1079, ¶¶26-27.

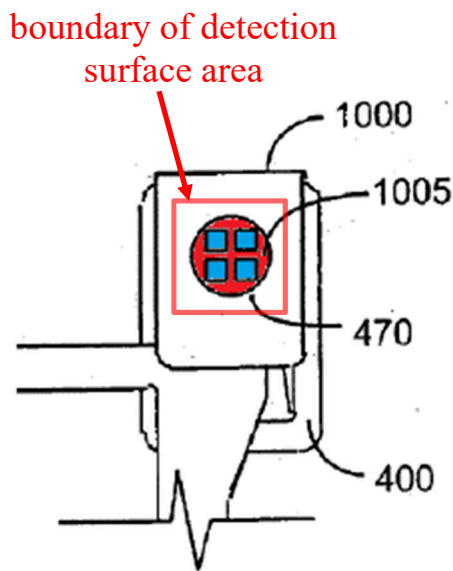


FIG. 11B

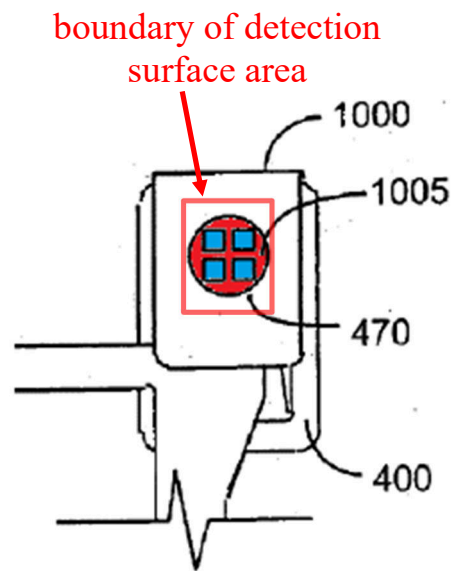


FIG. 11B

APPLE-1004, FIG. 11B (annotated according to Abdul-Hafiz's teachings)

Masimo's reliance on the Masimo LNOP sensor is misplaced. POR, 35. Masimo's LNOP sensor is not representative of Abdul-Hafiz because there are differences between the LNOP sensor and Abdul-Hafiz. APPLE-1079, ¶28. Even if the LNOP sensor had an aperture with an area larger than the detection surface area, that does not establish that this feature of the LNOP sensor necessarily follows from the Abdul-Hafiz's disclosures. Indeed, Masimo's LNOP sensor is

covered by at least 20 other patents, indicating that the sensor is not representative of Abdul-Hafiz. EX2079, ¶53; EX2043.

VII. Abdul-Hafiz also renders obvious an opening/window with an area smaller than the detector's detection surface area.

Apple proposed that a POSITA would have found it obvious to modify Abdul-Hafiz to have a smaller aperture (470) and explained that a POSITA would have been motivated to modify Abdul-Hafiz to have a smaller “opening”/“window” to “desirably reduce the extraneous light entering through the opening of the housing and the finger as a light guide” and to prevent “rays from optical noise sources such as ambient light 230 and piped light 240, which are typically incident on the detector 114 at a large angle of incidence, from reaching the active area of the detector.” Pet., 50-51; APPLE-1079, ¶29.

To that end, Webster corroborates what a POSITA would have known, that “minimize[ing] the effects from light other than the optical signals of interest” involves “decreas[ing] the angle of incidence to the photodiode.” APPLE-1011, 96-97, FIG. 6.6; APPLE-1079, ¶30. Further, Schulz also corroborates what a POSITA would have known, describing another example of a transmission probe with opaque material that blocks light and where a “window in the opaque material can be sized as needed to block the proper amount of light from entering the aperture to, for example, avoid saturation of the light detector.” APPLE-1080,

[0073]; APPLE-1079, ¶31.

Kimura also corroborates a POSITA's understanding by describing "a window 412 for limiting the angle of incidence at which light can enter the light-receiving device 404 is provided above the light-receiving device 404." APPLE-1081, 12:51-63, 14:19-47; APPLE-1079, ¶32. Kimura explains that that "the window width d " is made "to cut out light having an angle of incidence θ of over $\pm 30^\circ$ " because "extraneous light guided in through the skin of the finger F can be considered to be incident on the light-receiving device 404 at a large angle of incidence ($\theta \geq 30^\circ$)." APPLE-1081, 14:28-44. "Consequently, since extraneous light can be effectively cut out by limiting the window width d , it is possible to reduce erroneous detection caused by the influence of extraneous light." APPLE-1081, 14:44-47.

Based on a POSITA's knowledge and understanding as corroborated by these references, a POSITA understood that in transmission probes such as Abdul-Hafiz's, it would be desirable to have the opening configured to have a smaller area than the detection surface area of the detector to decrease the angles of incidence to the detector. APPLE-1079, ¶33. Because the modification to Abdul-Hafiz is merely configuring the aperture to have an area smaller than the detection surface area of the detector, the reasonable expectation of success is implicit.

Elekta Ltd. v. ZAP Surgical Systems, Inc., 81 F. 4th 1368, 1376 (Fed. Cir. 2023).

VIII. Raley enables measuring blood analyte levels using four LEDs.

Prior art is presumed enabled, and a party challenging enablement of the prior art may overcome that presumption with evidence that the practice of the invention would have required undue experimentation. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354-55 (Fed. Cir. 2003); *In re Antor Media Corp.*, 689 F.3d 1282, 1287–90 (Fed. Cir. 2012) (holding that prophetic examples in the prior art are still presumed to be enabling). Masimo completely ignores the many *Wands* factors that must be considered to carry the burden of establishing whether undue experimentation would have been required by a POSITA. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

Here, Masimo fails to show that Raley did not enable a POSITA to measure blood analyte levels using four wavelengths of light. POR, 21, 39-46. The testimony offered by Dr. Madisetti does not explain “with sufficient specificity, what and how much experimentation would have been required by one with ordinary skill, and why that amount of experimentation should be regarded as ‘undue.’” *Liberty Mutual Ins. Co. v. Progressive Casualty Ins. Co.*, CBM2013-00009, Paper 68, 40 (PTAB Feb. 11, 2014). Dr. Madisetti does not explain what level of experimentation is undue, nor does he sufficiently address all of the factors set forth in *Wands*. For instance, Masimo offers no evidence (from Dr. Madisetti or otherwise) to inform the level of complexity of experimentation necessary to

measure blood analyte levels using four wavelengths of light based on the state of the prior art and the relative skill of those in the art, much less to inform whether a POSITA would typically engage in such experimentation.

Masimo focuses on the absence of commercial devices. POR, 41-42, 45-46. But “[i]t is not, however, necessary that an invention disclosed in a publication shall have actually been made in order to satisfy the enablement requirement” and “the fact that the author of a publication did not attempt to make his disclosed invention does not indicate one way or the other whether the publication would have been enabling.” *In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985); *In re Antor Media Corp.*, 689 F.3d 1282, 1290 (Fed. Cir. 2012); *Novo Nordisk Pharm., Inc. v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347, 1355 (Fed. Cir. 2005); *Alcon Research Ltd. v. Barr Labs, Inc.*, 745 F.3d 1180, 1189 (Fed. Cir. 2014).

Further, there is a distinction between reducing an invention to practice in a prototype and commercializing the invention by selling products that embody the invention to the public at large. As the Federal Circuit makes clear from the cases above, it is not necessary to make a physical prototype of an invention as the publication itself serves to constructively reduce the invention to practice.

Masimo’s alleged evidence that Raley fails to enable its disclosure here relies almost exclusively on Masimo’s knowledge of commercial products, reflecting no knowledge of private, never commercialized prototypes, and failing to

substantively engage in the contents of the cited printed publications in the manner demanded by the Federal Circuit (i.e., presenting detailed evidence needed to support an enablement attack set forth in *Wands*).

Masimo's only technical argument alleges that a POSITA would not have known how to measure four blood analytes with only four wavelengths of light because of other unknown variables such as path length. POR, 42-45. But Masimo fails to show that any of these alleged additional "unknowns" could not be estimated, canceled out, or calculated to make them "knowns." APPLE-1079, ¶34. The one example Masimo gives of path length can be estimated away so that it is no longer an additional "unknown." As Masimo admits, "Secker explains that this problem of 'differing depth of penetration at various wavelengths' is limited to reflectance sensors and 'does *not* apply' to transmission sensors." POR, 64; APPLE-1006, 3:28-45; EX2079, ¶145; APPLE-1083, 91:18-92:2, 95:7-16. For transmittance sensors arranged in a fingertip probe such as those described in Raley and Abdul-Hafiz, the emitters are located very close together, and thus the light paths are very close together and the path lengths are approximately the same for light emitted by each emitter. APPLE-1011, 104, 144-145. Because the path lengths are approximately the same, the path lengths in the equations cancel out. *Id.*

IX. A POSITA would have reasonably expected success in modifying Abdul-Hafiz to measure oxygen saturation and at least one of carboxyhemoglobin and methemoglobin.

Masimo here again focuses on the absence of commercial devices. POR, 47. Masimo's arguments are conclusory as they conclude, without evidence, that Masimo being allegedly the first to commercialize a product that embodies the alleged invention means that no one else would have been able to make the alleged invention or expect success in doing so. But evidence of commercialization is NOT evidence that the alleged invention was not already known. An invention can be known through simple printed publication disclosure, with no requirement to produce a physical prototype, much less a commercialized product as advanced by Masimo. *In re Donohue*, 766 F.2d at 533; *In re Antor Media Corp.*, 689 F.3d at 1290. Masimo is conflating commercial concepts with legal concepts. Further, Masimo does not cite, and Apple is not aware of, any legal authority that requires actual success in the prior art as a prerequisite of obviousness. *Almirall, LLC v. Amneal Pharms. LLC*, 28 F.4th 265, 275 (Fed. Cir. 2022).

Masimo fails to show that a POSITA would not have reasonably expected success in modifying Abdul-Hafiz for the same reasons that Masimo fails to show that Raley did not enable a POSITA to measure blood analyte levels using four wavelengths of light. *Supra*, Section VIII. Specifically, Masimo's expert asserts, in a conclusory manner, that the calculation for the blood analytes would require

more than four unknowns and yet only identifies one alleged unknown as being the “path length,” failing to appreciate that this alleged unknown can be estimated away for transmission sensors like that of Abdul-Hafiz. APPLE-1079, ¶34. In failing to identify any other additional unknowns or otherwise explain why these unknowns also could not be addressed, like path length, through estimation or otherwise, Masimo has NOT provided any meaningful evidence to assert lack of enablement or expectation of success. Indeed, the Courts have placed a set of detailed factors to be considered with supporting evidence when it comes to enablement, which Masimo has failed to address. *In re Wands*, 858 F.2d at 737.

X. A POSITA would have been motivated to modify Abdul-Hafiz to measure more blood analytes.

Masimo’s focus on Abdul-Hafiz’s sensor being low cost and disposable (POR, 48-51) is misplaced as the claims do not require the sensor be low cost and disposable. APPLE-1079, ¶36. Masimo is improperly superimposing the purported goals and purpose of Abdul-Hafiz onto the POSITA. *Intel Corp. v. Qualcomm Inc.*, 21 F.4th 784, 800 (Fed. Cir. 2021); *Axonics, Inc. v. Medtronic, Inc.*, 73 F.4th 950, 957 (Fed. Cir. 2023). Although Abdul-Hafiz expresses certain goals, Masimo does not adequately identify any disclosure in either Abdul-Hafiz or Raley that disparages Apple’s articulated combination. *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1327 (Fed. Cir. 2009).

Further, “[i]t’s not necessary to show that a combination is ‘the best option, only that it be a suitable option.’” *Intel Corp.*, 21 F.4th at 800 (quoting *PAR Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1197–98 (Fed. Cir. 2014)); *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006). The existence of better alternatives does not obviate the motivation to make the combination. *In re Mouttet*, 686 F.3d 1322, 1334 (Fed. Cir. 2012). Masimo’s argument, if correct, does not undermine Apple’s showing that the Abdul-Hafiz+Raley combination would have been obvious. After performing the comparison that purportedly indicates the undesirability of the proposed combination, that combination would not vanish from a POSITA’s mind and suddenly become non-obvious. A POSITA would have been led to the combination when the additional benefit of measuring more analytes would outweigh the alleged added costs/inconvenience. As discussed in the Petition, measuring additional blood analytes is useful and desirable in some realistic situations which would be a benefit that offsets a more complex and more expensive device. Pet., 15, 18.

Masimo never asserts that a POSITA would definitively NOT incur the additional costs for the benefit of having more blood analytes being measured. As such, their evidence is inapposite. APPLE-1079, ¶35; ID, 32-33. The inquiry is not whether the multiple blood analyte device would be more expensive or costly

but rather whether a POSITA would accept such additional costs/inconvenience to get the benefit of the measurement of an additional blood analyte. Masimo fails to provide evidence on this point and, therefore, their evidence is deficient.

Masimo argues that the combination would have to be configured to include “the sensor’s LEDs in a separate reusable component (e.g., Raley’s connector-end (25))” and that resulting configuration “would have further increased cost because of the need to inspect and clean that component between patients” and “thus would have frustrated Abdul-Hafiz’s intended purpose by transforming its low-cost, fully disposable sensor into a more expensive, partly reusable sensor.” POR, 50. But the “test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference.” *In re Keller*, 642 F.2d 413, 425 (CCPA 1981). A POSITA is not compelled to blindly follow the teaching of one prior art reference over the other without the exercise of independent judgment. *Lear Siegler, Inc. v. Aeroquip Corp.*, 733 F.2d 881, 889 (Fed. Cir. 1984). As the Supreme Court recognized in *KSR*, “[a] person of ordinary skill is also a person of ordinary creativity, not an automaton.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007)). A POSITA would have been able to implement a low-cost and disposable sensor based on Abdul-Hafiz and Raley’s teachings by, for example, including the sensor’s LEDs in a disposable component. In this way, Abdul-Hafiz’s techniques would still yield its desired cost benefits

when applied to a multiple blood analyte device because of the various low cost attributes of Abdul-Hafiz's device that would still be preserved in the modified and enhanced multi-blood analyte device of the Abdul-Hafiz+Raley combination.

APPLE-1079, ¶37.

XI. A POSITA would have been motivated to modify Abdul-Hafiz to compensate for errors in the measurement of oxygen saturation.

As discussed above in Sections VIII-IX, Masimo's enablement and reasonable expectation of success arguments are flawed. POR, 52, 56. Further, as discussed above in Section X, Masimo provides no evidence that the "negative consequences" of the Abdul-Hafiz+Raley combination "were not outweighed by any countervailing benefit." POR, 52. And here again, Masimo focuses on the commercial landscape of products (POR, 52), which is not the correct legal inquiry. *In re Donohue*, 766 F.2d at 533; *In re Antor Media*, 689 F. 3d at 1290.

Masimo attempts to show no need to improve the accuracy of Abdul-Hafiz's oxygen saturation measurements by relying on the Masimo LNOP sensor. POR, 53-54. Masimo's LNOP sensor is not representative of Abdul-Hafiz because there are differences between the LNOP sensor and Abdul-Hafiz. APPLE-1079, ¶38. The differences between the LNOP sensor and Abdul-Hafiz establish that they are not identical, and the LNOP sensor at least embodies a different species of Abdul-Hafiz. Therefore, the accuracy of Masimo LNOP sensors does not necessarily

follow from Abdul-Hafiz's disclosures and does not necessarily reflect the accuracy of Abdul-Hafiz's measurement.

A POSITA would have found it obvious to take a different approach to improve Abdul-Hafiz's measurements based on prior art references such as Jarman, Barthelemy, and other prior art showing that there was a known need in the art to compensate for errors in oxygen saturation measurements resulting from carboxyhemoglobin and methemoglobin. Pet. 18; APPLE-1003, ¶68; APPLE-1007, 1:63-2:14; APPLE-1008, 3:25-37; APPLE-1079, ¶39. Raley expressly teaches that its probe with four emitters would be useful for measuring three or four blood analytes such as oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin, and methemoglobin. APPLE-1005, 5:65–6:2. Given the need in the art to compensate for errors in oxygen saturation measurements resulting from carboxyhemoglobin and methemoglobin and Raley's express teaching of a probe that measures blood analytes such carboxyhemoglobin and methemoglobin, a POSITA would have been motivated to combine the teachings of Abdul-Hafiz's pulse oximetry system and Raley's probe to compensate for errors in the measurement of oxygen saturation due to the presence of carboxyhemoglobin and methemoglobin. Pet., 15, 18-19; ID, 34. Apple's motivation is not merely to "build something better." POR, 54-55; APPLE-1079, ¶40. Rather, Dr. Kenny articulated a specific motivation (to improve oxygen saturation accuracy) and

explains a number of circumstances that would inspire the motivation, based on evidence of record (Jarman, Barthelemy, and other prior art), to support his conclusion of obviousness. APPLE-1003, ¶¶67-68; Pet. 18-20, 25-27; POR, 55-56; EX2046, 2; EX2047, 1; EX2057, 5.

Masimo's further reliance on Datex-Ohmeda's pulse oximeters is also misplaced. POR, 55. Datex-Ohmeda's pulse oximeters are not representative of Raley because there are differences between Datex-Ohmeda's pulse oximeters and Raley's disclosure. APPLE-1079, ¶41; EX2063, 22; APPLE-1005, 5:63-6:2. The differences between the Manual and Raley establish that they are not identical, and the pulse oximeter described in the Manual at least embodies a different species of Raley. Therefore, the sensitivity of the pulse oximeter described in the Manual does not necessarily follow from Raley's disclosure and does not necessarily reflect the sensitivity of Raley's measurements.

XII. The Abdul-Hafiz+Raley+Secker combination teaches at least eight or twelve LEDs comprising at least three different wavelengths.

“Nonobviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references.” *Bradium Technologies v. Iancu*, 923 F. 3d 1032, 1050 (Fed. Cir. 2019). Instead, each reference “must be read, not in isolation, but for what it fairly teaches in combination with the prior art as a whole.” *Id.* Here, Masimo is arguing each

reference individually, asserting that none discloses the overall claimed subject matter (POR, 4, 59-62), rather than properly evaluating the references' combined teachings. *Game & Tech. Co. v. Wargaming Grp. Ltd.*, 942 F.3d 1343, 1352 (Fed. Cir. 2019). Further, this is an obviousness ground and, therefore, "the question under 35 [U.S.C. §]103 is not merely what the references expressly teach but what they would have suggested to one of ordinary skill in the art at the time the invention was made." *Merck & Co. v. Biocraft Labs., Inc.*, 874 F.2d 804, 807–08 (Fed. Cir. 1989).

Neither Masimo nor Dr. Madisetti dispute that Raley discloses LEDs of four different wavelengths and Secker discloses four LEDs for each wavelength, but instead focus on Secker's purported deficiencies individually. However, *KSR* "does not support [the] theory that a person of ordinary skill can only perform combinations of a puzzle element A with a perfectly fitting puzzle element B. 550 U.S. at 406. To the contrary, *KSR* instructs that the obviousness inquiry requires a flexible approach," recognizing that "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton." *ClassCo, Inc. v. Apple, Inc.*, 838 F.3d 1214, 1219 (Fed. Cir. 2016). Here, a POSITA recognizing that Raley provides LEDs of four wavelengths and Secker provides four LEDs for each wavelength would have found it obvious to provide four LEDs for each of the four wavelengths, resulting in sixteen LEDs. APPLE-1079, ¶42.

XIII. A POSITA would have been motivated to add more LEDs to the Abdul-Hafiz+Raley combination.

“A reference must be considered for everything it *teaches* by way of technology and is not limited to the particular *invention* it is describing and attempting to protect.” *EWP Corp. v. Reliance Universal Inc.*, 755 F.2d 898, 907 (Fed. Cir. 1985) (emphases in original); *In re Applied Materials, Inc.*, 692 F.3d 1289, 1298 (Fed. Cir. 2012); *In re Kahn*, 441 F.3d 977, 990 (Fed. Cir. 2006); *In re Heck*, 699 F.2d 1331, 1333 (Fed. Cir. 1983). Secker plainly discloses a sensor including four LEDs for each wavelength. APPLE-1006, 15:35-46, FIG. 8. Even if Secker allegedly describes a reflectance sensor, this does not preclude a POSITA from utilizing Secker’s teachings in combination with prior art transmission sensors. APPLE-1079, ¶43. One of ordinary skill in the art is not an “automaton.” *KSR*, 550 U.S. at 421.

As Webster explains, in “transmission probes, as the photodiode has to detect the light transmitted through the tissue, the detector is placed in line with the LEDs so that the maximum amount of the transmitted light is detected.” APPLE-1011, 104. If the LEDs are not in line with the photodiode, then the amount of detected light decreases. *Id.* In line with textbook recommendations that the detector should be placed in line with the LEDs, Abdul-Hafiz discloses mounting the emitter at different positions to accommodate different sized patients or

different tissue site thicknesses and invites a POSITA to look to other electrical and mechanical structures that allow detector-emitter spacing adjustment. APPLE-1004, [0047], [0049]-[0050], FIGS. 11A-11B, 11D-11E; Pet., 78-79. To that end, a POSITA would have recognized that Secker's teachings allow detector-emitter spacing adjustment. APPLE-1079, ¶44. Indeed, Masimo admits that Secker describes techniques for adding and selecting LEDs to achieve the optimal light path. POR, 64-67; EX2079, ¶145.

The Petition never stated that Abdul-Hafiz alone describes or suggests “a *single sensor* that accommodates different sized patients or tissue thicknesses” as Masimo implies (POR, 68-69), and Abdul-Hafiz need not provide such a motivation or suggestion. As the Federal Circuit has stated, “evidence of a motivation to combine need not be found in the prior art references themselves, but rather may be found in ‘the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved.’” *DyStar Textilfarben GmbH & Co. v. CH Patrick Co.*, 464 F.3d 1356, 1366 (Fed. Cir. 2006); *Perfect Web Technologies, Inc. v. InfoUSA, Inc.*, 587 F. 3d 1324, 1329 (Fed. Cir. 2009); *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 665 (Fed. Cir. 2000). The Supreme Court confirmed that it is appropriate “to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having

ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue,” and “the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR*, 550 U.S. at 418.

In line with these teachings of Secker and Webster, Abdul-Hafiz discloses mounting the emitter at different positions to accommodate different sized patients or different tissue site thicknesses. APPLE-1006, 13:35-37, 14:19-22; APPLE-1011, 69, 143; APPLE-1004, [0047], [0049]-[0050], FIGS. 11A-11B, 11D-11E; Pet., 78-79; APPLE-1079, ¶45. A POSITA would have recognized that these variations in finger tissue and thicknesses exist even in transmittance applications and would have been motivated to provide a sensor that accommodates different sized patients or tissue thicknesses. This would obviate the need for the physician or clinician to select the appropriately sized sensor for the patient’s finger. Masimo does not dispute that it would be beneficial to provide a single sensor that accommodates different sized patients or tissue thicknesses.

The Petition also never stated that Secker describes or suggests using its approach of automatically selecting LEDs to accommodate different sized patients or tissue thicknesses. POR, 69-70. Rather, the Petition established that the Abdul-

Hafiz+Raley+Secker combination would provide such a sensor. Pet., 78-82.

Secker discloses that “[s]uch an automatic adaptation system may be used for **all kinds of applications, patients and tissue characteristics**; it always selects the best possible transmitter/receiver combination for a particular kind of measurement.” EX1006, 7:35-40. A POSITA would have also understood, based on Secker’s and Webster’s teachings, that the “thickness of the finger” changes “the path length for the light that is transmitted through the finger.” APPLE-1006, 13:35-37, 14:19-22; APPLE-1011, 69, 143. A POSITA would have recognized that these variations in finger tissue and thicknesses exist even in transmittance applications. APPLE-1079, ¶46. Secker’s description of reflection sensors does not constitute a teaching away from use of Secker’s teachings in transmittance sensors. *Meiresonne v. Google, Inc.*, 849 F.3d 1379, 1382 (Fed. Cir. 2017).

XIV. Conclusion

All Challenged Claims are unpatentable.

Respectfully submitted,

Dated 1-21-25

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CERTIFICATION UNDER 37 CFR § 42.24(d)

Under the provisions of 37 CFR § 42.24(d), the undersigned hereby certifies that the word count for the foregoing Petitioner's Reply to Patent Owner's Response totals 5,565, which is less than the 5,600 allowed under 37 CFR § 42.24.

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CERTIFICATE OF SERVICE

Pursuant to 37 CFR §§ 42.6(e)(1) and 42.6(e)(4)(iii), the undersigned certifies that on January 21, 2025, a complete and entire copy of this Petitioner's Reply to Patent Owner's Response and exhibits were provided via email to the Patent Owner by serving the email correspondence addresses of record as follows:

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