IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MASIMO CORPORATION,	:	
	:	
Plaintiff,	:	
	:	
v.	:	C. A. No. 09-080-LPS-MPT
	:	C. A. No. 11-742-LPS-MPT
PHILIPS ELECTRONICS NORTH AMERICA CORPORATION and PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH,	:	Consolidated Cases
	:	
Defendants.	:	

REPORT AND RECOMMENDATION

I. INTRODUCTION

This is a patent infringement case. Plaintiff Masimo Corporation ("Masimo") and defendants Philips Electronics North American Corporation and Philips Medizin Systeme Böblingen GMBH ("Philips Medizin") (collectively, "Philips" or "defendants") manufacture competing products in the field of pulse oximetry. Pulse oximetry allows for non-invasive measurement of the oxygen levels in a medical patient's hemoglobin.

Generally, pulse oximetry operates via a sensor placed over a thin section of a patient's body, such as the fingertip or earlobe of an adult, or the foot of an infant. The sensor emits red and infrared light through a cross-section of the patient's tissue and measures the amount of light absorbed. Using various algorithms, a monitor then processes the signal and calculates the patient's oxygenation level. Pulse oximetry systems are standard equipment in many clinical settings, either as stand-alone devices, or more commonly, as components of integrated multi-parameter patient monitors which track pulse, temperature, and other physiological vital signs.

II. BACKGROUND

On February 3, 2009, Masimo sued Philips alleging infringement of a number of Masimo's pulse oximetry-related patents.[1] Masimo filed an amended complaint on May 12, 2009.[2] In the amended complaint, Masimo alleges that Philips' production, use, and sale of pulse oximeters incorporating Philips' "Fourier Artifact Suppression Technology" ("FAST") as well as Philips' IntelliVue line of patient monitors infringe fourteen of Masimo's patents. Philips' infringement of eight of those patents is alleged to be willful, deliberate, and intentional because Philips had notice of the patents and the alleged infringement. Masimo requests monetary damages and seeks to enjoin Philips from further production, use, or sale of infringing products.

Philips answered the complaint on June 15, 2009.[3] In the answer, both Philips North America and Philips Medizin deny all allegations of infringement citing twelve defenses including, among others, invalidity of Masimo's patents, prosecution history estoppel, laches, unclean hands, patent misuse, and implied license. Philips North America concurrently filed counterclaims against Masimo. According to Philips North America, Masimo has infringed ten of Philips' patents through the production, use, and sale of various Masimo monitors, boards, sensors, and oximeters using patented Philips technology. Regarding six of these patents, since Masimo has had notice of the patents and the infringement, Philips North America alleges that Masimo's infringement is willful, deliberate, and intentional. Philips North America requests monetary damages and, for

[1] D.I. 1.
[2] D.I. 12.
[3] D.I. 15.

eight patents, seeks injunctive relief to prevent Masimo from further production, use, or sale of infringing products.

Philips North America's counterclaims also include seven antitrust claims focusing on Masimo's purported anticompetitive restrictions in its licensing agreements; its allegedly improper exclusion of competition in the sensor and patient cable markets; an anticompetitive settlement agreement stemming from a 2006 infringement suit with licensee Nellcor; and claims of exclusionary pricing and bundling practices designed to lock hospitals into Masimo pulse oximetry products. Masimo filed its answer to Philips North America's counterclaims on July 9, 2009, asserting its own counterclaims and defenses.[4] On August 3, 2009, Philips filed its answer to Masimo's counterclaims.[5]

On August 7, 2009, Masimo filed a motion to bifurcate and stay discovery on Philips North America's antitrust counterclaims,[6] which this court granted on March 11, 2010.[7] In its decision, this court found that bifurcation would assist in juror comprehension and increase efficiency without substantial prejudice to either party. This court also stayed discovery concerning Philips North America's antitrust counterclaims, finding that a stay would conserve economy because a trial on Masimo's patent claims could potentially eliminate or simplify Philips North America's antitrust counterclaims. A motion for reconsideration filed by Philips[8] was denied on April 19, 2010,[9] and Judge

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[4] D.I. 17.
[5] D.I. 20.
[6] D.I. 22.
[7] *Masimo Corp. v. Philips Elec. N. Am. Corp.*, C.A. No. 09-80-JJF-MPT, 2010 WL 925864 (D. Del. Mar. 11, 2010).
[8] D.I. 71.
[9] *Masimo Corp. v. Philips Elec. N. Am. Corp.*, C.A. No. 09-80-JJF-MPT, 2010 WL 1544423 (D. Del. Apr. 19, 2010).

Joseph J. Farnan, Jr. denied Philips' objections[10] to this court's order on July 15, 2010.[11]

On July 30, 2010, Philips filed a motion to bifurcate and stay discovery on patent damages.[12] In its motion, Philips sought bifurcation of the parties' patent damages claims, trial to be scheduled on patent damages to follow trial on the antitrust and patent misuse claims, and a stay of the remaining damages-related discovery until antitrust discovery proceeds. On October 6, 2010, this court denied Philips' motion.[13]

As noted above, Masimo brought suit against Philips, asserting infringement of fourteen patents. Philips answered asserting ten patents and seven antitrust counterclaims. For litigation and trial management purposes, the parties were ordered to reduce the number of patents involved to a more manageable level. The parties were initially able to reduce the original twenty-four patents to fourteen. Thereafter, the court reduced the number of patents to seven, with the remaining seven patents to be held in abeyance. Masimo had to select four of its remaining patents, while Philips had to select three of its remaining patents. Masimo chose U.S. Patent No. 6,263,222 ("the '222 patent"), U.S. Patent No. 5,632,272 ("the '272 patent"), U.S. Patent No. 7,215,984 ("the '984 patent"), and U.S. Patent No. 6,699,194 ("the '194 patent"). Philips selected U.S. Patent No. 5,448,991 ("the '991 patent"), U.S. Patent No. 6,122,535 ("the '535 patent"), and U.S. Patent No. 6,725,074 ("the '074 patent").

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[10] D.I. 96.

[11] *Masimo Corp. v. Philips Elec. N. Am. Corp.*, C.A. No. 09-80-JJF-MPT, 2010 WL 2836379 (D. Del. July 15, 2010). Judge Farnan retired from the bench during the pendency of this litigation and the case was reassigned to Judge Leonard P. Stark on August 18, 2010. *See* 08/18/2010 Docket Entry.

[12] D.I. 121. Pursuant to 28 U.S.C. § 636(c) and Fed. R. Civ. P. 73, the parties consented to the jurisdiction of the United State Magistrate Judge to conduct any and all proceedings and enter a final order as to Defendants Philips Electronics North America Corporation's and Philips Medizin Systeme Böblingen GMBH's Motion to Bifurcate and Stay Damages. D.I. 129.

[13] *Masimo Corp. v. Philips Elec. N. Am. Corp.*, 742 F. Supp. 2d 492 (D. Del. 2010).

On December 1, 2010, a *Markman* hearing was conducted and a Report and Recommendation on claim construction was issued on February 18, 2011.[14] Both parties filed objections,[15] and on January 17, 2012, Judge Leonard P. Stark adopted the Report and Recommendation, with the exception of the term "a signal processor," as used in claim 17 of the '222 patent.[16]

On August 19, 2011, Masimo filed an new action against defendants, C.A. No. 11-742-LPS-MPT, alleging infringement of Masimo's U.S. Pat. No. 7,530,955 ("the '955 patent").[17] On October 6, 2011, Masimo filed an amended complaint adding an allegation of infringement of its U.S. Pat. No. 8,019,400 ("the '400 patent").[18] Defendants answered the amended complaint on November 7, 2011.[19] On November 22, 2011, defendants moved to consolidate the court's consideration of the issues concerning the seven patents held in abeyance from the 09-80-LPS-MPT action with the two patents asserted by Masimo in the 11-742-LPS-MPT action, and to stay proceedings with regard to those nine patents.[20] On April 16, 2012, the court granted the motion to consolidate and denied the motion to stay.[21] Fact discovery closed on June 2, 2011 and expert discovery closed on July 16, 2012. No trial date has been set.

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[14] *Masimo Corp. v. Philips Elec. N. Am. Corp.*, C.A. No. 09-80-LPS-MPT, 2011 WL 678447 (D. Del. Feb. 18, 2011).

[15] D.I. 218; D.I. 219.

[16] *Masimo Corp. v. Philips Elec. N. Am. Corp.*, C.A. No. 09-80-LPS-MPT, 2012 WL 125759 (D. Del. Jan. 17, 2012).

[17] D.I. 1 (11-742-LPS-MPT). Citation to the docket of the 11-742-LPS-MPT matter will include that civil action number as a parenthetical. Citations not having a civil action number parenthetical are to the docket of the lead case, 09-80-LPS-MPT.

[18] D.I. 7 (11-742-LPS-MPT).

[19] D.I. 11 (11-742-LPS-MPT).

[20] D.I. 15.

[21] *Masimo Corp. v. Philips Elec. N. Am. Corp.*, C.A. No. 11-742-LPS-MPT, 2012 WL 1267979 (D. Del. Apr. 16, 2012).

Currently before the court are the following motions:

1. Masimo's Motion for Summary Judgment of Infringement of U.S. Patent No. 6,263,222;[22]

2. Philips' Motion for Summary Judgment of Invalidity of U.S. Patent No. 6,263,222;[23]

3. Philips' Motion for Summary Judgment of Invalidity and Noninfringement of U.S. Patent No. 7,215,984;[24]

4. Philips' Motion for Summary Judgment of Invalidity and Noninfringement of U.S. Patent No. 5,632,272;[25]

5. Philips' Motion for Summary Judgment of Invalidity of U.S. Patent No. 6,669,194;[26]

6. Masimo's Motion for Summary Judgment of Noninfringement and Invalidity of U.S. Patent No. 6,122,535;[27]

7. Masimo's Motion for Summary Judgment of Noninfringement and Invalidity of U.S. Patent No. 6,725,074;[28]

8. Masimo's Motion to Exclude the Testimony of John M. Turner Pursuant to Fed. R. Evid. 702;[29]

9. Philips' Motion for Summary Judgment on Laches with Respect to U.S. Patent Nos. 5,632,272, 6,263,222, and 6,999,194;[30]

10. Philips' Motion for Summary Judgment of No Willful Infringement;[31]

11. Philips' Motion for Summary Judgment Regarding Damages Issues;[32]

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[22] D.I. 404. . Motions listed as one through nine are addressed herein. Motions listed as ten through fifteen are addressed in another opinion.
[23] D.I. 410.
[24] D.I. 394.
[25] D.I. 402.
[26] D.I. 406.
[27] D.I. 393.
[28] D.I. 414.
[29] D.I. 381.
[30] D.I. 397
[31] D.I. 426.
[32] D.I. 424.

12. Masimo's Motion to Exclude Portions of the Testimony of Michael C. Keeley, Ph.D. Pursuant to Fed. R. Evid. 702;[33]

13. Philips' Motion to Exclude the Testimony of Michael J. Wagner;[34]

14. Masimo's Motion to Exclude the Expert Testimony of Drs. John H. Eichhorn, Thomas L. Higgins, and Edward A. Ochrock Pursuant to Fed. R. Evid. 702;[35] and

15. Philip's Motion to Exclude the Testimony of Timothy J. Quill.[36]

III. LEGAL STANDARDS

"Summary judgment is appropriate when, after opportunity for discovery and upon motion, there is no genuine dispute of material fact for trial and one party is entitled to judgment as a matter of law."[37]

To determine infringement, the court performs a two stop analysis: first, the court must determine the scope of the claims; second, the court must determine whether properly interpreted claims cover the accused products.[38]

Once the claims are construed, the court proceeds to determine whether properly interpreted claims cover the accused products. At trial, it is plaintiff's burden to establish infringement by a preponderance of the evidence.[39] To prove infringement, Masimo must show the accused products meet each claim limitation, either literally or under the doctrine of equivalents.[40] "Literal infringement of a claim exists when every

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[33] D.I. 388.
[34] D.I. 422.
[35] D.I. 385.
[36] D.I. 420.
[37] *Novartis Corp. v. Ben Venue Labs., Inc.*, 271 F.3d 1043, 1046 (Fed. Cir. 2001); *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1476 (Fed. Cir. 1998) ("Summary judgment is appropriate when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law."); *see* FED. R. CIV. P. 56.
[38] *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1455 (Fed. Cir. 1988).
[39] *Hughes Aircraft Co. v. United States*, 717 F.2d 1351, 1361 (Fed. Cir. 1983).
[40] *Seal-Flex, Inc. v. Athletic Track & Court Constr.*, 172 F.3d 836, 842 F3d. (Fed. Cir. 1999).

limitation recited in the claim is found in the accused device, i.e., when the properly construed claim reads on the accused device exactly."[41] If the accused products do not literally infringe an asserted claim, they may still infringe under the doctrine of equivalents under which an element of the accused device is equivalent to a claim limitation if the differences between the two are insubstantial.[42] Under the all elements rule, "the doctrine of equivalents does not apply if applying the doctrine would vitiate an entire claim limitation."[43] The application of the "all elements rule" doctrine is a question of law.[44]

A patentee may be prevented from invoking the doctrine of equivalents by prosecution history estoppel. Prosecution history estoppel requires that the claims of a patent be interpreted in light of the proceedings in the Patent and Trademark Office (PTO) during the application process.[45] Estoppel arises when an amendment is made to secure a patent and that amendment narrows the patent's scope.[46] In such cases, the "amendment may be presumed to be a general disclaimer of the territory between the original claim and the amended claim," and the patentee bears the burden of showing that the amendment does not surrender the particular equivalent in question.[47] The Supreme Court has recognized three situations in which this presumption barring equivalents would be overcome: (1) the equivalent was unforeseeable at the time of the

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[41] *Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 532 (Fed. Cir. 1996).
[42] *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29, 39-41.
[43] *Asyst Techs., Inc. v. Emtrak, Inc.*, 402 F.3d 1188, 1195 (Fed. Cir. 2005) (holding unmounted is not equivalent to mounted, and to so determine "would effectively read the 'mounted on' limitation out of the patent").
[44] *Lockheed Martin Corp. v. Space Sys./Loral, Inc.*, 324 F.3d 1308, 1318 (Fed. Cir. 2003).
[45] *Festo*, 535 U.S. at 734.
[46] *Id.* at 736.
[47] *Id.* at 740.

application; (2) the rationale underlying the patentee's amendment bears no more than a tangential relation to the equivalent; or (3) the patentee could not otherwise reasonably be expected to have described the insubstantial substitute.[48] Applicability of prosecution history estoppel is a question of law.[49]

A claim is invalid under 35 U.S.C. § 102 if it is anticipated by the prior art. A prior art reference anticipates a claim if it expressly or inherently describes each and every limitation set forth in the patent claim.[50] Inherent anticipation occurs when the prior art does not disclose a particular feature of the claimed invention, but that missing feature is necessarily present, or inherent, in the reference.[51]

To determine if a patent is invalid for obviousness under 35 U.S. § 103, a court first establishes the scope and content of the prior art, the level or ordinary skill in the art involved, and the difference between the prior art and the claims at issue.[52] A patent is invalid if in light of these determinations, the subject matter of the patent at issue would have been obvious to a person of ordinary skill in the art at the time of the asserted invention.[53] The underlying factual inquiries to be considered by the fact finder in its obviousness determination are: (1) the scope and content of the prior art; (2) the differences between the prior art and the claimed subject matter; (3) the level of ordinary skill in the pertinent art; and (4) secondary considerations of non-obviousness, such as commercial success, long felt but unresolved need, failure of others,

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[48] *Id.* at 740-41.

[49] *Panduit Corp. v. HellermannTyton Corp.*, 451 F.3d 819, 826 (Fed. Cir. 2006) (citing *Seachange Int'l, Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1378 (Fed. Cir. 2005)).

[50] *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002).

[51] *Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003).

[52] *Abbott Labs. v. Andrx Pharm., Inc.*, 452 F.3d 1331, 1335-36 (Fed. Cir. 2006).

[53] *Id.*

acquiescence of others in the industry that the patent is valid, and unexpected results.[54]

Claims of a patent may also be invalid for failing to meet the written description requirement under the first paragraph of 35 U.S.C. § 112 which provides:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

This requirement is intended "to prevent an applicant from later asserting that he invented that which he did not."[55]

A patent must describe an invention in sufficient detail to "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*."[56] Specifically, an inventor must "recount his invention in such detail that his future claims can be determined to be encompassed within his original creation."[57] Although there is no requirement that the written description "describe exactly the subject matter claimed," it "must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."[58]

When determining whether a patentee had possession of the claimed subject matter, "an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art" is required.[59] Possession is shown by describing the invention with all of its limitations using "such descriptive means as

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[54] *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966); *see also Perfect Web Tech., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1327 (Fed. Cir. 2009).

[55] *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003).

[56] *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed Cir. 1991).

[57] *Id.* at 1561 (citation omitted).

[58] *Union Oil Co. of Cal. v. Atl. Richfield Co.*, 208 F.3d 989, 997 (Fed Cir. 2000).

[59] *Ariad Pharms., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010).

words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention."[60] A "mere wish or plan" for obtaining the claimed invention is not an adequate written description.[61]

"Whether the written description requirement is met is a question of fact."[62] Compliance with the written description requirement, however, "is amenable to summary judgment in cases where no reasonable fact finder could return a verdict for the non-moving party."[63]

Invalidity must be shown by clear and convincing evidence.[64] An expert inappropriately "read[ing] into the reference elements that are not there"[65] is not clear and convincing evidence.

IV. Motions

1. Masimo's Motion for Summary Judgment of Infringement of U.S. Patent No. 6,263,222;[66] / Philips' Motion for Summary Judgment of Invalidity of U.S. Patent No. 6,263,222;[67]

The '222 Patent (Masimo Patent)

For the reasons discussed herein Masimo's motion for summary judgment of infringement of claims 17 and 18 of 222 patent[68] is denied, and Philips' motion for summary judgment of invalidity is granted in part and denied in part.[69]

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[60] *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997).
[61] *Regents of the Univ. Of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed. Cir. 1997).
[62] *Boston Scientific Corp. v. Johnson & Johnson Inc.*, 679 F. Supp. 2d 539, 553 (D. Del. 2010).
[63] *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1307 (Fed. Cir. 2008).
[64] *Id*. at 1305.
[65] *Genzyme Corp. v. Atrium Medical Corp.*, 315 F. Supp. 2d 552, 563 (D. Del. 2004).
[66] D.I. 404.
[67] D.I. 410.
[68] D.I. 404. The briefs addressing Masimo's motion of infringement are found at D.I. 405 (Masimo's opening brief), D.I. 492 (Philips' answering brief), and D.I. 591 (Masimo's reply brief).
[69] D.I. 410. The briefs regarding Philips' motion of invalidity are found at D.I. 413 (Philips' opening brief), D.I. 509 (Masimo's answering brief), and D.I. 597 (Philips' reply brief).

As noted previously, pulse oximeters consist of: a sensor which attaches to a patient's extremity, a cable attaching the sensor to the monitor, and a monitor which advises of oxygen saturation, pulse rate, and other relevant parameters. Oxygen saturation readings are provided by the monitor emitting light by way of the sensor through body tissue at red and infrared wavelengths, and detecting that light to provide first and second intensity signals, which represents the intensity of light at those wavelengths. Since oxygenated blood (HbO2) and deoxygenated blood (Hb) absorb the wavelengths of light differently, oxygen saturation is determined by the ratio of the absorption of red and infrared light passing through body tissues. Pulse oximeters differentiate the effect of the absorption of light by arterial or oxygenated blood from absorption by other body tissue through the pulsatile nature of arterial blood: arterial blood is alternating ("AC"), while other tissues, including venous blood and bone, are non-pulsatile and remain relatively constant ("DC"). The pulse oximeter's ability to distinguish is affected by patient motion, which introduces erratic noise or interference in the intensity signal, and thereby lessens or prevents discrimination of the pulsation of arterial blood from movement of venous blood, causing inaccurate measurement of arterial oxygen saturation and false alarms.[70] Discriminating erratic noise caused by movement of venous blood is difficult because patient motion is unpredictable. Because erratic noise usually could not be predetermined and/or subtracted from the measured signal through traditional signal filtering techniques, they were generally

[70] Movement of venous blood (through patient movement) may cause erratic noise which successively causes the ratio of red and infrared signals to inaccurately reflect arterial oxygen saturation.

ineffective in addressing this problem. [71]

The asserted claims in the '222 patent are directed to pulse oximeter technology having a signal processor for calculating oxygen saturation without significant interference in the calculation from motion induced noise, often resulting from motion of the patient.

Prior Claim Construction

In this litigation, the parties adopted the previously construction litigated in *Mallinckrodt, Inc. v. Masimo Corp.*, (the "Nellcor" case)[72] for "without significant interference" to mean "the calculated oxygen saturation is accurate enough for the purpose of which the calculation is being employed," and for "motion" to mean "movement of body tissue which causes erratic noise, that, in the absence of a filter, would cause the ratio of red to infrared signals to not accurately reflect the arterial oxygen saturation."[73] Since the parties agreed to the construction of those terms, the court did not construe them. The court, however, did construe "signal processors" to mean "a device that processes an input and output signal."[74]

A. Infringement

Masimo contends it is entitled to summary judgment as Philips' FAST algorithm infringes claims 17 and 18 of the '222 patent.

Claim 17

Claim 17 of the '222 patent recites:

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[71] The factual information is taken from the parties' briefs and is not in dispute. *See* D.I. 405, 413, 492, and 509.

[72] 147 Fed. Appx. 158 (Fed. Cir. 2005).

[73] *See* D.I. 162 at 19.

[74] *See* D.I. 319.

A physiological monitor that computes arterial oxygen saturation in tissue material having arterial and venous blood, the physiological monitor comprising:

> a light emitter which emits light of at least first and second wavelengths;
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> a light detector responsive to light from said light emitter which has passed through body tissue having arterial and venous blood, said light detector providing at least first and second intensity signals associated with said at least first and second wavelengths, each of said first and second intensity signals having, during motion of the tissue, at least a first signal portion indicative of arterial blood and a second signal portion indicative of motion induced noise; and
>
> a signal processor responsive to the first and second intensity signals to calculate arterial oxygen saturation without significant interference in the calculation from the motion induced noise portion of the first and second intensity signals.[75]

Regarding infringement of claim 17, the parties' dispute focuses on the last paragraph dealing with signal processor. The parties do not dispute that the other claim terms are met. The specific areas of disagreement are addressed below.

1. Calculation of Oxygen Saturation without Significant Interference from Motion Induced Noise

Masimo represents no reasonable dispute exists that the signal processor in the accused products "is responsive to the first and second intensity signals to calculate arterial oxygen saturation without significant interference in the calculation from the motion induced noise portion of the first and second intensity signals."[76] In so concluding, Masimo relies on the infringement reports of the parties' technical experts, which provide "[t]he FAST algorithm is designed and capable to accurately monitor

[75] D.I. 408, Ex. 2, '222 patent at 74:57-75:8.
[76] D.I. 405 at 12.

SpO2 even in the presence of artifact, including motion and low perfusion."[77] Masimo points to "numerous Philips documents [that confirm] FAST calculates oxygen saturation without significant interference from motion induced noise."[78]

Masimo also relies on a number of clinical studies as demonstrating "the superior performance of FAST relative to conventional technologies that fail to provide accurate measurements in the presence of erratic noise."[79] Masimo notes a study, "'Motion-

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[77] D.I. 408, Ex. 4, Phillips' Expert, Dr. Robert T. Stone (Stone Noninfr. Rpt.) at ¶ 1; D.I. 409, Ex. 5, Masimo's Expert, Dr. Gail D. Baura (Baura Infr. Rpt.) at ¶ 10.

[78] D.I. 405 at 12; *see also* D.I. 411, Ex. 19 at PHIL03208816 (testing which showed Philips' device "provide[d] reliable saturation and pulse rate values in the presence of various artifact conditions from [Philips'] motion database"); *id.*, Ex. 20 at PHIL03244749 (FAST "overcomes the traditional sensitivity of pulse oximetry measurement to patient movement and other artifacts"); *id.*, Ex. 21 at PHIL03244755 (FAST reduces "false alarms in presence of motion"); *id.*, Ex. 22 at PHIL01720069 (FAST overcomes "patient movement and other artifacts"); *id.*, Ex. 23 at PHIL01715763 (discussing "current motion tolerant algorithm"); D.I. 411, Ex. 24 at PHIL01711763 (explaining "motion tolerant algorithm"); D.I. 409, Ex. 6, U.S. Patent No. 6,122,535 (the "'535 patent") at PHIL02871242 (algorithm "uses patented digital techniques in the frequency domain and a proprietary analysis of the resulting Fourier spectrum to remove noise from the signal"); *id.*, Ex. 6 at PHIL02871251 (FAST "uses a patented frequency analysis algorithm to filter out noise in the sensor signal" overcoming "sensitivity to patient movement"); *id.*, Ex. 6 at PHIL02871257 (discussing "increase in measurement accuracy" in presence of noise); *id.*, Ex. 6 at PHIL02871258 (FAST provides "[i]ncreased measurement accuracy" with patients prone to movement); D.I. 411, Ex. 25 at PHIL03208506 (FDA report: "[b]ased on frequency domain signal analysis. Removes artifact and noise from the frequency information and calculates the ratio of the patient signal frequency"); *id.*, Ex. 27 at PHIL01762443 ("Performance is significantly improved with all modules, especially in the area of motion artifact rejection"); *id.*, Ex. 28 at PHIL01687619 (explaining the new FAST algorithm "can produce reliable results for pulse rate, SpO_2, and perfusion, even in the presence of artifacts, interferences, and low perfusion"); *id.*, Ex. 29 at MASP0441308 (FAST "uses patented digital techniques in the frequency domain and a proprietary analysis of the resulting Fourier spectrum to remove noise from the signal"); *id.*, Ex. 30 at PHIL00077316 (Philips noting Emergency Care Research Institute found FAST to be "good" as to "nuisance alarm performance"); D.I. 411, Ex. 31 at PHIL00439361 (Hewlett-Packard discussing results from study indicating "Agilent's [Philips] new algorithm [FAST], the Nellcor N395 and Masimo Set are very close in terms of SpO2 and pulse rate error under low perfusion, motion and motion at low perfusion").

[79] D.I. 405 at 12-13; *see also* D.I. 411, various journal articles addressing the performance of FAST, Ex. 32 at MASP0464763 ("Determining the Artifact Sensitivity of Recent Pulse Oximeters During Laboratory Benchmarking"); *id.*, Ex. 33 at MASP0412236 ("The Effects of Motion and Hypoxemia upon the Accuracy of 20 Pulse Oximeters in Human Volunteers"); *id.*, Ex. 34 at MASP0057450 ("'Motion-Resistant' Pulse Oximetry: A Comparison of New and Old Models"); *id.*, Ex. 36 at MASP0165602 ("The Effects of Motion Artifact and Low Perfusion on the Performance of a New Generation of Pulse Oximeters in Volunteers Undergoing Hypoxemia"); *id.*, Ex. 37 at MASP0249921 ("Reliability of Conventional and New Pulse Oximetry in Neonatal Patients"); D.I. 411, Ex. 38 at MASP0444198 ("Evaluation Next-Generation Pulse Oximetry"); *id.*, Ex. 39 at MASP0249346 ("A Laboratory Comparison of the Newest 'Motion-Resistant' Pulse Oximeters During Motion and Hypoxemia"); *id.*, Ex. 40 at MASP0249342 ("Clinical Use of New-Generation Pulse Oximeters in the Neonatal Intensive Care Unit").

Resistant' Pulse Oximetry: A Comparison of New and Old Models," which compared the performance of different products in the presence of motion, including Philips' monitors incorporating the FAST technology to Masimo products covered by the '222 patent, and concluded Philips' products performed well.[80] Masimo further references a Philips article that analyzed the ability of new-generation pulse oximeters, including those using FAST, to "filter out motion artifacts due to patients' movements."[81] In light of such evidence, Masimo contends "FAST calculates arterial oxygen saturation without significant interference in the calculation from motion-induced noise."[82]

Throughout its opposition brief, Philips focuses on Masimo's purported inconsistency between its arguments in support of infringement and its position taken distinguishing prior art in response to Philips' copending motion for summary judgment of invalidity of the '222 patent. Philips points to Dr. Baura's testimony that Claim 17 as construed is sufficiently broad to cover any pulse oximeter capable of measuring oxygen saturation in the presence of motion induced noise.[83] According to Philips, in its argument against invalidity, Masimo claimed the prior art references did not anticipate claim 17 because they failed to meet the specific level of motion tolerance Dr. Baura asserts the claims require. As a result, Philips maintains Masimo's infringement arguments are inconsistent with its invalidity arguments, and therefore, are insufficient

[80] D.I. 411, Ex. 34 at MASP0057452.
[81] D.I. 409, Ex. 7 at PHIL02004066; *id.*, Ex. 7 at PHIL02004073.
[82] D.I. 405 at 13; *see also* D.I. 412, (Baura Decl.) at ¶¶ 16-21.
[83] D.I. 431, Ex. 25 (Baura Depo.) at 123:8-13 (describing claim 17 as covering "any [motion-tolerant] technique whatsoever")

to support summary judgment.[84] Since Masimo fails to provide the required level of motion tolerance, as asserted by its expert, and has not demonstrated FAST meets any specific level of motion tolerance, Philip contends Masimo fails to meet its burden "of proving infringement in a manner consistent with its validity arguments,"[85] and is not entitled to judgment in its favor.

Philips argues the journal references cited by Masimo do not meet "some [specific] level of motion tolerance its expert Dr. Baura" understands is required under the claim,[86] and her opinion fails to demonstrate how to objectively determine that level of motion tolerance she asserts is necessary.[87]

As to the Philips' documents cited by Masimo, which show the FAST algorithm is marketed as motion tolerant, Philips contends none provide any explanation of whether or how the FAST algorithm achieves the level of motion tolerance which Masimo maintains the claims require.[88] Thus, Philips argues Masimo's position on validity that a threshold level of motion tolerance is required by the asserted claims, with its opposite contention on infringement, is an mere attempt to circumvent established case law. As a result, such conflicting positions raise genuine issues of material fact.[89]

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[84] *See Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001) (requiring claims must be "given the same meaning for the purposes of both validity and infringement analyses").

[85] D.I. 492 at 8.

[86] *Id.* at 6-12; *see also* D.I. 525, Ex. 90 (Baura Depo.) at 289:4-5, 237:20-22, 287:17-22; D.I. 431, Ex. 23 at 35-37, 39-40, 43-44, 45-46, ¶¶ 111-12, 117, 123, 127.

[87] D.I. 525, Ex. 90 at 173:2-22 (Baura testifying the measurement must be "accurate enough" for a "person skilled in the art"); *id.*, Ex. 90 at 174:1-175:20.

[88] D.I. 492 at 9.

[89] Those questions include whether a threshold level of motion tolerance is required, and whether Philips' FAST meets that required level. *Id.* at 9-11; *see also* D.I. 429, Ex. 14C (Stone Noninfr. Rpt.) ¶¶ 113-14; D.I. 525, Ex. 90, at 226:3-7 (Baura stating she is unable to determine whether a pulse oximeter infringes solely by examining clinical studies).

Regarding the performance studies, Philips points to Dr. Baura's testimony admitting they fail to objectively establish infringement.[90] Moreover, to the extent Masimo argues the claim prescribes, at a minimum, the level of motion tolerance its algorithm achieves, every study, as well as Masimo's witnesses, confirm FAST is not equal to Masimo's technology.[91] Philips concludes the evidence, including Masimo's expert's opinions, show assessing performance studies requires "a highly factual exercise that involves weighing the reliability of the studies themselves."[92]

Philips essentially argues Masimo has not shown FAST meets a threshold level of motion tolerance, warranting denial of judgment in its favor.[93]

2. Filter / Philips' FAST Technology

Masimo argues the asserted claims do not require a "filter,"[94] relying on the parties' agreed upon construction of "motion,"[95] which it propounds merely acknowledges erratic noise is caused by patient motion, a previously recognized problem in pulse oximetry, and does not mean a "signal processor" requires a filter.[96] Therefore, Masimo maintains the accused products satisfy the requirement of claim 17 of "a pulse oximeter with a 'signal processor' [that] calculates oxygen without significant interference from noise caused by motion."[97]

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[90] D.I. 525, Ex. 90 at 174:12-18, 226:1-7 (Baura admitting she cannot determine whether a pulse oximeter infringes solely by examining clinical studies, but is "based on a lot of things"); *id.* at 227:4-21; D.I. 525, Ex. 93 at 102:15-17.

[91] D.I. 492 at 10; *see also* D.I. 411, Exs. 32-34, 36-40; D.I. 525, Ex. 92 at 275:4-5; *id.*, Ex. 93 at 210:6-18.

[92] D.I. 492 at 12.

[93] *Id.*

[94] D.I. 405 at 14.

[95] D.I. 140, Joint Claim Construction Chart at 52.

[96] D.I. 405 at 14; D.I. 412 (Baura Decl.) at ¶ 28.

[97] D.I. 405 at 15.

Should a filter be required by the asserted claims, Masimo points to Dr. Stone's description of the FAST algorithm as demonstrating that FAST filters signal information from noise to calculate oxygen saturation:"[98]

> The goal of the FAST algorithm is to identify the fundamental frequency that is used to calculate oxygen saturation and pulse rate. To accomplish this goal, it performs a scoring process to select a peak, and then performs a number of checks to ensure it has selected the correct peak that is representative of the heart rate and the oxygen saturation. First, FAST identifies up to ten peaks according to their amplitude, and scores each peak individually. The scoring is done to find the frequency which is most probably the pulse rate. That single chosen frequency is then used to calculate the pulse rate.[99]

Masimo also relies on Dr. Stone's testimony that FAST stores in memory data associated with the selected peak, while data related to the other peaks, which receive negative scores, are not similarly retained,[100] that it would not be "wrong" to characterize the FAST frequency domain processing as a filter,[101] and removing a portion of the data (the non-stored data) in the frequency domain can be considered filtering.[102] Dr. Stone, however, defined filter, consistent with his understanding, as "a device that has a transfer function that is not unity over all frequencies or amplitudes . . . and that the output stays in the same domain."[103]

Masimo further points to numerous Philips documents describing FAST as a filter that removes noise from the signal used to calculate oxygen saturation.[104] Additionally,

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[98] *Id.*; D.I. 412 at ¶ 29.
[99] D.I. 408, Ex. 4 (Stone Noninfr. Rpt.) ¶ 117 (internal citations and quotations omitted).
[100] D.I. 405 at 15; D.I. 409, Ex. 10 (Stone Depo.) at 434:1-7, 438:2-17.
[101] D.I. 409, Ex. 10 at 398:17-18.
[102] *Id.* at 397:16-22.
[103] *Id.* at 94:2-11; 96:21-97:10; D.I. 409, Ex. 10 at 612:9-21.
[104] D.I. 412 (Baura Decl.), ¶¶ 30-33; D.I. 411, Ex. 46 at PHIL00541555 (Philips touting FAST as "filter" which removes noise); D.I. 409, Ex. 7 at PHIL02004064, PHIL02004073 (Philips describing ability of new generation devices, such as FAST, to "filter out motion artifacts due to patients' movements"); *id.*, Ex. 6, '535 patent at PHIL02871253 (FAST "uses a patented algorithm to filter out artifacts").

Philips' patent, the '535 patent directed to the FAST algorithm,[105] provides with FAST, frequency transformed signals are "filtered" and "other frequency components, whether noise or motion disturbances," cannot be found "in identical proportions on each frequency component."[106] Philips engineers also describe such filtering.[107] Based on this evidence, Masimo argues if claim 17 requires a filter, FAST satisfies every limitation because FAST is a filter."[108]

Masimo also relies on the doctrine of equivalents for infringement of FAST since any purported "differences between FAST and a 'filter' are insubstantial."[109]

Philips argues a filter is needed because claim 17 requires the calculation of arterial oxygen saturation without significant interference from motion induced noise, and "motion" means movement, which "in the absence of a filter," would cause the ratio of red to infrared signals to inaccurately reflect arterial oxygen saturation.[110] In light of

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[105] Masimo contends Philips admits its FAST products practice the '535 patent, and its engineers confirm the actual implementation of FAST is "very close" to what is described in the '535 patent. *See* D.I. 411, Ex. 51 at 18-19; *See* D.I. 405 at 19 n.6.

[106] D.I. 409, Ex. 6, '535 patent at PHIL02871234, 3:28-41.

[107] D.I. 411, Ex. 48 (Blank Depo.) at 45:22-46:12 (Michael Blank, former Hewlett-Packard employee, describing "motion artifact suppression" as "filtering the pulse from the SpO signals - from the troubles of the SpO2 signals, from noises, interferences"); *id.*, Ex. 49 at PHIL00439397 (Agilent stating "[p]eaks from noise and artifact are eliminated by failure to pass a number of qualifying tests leaving only the actual pulse and its harmonics"); *id.*, Ex. 50 at PHIL00689186 (Philips employee commenting "our FAST ALGORITHM filter is good enough to provide stable and correct readings"); *see also* D.I. 411, Ex. 35 at PHIL03245336 (Philips noting FAST "uses a patented frequency analysis algorithm to filter out noise in the sensor signal, thereby overcoming many of the issues associated with traditional pulse oximetry such as sensitivity to patient movement or ambient light"); *id.*, Ex. 35 at PHIL03245347 (same); *id.*, Ex. 35 at PHIL03245361 (Philips observing "[n]oise is rejected because it fails to meet most of the criteria" to "distinguish the clinically relevant signal from the noise"); *id.*, Ex. 35 at PHIL03245365 (Philips stating FAST "uses a patented frequency analysis algorithm to filter out noise"); D.I. 409, Ex. 8 at PHIL01712230 (same); D.I. 411, Ex. 49 at PHIL00439397 (Agilent describing algorithm "uses patented digital techniques in the frequency domain and a proprietary analysis of the resulting Fourier spectrum to remove noise from the signal"); *id.*, Ex. 56 at PHIL02774756 (same); *id.*, Ex 57 at PHIL00440492 (Agilent stating "[n]oise is easily and reliably rejected"); *id.*, Ex. 58 at PHIL02862741 (Hewlett-Packard representing "NEW SpO_2 Algorithm" has "Improved movement - Artefacts rejection" and "Filtering disturbances").

[108] D.I. 405 at 19.

[109] *Id.*; D.I. 412 at ¶¶ 35-36.

[110] D.I. 492 at 13.

the agreed-upon construction of motion, in the absence of a filter, noise would adversely affect the calculation, making a filter necessary to avoid "significant interference in the calculation from the motion induced noise."[111] It maintains characterizing FAST as a filter is incorrect, and the parties disagree as to the plain and ordinary meaning of the term filter.[112]

According to Philips, in the context of signal processing, filter means an input signal is subjected to a process "which passes or rejects portions of the signal and then . . . [the] remaining portion of the signal that is the portion of interest" remains.[113] Applying this definition, Philips' expert determined FAST is not a filter, and does not use a filter because the selection of a single peak is not the same as removing a portion of the input signal.[114] Philips argues its definition is consistent with the specification because the patent defines a "correlation canceler" as a device which "removes or filters" noise in the detected signals.[115]

Philips submits Masimo's expert opines the claims require the separation of the signal from noise, as opposed to removal, and concludes because "FAST separates signal information from erratic motion-induced noise," it is a filter.[116] Philips contends Dr. Baura incorrectly relies on Philips' documents that use filter in the general sense, and do not accurately describe the FAST algorithm, as confirmed by testimony of its

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[111] *Id.;* D.I. 429, Ex. 14C (Stone Noninfr. Rpt) at ¶¶ 116.
[112] *Id*.
[113] D.I. 525, Ex. 91 (Stone Depo.) at 93:2-12, 611:13-612:4, 94:5-11.
[114] *Id.* at 93:22-94:11, 96:2-20, 91:4-7, 91:18-22.
[115] D.I. 428, Ex. 2, '222 patent at 4:7-14 ("The correlation canceler is a device which takes a first and second input and *removes* from the first input all signal components which are correlated to the second input.") (emphasis added).
[116] D.I. 525, Ex. 90 (Baura Depo.) at 243:6-9 (testifying the claims "only require that [the algorithm] separate signal from noise."; D.I. 412 (Baura Decl.) at ¶ 29; *id*. at ¶¶ 30-33

witnesses.[117] As to the doctrine of equivalents, Philips notes Dr. Baura admits there is a difference between removal of noise and separation of noise, and under Philips' definition, FAST is not equivalent to a filter,[118] thereby resulting in a genuine issue of material fact.

Masimo's motion for summary judgment should be denied. Despite Masimo's arguments to the contrary, claim 17 requires a filter. As noted by the Federal Circuit in the prior Nellcor litigation, claim 17, as well as claim 18, are "directed to *filtering* the signals . . . to determine arterial oxygen saturation."[119] Specifically, claim 17 requires the signal processor to calculate arterial oxygen saturation without significant interference from motion induced noise, and based upon the parties' agreed-upon construction, "motion" means movement, which *in the absence of a filter*, would cause an erroneous arterial oxygen saturation reading. Therefore, by agreement, Masimo interjected "filter" into the function of a "signal processor."

In discussing Masimo's efforts to "solve the 'motion problem' encountered in the pulse oximetry field," the Federal Circuit specifically noted the solution was through the use of "particular *filtering algorithms*."[120] Moreover, when analyzing the Nellcor parties' arguments regarding collateral estoppel, that court included signal processor is part of

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[117] D.I. 525, Ex. 96 (Werner Haas Depo.) at 104:10-15; *id.*, Ex. 97 (Dieter Woehrle Depo.) at 137:8-10, 137:18-20; *id.*, Ex. 95 (Rolf Neumann Depo.) at 158:8-18 (Agilent employee, stating "[m]y recollection is that in the early 2000s, it was discovered that some of the marketing documents have falsely used or have used the wording ['filtering out noise'] that have some people falsely - caused false interpretation of how the algorithm is working"). As a result, prior to this litigation, Philips removed such wording from future documents.

[118] D.I. 525, Ex. 90 at 158:21-159:6, 160:14-161:8.

[119] *Mallinckrodt, Inc. v. Masimo Corp.*, 147 Fed. Appx. 158, 163 (Fed. Cir. 2005) (emphasis added).

[120] *Id*.

the "filter" terms used in claims 17 and 18.[121] Contrary to Masimo's claims, there is ample evidence that signal processor was previously considered by it to be a filter in its prior litigation involving the '222 patent.

Since the parties' experts disagree over the meaning of filter, that is whether a filter functions to separate rather than remove noise, as well as whether FAST operates as a filter, under literal infringement, or alternatively, under the doctrine of equivalents, there is a question of fact for determination by a jury.[122]

Regarding whether claim 17 requires a certain level of motion tolerance, Dr. Baura acknowledged, although a threshold must be met, it varies based upon the purpose for which the calculation is being employed.[123] According to Dr. Stone, Dr. Baura fails to identify the particular mechanism in the FAST algorithm which would satisfy the requirement in claim 17 "that oxygen saturation is calculated 'without significant interference in the calculation from the motion induced noise portion,'" and thus fails describe how FAST is motion tolerant within the scope of the claim.[124] In the previous Nellcor litigation, the Federal Circuit upheld the district court's finding that "without significant interference" was not indefinite based on Nellcor's expert agreeing that the construction was not ambiguous to one skilled in the art.[125] Here, no such

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[121] *Id.* at 168.

[122] Because filter is not in the claim language of the '222 patent, the court will not construe the term. *Mobilemedia Ideas, LLC v. Apple Inc.*,10-258-SLR, 2012 WL 6044777, at *31 (D. Del. Nov. 8, 2012). Since filter was not construed by the court, that the term is to be given its plain and ordinary meaning. *See CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002).

[123] D.I. 525, Ex. 90 at 173:2-22 (testifying the level of accuracy required is that "of a person who is skilled in the art, that the algorithm causes an accurate-enough saturation for the purposes of which the calculation is being employed.").

[124] D.I. 429 Ex. 14C (Stone Noninfr. Rpt.) at ¶¶ 113-14.

[125] *Mallinckrodt*, 147 Fed. Appx. at 179-80 (Fed. Cir. 2005) (The court further determined in light of this admission and its failure to present any contrary evidence, Nellcor's indefiniteness challenge was merely attorney argument.).

admission exists on the part of Philips, and conflicting evidence regarding the level of motion tolerance through its expert has been adduced by Philips.[126] Because the experts disagree regarding the level of motion tolerance as required by claim 17, and whether Philips' algorithm meets that required level of motion tolerance, these issues are also left for the jury.

Claim 18

Claim 18 of the '222 patent recites:

> The physiological monitor of claim 17, wherein said motion induced noise is indicative of the attenuation due to venous blood in the tissue during motion.[127]

Claim 18 is a dependant on claim 17, and limits the motion-induced noise to that caused by venous blood.[128]

Based on the previous analysis herein, because summary judgment is denied for independent claim 17, and claim 18 is dependent of claim 17, summary judgment is necessarily inappropriate as to claim 18.[129]

B. Invalidity[130]

Philips contends claims 17 and 18 of the '222 patent are invalid for failing to meet the written description requirement of 35 U.S.C. § 112, and anticipated by U.S. Patent

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[126] *See* D.I. 412 (Baura Decl.) ¶ 21(In her analysis concluding FAST infringes, she opines noise and artifact are *filtered* and eliminated by their failure to "*pass qualifying tests*," or thresholds.) (emphasis added).

[127] *Id.*, Ex. 2, '222 patent at 75:9-11.

[128] *Mallinckrodt*, 147 Fed. Appx. at 163; *see also*, D.I. 428, Ex. 2 '222 patent 75: 10-11.

[129] *IMX, Inc. v. LendingTree, LLC*, 405 F. Supp. 2d 479, 486 (D. Del. 2005) (denying summary judgment of infringement of dependent claims where plaintiff failed to sufficiently demonstrate infringement of independent claims upon which dependent claims relied).

[130] Philips notes since "claim 17 is invalid . . . , so too is dependent claim 18." D.I. 413 at 9 n.3; *see also Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1198 (Fed. Cir. 1999) (finding claim 1 invalid, and because "dependent claims 2-8 and 10 stand or fall with independent claim 1 . . . these claims are also invalid").

No. 4,955,379 to Hall (the "'379 patent" or "Hall").

1. Written Description

Philips notes the inventor and the parties' experts agree the correlation canceler embodiments are the only techniques disclosed for calculating oxygen saturation without significant interference from motion induced noise.[131] The use of a correlation canceler is described throughout the specification as "the present invention."[132] Additionally, Masimo told the PTO its invention was limited to a pulse oximeter that utilized correlation cancellation techniques.[133] As a result, Philips argues the '222 patent does not provide adequate written description of a non-correlation canceler.

Philip further argues the breadth of the claims as applied by Masimo's expert is not supported by the written description because she reads the asserted claims broad enough to cover any motion tolerant pulse oximeter.[134]

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[131] D.I. 429, Ex. 14B (Stone Inv. Rpt.) at ¶ 16 ("the '222 Patent does not disclose the use of any algorithm to calculate oxygen saturation without significant interference in the calculation from motion induced noise other than by using a correlation canceler"); D.I. 431, Ex. 25 (Baura Depo.) at 137:22-138:3, 146:5-147:9 ("There are no techniques that are not correlation cancelers that are described"); D.I. 433, Ex. 45 (Mohamed Diab Depo.) at 118:21-119:18 (Diab, named inventor of the '222 patent, could not identify any algorithm using non-correlation cancellation techniques, that is, where neither primary nor secondary references were used).

[132] *See*, e.g., D.I. 428, Ex. 2, '222 patent at 12:61-64 ("The present invention is a processor which determines either a secondary reference n'(t) or a primary reference s'(t) for use in a correlation canceler, such as an adaptive noise canceler."); *id.*, Ex. 2, '222 patent at 4:54-57 ("The signals are processed via the signal processor of the present invention to acquire either a secondary reference or a primary reference which is input to a correlation canceler, such as an adaptive noise canceler.").

[133] D.I. 428, Ex. 11 at 8 (Masimo representing "[i]n the present application . . . the signals are processed with an adaptive filter"). The specification of '222 patent provides an adaptive noise canceler is a correlation canceler. *See id.*, Ex. 2, '222 patent at 4:7-10, 6:30-32.

[134] D.I. 413 at 10. D.I. 429, Ex. 14B at ¶ 16; D.I. 431, Ex. 25 (Baura Depo.) at 123:8-13 (stating claim 17 "covers any [motion tolerant] technique"); *id.* at 115:20-116:1 (testifying there are "techniques other than correlation canceling techniques that could be used to practice [c]laim 17"); *id.* at 116:20-117:4 (stating claim 17 covers "techniques other than correlation canceling techniques"); *id.* at 116:4-16 (identifying "independent component analysis" as a technique other than correlation canceling); *id.* at 178:17-22 (agreeing "that if someone came up with an entirely new way to calculate saturation without substantial interference with motion-induced noise that wasn't correlation canceling, it wasn't [independent

Pointing to Dr. Baura's testimony, Philips emphasizes her admission that Masimo did not invent every technique that could meet the last paragraph of claim 17, but maintains the claim allows Masimo to exclude anyone from using any technique meeting the required calculation.[135]

Philips argues the specification of the '222 patent only describes the particular type of motion tolerant pulse oximeter Masimo invented, but fails to delinate in sufficient detail other types of motion-tolerant pulse oximeters.[136]

Masimo counters the '222 patent describes many different techniques, including non-correlation cancelers, for calculating oxygen saturation consistent with claims 17 and 18, thereby allowing one of ordinary skill in the art to understand that, at the time of filing of the application, it possessed the claimed signal processor.[137] Masimo states correlation canceling, itself, is a broad concept.[138] Additionally, it maintains the '222 patent discloses the technique used in the accused FAST algorithm, spectral estimation techniques, for calculating arterial oxygen saturation in the presence of motion induced noise.[139]

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component analysis], something completely new . . . would be covered by [c]laim 17").

[135] *Id.*; D.I. 431 Ex. 25 at 178:17-22.

[136] D.I. 413 at 12; *see also* D.I. 431, Ex. 25 at 116:4-16 (identifying technique other than correlation canceling); D.I. 429 Ex. 14B (Stone Supple. Inv. Rpt.) at ¶ 16; D.I. 428, Ex. 1, U.S. Patent No. 5,632,272 (the "'272 patent") at 50:30-51:55, 55:14-58:45 (identifying "Bank of Filters" and "Complex FFT" in later filed '272 patent).

[137] D.I. 509 at 9; *see also* D.I. 511 (Baura Dec.) at ¶ 6; D.I. 431, Ex. 23 (Baura Valid. Rpt.) at ¶¶ 332-35; D.I. 510, Ex. 3 (Baura Depo.) at 137:16-142:13; D.I. 429, Ex. 14B at 2, ¶ 6.

[138] D.I. 428, Ex. 2, '222 patent at 49:36-55 ("it will be understood that correlation cancellation techniques other than joint process estimation may be used together with the reference signals of the present invention. These may include but are not limited to least mean square algorithms, wavelet transforms, spectral estimation techniques, neural networks, Weiner filters, Kalman filters, QR-decomposition based algorithms among others"); D.I. 510, Ex. 1 (Transcript Claim Construction Hearing) at 113:19-114:2, 107:3-12; D.I. 163 at 9-10.

[139] D.I. 428, Ex. 2, '222 patent at 49:36-44; D.I. 511 at 2, ¶ 8; D.I. 510, Ex. 3 at 138:12-139:16; D.I. 431, Ex. 23 at 117, ¶ 335; D.I. 431, Ex. 24 (Baura Infr. Rpt.) at ¶ 9.

Masimo relies on the Federal Circuit holding in *Rexnord Corp. v. Laitram Corp.* that "an applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention."[140] As to the Federal Circuit cases cited by Philips, Masimo argues this court, in its analysis of claim construction, has not limited the scope of claim 17 in the '222 patent to a correlation canceler,[141] and legal precedent has not found lack of written description merely because the claims are broader than the disclosed examples.[142] It disputes Philips' argument that Dr. Baura testified claims 17 and 18 are broad enough to cover any motion tolerant pulse oximeter; rather her testimony was simply those claims control the issue of infringement.[143]

In analyzing whether the specification meets the written description clause of section 112, two closely related requirements must be met. The specification

> must described the manner and process of making and using the invention so as to enable a person skilled in the art to make and use the full *scope* of the invention *without undue experimentation.* Second, it must described the invention sufficiently to convey to a person of skill in the art that the patentee had possession of the claimed invention *at the time of the application*, i.e. that the patentee invented what is claimed.[144]

"[T]he hallmark of written description is disclosure."[145] However, "if the claimed

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[140] 274 F.3d 1336, 1344 (Fed. Cir. 2001).

[141] D.I. 509 at 11-12; *see also Crown Packaging Tech., Inc. v. Ball Metal Beverage Container Corp.*, 635 F.3d 1373, 1382 (Fed. Cir. 2011) (distinguishing *LizardTech* and *ICU Med.* cases because "[i]n each of those cases, the specification unambiguously limited the scope of the invention"); D.I. 319 at 2-5; D.I. 510, Ex. 1 at 107:3-12; D.I. 510, Ex. 3 at 137:16-142:13; D.I. 431, Ex. 23 at ¶¶ 332-35; D.I. 428, Ex. 2, '222 patent at 49:36-44.

[142] D.I. 509 at 12; *see also Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1371 (Fed. Cir. 2009) ("[a] patent claim is not necessarily invalid for lack of written description just because it is broader than the specific examples disclosed."); *Ariad Pharms., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010) ("[t]he written description requirement does not demand either examples or an actual reduction to practice.").

[143] D.I. 510, Ex. 3 (Baura Depo.) at 123:8-13, 178:17-22.

[144] *LizardTech, Inc.*, 424 F.3d at 1344-45 (emphasis added) (internal quotations omitted).

[145] *Ariad Pharmaceuticals, Inc.*, 598 F.3d at 1351 (Fed. Cir. 2010).

invention does not appear in the specification . . . the claim . . . fails regardless [of] whether one of skill in the art could make or use the claimed invention."[146] The parties agree the embodiments of the '222 patent only disclose the use of an algorithm for calculating oxygen saturation without significant interference in that calculation from motion induced noise through a correlation canceler.

Dr. Stone maintains a person of ordinary skill in the art would not understand Masimo had possession of the independent component analysis technique, because "every description and embodiment disclosed uses a signal processor that determines a primary or a secondary reference for use in a correlation canceler."[147] Although he acknowledges the court's construction of signal processor, he distinguishes that construction from what one skilled in the art would view as the invention because, in his opinion, the patent does not disclose the use of an algorithm for calculating oxygen saturation without significant interference in that calculation from motion induced noise other than through a correlation canceler. Because of the failure to disclose anything other than a correlation canceler, Dr. Stone opines extensive experimentation would be necessary to develop algorithms for motion tolerance in the absence of correlation cancellation techniques.[148]

Dr. Baura agrees the only techniques identified in the specification were correlation cancelers,[149] but argues in her reports and declarations that the patent encompasses algorithms other than the correlation cancellation techniques cited in the

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[146] *Id.* at 1348.
[147] D.I. 429, Ex. 14B (Stone Inv. Rpt) at ¶¶ 11-12.
[148] *Id.* at 4-5, ¶ 16.
[149] D.I. 431, Ex. 25 (Baura Depo.) at 112:16-114:15, 137:17-139:14.

specification.[150] Her opinions, however, simply provide a bald statement that a person of ordinary skill in the art would understand how to make and use the signal processor of claim 17 without undue experimentation.[151] All techniques, quoted from the patent and referenced in her declaration as spectral estimation techniques, are correlation cancelers or correlation canceling techniques.[152] She never explains how or why one skilled in the art would recognize the disclosure covered all techniques that analyze signals in the frequency domain without a correlation canceler. Such conclusory comments are insufficient to avoid summary judgment.[153]

In deposition, however, she identified independent component analysis ("ICA") that is not a correlation canceling technique[154] which could be use to practice claim 17, but admitted she was unaware of any non-correlation canceler methodology in 1991 when the specification in question was filed.[155] Moreover, when specifically asked whether someone skilled in the art could easily practice claim 17 in that time frame without using correlation cancellation techniques, Dr. Baura did not know or did not have an opinion.[156] She further opined Masimo's success in developing a pulse oximeter that provided accurate readings in the presence of motion was through

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[150] *Id.*, Ex. 23 (Baura Valid. Rpt.) at ¶¶ 332-35; *see also Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1366-68 (Fed. Cir. 2006).

[151] *Id.*

[152] D.I. 511 at ¶¶ 6-7; D.I 431, Ex. 23 at 139:3-14 (Baura testifying spectral estimation is the easiest correlation canceling technique and indicates separation of signal and noise in the frequent domain).

[153] *See Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571 (Fed. Cir. 1997) (finding conclusory expert testimony insufficient to defeat summary judgment motion).

[154] ICA is a technique not based on correlation canceling because it does not assume linearity, while correlation canceling is a linear system. D.I. 431, Ex. 23 at 115:20-116:16.

[155] D.I. 431, Ex. 23 at 122:5-10. Her deposition taken in 2012 suggests the ICA algorithm was available within the last fifteen years, and thus sometime after the 1991 filing date of the '222 patent.

[156] *Id.* at 122:21-123:4.

correlation canceling techniques.[157]

Masimo relies heavily on the construction by this court regarding signal processor as evidence that the written description requirement under § 112 has been satisfied. This argument not only permeates Masimo's brief, but is also replete in Dr. Baura's expert reports and deposition, which often mix the analyses of claim construction, infringement and validity. However, in construing claim terms, the court must find a clear intent "to limit the claim scope using words or expression of *manifest exclusion or restriction*,"[158] or a clear disclaimer or disavowal by the patentee of the claim scope.[159] As Masimo repeatedly noted in its brief, the scope of the claim may be broader than the specification. Further, during the claim construction phase, the parties agreed the ordinary meaning of a signal processor to be a device that processes an input or output signal, with their dispute resting on whether the specification *limited* claim 17, but not on whether the specification supported that broad, generic construction through its written disclosure. None of the expert reports, declarations or depositions were available at the time of claim construction.

Although the written description requirement does not demand that every nuance of the claim be explicitly described in the specification, it must show that the inventor had possession of the claimed subject matter as of the filing date.[160] "Possession means 'possession as shown in the disclosure. . . .'"[161] Claims 17 and 18 speak of a

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[157] *Id.* at 145:5-13.
[158] *Liebel-Flarsheim Co v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2008) (emphasis added).
[159] *Rambus Inc. v. Infineon Techs. Ag*, 318 F.3d 1081, 1095 (Fed. Cir. 2003).
[160] *Ariad Pharms. Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010).
[161] *Crown Packaging Techology, Inc. v. Ball Metal Beverage Container Corp.*, 635 F.3d 1373, 1380 (Fed. Cir. 2011).

signal processor generically; the specification, however, only describes correlation canceler techniques,[162] and Dr. Baura admits at the time of the invention only correlation cancellation techniques were known to one skilled in the art. Similar to *Lizard Tech*, nothing in claim 17 and dependent claim 18 or the specification constitutes an adequate description of all signal processors for use in a non-correlation canceler. Therefore, Philips' motion for summary judgment on written description is granted.

2. Anticipation: U.S. Patent No. 4,955,379 to Hall (the "'379 patent" or "Hall")[163]

The parties primarily disagree on whether the '379 patent addresses the problem of erratic noise, as required by claim 17 of the '222 patent. Philips argues the '379 patent discloses a pulse oximeter that excludes motion artefact from the wanted signal,[164] by disclosing "a motion artefact rejection system for pulse oximeters" and, more specifically, "a system for filtering out signals due to patient movement, i.e. motion artefact signals, from wanted signals."[165] Under Philips' analysis, the '379 patent employs "a motion artefact detector system [which] decides by examination of the variability of the amplitude and frequency of the incoming AC signals whether motion artefact is present."[166] If a motion artefact is not present, oxygen saturation is

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[162] *LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d at 1344-47.

[163] There is no dispute that if independent claim 17 is anticipated, dependent claim 18 is as well. *See* D.I. 429, Ex. 14A (Stone Inv. Rpt.) at 50, ¶¶ 180-186; D.I. 431, Ex. 23 (Baura Valid. Rpt.) at ¶ 129; *id.*, Ex. 25 (Baura Depo.) at 110:8-15. Philips represents numerous other prior art references explicitly disclose the calculation of oxygen saturation in the presence of motion induced noise. *See* D.I. 433, Ex. 41, U.S. Patent No. 4,911,167 (the "'167 patent") at 5:21-25; *id.*, Ex. 39, U.S. Patent No. 5,190,038 (the "'038 patent") at 1:6-14; *id.*, Ex. 42, U.S. Patent No. Re. 33,643. Since Philips only moved on Hall for summary judgment, the analysis herein is limited to the '379 patent.

[164] D.I. 429, Ex. 14A at ¶ 169; D.I. 431, Ex. 25 at 236:14-19 (noting '379 patent disclosed a motion tolerant pulse oximeter).

[165] D.I. 432, Ex. 36, '379 patent at 1:6-9.

[166] *Id.* at 3:12-15.

"determined by normal oximeter algorithms."[167] On the other hand, if motion artifact is present, the "AGC system is frozen, fixing the gain level, and the bandpass filter is configured in a feedback loop."[168] Therefore, "when motion artefact is present, the bandpass filters can stay tuned to the pulse rate, tracking its change."[169] Consequently, the invention in the '379 patent "reduces the severity of [error from patient movement]" thereby enabling more accurate measurement of arterial blood oxygen saturation and pulse rate.[170] In light of the above and because the asserted claims recite a pulse oximeter that calculates oxygen saturation without significant interference from motion induced noise, Philips argues the '379 patent anticipates the '222 patent.[171]

Philips notes Dr. Baura's primary basis that Hall does not anticipate is her disbelief in its disclosure, despite having never tested, used or applied the Hall algorithm.[172]

According to Philips, Dr. Baura's opinion that the '379 patent does not anticipate because its algorithm is not sufficiently motion tolerant is unfounded since she fails to provide the threshold limit required by the asserted claims.[173] Therefore, her positions

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[167] *Id.* at 3:15-17.
[168] *Id.* at 3:21-23.
[169] *Id.* at 3:32-34.
[170] *Id.* at 1:18-21.
[171] D.I. 413 at 17. Philips originally pointed to Dr. Baura's incorrect assumption that the Hall algorithm was incorporated in a pulse oximeter which was not effective with motion induced noise. However, as evidenced by the unrefuted declaration of Mike Polson, the engineer responsible for the development of that devise, the Hall algorithm was never used in that pulse oximeter. D.I. 413 at 16-17; D.I. 433, Ex. 40 ¶¶ 4-6. Masimo contends Dr. Baura's opinions regarding Hall as "incapable of handling erratic noise are not premised on the operation" of that device. *See* D.I. 509, n.2.
[172] *Id.* at 16; *See* D.I. 431(Baura Depo.) at 237:20-22; 287:17-22; 289:4-5.
[173] *Id.* at 18; *see also* D.I. 431, Ex. 25 at 171:21-172:7 ("the threshold is that it's not accurately reflecting the arterial oxygen saturation"); *id.* at 173:17-22 (the specific level of accuracy is "that the algorithm causes an accurate-enough saturation for the purposes of which the calculation is being employed"); *id.* 175:6-20 (same); *id*. at 174:1-5 ("a person skilled in the art would have the same agreement as to what is accurate enough as others skilled in the art").

on validity and infringement are irreconcilable: she opines the asserted claims cover any motion tolerant pulse oximeter, but in analyzing the Hall patent which falls within her broad claim application, she merely disbelieves it works well enough to anticipate the '222 patent, absent any contrary evidence.[174]

Masimo counters that the '379 patent fails to disclose or enable a pulse oximeter that addresses the problem of erratic noise, relying on the parties' agreed to construction of motion.[175] It states the '379 patent "merely discloses a traditional filtering technique known as a frequency-locked loop or bandpass tracking filter tuned to the patient's pulse rate" which cannot remove erratic noise.[176] Because Hall employs a tracking filter technique which passes "all frequencies in the locked-frequency range, including the pulsating signal and noise," and when selecting the dominant frequency, it incorrectly assumes noise will have a smaller peak than the frequency associated with the pulse rate.[177] Masimo contends Hall is "directed to predictable 'motion artifact

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[174] D.I. 413 at 19.

[175] D.I. 509 at 16; *see also* D.I. 162 at 19 (parties' stipulated meaning of the term "motion" as "movement of body tissue which causes erratic noise, that, in the absence of a filter, would cause the ratio of red to infrared signals to not accurately reflect the arterial oxygen saturation"); D.I. 511 (Baura Decl.) at ¶ 11; D.I. 431, Ex. 23 (Baura Valid. Rpt.) at ¶ 120.

Initially, Masimo, as well as Dr. Baura, relied on the purported determination by the PTO that Hall does not invalidate the '222 patent, with Masimo emphasizing the heavier burden imposed on Philips. D.I. 509 at 16. However, the PTO, on September 20, 2012, granted reexamination of the asserted claims at issue, confirming "[t]he teachings of Hall . . . were not previously considered nor addressed during a prior examination." D.I. 601, Ex. 155 at 7-8. In allowing reexamination, Hall was found as raising "substantial new questions of patentability as to claims 17 and 18." *Id.* at 6. Therefore, the PTO did not originally find the '222 patent patentable over Hall.

[176] D.I. 509 at 17; *see also* D.I. 432, Ex. 36, '379 patent at 3:12-39; D.I. 511at ¶¶ 12-13; D.I. 431, Ex. 23 (Baura Valid. Rpt.) at ¶ 120; D.I. 510, Ex. 3 (Baura Depo.) at 235:10-236:1, 237:3-4, 238:3-20.

[177] D.I. 509 at 17; *see also* D.I. 511at ¶¶ 14-16; D.I. 432, Ex. 36, '379 patent at 4:1-6 ("a pulse oximeter for making a measurement of blood oxygen saturation which produces pulsatile signals in response to a patient's pulsating arterial blood flow in a first variable range of frequencies and motion artefact signals at frequencies outside of said first variable range of frequencies"); D.I. 428, Ex. 2, '222 patent at 5:6-13 (noting noise is "unpredictable"); *id.*, Ex. 2, '222 patent at 2:51-57 ("[t]raditional signal filtering techniques are frequently totally ineffective and grossly deficient in removing these motion induced effects from a signal"); D.I. 431, Ex. 23 at ¶ 120.

signals outside' of the 'range of frequencies,'" while erratic motion induced noise addressed in the '222 patent is unpredictable, "and may appear at any frequency range."[178] According to Dr. Baura, erratic noise is often located in the "same frequency spectrum as the pulse rate," causing traditional tracking filters to be ineffective.[179] Under Hall, the bandpass tracking filter locks onto the dominant frequency, which could be reading heart rate or noise, and is unable to distinguish between the them.[180] Additionally, Hall "incorrectly assumed that the heart rate transitions smoothly," while the heart rate in ill patients frequently "changes abruptly and varies considerably," thereby preventing a bandpass tracking filter to accurately plot the heart rate.[181]

Masimo emphasizes "Dr. Baura consistently testified that, despite [the '379 patent's] reference to addressing patient motion in the Background of the Invention, [the '379 patent] does not disclose any technology that could calculate arterial oxygen saturation in the presence of erratic noise and anticipate the '222 Patent claims."[182] Masimo also argues there is no inconsistency between Dr. Baura's conclusions that "[the '379 patent] does not anticipate while FAST infringes,"[183] because she reviewed Philips' admissions, objective clinical studies and Philips' source code, to distinguish Philips' FAST algorithm, as calculating arterial saturation without significant interference in the calculation from motion-induced noise, while the '379 patent does not.[184]

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[178] D.I. 509 at 17; D.I. 423, Ex. 36 '397 patent at 4:3-6; D.I. 511at ¶ 15.
[179] D.I. 511at ¶ 15.
[180] *Id*. ¶ 16; D.I. 431, Ex. 23 at ¶ 120.
[181] D.I. 511 at ¶ 17.
[182] D.I. 509 at 19; *see also* D.I. 510, Ex. 3 at 229:10-12, 235:10-241:3.
[183] D.I. 509 at 20.
[184] *Id.*; *see also* D.I. 412 (Baura Decl.) at ¶¶ 11, 16; D.I. 429, Ex. 14C (Stone Inv. Rpt.) at ¶¶ 8-9, 11; D.I. 431, Ex. 24 at ¶ 10; *id.* at ¶¶ 120-21.

Philips' motion of anticipation by Hall should be denied. Anticipation requires a single prior art reference disclose each and every limitation of the claimed invention.[185] As discussed previously herein, Dr. Baura opines under claim 17, where oxygen saturation must be calculated without significant interference from motion induced noise, requires a certain level of motion tolerance, which varies based upon the purpose for which the calculation is being employed.[186] Dr. Baura concludes the '379 patent does not address motion-induced (erratic) noise as the '222 patent does because it locks onto the dominant peak, presuming it to be noise.[187]

Philips has not adequately demonstrate by clear and convincing evidence that the '379 patent discloses motion tolerance as required by the '222 patent as evidenced by Dr. Baura's opinions which describe both the deficiencies and differences between the '379 patent and the asserted claims' filtering techniques. Thus, the issue of Hall as anticipating the '222 patent should be left for the jury regarding both claims.

2. Philips' Motion for Summary Judgment of Invalidity and Noninfringement of U.S. Pat. No. 7,215,984 ("the '984 patent")[188]

The '984 Patent (Masimo Patent)

Masimo accuses Philips' Fourier Artifact Suppression Technology ("FAST") of infringing claims 1-5, 15, 16, 19, 20, 22, and 52-54 of the '984 patent.[189] Philips filed counterclaims for noninfringement, invalidity, and unenforceablity of the '984 patent.

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[185] *Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1379-80 (Fed. Cir. 2003).

[186] D.I. 525, Ex. 90 at 173:2-22 (testifying the level of accuracy required is that "of a person who is skilled in the art, that the algorithm causes an accurate-enough saturation for the purposes of which the calculation is being employed.").

[187] D.I. 431, Ex. 23 at ¶ 120.

[188] D.I. 394. The briefs are found at D.I. 395 (Philips' opening brief), D.I. 515 (Masimo's answering brief), and D.I. 592 (Philips' reply brief).

[189] Claims 1, 52, and 53 are independent claims.

Philips now moves for summary judgment that the '984 patent is invalid and that FAST does not infringe.

In describing the "Field of the Invention," the '984 patent recites:

> The present invention relates to the field of signal processing. More specifically, the present invention relates to the processing of measured signals, containing a primary signal portion and a secondary signal portion, for the removal or derivation of either the primary or secondary signal portion when little is known about either of these components. More particularly, the present invention relates to modeling the measured signals in a novel way which facilitates minimizing the correlation between the primary signal portion and the secondary signal portion in order to produce a primary and/or secondary signal. The present invention is especially useful for physiological monitoring systems including blood oxygen saturation systems.[190]

The asserted claims of the '984 patent are directed at the use of at least one of two calculation techniques for calculating a value representative of a physiological

[190] '984 patent, 1:18-30.

characteristic of a patient, such as oxygen saturation or pulse rate.[191] The specification describes the use of multiple "processing functions" in association with Figure 14:

[191] *See, e.g.*, D.I. 429, Ex. 14A (Stone Inv. Rpt.) ¶¶ 188-89; D.I. 431, Ex. 22 (Baura Infr. Rpt.) ¶ 50.

As illustrated in Figure 14, signals detected by a pulse oximetry sensor are subjected to demodulation 400 and decimation 402. The demodulated and decimated signals are then provided to a statistics module 404 (i.e., a "first calculation technique") and a saturation transform module 406 (i.e., a "second calculation technique"). Modules 404 and 406 are each capable of calculating oxygen saturation using two different techniques.[192] The results are then "forwarded to saturation operations, as represented by a saturation calculation module 408 and pulse rate operations, as represented in a

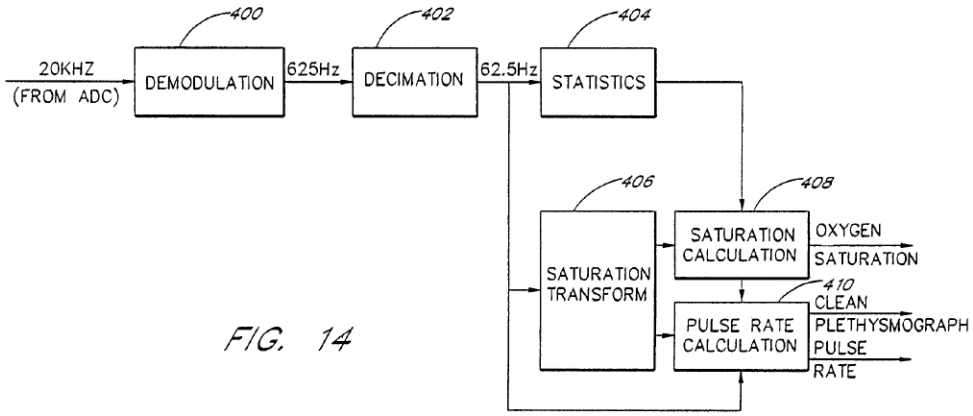

FIG. 14

[192] *See, e.g.*, '984 patent, 41:66-42:4 ("[T]he statistics module 404 provides first order oximetry calculations and RMS signal values for the red and infrared channels. The statistics module also provides a cross-correlation output which indicates a cross-correlation between the red and infrared signals."); '984 patent, 43:36-46 ("[T]he saturation transform module 406 comprises a reference processor 530, a correlation canceler 531, a master power curve module 554, and a bin power curve module 533. The saturation transform module 406 can be correlated to FIG. 7a which has a reference processor 26 and a correlation canceler 27 and an integrator 29 to provide a power curve for separate signal coefficients as depicted in FIG. 7c. The saturation transform module 406 obtains a saturation spectrum from the snapshots of data. In other words, the saturation transform 406 provides information of the saturation values present in the snapshots.").

pulse rate calculation module 410."[193]

Philips' Fourier Artifact Suppression Technology ("FAST")

According to Philips, its accused FAST is an algorithm incorporated into pulse oximeters that calculates a patient's blood oxygen saturation and pulse rate that was first developed in the 1990s by Agilent Technologies ("Agilent") prior to its acquisition by Philips.[194]

Philips' FAST algorithm originally included only a single frequency-domain calculation technique,[195] but all versions of FAST released since March 2004 include two algorithms for processing detected signals.[196] One of the algorithms processes signals in the frequency domain (the "frequency-domain algorithm") and the other processes signals in the time domain (the "time-domain algorithm").[197] The frequency-domain algorithm makes its calculations on approximately eight seconds of data and the time-domain algorithm makes its calculations on approximately two seconds of data.[198] Because the frequency-domain algorithm needs eight seconds of data, the time-domain algorithm was developed "to improve the start-up time of the [FAST] algorithm."[199] As

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[193] '984 patent, 40:26-31.

[194] D.I. 395 at 3.

[195] D.I. 515 at 3; D.I. 431, Ex. 22 (Baura Infr. Rpt.) at ¶ 62 (stating FAST versions prior to 3.13 only performed a frequency-domain calculation).

[196] D.I. 429, Ex. 14C (Stone Noninfr. Rpt.) at ¶ 6 ("It is my understanding that Philips added its time-domain algorithm to FAST version 3.13 in March 2004. Further, it is my understanding that all versions of FAST since that time have implemented a time-domain algorithm." (citations omitted)); D.I. 431, Ex. 22 (Baura Infr. Rpt.) at ¶ 38 (including chart indicating FAST version 3.13 as first version including two algorithms).

[197] D.I. 429, Ex. 14C at ¶ 7 (discussing the time-domain algorithm); D.I. 431, Ex. 22 at ¶ 62 ("Fast algorithm versions 3.13 and later performed two different calculations on the red and infrared sampled data: 1) a frequency-domain calculation and 2) a time-domain calculation." (footnote omitted)).

[198] D.I. 430, Ex. 15 (Stone Depo.) at 332:11-333:3; D.I. 431, Ex. 25 (Baura Depo.) at 338:22-340:3; D.I. 431, Ex. 22 at ¶¶ 66-67, 73.

[199] D.I. 429, Ex. 14C (Stone Noninfr. Rpt.) at ¶ 7; D.I. 431, Ex. 22 (Baura Infr. Rpt.) at ¶ 56.

Philips explained to the FDA, the frequency-based algorithm "provides better performance and more reliable results compared to the time-based analysis when artifacts are present in the raw signals."[200] In contrast, "under non-artifact conditions the time-based algorithm can provide a valid output much sooner, i.e., while the FFT algorithm is still acquiring data for its analysis."[201] Philips' technical expert, Dr. Robert T. Stone, explains "FAST generally utilizes the results of the frequency-domain algorithm whenever they are available. It only utilizes the output of the time-domain algorithm at start-up and after some extended period . . . of failure of the frequency-domain algorithm to produce an output."[202]

Parties' Positions

Philips contends, as written, all but two of the asserted claims of the '984 patent are anticipated by prior art U.S. Patent No. 5,355,882 to Ukawa ("the '882 patent" or "Ukawa") and U.S. Patent No. 4,955,379 to Hall ("the '379 patent" or "Hall"). It argues there is no dispute each reference discloses a device with two calculation techniques for calculating oxygen saturation. According to Philips, in response to these references, Masimo seeks to construe the claims contrary to their plain meaning to require "parallel, alternative calculations" that receive the same "time window" of input data. Philips maintains Masimo's interpretation is unsupported by the claims and should be rejected.

Philips avers that Masimo's technical expert, Dr. Gail D. Baura, admits Ukawa and Hall are indistinguishable if the court does not adopt her interpretation of the claims.

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[200] D.I. 516, Ex. 10 at PHIL03208842.
[201] *Id.*
[202] D.I. 429, Ex. 14C at ¶ 10 (citations omitted).

Therefore, Philips argues, under a proper interpretation, the asserted claims are anticipated by Ukawa and Hall.

Philips contends, even under Masimo's proposed construction, Dr. Baura admits that FAST does not meet those limitations. Philips maintains there is no dispute that FAST has two algorithms for calculating oxygen saturation, and those two algorithms do not receive the same "time window" of data because "the time-domain algorithm" receives only two seconds of input while "the frequency-domain algorithm" receives eight seconds of data. As a result, Philips concludes there is no dispute that FAST does not infringe the asserted claims of the '984 patent under Masimo's proposed construction.

Lastly, Philips argues, regardless of how the claims are construed, the court should also grant summary judgement of noninfringement of claims 15-16, 19-20, and 53-54 as each of those claims recite functions to be performed by the "processing module." Philips states it is undisputed the accused features are performed not by the processing module, but instead by one of the two calculators.

Masimo disputes each of Philips' assertions. First, Masimo insists it is not trying to deviate from the ordinary meaning of the asserted claims, stating "[t]he claims at issue cover a system or method that calculates a physiological parameter of the pulsing blood by using two calculators, where each calculator uses a different calculation technique for the same parameter of pulsing blood to process the incoming signals from the same detected light."[203]

[203] D.I. 515 at 1.

Masimo also rejects Philips' assertion that Ukawa and Hall invalidate the asserted claims of the '984 patent. Its initial position with regard to Ukawa is that it is not prior art. It also notes its disagreement with Philips' assertion that there is no dispute that Ukawa and Hall each disclose a device with two calculation techniques for calculating oxygen saturation. Masimo insists each reference discloses a single calculator, not two, as required by the claims.[204]

With regard to infringement, Masimo states Philips agrees FAST has two algorithms for calculating oxygen saturation and also does not dispute that these algorithms employ different calculation techniques, they calculate at the same time, or the oxygen saturation they compute is for pulsing blood. Masimo argues Philips' non-infringement position (that these two algorithms do not receive the same "time window" of data) is incorrect. Masimo maintains both calculation techniques process all the data because they run continuously, thereby providing constantly updated oxygen saturation.[205]

Finally, Masimo notes its disagreement with Philips' non-infringement argument for some claims that the accused features are performed not by the processing module, but instead by one of the two calculators. Masimo maintains that, depending on the claim at issue, the feature in question is either performed by the processing module, and/or the claim does not specify which module performs the feature.[206]

A. Disputed Claim Language

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[204] *Id.*
[205] *Id.*
[206] *Id.* at 1-2.

In briefing on this motion, each party accuses the other of offering interpretations of the claim language not supported by a plain reading of the claims; accusations each deny. Each party notes claim construction has concluded and urges the court to apply the plain and ordinary meaning of the terms as purportedly reflected in their respective interpretations of those terms.

During claim construction, Masimo maintained the asserted claims of the '984 patent "are readily understandable without elaboration," and "[t]he surrounding language in Claims 1, 52, and 53 already provide sufficient context for these terms, explaining what is required of the calculation techniques, and how they are used to determine an oxygen saturation."[207] Masimo argued "unrecited limitation[s] should not be injected into the claims under the guise of claim construction."[208] Philips proposed a narrowing construction which the court rejected, agreeing with Masimo that no additional construction was needed.[209] Philips now contends Masimo is stepping away from its prior position and seeks to add new, unsupported, limitations into the claims. Masimo insists that contention is untrue and it has consistently applied the plain and ordinary meaning to the claims. Masimo argues that, after failing to narrow the asserted claims during the *Markman* process, it is Philips who ignores the plain and ordinary meanings of the claims and makes construction arguments in an effort to broaden the claims in support of its invalidity contentions.

Independent claim1 recites:

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[207] D.I. 164 at 12.
[208] D.I. 175 at 12.
[209] *Masimo Corp. v. Philips Elec. N. Am. Corp.*, C.A. No. 09-80-LPS-MPT, 2011 WL 678447, at *4 (D. Del. Feb. 18, 2011); *Masimo Corp. v. Philips Elec. N. Am. Corp.*, C.A. No. 09-80-LPS-MPT, 2012 WL 125759, at *1 (D. Del. Jan. 17, 2012).

1. A physiological monitoring system including an optical probe configured to output one or more intensity signals representative of at least one physiological characteristic of body tissue, and a signal processing device configured to accept the one or more intensity signals and configured to determine a resulting value indicative of the at least one physiological characteristic, the physiological monitoring system comprising:

> an optical probe including a light-sensitive detector configured to detect light of at least first and second wavelengths attenuated by body tissue carrying pulsing blood and configured to output one or more intensity signals based on the detected light; and
>
> a signal processing device including:
>
> > a first calculator capable of utilizing a first calculation technique to determine at least a first ratio representative of at least one physiological characteristic of the pulsing blood based on at least one of the one or more intensity signals generated from said detection of said light at said at least first and second wavelengths,
> >
> > a second calculator capable of utilizing a second calculation technique different from the first calculation technique, to determine at least a second ratio representative of the at least one physiological characteristic based on at least one of the one or more intensity signals generated from said detection of said light at said at least first and second wavelengths, and
> >
> > a processing module configured to utilize at least one of the first and second calculators to determine a resulting value indicative of the at least one physiological characteristic.[210]

Philips contends a plain reading of the claim demonstrates: 1) "[w]hile the signal processing device must include two calculators, each calculator is only required to be *capable of* performing a calculation technique–the claim does not require that *both* calculators actually calculate a physiological characteristic every time a calculation is

[210] '984 patent, claim 1.

performed";[211] 2) "the claims only require that each calculator be capable of determining a ratio based on *at least one* of the detected intensity signals . . . each calculator is not required to use the *same* intensity signals";[212] and 3) "the claim requires only that the processing module utilize *at least one* of the calculators, not both calculators."[213]

According to Masimo, Philips' positions are unsupported by the claim language and are provided in an attempt to broaden the claims in order to argue invalidity. Masimo contends the claim does require both calculators to calculate a physiological characteristic every time a calculation is performed; the input signals for the first and second calculators are the same; and output from both calculators must be available to the processing module.

Philips maintains that, to avoid anticipation by Ukawa and Hall, Dr. Baura's invalidity report includes new non-existent claim limitations at odds with the plain meaning of the claim language.[214] In that report, Dr. Baura opined a particular prior art reference does not anticipate claim 1 of the '984 patent because:

> [The prior art reference] does not disclose the use of a first calculator capable of utilizing a first calculation technique to determine at least a first ratio representative of at least one physiological characteristic of the pulsing blood based on at least one of the one or more intensity signals generated from said detection of said light at said at least first and second wavelengths, and a second calculator capable of utilizing a second calculation technique different from the first calculation technique, to determine at least a second ratio representative of the at least one physiological characteristic based on at least one of the one or more intensity signals generated from said detection of said light at said at least first and second wavelengths (hereinafter "*parallel, alternative calculations of a signal to determine first and second ratios*"), and utilization of at least

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[211] D.I. 395 at 8 (emphasis in original).
[212] *Id.*
[213] *Id.*
[214] D.I. 395 at 7 (citing D.I. 431, Ex. 23 (Baura Valid. Rpt.) at ¶¶ 131, 134).

one of the calculations to determine a resulting value indicative of a physiological characteristic.[215]

When asked to explain her opinion that claim 1 requires "parallel, alternative calculations of a signal to determine first and second ratios,"[216] Dr. Baura testified the claim requires "the same time window of data . . . to go into the first calculator and the second calculator,"[217] and "[b]oth calculations occur at the same time, and then the processing module determines which calculator is right or should be utilized."[218] Dr. Baura purportedly admits her validity opinions regarding the independent claims are based entirely on those claim interpretations,[219] but Philips argues the claims provide no support for either of those limitations.[220]

Philips insists it has never taken a different position regarding the meaning of the claims than it now takes.[221] In contrast, Philips states Dr. Baura's opening report on infringement did not apply Masimo's purportedly new interpretation of the claims. Rather, she only alleged Philips' algorithm is capable of utilizing different algorithms and thus infringes. She did not discuss her "parallel, alternative calculations" interpretation,

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[215] D.I. 431, Ex. 23 at ¶¶ 131 (emphasis added); *see also, e.g.*, D.I. 431, Ex. 23 at ¶ 139 (stating Ukawa does not anticipate claim 1 of the '984 patent because it "does not disclose the use of parallel, alternative calculations of a signal to determine first and second ratios, and a utilization of at least one of the calculations to determine a resulting value"); D.I. 431, Ex. 23 at ¶ 140 (stating Hall does not anticipate claim 1 of the '984 patent because it "does not disclose the use of parallel, alternative calculations of a signal to determine first and second ratios, and a utilization of at least one of the calculations to determine a resulting value ").

[216] Dr. Baura similarly opined that independent claims 52 and 53 require "parallel, alternative calculations of a signal to determine first and second ratios." *See, e.g.*, D.I. 431, Ex. 23 at ¶¶ 211-12, 218-19.

[217] D.I. 431, Ex. 25 (Baura Depo.(7/16/12)) at 272:4-7.

[218] D.I. 431, Ex. 25 at 263:22-264:3.

[219] D.I. 395 at 7 (citing D.I. 431, Ex. 25 at 270:6-10 ("Q. Is it fair to say that your opinion related to Claim 1 and whether it's anticipated depends entirely on your interpretation of the claim that it requires parallel alternative calculations? A. Well, that's what's stated in the claim.").

[220] D.I. 395 at 7.

[221] D.I. 592 at 2 (citing D.I. 429, Ex. 14A (Stone Inv. Rpt.) App. C).

providing no analysis as to how FAST infringes under that interpretation.[222] Philips argues it was only in response to its invalidity report, that Dr. Baura "concocted her new interpretation in an effort to distinguish the cited references."[223]

Philips first argues that although the signal processing device must include two calculators, the claims only require each calculator to be *capable of* performing a calculation technique, not that *both* calculators actually calculate a physiological characteristic every time a calculation is performed.

Masimo disputes that argument, citing the claim language that a first calculator "*determine* at least a first ratio," and a second calculator "*determine* at least a second ratio."[224] Based on that language, Masimo concludes the claim requires that the calculators actually determine their respective ratios.[225] Masimo contends the language relied on by Philips regarding each calculator being "capable of utilizing" a calculation technique does not suggest only one calculator need determine its ratio, rather, the "capable" language is associated with the calculation technique, but the claims require both calculators "to determine" ratios.[226]

Philips responds Masimo selectively quotes the claim language and omits key language. For instance, Philips contends Masimo omits the "capable of" language in claim 1, which recites "a first calculator capable of utilizing a first calculation technique to determine at least a first ratio" and "a second calculator capable of utilizing a second calculation technique different from the first calculation technique, to determine at least

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[222] *Id.* (citing D.I. 431, Ex. 22 (Baura Infr. Rpt.) at 164).
[223] *Id.* (citing D.I. 431, Ex. 23 (Baura Valid. Rpt.) ¶¶ 131, 134).
[224] *Id.* at 5 (emphasis in original).
[225] *Id.* (citing D.I. 516, Ex. 11 (Baura Depo. Tr. (7/16/2012) at 267:3-268:8)).
[226] D.I. 515 at 5.

a second ratio."[227] According to Philips, there is no way to reconcile Masimo's interpretation with the "capable of" language of the claim. Philips insists the underlined claim language demonstrates Masimo's position is incorrect.[228]

Philips also states Dr. Baura's only support for her opinion, that both calculators actually determine their respective ratios, is her testimony that: "[i]f you're capable of determining, I believe you determine."[229] Philips contends Dr. Baura's argument is contrary to the plain and ordinary meaning of the word "capable," giving as an example a vehicle that may be capable of traveling 100 miles-per-hour, but that does not mean that it always travels 100 miles-per-hour. Philips also maintains Dr. Baura's interpretation is contrary to established Federal Circuit precedent that claims reciting merely the capability of performing a function do not require actual performance of that function.[230]

The court agrees with Philips' interpretation. As Philips notes, the claim requires, e.g., "a first calculator *capable of* utilizing a first calculation technique to determine at least a first ratio." Rather than writing the limitation as "a first calculator utilizing a first calculation technique to determine at least a first ratio," the drafter included the "capable of" language which indicates the ability of "a first calculator" to "determine at least a first ratio," not that both the first and second calculators are required to actually calculate a physiological characteristic every time a calculation is performed.

Philips next argues the claims only require each calculator be capable of

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[227] D.I. 592 at 3 (emphasis in original).
[228] *Id.*
[229] *Id.* at 8 (quoting D.I. 431, Ex. 25 (Baura Depo. Tr. (7/16/2012)) at 268:7-8).
[230] D.I. 592 at 2 (citing *Intel Corp. v. U.S. Int'l Trade Comm'n*, 946 F.2d 821, 832 (Fed. Cir. 1991)).

determining a ratio based *at least one* of the detected intensity signals.[231] According to Philips, each calculator is not required to use the *same* intensity signals.[232] Although Philips acknowledges the same or overlapping time windows of data may be used, it insists the claims do not require each calculator to use the same input data.[233]

Masimo counters claim 1 recites that the calculations from both calculators are "from *said* detection of *said* light at *said at least first and second wavelengths.*"[234] Masimo concludes, therefore, the claims make clear the input signals of the first and second calculators are the same because both calculators use "*said* detection of *said* light."[235]

Philips again states Masimo omits relevant claim language, reiterating claim 1 requires each calculation technique be based on "*at least one of the one or more intensity signals* from said detection of said light."[236] Philips asserts a plain reading of that language shows each calculator must be capable of using *at least one* of the detected intensity signals, not *all* of the detected intensity signals; thus the techniques need not use the same input data.[237]

The claim language requiring a calculation technique to be based on "at least one" of the "one or more intensity signals" supports Philips' interpretation that not all of the detected intensity signals are required to be used and, therefore, each calculator is not required to use the same intensity signals.

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[231] D.I. 395 at 8 (emphasis in original).
[232] *Id.* (emphasis in original).
[233] *Id.*
[234] D.I. 515 at 5 (emphasis in original).
[235] *Id.*
[236] D.I. 592 at 3 (emphasis in original).
[237] *Id.*

Finally, Philips argues the claim only requires the processing module to utilize *at least one* of the calculators, not both calculators.[238] Masimo contends that argument would make having two calculators meaningless.[239] Masimo points out in claims 1 and 53, the processing module is "configured to utilize at least one of the first *and* second calculators to determine a *resulting value* . . . ."[240] Masimo states Philips argues as if the word "and" says "or."[241] Masimo maintains in order to be configured to use at least one of the first *and* second calculators to determine a *resulting value*, output from both calculators must be available to the processing module.[242] Masimo contends that makes sense because if only one calculator was connected to the processing module, the other calculator would be rendered useless.[243]

Philips insists it is not trying to replace the "and" with "or" in the last limitation of claims 1 and 53, again emphasizing the limitation recites "utilize *at least* one of the first and second calculators."[244] Philips argues "[t]hat means what it says–use at least one of the calculators. It does not require <u>both</u> calculators be used."[245]

As with Philips' previous argument, the court agrees the use of "at least one" demonstrates the claim does not require the processing module to utilize both calculators. Contrary to Masimo's assertion, that interpretation does not render one of the calculators useless. Output from both calculators *might* be utilized by the

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[238] D.I. 395 at 8.
[239] D.I. 515 at 5-6.
[240] *Id.* at 6 (emphasis in original).
[241] *Id.*
[242] *Id.* (citing D.I. 516, Ex. 11 (Baura Depo.) at 268:13-269:14).
[243] D.I. 515 at 6.
[244] D.I. 592 at 3 n.2 (emphasis in original).
[245] *Id.*

processing module, but the claim does not include that requirement.

B. Validity

Philips contends the asserted claims of the '984 patent are invalid in light of Ukawa and Hall.

1. Ukawa

The '984 patent was filed May 4, 2004 and claims priority to an application filed October 7, 1994. Ukawa issued on October 18, 1994, but was filed July 8, 1993. Therefore, Philips contends Ukawa is prior art to the '984 patent under 35 U.S.C. § 102(e). Because Masimo argues Ukawa is not prior art to the '984 patent, the court addresses this issue prior to the parties' validity arguments.

Section 102(e) recites:

> A person shall be entitled to a patent unless . . .
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language . . . .[246]

The issue, therefore, is whether Ukawa was "filed in the United States before the invention" by Masimo, i.e., whether Ukawa's July 8, 1993 filing date predates Masimo's invention date. Citing the declaration of Mohamed K. Diab, one of the named inventors of the '984 patent, Masimo maintains it actually reduced to practice the inventions at

[246] 35 U.S.C. § 102(e).

issue by at least not later than October 10, 1992, months before the July 8, 1993 Ukawa filing date.[247] Masimo contends Philips ignores evidence establishing Masimo's invention of the relevant subject matter in the '984 patent before the Ukawa filing date, purportedly demonstrating Philips' motion is baseless.[248]

Philips states, prior to summary judgment, Masimo did not dispute Ukawa is prior art despite having been aware of Philips' reliance on Ukawa as prior art to the '984 patent for more than two years.[249] Philips avers Masimo never disputed Ukawa's status as prior art despite having the opportunity to do, for example, in its responses to Philips' invalidity contentions and its expert report.[250] Instead, Masimo contested whether a different reference was § 102(e) prior art in its responses to invalidity contentions and expert reports.[251] Philips argues, therefore, it "properly relied on Ukawa as prior art and has been completely sandbagged by Masimo's new argument."[252]

Philips characterizes as improper Masimo's reliance on "an untested, self-serving affidavit from the inventor himself, unsupported by expert testimony, that Masimo's early source code actually meets the limitations of the '984 Patent."[253] According to Philips,

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[247] D.I. 515 at 6 (citing D.I. 516, Ex. 13 (Masimo's supplemental responses and objections to Philips' first set of interrogatories) at 31; D.I. 519 (Decl. of Mohamed K. Diab) at ¶¶ 10-15). Diab is a named inventor of the '984 patent. D.I. 519 at ¶ 10.

[248] *Id.* at 7.

[249] *Id.* (citing D.I. 601, Ex. 163 (Philips' 6/30/10 '984 patent invalidity contentions including Ukawa as a reference)).

[250] D.I. 601, Ex. 164 (Masimo's 7/30/10 response to Philips' invalidity contentions) at 95-96 (discussing claim limitations claim purportedly not disclosed by Ukawa, but not disputing Ukawa as prior art); D.I. 431, Ex. 23 (Baura's 6/15/12 Valid. Rpt.) at ¶ 139 (same).

[251] D.I 601, Ex. 164 at 57 (The Kaestle reference "considered alone or in combination with other references, does not invalidate any of the asserted claims of the '194 patent. For example, Kaestle was filed in the United States after the invention by Masimo."); D.I. 431, Ex. 23 at ¶¶ 227-28 (Baura opining "Kaestle is not prior art under § 102(e) because, in my opinion, Masimo reduced to practice each of the inventions covered by the asserted claims of the '194 Patent prior to the April 12, 1997 filing date of the foreign application to which Kaestle claims priority").

[252] D.I. 592 at 7.

[253] *Id.*

"Masimo's request that the Court take the inventor's word for it that Ukawa is not prior art is insufficient to defeat summary judgment."[254]

The court is not inclined to conclude Diab's declaration creates an issue of fact as to whether Ukawa is prior art to the '984 patent. Philips represents that at no point prior to its opposition to this summary judgment motion did Masimo challenge Ukawa's status as prior art. Masimo failed to raise this issue despite being aware of Philips' reliance on that reference at least as of June 30, 2010, the date of Philips' invalidity contentions.[255] In its July 30, 2010 responses to Philips' invalidity contentions, Masimo argued a different reference was not § 102(e) prior art,[256] but, with respect to Ukawa, merely responded by asserting the absence of certain claim limitations.[257] Similarly, Dr. Baura's June 15, 2012 validity report states her opinion that a different reference was not § 102(e) prior art[258] and, again with respect to Ukawa, provides only that Ukawa is not invalidating prior art for failure to disclose each of the limitations of the asserted '984 patent claims. Dr. Baura opines a different reference was not § 102(e) prior art, but offers no such opinion as to Ukawa. Dr. Baura failed to so opine despite Masimo's representation in its November 30, 2011 supplemental responses to Philips' first set of interrogatories that the inventions set forth in the asserted claims of the '984 patent were purportedly reduced to practice by October 1992, the same time-frame alleged in

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[254] *Id.* (citing *Singh v. Brake*, 48 Fed. Appx. 766, 772 (Fed. Cir. 2002) ("evidence of the inventive facts must not rest alone on the testimony of the inventor himself); *Yatzus v. Appoquinimink School Dist.*, 458 F. Supp. 2d 235, 347 (D. Del. 2006) ("The court declines to find that genuine issues of material fact have been generated by plaintiff's affidavit containing new, untested, contradictory facts . . . ."); *Laboratory Skin Care, Inc. v. Limited Brands, Inc.*, C.A. No. 16-601-JJF, 2009 WL 2524577, at *2-*3 (D. Del. Aug. 17, 2009) (holding that new theory could not be raised for first time on summary judgment)).

[255] D.I. 601, Ex. 163.

[256] *Id.*, Ex. 164 at 57.

[257] *Id.* at 95-96.

[258] D.I. 431, Ex. 23 at ¶¶ 227-28.

Diab's declaration.[259] As those supplemental responses were dated more than six months prior to Dr. Baura's validity report, the absence of an opinion that Ukawa is not § 102(e) prior art cannot be explained as the result of new information coming to light after Dr. Baura completed her report. Whether the result of oversight or gamesmanship, first raising this issue in response to Philips' motion for summary judgment deprived Philips the opportunity to meaningfully respond to or rebut inventor Diab's declaration. Consequently, the court determines Masimo has not created an issue of fact as to whether Ukawa is prior art to the '984 patent. The court now considers the parties' respective positions on the validity of the asserted '984 patent claims.

Philips argues Ukawa anticipates claims 1-5, 15, 19, 20, 22, 52, and 53 and renders obvious claims 16 and 54 of the '984 patent.[260] Philips states it is undisputed that Ukawa discloses a pulse oximeter capable of calculating oxygen saturation using first and second calculation techniques.[261] Philips notes Dr. Baura explained the techniques in her validity report:

> Ukawa discloses a "***first computing means*** that computes the ratio between the pulsating components of light absorbance . . . on the basis of the dc components and pulsating components of the respective wavelengths that are obtained from [detectors]." Ukawa then discloses a "correction circuit" that detects the "degree of fluctuation in the absorbance ratio as produced from said first computing means" and computes a "corrected absorbance ratio" if there is a fluctuation in the absorbance ratio. A ***second computing means*** then computes the oxygen saturation of arterial blood "on the basis of the absorbance ratio produced from the

[259] D.I. 516, Ex. 13 at 31. Diab was listed as one with knowledge regarding the conception, diligence, and reduction to practice of the '984 patent inventions in that document.

[260] D.I. 395 at 10. Ukawa was not cited during prosecution. *Id.*

[261] *Id.* (citing D.I. 429, Ex. 14A (Stone Inv. Rpt.) at ¶¶ 215-216); D.I. 431, Ex. 23 (Baura Valid. Rpt.) at ¶ 139; D.I. 431, Ex. 25 (Baura Depo.) at 290:5-18.

correction circuit."[262]

Based on that explanation, Philips maintains "Ukawa discloses the calculation of oxygen saturation using the 'first computing means' if there is no fluctuation in the detected signals and the 'second computing means' if there is fluctuation in the detected signals."[263]

Philips states Dr. Baura admits claim 1 is anticipated by Ukawa should the court disagree with her interpretation of the claims.[264] It also maintains Dr. Baura admits that if claim 1 is invalid over Ukawa, claims 2-4 and 15 are likewise invalid.[265] Based on that purported admission, Philips argues claims 2-4 and 15 are anticipated for the same reasons as claim 1.[266]

Masimo contends Ukawa does not anticipate the '984 patent. Masimo states Ukawa discloses only a single calculation technique for determining oxygen saturation. Masimo acknowledges Ukawa discloses multiple calculation steps, but states those steps are performed in sequence, the output of each calculation step provides the input for the next calculation step.[267]

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[262] *Id.* at 11 (quoting D.I. 431, Ex. 23 (Baura Valid. Rpt.) at ¶ 139 (citations omitted and emphasis omitted; emphasis added by Philips).

[263] D.I. 395 at 11.

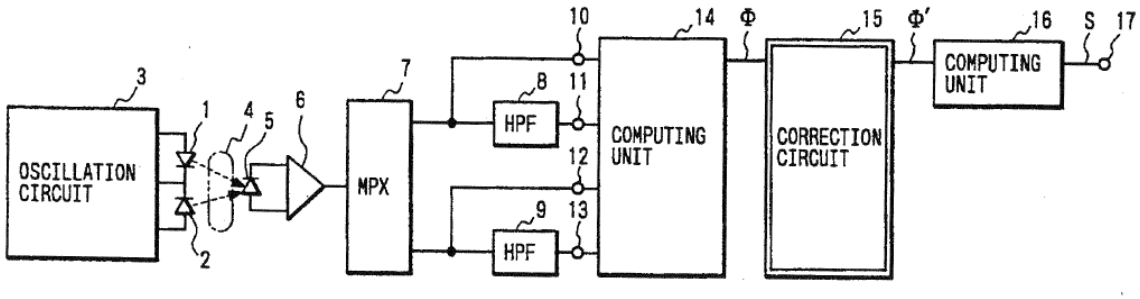
[264] *Id.* at 11 (citing D.I. 431, Ex. 25 at 278:1-3 ("Q. Is it true that your opinions on invalidity for Claim 1 are based entirely on that interpretation [that claim 1 of the '984 patent requires the same input to go into both calculators and that both calculators actually perform a calculation]? A. Yes.")); *see also* D.I. 431, Ex. 25 at 270:6-10 ("Q. Is it fair to say that your opinion related to Claim 1 and whether it's anticipated depends entirely on your interpretation of the claim that it requires parallel alternative calculations? A. Well, that's what's stated in the claim.").

[265] *Id.* at 11-12 (citing D.I. 431, Ex. 25 at 261:8-13 ("Q. Do you agree that Claims 2 through 4 of the '984 rise and fall with Claim 1 as far as their validity? A. 2, 3 and 4? Q. Yes. A. Yes."); D.I. 431, Ex. 23 at ¶¶ 146, 153, 160, 178 (stating only that "[a]s noted above, Claim 1 is not anticipated by Ukawa. Because Claim 1 is not anticipated by Ukawa, [Claims 2, 3, 4, and 15 are] not anticipated by Ukawa")).

[266] D.I. 12.

[267] D.I. 515 at 7 (citing D.I. 431, Ex. 23 at ¶ 139).

In explaining why Ukawa does not anticipate claim1 or dependent claims 2-4 and 15, Masimo refers to Figure 1 of Ukawa:



As illustrated in Figure 1, computing unit 14 providing an initial red-to-infrared ratio (**Φ**).[268] Correction circuit 15 applies a correction to the ratio, to provide an adjusted red-to-infrared ratio (**Φ'**).[269] The computing unit 16 only uses the corrected ratio (**Φ'**) to determine saturation (**S**).[270] Masimo states the saturation calculation of computing unit 16 is the final step in the sequential calculations.[271]

Masimo notes Philips' claim chart identifies the computing unit 16 as the "second computing means."[272] Masimo states the computing unit merely converts the calculated adjusted ratio (**Φ'**) into oxygen saturation. According to Dr. Baura, the computing unit 16 is not capable of using any calculation technique to determine a ratio because it merely accepts the corrected ratio provided to it and converts it to saturation.

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[268] *Id.* (citing Ukawa, Fig. 1, 3:47-56, 5:29-46).
[269] *Id.* (citing Ukawa, Fig. 1, 4:59-65, 5:4-9, 6:7-15).
[270] *Id.* (citing Ukawa, Fig. 1, 4:67-5:2, 6:17-27).
[271] *Id.* (citing D.I. 431, Ex. 23 at ¶ 139).
[272] *Id.* (citing D.I. 395, App. A at 2).

Therefore, computing unit 16 cannot satisfy the second calculator of claim 1.[273]

Masimo also argues Philips does not identify any additional processing module in Ukawa corresponding to the final limitation of claim 1. Dr. Baura opines that since Philips identifies the module that determines saturation (computing unit 16, the last step in the calculations illustrated by Figure 1) as the second calculator, there is nothing more in Ukawa to determine a resulting oxygen saturation from at least one of the first and second calculators.[274]

Philips responds that if the court rejects Masimo's interpretations of the claims, as it has, Dr. Baura's purported admissions at deposition demonstrate it is entitled to summary judgment.[275] Philips also contends Dr. Baura's declaration submitted with Masimo's opposition brief contradicts her prior testimony and, therefore, should not be permitted to create an issue of fact to defeat summary judgment.[276]

The court disagrees with Philips. Initially, the court notes Philips only cites to specific examples of purported contradictions between Dr. Baura's deposition testimony and her declaration with respect to the Hall reference, not Ukawa. With respect to

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[273] *See* D.I. 518 (Baura Decl.) at ¶ 4 ("The 'second computing means' in Ukawa is the computing unit 16 that uses a corrected ratio **Φ'** to determine saturation. Ukawa 2:46-48; 6:16-24. However, the computing unit 16 does not determine any ratio. It only accepts the corrected ratio provided to it by the correction circuit 15 and converts the corrected ratio to saturation. *Id.* Accordingly, computing unit 16 is not a "second calculator capable of utilizing a second calculation technique different from the first calculation technique, to determine at least a second ratio.").

[274] *See Id.* at ¶ 5 ("Philips has not identified what in Ukawa corresponds to 'a processing module configured to utilize at least one of the first and second calculators to determine a resulting value indicative of the at least one physiological characteristic' as recited in Claim 1. It appears that Philips is relying on the same 'second computing means,' of computing unit 16, for both the 'second calculator' and 'processing module' limitations. Because Claim 1 requires that the 'processing module' be separate and distinct from the first and second calculators that it utilizes, the calculators cannot be the same as the processing module. Accordingly, Philips has not shown that Ukawa discloses a 'processing module' that would be separate and distinct from what Philips identified as the 'second calculator.'").

[275] D.I. 592 at 1, 4-6. Masimo disputes Philips' characterization of Dr. Baura's testimony. D.I. 515 at 8-9.

[276] D.I. 592 at 5.

Ukawa, Dr. Baura's declaration does not seem to challenge Philips' assertion that two calculation techniques are disclosed therein, e.g., "[t]he 'second computing means' in Ukawa is the computing unit 16 that uses a corrected ratio Φ' to determine saturation."[277] Instead, she opines that that "second computing means" does not meet the requirement of claim 1 that the invention has a "second calculator capable of utilizing a second calculation technique different from the first calculation technique, to determine at least a second ratio."[278] She supports that opinion by stating "the computing unit 16 does not determine any ratio. It only accepts the corrected ratio provided to it by the correction circuit 15 and converts the corrected ratio to saturation."[279] Philips does not directly address this opinion. Nor does Philips directly address Dr. Baura's opinion that Philips has failed to show "Ukawa discloses a 'processing module' that would be separate and distinct form what Philips identified as the 'second calculator'" as she opines is required by claim 1.[280] Consequently, the court finds a question of fact with regard to those two elements which precludes the grant of summary judgment as to claim 1 of the '984 patent. Also, because the court determines summary judgment should be denied as to claim 1, summary judgment must also be denied as to either anticipation or obviousness with regard to the asserted claims that are dependent or multiple-dependent therefrom. Therefore, summary judgment is also denied as to claims 2-5, 15, 16, 19, 20, and 22.

With regard to the remaining independent claims, claims 52 and 53, Philips notes

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[277] D.I. 518 at ¶ 4 (citing Ukawa, 2:46-48, 6:16-24).
[278] *Id.* at ¶ 4.
[279] *Id.* (citing Ukawa, 2:46-48, 6:16-24).
[280] *Id.* at ¶ 5.

each contain very similar limitations to claim 1.[281] It contends "the validity analysis for claim 52 is identical as for claims 1 and 20, and . . . the validity analysis of claim 53 is identical as for claims 1 and 15. Thus, for the same reasons discussed . . . with respect to claims 1, 15 and 20, and as illustrated in Appendix A [to Philips' opening brief], claims 52 and 53 are anticipated by Ukawa."[282] Masimo disagrees that the validity analysis for claims 52 and 53 is identical to other claims.[283]

Claim 52 recites:

> 52. A method of determining a physiological characteristic of pulsing blood, the method comprising:
>
> > receiving first and second intensity signals from a light sensitive detector which detects light of at least first and second wavelengths transmitted through body tissue carrying pulsing blood; and
> >
> > utilizing at least one of at least first and second calculation techniques to determine a value indicative of the physiological parameter based upon at least one of the first and second intensity signals, wherein the utilizing comprises qualifying the value for inclusion, depending upon different conditions of the first and second intensity signals, and wherein the first calculation technique is different from the second calculation technique.[284]

Masimo points to the language "utilizing at least one of at least first and second calculation techniques to determine a value indicative of the physiological parameter . . . wherein the utilizing comprises qualifying the value for inclusion . . . ." Masimo states "Ukawa discloses that the computing unit 16 *always* calculates oxygen saturation using the corrected ratio **Φ'**."[285] Dr. Baura opines, therefore, Ukawa does not disclose

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[281] D.I. 395 at 13.
[282] *Id.*
[283] D.I. 515 at 11.
[284] '984 patent, claim 52.
[285] D.I. 515 at 11 (emphasis in original) (citing Ukawa, 6:17-27).

any qualifying a value for inclusion.[286] As Philips did not respond to this argument, the court determines a question of fact exists regarding that element and denies summary judgment as to claim 52.

The court agrees with Philips that, as to claim 53, referring to the validity of claim 1 is appropriate. As with claim 1, claim 53 recites "A physiological monitoring system comprising: A light-sensitive detector . . . and a signal processing device . . . including: a first calculator . . . a second calculator . . . and a processing module."[287] Dr. Baura's opinion that Philips has failed to show "Ukawa discloses a 'processing module' that would be separate and distinct form what Philips identified as the 'second calculator'" as required by claim 1 is equally applicable to claim 53.[288] As with claim 1, therefore, the court finds a question of fact exists regarding that element and denies summary judgment as to claim 53. Also, because there is a question of fact as to whether Ukawa discloses all of the elements of claim 53, summary judgment must be denied as to Philips' obviousness argument with regard to claim 54 which depends from claim 53.

Consequently, summary judgment of invalidity of the asserted claims of the '984 patent over Ukawa is denied.

2. Hall

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[286] *Id.* at 11 (citing D.I. 431, Ex. 23 at ¶ 211 ("Ukawa . . . does not disclose qualifying a value determined from this calculation for inclusion depending on different conditions of the first and second intensity signals" and, therefore, "Ukawa does not anticipate Claim 52.").

[287] '984 patent, claim 53.

[288] D.I. 518 at ¶ 5. Masimo also points to the recitation in claim 53 of "said utilization based at least in part on a property of the one or more intensity signals" and argues "Ukawa, however, discloses that the computing unit 14, the correction circuit 15, and the computing unit 16 are always utilized." D.I. 515 at 11 (citing Ukawa, 5:4-9). Dr. Baura opines Ukawa does not disclose utilization based on a property of an intensity signal." D.I. 515 at 11 (citing D.I. 431, Ex. 23 at ¶ 218 ("Ukawa . . . does not disclose utilization of on of the parallel calculations based at least in part on a property of the signal" and, therefore, "Ukawa does not anticipate claim 53."). Philips did not respond to this argument by Masimo.

Philips argues Hall anticipates most of the asserted claims of the '984 patent. Hall issued on September 11, 1990, and is thus prior art to the '984 patent under 35 U.S.C. § 102(b) which recites: "[a] person shall be entitled to a patent unless– . . . (b) the invention was patented . . . in this or a foreign country . . . more than one year prior to the date of the application for patent in the United States . . . ."[289] Philips notes Hall was cited during prosecution, but was never used in a rejection of the claims.[290]

Philips states it is undisputed Hall discloses a pulse oximeter capable of calculating oxygen saturation using first and second calculation techniques.[291] Philips notes Dr. Baura explained the techniques in her validity report:

> Hall discloses that **when [motion] artifact is not present**, the band pass filter is tuned to the pulse rate as determined by the normal oximeter algorithms. **When artifact is present**, the band pass filter is configured in a feedback loop where the output directly tunes the band pass filter forming a frequency-locked loop or tracking filter. . . . Hall employs a single calculation technique at any particular time, with **the choice of technique** depending on the presence or absence of artifact.[292]

Based on the explanation, Philips contends "Hall uses one technique when motion artifact is not present in the detected signals and another technique when motion is

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[289] 35 U.S.C. § 102(b). Masimo does not contest Hall is prior art to the '984 patent.

[290] Masimo argues since Hall was not used in a rejection of the claim is an indication the examiner thought Hall was not material. Masimo notes the examiner is presumed to have done his job and considered every prior art reference cited during the examination. D.I. 515 at 12. However, an order granting reexamination of the certain claims of the '984 patent, with an October 10, 2012 mailing date, stated "[a]lthough . . . Hall . . . [has] been cited by the Patent Owner during the prosecution of the original patent '984, *there is no indication in the file history that arguments submitted by the requester have been previously considered by the Examiner,*" and "[t]he teachings of Hall discussed herein are not cumulative to any written discussion on the record of the teachings of the prior art, *were not previously considered nor addressed during a prior examination*, and the same question was not the subject of a final holding of invalidity in the Federal Courts." D.I. 601, Ex. 156 ('984 Patent Reexam Grant) at 4, 13 (emphasis added).

[291] D.I. 395 at 15 (citing D.I. 429, Ex. 14A (Stone Inv. Rpt.) at ¶¶ 169-70; D.I. 431, D.I. Ex. 23 (Baura Validity Rpt.) at ¶ 140; D.I. 431, Ex. 25 (Baura Depo.) at 284:15-285:9).

[292] *Id.* (quoting D.I. 431, Ex. 23 (Baura Valid. Rpt.) at ¶ 140 (citations omitted and emphasis added by Philips).

present."[293] Philips contends Hall discloses all of the limitations of claims 1-5, 15, 19, 20, 22, 52, and 53 of the '984 patent.[294]

As with Ukawa, Philips contends Dr. Baura admits claim 1 is anticipated by Hall should the court disagree with her interpretation of the claims.[295] Philips reiterates its contention that Dr. Baura also admits claims 2-4 and 15 are not separately patentable over Hall.[296]

Masimo argues Hall discloses only one calculator that tunes its function to determine one ratio. It states Philips identifies a single red and infrared bandpass pair as being both the first calculator and the second calculator, but fails to explain how the same bandpass filter can be both the first calculator and the second calculator as required by claim 1.[297]

Without reiterating Masimo's additional arguments concerning claim 1, or Philips' responses to each of Masimo's arguments about that claim, the court finds a question of fact as to whether Hall discloses every limitation in claim 1.

Claim 1 requires "a signal processing device including: A first calculator capable

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[293] *Id.* at 15.

[294] *Id.*

[295] *Id.* at 16 (citing D.I. 431, Ex. 25 at 278:1-3 ("Q. Is it true that your opinions on invalidity for Claim 1 are based entirely on that interpretation [that claim 1 of the '984 patent requires the same input to go into both calculators and that both calculators actually perform a calculation]? A. Yes.")); *see also* D.I. 431, Ex. 25 at 270:6-10 ("Q. Is it fair to say that your opinion related to Claim 1 and whether it's anticipated depends entirely on your interpretation of the claim that it requires parallel alternative calculations? A. Well, that's what's stated in the claim.").

[296] *Id.* (citing D.I. 431, Ex. 25 at 261:8-13 ("Q. Do you agree that Claims 2 through 4 of the '984 rise and fall with Claim 1 as far as their validity? A. 2, 3 and 4? Q. Yes. A. Yes."); D.I. 431, Ex. 25 at 285:22-286:4 ("Q. You agree that if Claim 1 is anticipated by Hall, that Claim 15 would be anticipated by Hall; right? A. I agree that if Claim 1–I agree–yes, I agree."); D.I. 431, Ex. 23 at ¶¶ 147, 154, 161, 179 (stating only that "[a]s noted above, Claim 1 is not anticipated by Hall. Because Claim 1 is not anticipated by Hall, [Claims 2, 3, 4, and 15 are] not anticipated by Hall")).

[297] D.I. 515 at 13.

of utilizing a first calculation technique . . . [and] a second calculator capable of utilizing a second calculation technique different from the first calculation technique . . . ."[298] Therefore, the claim requires: (1) a first calculator capable of utilizing (2) a first calculation technique and (3) a second calculator capable of utilizing (4) a second calculation technique. Philips argues only that "Hall discloses a pulse oximeter capable of calculating oxygen saturation using *first and second calculation techniques*."[299] There is a question of fact as to whether Hall discloses *first and second calculators* capable of utilizing first and second calculation techniques.

Hall's "Summary of the Invention" recites:

> In a first embodiment, the present invention relates to a pulse oximeter apparatus characterized in that it comprises *a bandpass filter* adapted to *selectively* exclude motion artefact from wanted signal. In order to achieve this, *the filter* must initially be tuned to the pulse rate. Moreover, as the pulse rate changes, *the filter* is so-adapted that its pass-band will follow the frequency change.[300]

Indeed, although Dr. Stone purports to identify a first and second calculator in Hall's specification, he cites language referring to the *same* bandpass filter. Dr. Stone's invalidity report states:

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[298] '984 patent, claim 1.

[299] D.I. 395 at 15 (emphasis added). *See also id.* at 10 (It is undisputed that . . . [Hall] . . . utilize[s] *multiple calculation techniques* to calculate oxygen saturation." (emphasis added)); D.I. 592 at 4 ("[Dr. Baura] admitted that . . . Hall . . . disclose[s] *multiple calculation techniques*." (emphasis added)). In support of these statements, Philips cites Dr. Baura's testimony concerning whether Hall discloses *two calculation techniques*. *See, e.g.*, *id.* (citing D.I. 431, Ex. 25 at 284:10-285:9 ("Q. You say, [at paragraph 140 of your validity report] 'Hall employs a single calculation technique at any particular time with the choice of technique depending on the presence or absence of artifact.' Is that accurate? A. Yes. Q. So you agree that Hall discloses two techniques? A. But they are not parallel. Q. You agree that Hall discloses two techniques? A. I agree that Hall discloses two techniques which are not parallel. Q. Okay. And you agree that Hall chooses between those two techniques depending on the presence or absence of artifact; right? A. Yes. It's configured to be tuned. I don't know about the word chose. Q. I'm just using your words. You said choice. A. The choice of a technique. Okay. Q. So you agree that Hall cho[o]ses between the two techniques; right? A. I agree that Hall chooses between the two techniques which are not parallel.").

[300] D.I. 432, Ex. 36 (Hall) at 2:50-57 (emphasis added).

> Hall discloses a first calculator for calculating pulse oxygen saturation using a first ratio when motion artifact is not present in the detected signals. (*See, e.g.*, 1:30-50; 3:15-21.) Specifically, Hall discloses that "[i]f artefact is not judged present, [a] bandpass filter is tuned to the pulse rate as determined by the normal oximeter algorithms." (*See, e.g.*, 3:15-17).[301]

The court notes Dr. Stone provided the alteration "[a] bandpass filter." The Hall specification recites "the bandpass filter."[302] Dr. Stone's identification of the second calculator recites:

> Hall discloses a second calculator for calculating pulse oxygen saturation using a second ratio when motion artifact is present. (*See, e.g.*, 1:30-50; 3:21-39). Specifically, Hall discloses that "[w]hen artefact is present, the AGC system is frozen, fixing the gain level, and the bandpass filter is configured in a feedback loop . . . ." (*See, e.g.*, 3:21-24). "Thus, when motion artifact is present, the bandpass filters can stay tuned to the pulse rate, tracking its change [and] . . . [t]he errors in oxygen saturation measurements, as well as pulse rate, caused by patient movement are thus advantageously reduced." (*See, e.g.*, 3:32-39).[303]

Thus, it appears as though Dr. Stone opines the first and second calculators both are the same bandpass filter which when artifact is not present is tuned to the pulse rate and when artifact is present is configured in a feedback loop. Because the court finds a question of fact as to whether Hall discloses the first and second calculator recited in claim 1 of the '984 patent, summary judgment must be denied. As with Ukawa, such a determination means summary judgment must also be denied for dependent or multiple-dependent therefrom: claims 2-4, 15, 19, 20, and 22.

Claim 53 also recites a "signal processing device including: a first calculator capable of utilizing a first calculation technique . . . [and] a second calculator capable of

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[301] D.I. 429, Ex.14A, App. C at 11.
[302] D.I. 432, Ex. 36 (Hall) at 3:16.
[303] D.I. 429, Ex. 14A, App. C at 12.

utilizing a second calculation technique different from the first calculation technique . . . ."[304] Dr. Stone cites the same disclosure from Hall to identify the first and second calculators in claim 53 as he did for claim 1.[305] Consequently, for the same reasons summary judgment is denied as to claim 1, it is also denied as to claim 53.

As with Ukawa, Philips argues claim 52 contains similar limitations to those in claims 1, 15 and 20 and the reasons it argued Hall anticipated those claims are equally applicable to claim 52.[306]

Masimo notes Philips provides no invalidity arguments to claim 52 and again points to the language "utilizing at least one of at least first and second calculation techniques to determine a value indicative of the physiological parameter . . . wherein the utilizing comprises qualifying the value for inclusion . . . ."[307] Masimo contends Philips fails to explain how Hall qualifies any value for inclusion and states, to the contrary, Hall discloses the output of the bandpass filter is always used to calculate oxygen saturation.[308] Once again, Philips did not specifically respond to the argument and, as a result, the court finds a question of fact exist as to whether Hall discloses qualifying any value for inclusion." Consequently, summary judgment is denied as to claim 52.

C. Infringement

Philips contends that its FAST algorithm does not infringe regardless of which

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[304] '984 patent, claim 53.
[305] *See* D.I. 14A, App. C at 50.
[306] D.I. 395 at 17.
[307] D.I. 515 at 17.
[308] *Id.* (citing Hall, 2:50-57 ("[A]s pulse rate changes, the filter is so-adapted that its pass-band will follow the frequency change.")).

party's interpretation of the claims is adopted. It argues if Masimo's interpretation of the claims is adopted, Philips' FAST algorithm does not infringe any of the asserted claims because its time- and frequency-domain algorithms use different time windows of data. Philips also contends its FAST algorithm does not infringe claims 15, 16, 19, 20, 53, and 54 because Dr. Baura purportedly admitted that the functions recited are not performed by the processing module, as claimed, but are instead performed by one of the calculators.

In arguing its non-infringement position, Philips contends, even if the court accepted Masimo's interpretation of the claim language, it is still entitled to summary judgment of non-infringement. Philips then presents its argument for non-infringement of all the asserted claims of the '984 patent by attempting to demonstrate its FAST algorithm does not infringe under Masimo's interpretation based on its argument that FAST's time- and frequency algorithms use different time windows of data. In briefing, Philips does not explain why FAST does not infringe if the court accepted Philips' interpretations of the claim language, which it has. Consequently, the court is forced to address the parties' arguments as briefed, and determine whether Philips' argument is correct that FAST does not infringe even under Masimo's narrower interpretation of the claim language.

Philips contends "[i]t is undisputed that FAST includes both time- and frequency-domain algorithms that make calculations on <u>different</u> time windows of data . . . and thus FAST does not infringe the asserted claims of the '984 patent."[309] Philips notes Dr.

[309] D.I. 395 at 17-18 (emphasis in original).

Baura testified the claims require "the same time window of data has to go into the first calculator and the second calculator," and the inputs "have to be identical."[310] Contrary to that requirement, Philips states Dr. Baura acknowledged FAST's time- and frequency-domain algorithms do not utilize the same time windows of data.[311]

Philips contends there is no dispute that the time-domain algorithm for all versions of FAST receives an input time window of approximately two seconds[312] and the frequency-domain algorithm makes calculations based on an input time window of approximately eight seconds.[313] Philips contends it is impossible to argue a two second time window is identical to an eight second time window. Based on those differing time windows, therefore, Philips maintains FAST does not infringe the claims of the '984

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[310] *Id.* at 18 (citing D.I. 431, Ex. 25 at 272:4-7, 274:5-13). Philips emphasizes Dr. Baura repeatedly stressed during deposition that the time window input to each algorithm must be identical under her interpretation of the claims. *Id.* at 19 (citing D.I. 431, Ex. 25 at 271:13-17 ("I'm saying using the same window to make a calculation. The same time interval."), 272:4-7 ("Q. Your opinion about the scope of Claim 1 is that the same time window of data has to go into the first calculator and the second calculator? A. Yes."), 272:20-273:4 ("It's because they have the same time window that is input to each calculator."), 274:1-12 (The input to each calculator has "to be identical because they both come from the original signal that's read from the detector.") and 276:18-277:1 ("They have to be identical inputs.")).

[311] *Id.* at 18 (citing D.I. 431, Ex. 25 at 276:13-17 ("Q. So for version 3.70, the time window used as an input to the frequency domain is different than the time window used as an input to the time domain? A. Yes."). The court notes that, in the previous question, Dr. Baura did not agree with that statement with regard to other versions of FAST. *See* D.I. 431, Ex. 25 at 276:7-12 ("Q. Do you understand that the calculation of SpO2 that is performed by the time domain algorithm is performed on the basis of a different data window than the frequency domain algorithm in the FAST algorithm? A. That is not true for previous versions, but I do understand that for 3.70.").

[312] *Id.* (citing D.I. 430, Ex. 15 at 332:11-20 (Dr. Stone testifying the time-domain processing spans approximately two seconds); D.I. 431, Ex. 25 at 337:9-338:5 (Dr. Baura testifying the time domain algorithm used was beat-to-beat)); *see also id.* Ex. 22 at ¶ 38 (Chart in Dr. Baura's infringement report showing seven versions of FAST time-domain algorithm as "2-second window" and three other versions of FAST algorithm as "beat-to-beat"); D.I. 430, Ex. 15 at 339:9-12 (Dr. Stone explained "beat-to-beat" processing by stating "[t]he time domain is intended to process, in the later versions processes whenever it finds a beat. So it could be up to 2 seconds, it could be less than that. so it's cycling looking for a beat.").

[313] *Id.* (citing D.I. 430 at 332:21-333:3 (Dr. Stone testifying the frequency-domain algorithm calculates based on approximately eight seconds of data) and 338:8-12 (same) ; D.I. 431, Ex. 25 at 338:18-21 (Dr. Baura likewise explaining the frequency-domain algorithm calculates based on approximately eight seconds of data)).

patent under Masimo's interpretation of the claims.[314]

Masimo contends Philips' argument that the frequency-domain and time-domain techniques in FAST do not have as inputs the identical "time window" is misplaced because the claims do not recite a "time window" of data; the claims require each calculator to receive data "from *said detection of said light* at said at least first and second wavelengths."[315] It states that language means the same data is input to each calculator.[316] Masimo notes in response to Philips' question about a possible requirement to use the same time window, Dr. Baura explained that "[i]t's the input that matters. If one calculator is going faster than the other calculator, that's–that would be fine. It's the input data."[317]

Masimo contends FAST satisfies the claim language. According to Dr. Baura:

> Philips' FAST algorithm performs two calculation techniques on the same data. The red an infrared signals are inputs to both the frequency domain and the time domain calculators. Both of these calculators process all of the red and all of the infrared data. Both the time-domain and frequency-domain algorithms begin operating at the same time when one begins to monitor a patient. Both algorithms continue to calculate outputs while the pulse oximeter is operational.[318]

Masimo argues Dr. Baura's opinion thus rebuts Philips' argument that since the time- and frequency-domain algorithms evaluate different time-windows, the two calculators do not process the same data because the input data is the same, regardless of the size of the data packet.[319] Masimo contends because each calculator processes all the

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[314] *Id.* at 18-19.
[315] D.I. 515 at 18 (emphasis in original).
[316] *Id.*
[317] *Id.* (citing D.I. 516, Ex. 11 at 272:8-13, 277:16-19 ("Q. You are taking the interpretation of Claim 1 of the '984 that it requires the same input to go into both calculators? A. Yes.")).
[318] D.I. 518 at ¶ 29.
[319] D.I. 515 at 19 (citing D.I. 518 at ¶ 29).

data, all the time, in parallel, even if Philips were correct that identical time windows were required, FAST would still infringe.[320]

Dr. Baura further opines:

> Even if the asserted claims required that the time-window size of the input data be the same for both the time domain calculator and the frequency domain calculator, FAST would still infringe. The eight-second frequency-domain time-window is adjusted every two seconds, and uses six seconds of data from the prior time window. The time-domain algorithm uses two second intervals. Each calculator in FAST processes all the data, all the time, in parallel, and any differences between processing the time-domain data in two-second intervals and processing the frequency-domain in eight second intervals with two-second adjustments would be insubstantial.[321]

The court agrees with Philips that, as recited above, Dr. Baura repeatedly testified the claims require each algorithm receive an identical time window.[322] The court also agrees with Philips that Masimo's argument that four calculations by the time-domain algorithm (on two seconds of data) is equivalent to one calculation by the frequency-domain algorithm (on eight seconds of data) is unreconcilable with Dr. Baura's opinion that the inputs going into each calculator "have to be identical."[323] Even Dr. Baura's declaration acknowledges that FAST makes the time-domain calculation every two seconds and the frequency-domain calculation every eight seconds.[324] As Philips succinctly puts it, "[t]wo seconds is not eight seconds."[325] Consequently, the court grants Philips' motion for summary judgment of non-infringement of the asserted

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[320] *Id.*

[321] D.I. 518 at ¶ 30.

[322] Masimo should not be able to create a question of fact to defeat summary judgment via Dr. Baura's new declaration if it contradicts her prior testimony. *See, e.g.*, *Sinskey v. Pharmacia Ophthalmics, Inc.*, 982 F.2d 494, 498 (Fed. Cir. 1992) ("A party cannot create an issue of fact by supplying an affidavit contradicting [its] prior deposition testimony, without explaining the contradiction or attempting to resolve the disparity."), *abrogated in part on other grounds*, *Pfaff v. Wells Elecs.*, 525 U.S. 55, 67-68 (1998).

[323] D.I. 592 at 9-10 (citing D.I. 431, Ex. 25 at 272:4-7, 274:5-13).

[324] D.I. 518 at ¶ 30.

[325] D.I. 592 at 10.

claims of the '984 patent.[326]

3. Philips' Motion for Summary Judgment of Invalidity and Noninfringement of U.S. Patent No. 5,632,272;[327]

'The 272 Patent (Masimo Patent)

For the reasons discussed herein, Philips' motion for summary judgment of noninfringement and invalidity of claims 9, 12-16, and 18 of the "'272 patent is denied.[328]

Claim 9

Claim 9 of the '272 patent recites in full:

> In a signal processor for processing at least first and second measured signals, each containing a primary signal portion and a secondary signal portion, said first and second signals substantially adhering to a predefined signal model, a method comprising the steps of:
>
> > sampling said first and second signals over a period to obtain a first series of data points representing said first signal over said period and a second series of data points representing said second signal over said period;
> >
> > transforming said first series of data points into a first transformed series of points having at least a frequency component and a magnitude component and transforming said second series of data points into a second transformed series of points having at least a frequency component and a magnitude component;
> >
> > comparing said first and second transformed series of points to obtain a third series of comparison values having a magnitude component and at least a frequency component;
> >
> > selecting at least one of said comparison values that has a magnitude within a selected threshold; and

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[326] In light of this determination, the court need not consider the parties' arguments concerning Philips' contentions with regard the processing module limitation in certain of the asserted claims.

[327] D.I. 402.

[328] The briefs are found at D.I. 403 (Philips' opening brief), D.I. 512 (Masimo's answering brief), and D.I. 598 (Philips' reply brief).

from said selected at least one comparison value, determining a resulting value consistent with the predefined signal model.[329]

Claim 14

Claim 14 of the '272 patent recites in full:

In a signal processor for processing at least first and second measured signals, each containing a primary signal portion and a secondary signal portion, said first and second signals substantially adhering to a signal model for blood constituent saturation, a method comprising the steps of:

sampling said first and second signals over a period to obtain a first series of data points representing said first signal over said period and a second series of data points representing said second signal over said period;

transforming said first and second series of data points from time domain to frequency domain to obtain a first transformed series of points and a second transformed series of points, said first and second transformed series of points having a magnitude component and at least a frequency component;

determining a series of ratios of magnitudes with respect to frequency of ones of said first transformed series of points to ones of said second transformed series of points;

selecting at least one of the ratios from said series of ratios that has a magnitude within a selected threshold; and

from said selected at least one of the ratios, determining a resulting value consistent with the signal model.[330]

A. Infringement

Philips contends it does not infringe the '272 patent because, while independent claims 9 and 14[331] of the '272 patent require performing "point-by-point comparisons"

[329] D.I. 428, Ex. 1, '272 patent.
[330] *Id*.
[331] These are the only independent claims asserted to be infringed.

of "a first series of data points" and "a second series of data points"[332] to calculate oxygen saturation, FAST, Philips' accused algorithm, calculates oxygen saturation using the slope of a "regression line" of identified peak(s),[333] and perfusion values are generated using red and infrared values for each peak.[334] Philips argues, in its FAST algorithm, "[e]ach selected peak has different values associated with it that are used to calculate the regression line, including red values ('RED'), an average red value ('REDavg'), infrared values ('IRED'), and an average infrared value ('IREDavg')."[335] Further, Philips maintains Masimo's infringement theory, where FAST compares average red and average infrared values, is incorrect.[336]

1. Saturation Values

Philips argues "FAST does not generate a 'series of saturation values corresponding to the series of peak areas' by performing a point-by-point comparison of the average red and average infrared values;"[337] FAST uses the following formula to generate a regression line for each selected peak:

$$\text{Regression Line Slope} = \frac{\sum((\text{RED} - \text{REDavg}) \times (\text{IRED} - \text{IREDavg}))}{\sum((\text{IRED} - \text{IREDavg})^2)}$$ [338]

As evidenced by the diagram above, Philips maintains the regression line slope is

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[332] D.I. 428, Ex. 1, '272 patent at PHIL03211369; D.I. 210 at 6-8; D.I. 319.

[333] D.I. 429, Ex. 14C (Stone Noninfr. Rpt.)at ¶¶ 4, 44, 268; D.I. 431, Ex. 22 (Baura Infr. Rpt.) at ¶ 88.

[334] D.I. 403 at 19.

[335] D.I. 431, Ex. 22 at 95-96.

[336] D.I. 403 at 12-13; D.I. 431, Ex. 22 at 94 (stating the average red values are the first transformed series of points and the average infrared values are the second transformed series of points); *id.*, Ex. 25
(Baura Depo.) at 398:13-16, 399:1-5.

[337] D.I. 431, Ex. 22 at 97-99; *id.*, Ex. 25 at 400:1-5; D.I. 429, Ex. 14C at ¶ 53.

[338] *Id.* at ¶¶ 89-92; *id.*, Ex. 22 at 97-98.

calculated by dividing the covariance over the infrared variance, not by comparing average red and average infrared values.[339] More specifically, it argues while average red and average infrared values are "used" in the calculation of the regression line slope, the slope is not calculated by "comparing" these values on a point-by-point basis.[340] Thus, Philips alleges the series of saturation values calculated from the slope of the regression line do not infringe the asserted claims of the '272 patent literally or under the doctrine of equivalents.[341]

Masimo counters by arguing FAST performs the requirements for claims 9 and 14 of "calculating point-by-point comparisons of the first and second transformed signals,"[342] relying on its expert's conclusion that calculating the regression line slope satisfies the calculating point-by-point comparisons limitation because the slope of the regression line for each peak is calculated.[343] For example, "FAST identifies up to ten peaks in the frequency domain, and determines oxygen saturation for each of the peaks."[344] Further, the saturation is determined by using "the covariance of the red and infrared values and the variance of the infrared values to determine a regression

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[339] D.I. 403 at 13-14.

[340] D.I. 428, Ex. 7 at 7 (showing Masimo argued during prosecution, to avoid a rejection over prior art, that the first and second series of points must be compared); D.I. 429, Ex. 14C at ¶ 53; *id.* at ¶¶ 50-51; *id.* at ¶ 356 (explaining the difference between a point-by-point comparison and a regression line); D.I. 431, Ex. 25 (Baura Depo.) at 438:6-9 (Dr. Baura admitting a comparison requires one value on one side of an operator and another value on another side of the operator).

[341] D.I. 431, Ex. 25 at 397:16-398:6.

[342] D.I. 210 at 31; D.I. 514 (Baura Decl.) at ¶¶ 18-19 (stating, for FAST, regression lines for each peak are point by point comparisons of the first and second transformed signals); D.I. 431, Ex. 22 at 96-99 (same).

[343] D.I. 431, Ex. 22 at ¶¶ 88-103; *id.* at 97-98, 105-06; D.I. 513, Ex. 5 (Baura Depo.) at 399:11-400:5; *id.* at 401:9-21.

[344] D.I. 512 at 16; s*ee also* D.I. 513, Ex. 1 at 45:21-46:16, 68:13-17; D.I. 431, Ex. 22 at 92-96.

line slope that provides the red-to-infrared ratio for each of the peaks."[345] Under Masimo's analysis, because the slope is calculated for each peak categorized by frequency, the ratios for each peak are "frequency consistent or point-by-point" comparisons,[346] purportedly consistent with the court's construction.[347] Masimo relies on Dr. Baura's explanation "that if the 'slope,' (which is the regression line slope) does not literally fall within the claim limitation, the claim limitation would be met under the doctrine of equivalents.[348]

Masimo maintains red and infrared signals, the first and second transformed series of points, are used to determine a series of saturation values, the third series of comparison values with a magnitude and frequency component.[349] More specifically, FAST determines a saturation value for up to ten peak areas by comparing red and infrared values, and generates a linear regression in the peak area.[350] Between a corresponding saturation value, and a slope or ratio, there is a "one-to-one relationship."[351] Philips counters there is no comparison when the regression slope is calculated. Masimo contends Philips treated slopes, which involve a comparison, or calculation, with red and infrared values, as ratios,[352] and at each point, this calculation takes into account red and infrared values. Therefore, because Masimo shows that

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[345] D.I. 512 at 16; *see also* D.I. 513, Ex. 1 at 103:10-105:15; *id.*, Ex. 6 at PHIL03221005; D.I. 431, Ex. 22 at 96-99; D.I. 514 at 7, ¶¶ 19-20.

[346] D.I. 514 ¶ 20; D.I. 513, Ex. 1 at 103:10-105:15; D.I. 1, Ex. 1, '272 patent at 51:10-12 (discussing Bank of Filters embodiment); D.I. 431, Ex. 22 at 95 (Dr. Baura's analysis of Bank of Filters embodiment).

[347] D.I. 210 at 7.

[348] D.I. 431, Ex. 22 at ¶ 102 (wherein Dr. Baura addresses why calculating slope is substantially the same as calculating ratio under the claim language).

[349] D.I. 431, Ex. 22 at 97-99.

[350] *Id.* at ¶¶ 88-103.

[351] *Id.* at ¶ 95.

[352] *Id.* at ¶¶ 88-103.

red and infrared signals are compared[353] at each peak, saturation values are generated, and a linear regression is determined, there is a genuine issue of material fact whether FAST performs point-by-point comparisons of a first and second series of data points, and Philips motion for summary judgment on infringement is denied on this issue.[354]

2. Perfusion Values

Philips argues although "Masimo alleges that FAST's calculation of perfusion values constitutes the point-by-point comparison recited by the asserted claims, Dr. Baura admits that the perfusion values are not generated using the average red and average infrared values."[355] Philips references Dr. Baura's conclusion:

> Philips' FAST algorithm also uses corresponding red and infrared values located at the *maximum* of each peak area to calculate an estimate of perfusion. The estimate of perfusion comes from a combination of 0/119 red with 0/641 infrared. Accordingly, the series of perfusion values associated with the series of peak areas is another example of a series of comparison values having a magnitude component and at least a frequency component.[356]

As such, Philips contends red and infrared values for each peak, as opposed to average red and average infrared values, are used by FAST to generate perfusion values.[357] Philips argues there is no evidence that red and infrared values correspond to the first and second series of data points claimed in the '272 patent.[358] Therefore, Philips asserts FAST's calculation of perfusion values does not infringe the asserted

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[353] The court construed "comparing" to mean "calculating point-by-point comparisons of the first and second transformed signals." D.I. 210 at 31.

[354] D.I. 431, Ex. 22 at ¶ 103 (Baura's analysis why calculating saturation is substantially the same as calculating ratio under the claim language).

[355] D.I. 403 at 15.

[356] D.I. 431, Ex. 22 at 99 (emphasis added); *id.*, Ex. 25 (Baura Depo.) at 400:15-19.

[357] *Id.*; *see also* D.I. 429, Ex. 14C (Stone Noninf. Rpt.) at ¶ 357.

[358] D.I. 403 at 15.

claims of the '272 patent because the claims require the third set of values or series of ratios be generated by comparing the first and second series of data points.[359]

Masimo counters, relying on Dr. Baura's comment, "the FAST algorithm infringes because it uses the maximum red and infrared points at each peak to obtain comparison values to calculate perfusion."[360] Dr. Baura opines "the red values correspond to the first series of data points and the infrared values correspond to the second series of data points;"[361] specifically, the red signals are a first "transformed series of points having at least a frequency component and a magnitude component" and the infrared signals are a second "transformed series of points having at least a frequency component and a magnitude component."[362] She further concludes the maximum red and infrared values at each peak are used to obtain comparison values to calculate perfusion.[363] These values are also used to perform a linear regression.[364]

In other portions of her expert report, Dr. Baura concludes the "FAST algorithm uses *the average red and infrared values of a peak area* to perform a linear regression of all red and infrared values in the peak area."[365] Specifically, she notes "[t]he *red average values* calculated for each peak area is a first 'transformed series of points having at least a frequency component and a magnitude component,'" and "[t]he *infrared average values* calculated for each peak area is a second 'transformed series

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[359] *Id.*
[360] D.I. 512 at 20; s*ee also* D.I. 431, Ex. 22 at 90-100.
[361] D.I. 512 at 20.
[362] D.I. 431, Ex. 22 at 94.
[363] *Id.*, Ex. 22 at 99.
[364] *Id.*, Ex. 22 at 97.
[365] *Id.* (emphasis added).

of points having at least a frequency component and a magnitude component.'"[366] Further, Dr. Baura opines the FAST algorithm infringes because it uses the maximum red and infrared points at each peak to obtain comparison values to calculate perfusion. If these maximum red and infrared points from *each peak*, or signals, are ultimately used to calculate perfusion, and these signals are sampled over a period, there would indeed be the use of *average red and infrared* values in a *peak area*.[367]

Because genuine issues exists on whether red and infrared values, or their averages, are used to generate perfusion values, Philips' motion for summary judgment of infringement on this issue is denied.

B. Invalidity: Written Description[368]

Philips alleges claims 9 and 14[369] of the '272 patent are invalid for failure to satisfy the written description requirement of 35 U.S.C. § 112. Specifically, it argues the Bank of Filters embodiment does not transform a first and second series of data points to create a first transformed series of data points and a second transformed series of data points. Philips further contends the Complex FFT[370] does not select a

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[366] *Id.*, Ex. 22 at 94 (emphasis added).

[367] The term "average" means "the result obtained by adding several quantities together and then dividing this total by the number of quantities; the mean." *Oxford English Dictionary*, http://english.oxforddictionaries.com/definition/average?region=us&rskey=jNuuvp&result=1 (last visited Dec. 4, 2012).

[368] Philips points out the threshold limitations were not part of the originally filed claims. *See* D.I. 428, Ex. 6 (Masimo amendment of claims to include the term "threshold"). Philips also relies on case law that a patentee cannot add claims without support in the original application. *See Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1255 (Fed. Cir. 2004) ("The written description requirement prevents applicants from using the amendment process to update their disclosures (claims or specifications) during their pendency before the patent office."); *TurboCare Div. Of Demag Delaval Turbomach. Corp. v. Gen. Elec. Co.*, 264 F.3d 1111, 1118 (Fed. Cir. 2001) ("When the applicant adds a claim or otherwise amends his specification after the original filing date, . . . the new claims or other added material must find support in the original specification.").

[369] Claims 9 and 14 are the only independent claims asserted to be invalid.

[370] The Complex FFT is a frequency domain algorithm in the '272 patent. D.I. 403 at 3.

value from a series of comparison values or ratios based on a threshold.

Independent claim 9 of the '272 patent recites comparing "*first* and *second* transformed series of points to obtain a *third series of comparison values having a magnitude component and at least a frequency component*," followed by "selecting at least one of said comparison values *that has a magnitude within a selected threshold*."[371] Independent claim 14 of the '272 patent recites "determining a *series of ratios of magnitudes* with respect to frequency of ones of said first transformed series of points to ones of said second transformed series of points," followed by "selecting at least one of the ratios from said series of ratios that has a magnitude *within a selected threshold*."[372] The court construed "comparing" in claim 9, and "determining" in claim 14, to mean "calculating point-by-point comparisons of the first and second transformed signals"[373]

1. Selecting Values/Ratios from a Set of Comparison Values/Ratios by Comparing the Values/Ratios to a Threshold

Philips maintains "the claimed Complex FFT algorithm transforms the detected red and infrared signals using 'complex FFT modules 652, 654,'"[374] and then the transformed signals travel to a "point-by-point ratio module 670" which "takes the red over infrared ratio of the values on a point-by-point basis."[375] Philips alleges the "point-by-point ratio module 670" generates the "third series of comparison values" recited by

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[371] D.I. 428, Ex. 1, '272 patent at PHIL03211369 (emphasis added).
[372] *Id.* (emphasis added).
[373] D.I. 210 at 6-8; D.I. 319.
[374] D.I. 428, Ex. 1, '272 patent at PHIL03211332 (showing Fig. 25B); *id.*, Ex. 1, '272 patent at 56:18-20 ("The complex FFT modules 652,654 perform complex FFTs on respective infrared and red channels on the data snapshots"); D.I. 429, Ex. 14A (Stone Inv. Rpt.) at ¶ 83.
[375] D.I. 428, Ex. 1, '272 patent at PHIL03211332 (showing Fig. 25B); *id.*, Ex. 1, '272 patent at 56:55-58; D.I. 429, Ex. 14A at ¶ 83.

claim 9, and the "series of ratios of magnitudes" recited by claim 14.[376] Philips argues the '272 patent does not disclose or suggest the selecting of a value from that series of points using a threshold.[377]

Figure 25B[378] illustrates the aforementioned:

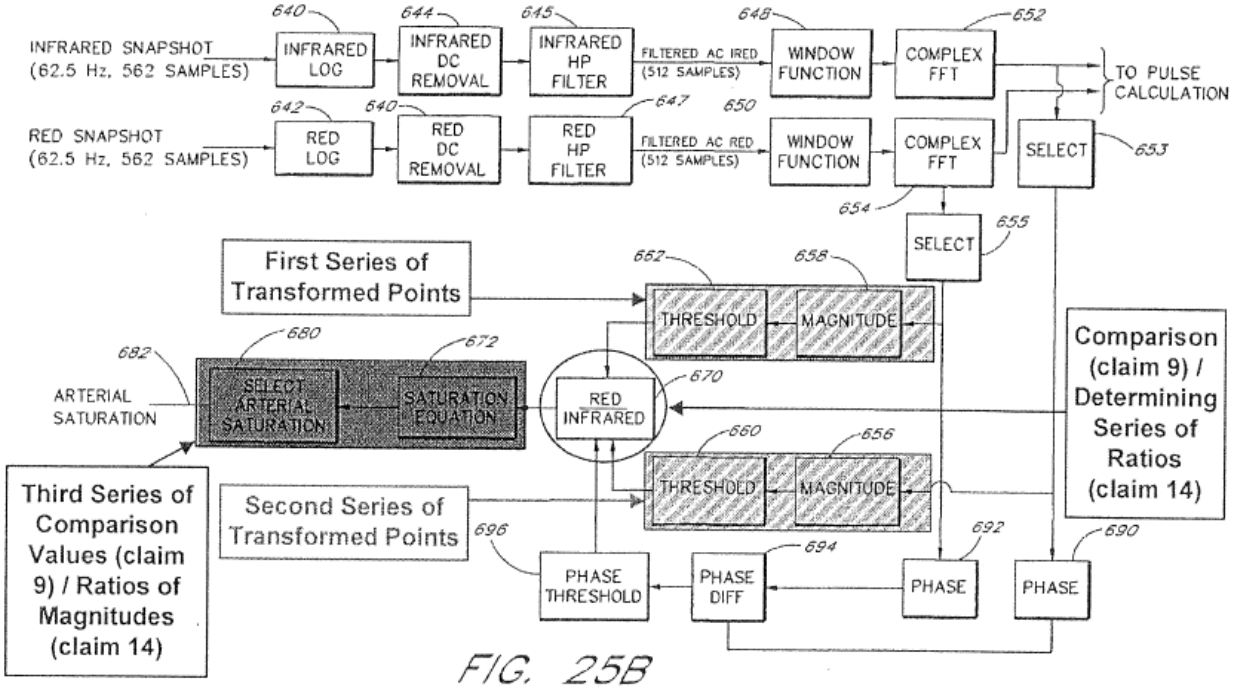


FIG. 25B

According to Philips, "while the magnitude of each of the points in the transformed red and infrared signals [in modules 656 and 658] are provided to threshold modules 660 and 662, there is no disclosure of comparing the output of the 'point-by-point ratio module 670' . . . to a threshold, as recited by the claims."[379] Philips, therefore, argues "the '272 Patent does not show possession of an algorithm

[376] D.I. 429, Ex. 14A at ¶¶ 83, 394-95; D.I. 431, Ex. 25 (Baura Depo.) at 392:16-393:12; D.I. 430, Ex. 21 (Baura Decl.)at ¶ 37.

[377] Philips argues Dr. Baura stated in her opinion that a ratio does not constitute a comparison. *See* D.I. 431, Ex. 25 at 436:4-6. As such, Philips assumes a ratio does not constitute a comparison of two numbers.

[378] For explanatory purposes, Philips made alterations to Fig. 25B. *See* D.I. 403 at 9.

[379] D.I. 403 at 9; *see also* D.I. 428, Ex. 1, '272 patent at 56:47-57:19; D.I. 429, Ex. 14A at ¶ 83.

that performs the claimed 'thresholding' to select a value using the Complex FFT."[380]

In response to Dr. Baura's conclusion that module 408 performs thresholding operations,[381] Philips argues the thresholding operations performed by module 408 "are not applied to the comparison values/ratios output by 'point-by-point ratio module [670]' in the Complex FFT algorithm, and thus, do not provide any support for the asserted claims of the '272 Patent."[382] Philips also contends module 408 does not exist in the Complex FFT algorithm.[383]

According to Philips, the '272 patent identifies "the Complex FFT algorithm as an 'alternative' to the algorithm illustrated in, and described with respect to, Figure 14."[384] Further, "the operations of FIG. 25A can replace the operations of FIG. 14."[385] The following figure[386] shows that replacement:

[380] D.I. 403 at 9.

[381] D.I. 428, Ex. 1, '272 patent at PHIL03211319 (showing Fig. 14); *id.*, Ex. 1, '272 patent at 46:28-32; D.I. 431, Ex. 25 at 368:21-369:2, 371:2-10; *id.*, Ex. 23 at ¶ 324.

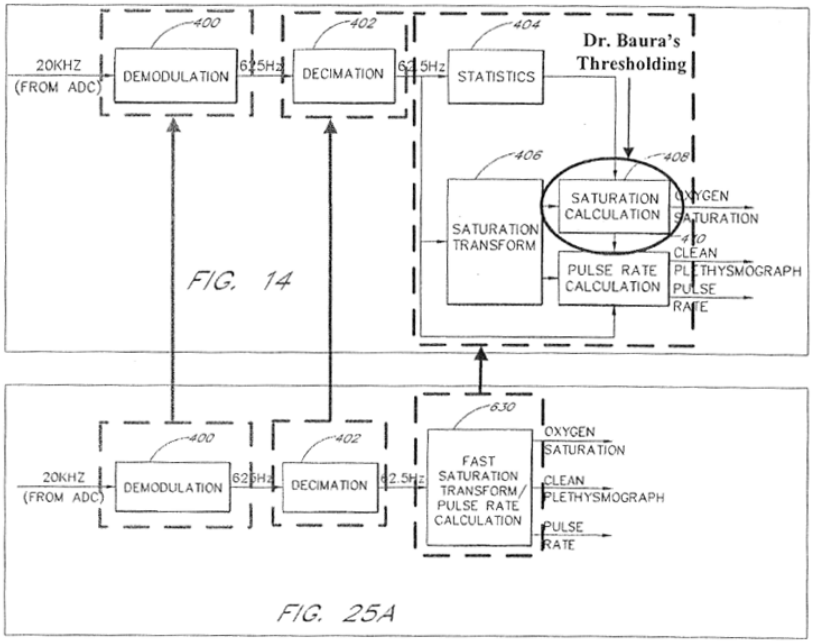
[382] D.I. 403 at 10.

[383] D.I. 430, Ex. 15 (Stone Depo.) at 615:14-617:19.

[384] D.I. 403 at 10; *see also* D.I. 428, Ex. 1, '272 patent at 55:14 ("Alternative To Saturation Transform-Complex FFT").

[385] D.I. 428, Ex. 1, '272 patent at 55:30-31; D.I. 430, Ex. 15 at 322:21-323:7; D.I. 431, Ex. 25 at 389:3-7.

[386] For explanatory purposes, Philips made alterations to Figs. 14 and 25A. *See* D.I. 403 at 10.



As shown in the above figure, because the operations of modules 404, 406, 408, and 410 in the Saturation Transform embodiment can be replaced by the operations of module 630 in the Complex FFT embodiment, Philips maintains "the thresholding operations in module 408 are not part of the Complex FFT algorithm."[387] Philips argues Dr. Baura merely provided a conclusory opinion[388] "that the Complex FFT retains the thresholding functionality of module 408."[389]

2. Bank of Filters

Masimo counters there are at least two techniques that provide written description support for the asserted claims. The first is the "Bank of Filters" frequency domain technique for determining potential oxygen saturation values.[390] Masimo

[387] D.I. 403 at 11; *see also* D.I. 431, Ex. 25 (Baura Depo.) at 389:3-7; D.I. 430, Ex. 15 (Stone Depo.) at 323:19-324:10.

[388] *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) (affirming summary judgment of obviousness because statements by patentee's expert were conclusory and failed to raise a genuine issue of material fact); *Lemelson v. U.S.*, 752 F.2d 1538, 1551 (Fed. Cir. 1985) (giving "no weight to the series of conclusory statements offered by [plaintiff's] expert witness").

[389] D.I. 403 at 11.

[390] D.I. 1, Ex. 1, '272 patent at 50:42-67; D.I. 514 (Baura Decl.) at ¶ 5.

argues “the Bank of Filters can be used in place of the saturation transform module 406 in Figure 14."[391]

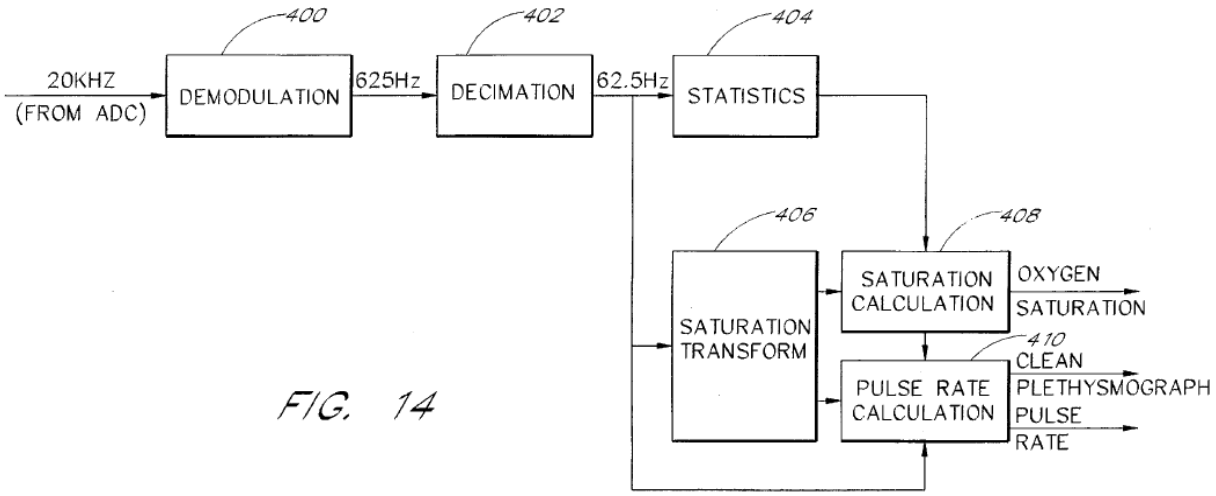


FIG. 14

As shown in Figure 14, the output of saturation transform module 406 is provided to saturation calculation module 408. When saturation transform module 406 is replaced by the Bank of Filters, the saturation can be determined “in a manner similar to the processing in the saturation calculation module 408.”[392]

The Bank of Filters is shown in Figure 23.[393]

[391] D.I. 512 at 8; *see also* D.I. 1, Ex. 1, ‘272 patent (showing Fig. 14); *id.*, Ex. 1, ‘272 patent at 50:32-34 (“An alternative to the saturation transform of the saturation transform module 406 can be implemented with a bank of filters as depicted in FIG. 23"); *id.*, Ex. 1, ‘272 patent at 50:30-31 (“Alternative To Saturation Transform Module - Bank Of Filters”).

[392] D.I. 1, Ex. 1, ‘272 patent at 51:32-43.

[393] *Id.* (showing Fig. 23).

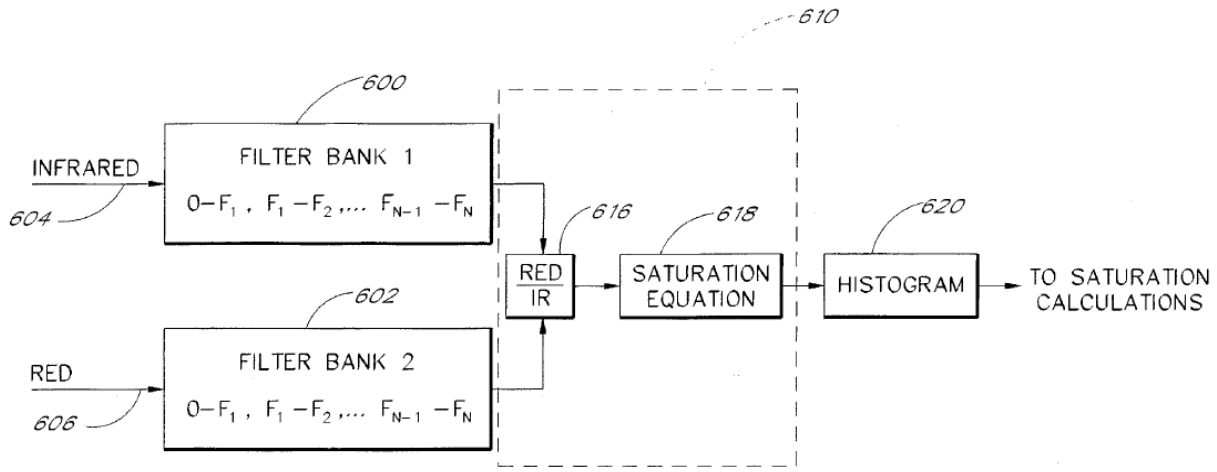


FIG. 23

Masimo argues the Bank of Filters embodiment corresponds to each of the asserted claims by using two filter banks to transform red and infrared samples into a series of points with frequency and magnitude components, followed by the calculation of the ratio of the magnitudes for the transformed red and infrared signals.[394] When saturation is calculated in module 408, Masimo maintains there is thresholding because "[i]f the saturation value is lower than the seed saturation, . . . the peak is replaced with the seed saturation value."[395] "Because the Bank of Filters replaces the saturation transform module 406 in Figure 14," according to Masimo, "[a] threshold

[394] *Id.* at 50:36-42 (noting the first filter bank 600 receives infrared signal samples, while the second filter bank 602 receives red signal samples); *id.* at 50:52-51:12 (explaining how the filter banks transform red and infrared samples into a series of points with frequency and magnitude components); *id.* at 51:9-31 (explaining how the ratio of the magnitudes for the transformed red and infrared signals are calculated).

[395] D.I. 512 at 10; *see also* D.I. 1, Ex. 1, '272 patent at 45:33-44, 46:21-27 (noting bin statistics, including red and infrared magnitude values, the seed saturation value, and a value representing the cross-correlation between the red and infrared signals, are provided to saturation calculation module 408); *id.*, Ex. 1, '272 patent at 46:28-38 (describing determination of acceptable bin data); D.I. 514 (Baura Decl.) at ¶¶ 12-13; D.I. 431, Ex. 23 (Baura Valid. Rpt.) at ¶ 324 (thresholding satisfies limitations in claims 9 and 14).

operation applies to the output of the Bank of Filters."[396] Additionally, Masimo points out that Philips was fully aware the asserted claims cover the Bank of Filters embodiment.[397]

Philips' motion for summary judgment as to Masimo's Bank of Filters argument is denied. Philips argues Masimo cannot rely on the Bank of Filters embodiment to support its claims because Masimo identified this embodiment for the first time on summary judgment,[398] and further contends "[t]here is simply no disclosure in the specification of the '272 Patent that describes selecting a value from a series of comparison values or ratios using a threshold."[399] Despite Philips arguments to the contrary, it brought up the Complex FFT algorithm in its opening brief, and generally discussed that disclosure in the specification. Masimo's answering brief is responding to arguments raised in Philips' opening brief.[400] As such, the court will address Masimo's Bank of Filters argument.

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[396] D.I. 512 at 10; *see also* D.I. 1, Ex. 1, '272 patent at 50:30-34.

[397] D.I. 184 (Transcript Claim Construction Hearing) at 149:22-150:2 (Masimo's counsel stating "[o]ne of the frequency domain embodiments disclosed in the patent is a complex FFT; however, there's another frequency domain embodiment disclosed . . . . It's called a bank of filters"); *id.* at 155:19-22 (Masimo's counsel: "[t]he bank of filters an[d] the complex FFT are two frequency embodiments that don't require a correlation canceler or specific equations"); *id.* at 175:1-7 (Masimo's counsel: "[t]here is more than just one frequency domain embodiment. . . . [t]he bank of filters is also a frequency embodiment and it's described in the patent beginning at Column 50, Line 30 going to Column 51, Line 55"); *id.* at 194:17-19 (Masimo's counsel: "[t]here is that other embodiment I mentioned in the frequency domain, the bank of filter[s]"); D.I. 181 (Baura Decl.) at ¶¶ 8, 30, 33 (discussing Bank of Filters and Complex FFT embodiments); D.I. 513, Ex. 3 (Diab Depo.) at 40:12-41:6, 84:13-85:16, 86:4-87:16, 153:5-18 (identifying Bank of Filters embodiment as frequency domain algorithm); *id.*, Ex. 4 (William W. Melek, Masimo's Expert Depo.) at 322:16-323:16 (conceding Bank of Filters is a frequency transform); D.I. 431, Ex. 22 (Baura Infr. Rpt.) at 94-95 (opining whether the asserted claims cover the Bank of Filters embodiment); D.I. 429, Ex. 14C (Stone Inv. Rpt.) at ¶¶ 37-41 (discussing whether the asserted claims cover the Bank of Filters embodiment).

[398] D.I. 598 at 4.

[399] D.I. 403 at 11.

[400] *Norman v. Elkin*, 726 F. Supp. 2d 464, 468 n.2 (D. Del. 2010) (denying motion to strike because plaintiff did not reserve material for the reply brief which should be included in a full and fair opening brief, but responded to arguments raised in defendants' answering brief).

Essentially, Philips argues the Bank of Filters embodiment does not transform a first and second series of data points to create a first transformed series of data points and a second transformed series of data points. As Masimo notes, however, "[a]n alternative to the saturation transform of the saturation transform module 406 can be implemented with a bank of filters as depicted in FIG. 23."[401] Further, Masimo shows that the Bank of Filters embodiment uses two filter banks to transform red and infrared samples into a series of points with frequency and magnitude components, followed by the calculation of the ratio of the magnitudes for the transformed red and infrared signals.

As a result, a genuine factual issue exists as to whether the written description conveys to those skilled in the art that Masimo possessed the claimed invention, specifically, that the Bank of Filters embodiment transforms a first and second series of data points to create a first transformed series of data points and a second transformed series of data points.[402] Further, because Masimo presents evidence that thresholding occurs in module 408, where saturation is calculated, which is fed by module 406, or the Bank of Filters, and Philips does not dispute module 408 performs thresholding operations, raises another issue that makes summary judgment inappropriate.[403]

3. Complex FFT

Masimo submits the second technique which provides written description

[401] D.I. 1, Ex. 1, '272 patent at 50:32-34.
[402] *Id.* at 51:9-31.
[403] D.I. 403 at 9-10.

support is the "complex FFT" technique because "[u]ntil this Motion, it was undisputed that the asserted claims were supported by the Complex FFT disclosure."[404] Masimo points out, although Philips argues the Complex FFT operations eliminate the operations of Figure 14, only module 406 is replaced and the other modules or functionality remain.[405] Therefore, Masimo contends the Complex FFT embodiment provides written description support for the limitations of "selecting at least one of said comparison values that has a magnitude within a selected threshold," and "selecting at least one of the ratios from said series of ratios that has a magnitude within a selected threshold."[406]

Essentially, Philips argues the Complex FFT does not select a value from a series of comparison values or ratios based on a threshold. Independent claims 9 and 14, however, indicate the ratios must have a magnitude within a threshold. The patent provides threshold modules 660 and 662 determine whether a magnitude of an individual point is above a certain threshold.[407] Further, FIG. 25B shows, and the patent discusses, two sets of data points being forwarded to a point-by-point ratio

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[404] D.I. 1, Ex. 1, '272 patent at 55:14 ("Alternative To Saturation Transform - Complex FFT"); D.I. 163 at 12 (Philips stating "[c]laims 9 and 14 of the '272 patent are directed to the Fast Saturation Transform [Complex FFT], which is the frequency domain embodiment described in columns 55-58 of the '272 patent"); D.I. 184 (Transcript Claim Construction Hearing**)** at 188:16-18 (Philips' counsel stating "[t]he embodiment that's the subject of Claims 9 and 14 is the FFT embodiment. It's described in Figure 25b").

[405] D.I. 1, Ex. 1, '272 patent at 55:28-30 ("FIG. 25A corresponds *generally* to FIG. 14, *with the fast saturation transform replacing the previously described saturation transform*") (emphasis added); D.I. 431, Ex. 23 at ¶ 324 (opining the complex FFT calculations can be an alternative to module 406); *id.*, Ex. 25 at 389:10-390:6 (stating "when it replaces it, it also includes some of the functionality that it's replacing"); D.I. 514 (Baura Decl.) at ¶¶ 14-17 (concluding the complex FFT calculations can be an alternative to module 406).

[406] D.I. 431, Ex. 23 at ¶ 324 (opining that claims 9 and 14 of the '272 patent disclose how to select a value from a set of comparison values by comparing the value to a selected threshold); D.I. 514 at ¶¶ 5-17 (same); D.I. 429, Ex. 14A (Stone Inv. Rpt.) at ¶¶ 393-96 ("there is no disclosure in the specification describing how to select a value from a set of comparison values by comparing the values to a selected threshold").

[407] D.I. 1, Ex. 1, '272 patent at 56:47-54.

module 670 where a comparison is made of samples, and resulting ratios are an outcome.[408] A ratio is then accepted into saturation equation module 672 to determine a saturation value.[409] Therefore, a genuine issue of material fact concerns whether the Complex FFT selects a value from a series of comparison values based on a threshold when analyzing Fig. 25B.

The patent also provides "FIG. 25A corresponds generally to FIG. 14, with the fast saturation transform replacing the previously described saturation transform."[410] The fast saturation transform in FIG. 25A is module 630, and the saturation transform in FIG. 14 is module 406. Module 630 is detailed in figures 25B and 25C. While Philips argues Dr. Baura opines module 408 performs thresholding operations, she never limited thresholding to module 408.[411] Even if thresholding was limited to module 408, as FIG. 25A corresponds to FIG. 14, with module 630 replacing module 406, there is a question as to whether FIG. 14 would operate in the same way with module 630. For the aforementioned reasons, a genuine issue of material fact remains, whether the written description conveys to those skilled in the art that Masimo possessed the claimed invention, particularly, whether the Complex FFT selects a value from a series of comparison values or ratios based on a threshold.

4. Masimo's Motion to Exclude the Testimony of John M. Turner Pursuant to FED. R. EVID. 702.[412] Masimo's Motion for Summary Judgment of Noninfringement and Invalidity of U.S. Patent No. 6,725,074;[413]

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[408] *Id.* at 56:55-57:19.
[409] *Id.* at 57:20-30.
[410] *Id.* at 55:28-30.
[411] D.I. 431, Ex. 25 (Baura Depo.) at 368:6-369:2.
[412] D.I. 381.
[413] D.I. 414.

The '074 Patent (Philips Patent)

Masimo moves to exclude the testimony of Philips' expert, Dr. John M. Turner,[414] and for summary judgment of non-infringement and invalidity of the '074 patent.[415] Because the finding on Masimo's motion to exclude Philips' expert directly affects the outcome of its summary judgment motion on liability, the issue of Dr. Turner's qualifications will be addressed first.

Legal Standard-Expert Witnesses

Masimo argues Dr. Turner, Philips' expert on infringement and validity of the '074 patent, is unqualified pursuant to Federal Rule of Evidence ("FED. R. EVID.") 702 and admission of his purportedly unqualified testimony would only serve to confuse the jury.

In relevant part, FED. R. EVID. 702 provides:

> If scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

The Supreme Court has interpreted Rule 702 as "[confiding to the judge] some gatekeeping responsibility in deciding questions of the admissibility of proffered expert testimony."[416] The Third Circuit has analyzed Rule 702 as having "three distinct

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[414] D.I. 381. The briefs are found at D.I. 382 (Masimo's opening brief), D.I. 520 (Philips' answering brief) and D.I. 579 (Masimo's reply brief).

[415] D.I. 414. The briefs are found at D.I. 415 (Masimo's opening brief), D.I. 523 (Philips' answering brief) and D.I. 589 (Masimo's reply brief).

[416] *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 600 (1993) (Rehnquist concurring in part and dissenting in part).

substantive restrictions on the admission of expert testimony: qualifications, reliability, and fit."[417] Here, Masimo seeks to exclude Dr. Turner's testimony based on his alleged lack of expert qualification.

When determining expert qualification, the Third Circuit articulated the following standard:

> Rule 702 requires the witness have "specialized knowledge" regarding the area of testimony. The basis of this specialized knowledge "can be practical experience as well as academic training and credentials." We have *interpreted the specialized knowledge requirement liberally*, and have stated that this policy of liberal admissibility of expert testimony "extends to the substantive as well as the formal qualification of experts." However, "at a minimum, a proffered expert witness . . . must possess skill or knowledge greater than the average layman."[418]

The Third Circuit also noted "a broad range of knowledge, skills, and training qualify an expert as such," and "eschewed imposing overly rigorous requirements of expertise and have been satisfied with more generalized qualifications."[419] "[I]t is an abuse of discretion to exclude testimony simply because the trial court does not deem the proposed expert to be the best qualified or because the proposed expert does not have the specialization that the court considers most appropriate."[420]

Additionally, the Third Circuit recognizes "the exclusion of critical evidence is an extreme sanction, not normally to be imposed absent a showing of willful deception or flagrant disregard of a court order by the proponent of the evidence,"[421] and identified several factors to be considered in deciding whether to exclude testimony:

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[417] *See Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000).
[418] *Woldorf v. Shuta*, 142 F.3d 601, 625 (3d Cir. 1998) (citations omitted) (emphasis added).
[419] *In re Paoli R.R. Yard PCB Litig*., 35 F.3d 717, 741 (3d Cir. 1994).
[420] *Holbrook v. Lykes Bros. S.S. Co.*, Inc., 80 F.3d 777, 782 (3d Cir. 1996).
[421] *Id*. at 791-92 (citations and internal quotation marks omitted).

> (1) the prejudice or surprise in fact of the party against whom the excluded witnesses would have testified, (2) the ability of that party to cure the prejudice, (3) the extent to which waiver of the rule against calling unlisted witnesses would disrupt the orderly and efficient trial of the case or of other cases in the court, and (4) bad faith or willfulness in failing to comply with the district court's order.[422]

Further, under Third Circuit law, "the importance of the excluded testimony should be considered."[423]

Dr. Turner

Masimo argues Dr. Turner should be precluded from testifying because he is not a qualified expert. Specifically, it contends Dr. Turner is not an expert on fuzzy logic.[424] Masimo points to Dr. Turner's testimony and purportedly inadequate experience as evidence of his lack of qualification to offer expert testimony regarding the subject matter of the '074 patent.

Masimo claims Dr. Turner's testimony regarding his level of expertise in fuzzy logic demonstrates he is not a qualified expert,[425] because he concedes he is not an expert in uncertain or fuzzy logic, has had no formal education or training, no professional experience with, including prior employment or consulting work, never previously provided an expert opinion about, and never designed a system or written a

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[422] *Id*.

[423] *Konstantopouls v. Westvaco Corp*., 112 F.3d 710, 719 (3d Cir. 1997) (citations and internal quotations omitted).

[424] D.I. 382 at 1. Masimo contends the '074 Patent is about fuzzy logic. The fuzzy logic element is found in claim 1 of the '074 patent. Claim 5 of the '074 patent is dependant on claim 1. Both parties agree resolution of claim 1 is the primary dispute under '074 patent.

[425] "Fuzzy logic" was construed as "multivalued (as opposed to binary) logic developed to deal with imprecise or vague data. Fuzzy logic allows for partial membership in a set, values between 0 and 1, shades of gray and maybe; it introduces the concept of the 'fuzzy set.'" *Masimo v. Philips Elec. N. Am. Corp.*, C.A. No. 09-80-LPS-MPT, 2011 WL 678447, at *14 (D. Del. Feb. 18, 2011), *adopted in part*, *Masimo v. Philips Elec. N. Am. Corp.*, C.A. No. 09-80-LPS-MPT, 2012 WL 125759, at *1 (D. Del. Jan. 17, 2012).

computer software program using fuzzy logic.[426] Based on this testimony, Masimo submits Dr. Turner is unqualified as an expert on fuzzy logic and should, therefore, be prohibited from testifying, asserting he "lacks ***any*** knowledge, training, education or experience to qualify as an expert" on fuzzy logic.[427]

Philips responds Dr. Turner is qualified as an expert in the field of "digital signal processing, source code and medical devices,"[428] and this field includes the technology disclosed in the '074 patent, namely, the use of uncertain and fuzzy logic software applications in medical devices. Because Dr. Turner possesses at least ordinary skill in the art,[429] Philips argues he can provide helpful testimony on how software using uncertain and fuzzy logic works within the devices at issue. Philips contends Dr. Turner's heightened skill set comes from his: (1) Ph.D. in electrical and computer engineering; (2) prior familiarity with fuzzy logic; (3) review of prior art involving fuzzy logic; (4) "more than 25 years of experience designing and develop[ing] medical devices and systems, including many devices that incorporate complicated digital signal processing"; (5) prior work in pulse oximetry; and (6) involvement in various startup companies in the medical device field.[430]

Dr. Turner is qualified to offer expert testimony regarding infringement and validity of the '074 patent because his knowledge, skill, experience, training and education in the field of digital signal processing, source code, and medical devices provide an adequate foundation for his expert opinion and testimony on the application

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[426] D.I. 382 at 7, relying on D.I. 383, Ex. 2 (Turner Depo.) at 55:11-19; 183, 184 .
[427] *Id*. at 6 (emphasis in original).
[428] D.I. 520 at 1.
[429] *Id*. at 6.
[430] *Id*. at 3-4.

of uncertain logic and fuzzy logic in the '074 patent. Just as a an aeronautical engineer might opine on the mechanics of bumble bee flight,[431] an individual with Dr. Turner's background is qualified to offer expert testimony regarding the application of uncertain and fuzzy logic in software applications used in medical devices.[432]

In support of its argument, Masimo relies on *Eaton v. Rockwell Int'l Corp*.[433] Such reliance is misplaced. The technology in *Eaton* involved automobile transmissions, and the critical issue was "the concept of dithering or breaking torque" in a master clutch transmission.[434] Rockwell argued its expert, having almost 40 years experience working on transmissions, was qualified to offer testimony about the patent at issue. In precluding the expert's testimony, the court noted the proffered expert: (1) had almost no experience with the specific subject matter; (2) admitted not knowing how Rockwell's accused system operated;[435] (3) testified he was neither an expert in breaking torque nor the accused system, and most importantly; (4) was admittedly unqualified to opine about how a proffered prior art patent operated as prior art and anticipated the patent-at-issue.[436]

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[431] *Berry v. City of Detroit*, 25 F.3d 1342, 1350 (6th Cir. 1994). Although *Berry* is a nonbinding decision from a sister circuit, the case is instructive because of its analogous situation to the instant matter. Its analysis is also consistent with the liberal admissibility standards proscribed by the Third Circuit.

[432] In its reply brief, Masimo argues for a more stringent standard in admitting expert testimony than required by the Third Circuit by citing additional cases from other jurisdictions. In those cases, testimony was excluded because the expert was providing opinion on subject matter outside of his or her field. Unlike in the cases cited by Masimo, Dr. Turner has extensive knowledge in software design and its implementation in various medical devices, and is qualified to explain how *different* types of software operate in *different* medical devices.

[433] C.A. No. 97-421-JJF, 2001 U.S. Dist. LEXIS 17054 (D. Del. Oct. 10, 2001).

[434] *Id.* at *63.

[435] *Id*. The expert testified he had minimal experience with transmissions using a master clutch, and had no knowledge on how the accused system controlled fuel, broke torque or dithered.

[436] *Id*. at 63-64.

Unlike *Eaton*, Dr. Turner does have knowledge about the technology described and addressed in the '074 patent. His testimony corroborates he understands the application and operation of uncertain and fuzzy logic.[437] When asked, Dr. Turner was able to define and describe uncertain logic, fuzzy logic, multivalued logic, and certain logic and explain the differences among them. Whether Masimo's expert disagrees with Dr. Turner's analysis is irrelevant, and goes to weight. Moreover, Dr. Turner testified he was aware of uncertain and fuzzy logic being used in software applications since the late 1990's.[438] Contrary to the excluded expert in *Eaton*, Dr. Turner is knowledgeable about the subject matter in dispute as evidenced by the analysis in his expert report[439] and his deposition. Dr. Turner's knowledge of uncertain and fuzzy logic, and its application in the '074 patent, is markedly distinguishable from the expert in *Eaton*.

Because Dr. Turner indicated he is not an expert in uncertain or fuzzy logic,[440] Masimo argues, in light of *Eaton*, he should be excluded. While the expert in *Eaton* admitted his lack of expertise on the central issue, he had other significant deficiencies, including how the accused product functioned, no experience in designing transmissions and no understanding of the teachings of a relevant prior art reference. In contrast, Dr. Turner designs software and medical equipment, holds several patents in the software and medical fields, is a Ph.D. in electrical engineering

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[437] D.I. 383, Ex. 2 (Turner Depo.) at 55-57.
[438] *Id.*, Ex. 2 at 183:15-18.
[439] D.I. 383, Ex. 3 (Turner Noninfr. Rpt.).
[440] A review of the entire line of questioning provided in the parties' exhibits demonstrates Dr. Turner has the necessary expertise under the required analysis of Rule 702. *See* D.I. 383., Ex. 2 at 54:1-57:21; 114: 2-121:22; 174:15-185:19.

and computer science, and has provided expert testimony related to medical devices and software systems in the past. Further, he was generally familiar with fuzzy logic, studied the same references referred to in the patent and used by the inventor to learn fuzzy logic, and reviewed and understands the Bosque prior art reference, which explains an application of fuzzy logic in pulse oximeters.[441] In addition, Dr. Turner reviewed and analyzed the relevant source code. As a result of his review briefly described herein, he disagrees with Dr. Melek's more recent refinement of the extent of education necessary to understand uncertain and fuzzy logic.[442] As the evidence shows, Dr. Turner has the requisite qualifications in the field of digital signal processing, source code, and medical devices, to provide expert testimony explaining how uncertain and fuzzy logic works in medical device software. Further, as a digital signal processing and computer programming expert for over 25 years, he is competent to review source code and explain how it operates, and whether it is consistent with the court's claim constructions and the '074 patent claims-at-issue.

Finally, Dr. Turner, unlike the expert in *Eaton*, addresses the qualifications of a person of ordinary skill in the art.[443] Moreover, according to Dr. Melek, Masimo's expert, "a person of ordinary skill in the art described in the '074 would have a Bachelors or Masters degree in mathematics, engineering, or computer science with education or training in the application of fuzzy logic."[444] Dr. Melek's original

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[441] D.I. 527, Ex. 137 at 99:10-15; D.I. 528, Ex. 139 at 94:11-18, 114:18-115:18.
[442] *See* n. 32, *infra.*
[443] *Id*., Ex. 2 at 119-121; Ex. 3, at 13, ¶ 48.
[444] D.I. 528, Ex. 144 at ¶ 15. Dr. Melek's original definition of the level of ordinary skill in the art consisted of that single sentence in his report dated October 19, 2010 in support of Masimo's claim construction. In that report, he also referenced certain literature similar to the materials reviewed by Dr. Turner, including the textbook used by the inventor to educate himself on fuzzy logic. *Id.* at ¶ 17. In his

qualifications are consistent with Dr. Turner's knowledge, background, education and experience.

Masimo also discussed *Sundance v. Demonte*,[445] where the Federal Circuit reversed the lower court's admission of testimony by the defendant's patent law expert, a patent attorney. Noting the court's gatekeeping role in *Kumho Tire Co v. Carmichael*[446] to assure under FED. R. EVID 702 that admitted expert testimony is both reliable and relevant, the court determined a patent attorney was not qualified to testify on issues of infringement and invalidity because such matters are analyzed "from the perspective of a person of ordinary skill in the art."[447] In the absence of any showing that the patent lawyer also had technical expertise in the scope of the field of the invention, his testimony was improper and inadmissible.[448] In so finding, the Federal Circuit reaffirmed the application of Rule 702 in patent matters, which does not require an expert witness to possess something more than ordinary skill in the art. "A witness possessing merely ordinary skill will often be qualified to present expert testimony both in patent trials and more generally."[449]

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expert report on invalidity, Dr. Melek redefined or changed the qualifications as requiring a Masters or Ph.D. degree, at least five years of training or experience in the application of the subject, and "an understanding of the different types of uncertain logic," as well as adding more detail regarding who is a qualified expert and suggesting Dr. Turner's qualifications are inadequate. *Id.*, Ex. 136 at 8, ¶ 34; D.I. 384. In his deposition in July 2012, Dr. Melek advised he changed his definition by only excluding a bachelor's degree to reflect what he recently learned was occurring in academia in 2012. The '074 patent was filed in 1999 and issued 2004. D.I. 580, Ex. 13, at 143:14-144:8; 148:20-149:8. Dr. Melek further implies because his training and experience exceeds that of Dr. Turner, then Dr. Turner is not qualified, which is inconsistent with *Sundance v. Demonte*, 550 F.3d 1356, 1363 (Fed. Cir. 2009). Masimo's constant modification of what is necessary for one of ordinary skill in the art makes this issue a moving target, and not the type of evidence sufficient for summary judgment. *See Yatzu v. Appoquinimick Sch. Dist.*, 458 F. Supp. 2d 235, 247 (D. Del. 2006).

[445] 550 F.3d 1356 (Fed. Cir. 2009).
[446] 119 S.Ct. 1167 (1999).
[447] *Sundance*, 550 F.3d at 1361.
[448] *Id.* at 1362-63.
[449] *Id.* at 1363.

Dr. Turner's expertise, education, skill and experience in the field of digital signal processing, source code, and medical devices qualifies him as one of ordinary skill in the art, competent to testify on uncertain and fuzzy logic in relation to in the '074 patent.[450] Any purported deficiency in Dr. Turner's knowledge of uncertain or fuzzy logics goes to weight, rather than admissibility of his testimony,[451] which may be addressed through appropriate cross-examination by Masimo.

Conventional Logic v. Fuzzy Logic[452]

To understand the parties' arguments regarding infringement and invalidity, a discussion of conventional logic v. fuzzy logic is necessary.

In conventional binary logic, a proposition is either "true" or "false," that is a proposal or condition is satisfied or not. When used in software implementations, it is usually defined as IF-THEN-ELSE logic statements which are either met or not met with certainty.

Uncertain logic is designed to address uncertainty, and includes probability theory, Bayesian networks and fuzzy logic. While probability measures the likelihood of an event occurring and may be expressed in a number, fuzzy logic is another way of dealing with uncertainty, which allows each proposition to be satisfied or true, but to a varying degree. To express or convey the degree of truth, fuzzy logic employs partial membership in a "fuzzy set" because the proposition is both true and false, but each

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[450] As noted previously, Dr. Turner considered and reviewed the literature in the area of fuzzy logic, reviewed and analyzed the '074 patent and prior art and was familiar with the court's claim construction.

[451] *Holbrook v. Lykes Bros. Steamship Co., Inc. et al.*, 80 F.3d 777, 782 (3d Cir. 1996).

[452] The parties generally agree as to the differences between conventional and fuzzy logic. The discussion of conventional and fuzzy logic is taken from D.I. 415 at 2-5 and D.I. 523 at 1-3.

only to a degree.

In explaining fuzzy logic, Masimo relies on an example in the Altrock text, an authority cited in the '074 patent, which both parties agree is authoritative.[453] That example discussed deciding whether a patient with a temperature has a "high fever."[454] Applying conventional logic, a high fever set could be defined as a body temperature of at least 102°F, which would cause a temperature of 101.9° not to be so included in this set.[455] Under conventional logic, temperatures can only belong to one set.[456] Because fuzzy logic uses partial membership in the high fever set example, it would allow a given temperature to belong partially to the high fever set, as well as partially to another set, such as a low fever set.[457] Fuzzy sets, therefore, do not have crisply defined membership, but allow parts to have grades of membership from 0 to 1.[458]

Where the parties disagree is in the application of fuzzy logic and whether conventional logic, math, averages, IF-THEN-ELSE statements and precision can be used in fuzzy logic processes.[459] Masimo contends equations designed to calculate averages or scaling equations do not constitute fuzzy logic. Philips maintains such concepts are inherent to how fuzzy logic is implement, disputing Masimo's argument that the calculated confidence values (fRawConf) in its source code do not represent partial memberships in sets, because each number is a precise calculation.[460]

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[453] D.I. 415 at 3-5; D.I. 523 at 1-3; D.I. 417, Exs. 10, 11 Altrock text, *Fuzzy Logic and Neurofuzzy Applications Explained*. Philips agrees the high fever example used by Masimo was "a good one." D.I. 523 at 2.

[454] D.I. 415 at 3 (citing D.I. 417, Ex. 11 at MASP0579219-220 ; D.I. 419, Melek Decl. ¶¶ 23-24).

[455] *Id.*

[456] D.I. 415 at 4.

[457] *Id.* at 3-4.

[458] *Id.*

[459] D.I. 415 at 10-13; D.I. 523 at 1-3.

[460] *Id.*

According to Philips, "the same is true of fuzzy logic sets," and "[w]hat makes the 'high fever' set fuzzy is not the lack of precision in its membership," but "that it accommodates partial degrees of membership rather than just a binary membership (TRUE or FALSE)."[461] As evidence that mathematics and averages are used in the implementation of fuzzy logic, Philips points to the '074 patent where the fuzzy logic software employed to implement the invention, the inventor used a weighted average function called GAMMA.[462]

A. Infringement

1. Literal Infringement

Independent claim 1 of the '074 patent teaches, *inter alia*, a method to evaluate data by means of "uncertain logic, including fuzzy logic."[463] Masimo maintains because its accused product, Signal IQ software, does not use fuzzy logic, it cannot infringe.[464]

Signal IQ is part of the SET algorithm[465] which determines a confidence associated with oxygen saturation calculations. Specifically, "Signal IQ is a visual indicator of the system's confidence level in the displayed arterial oxygen saturations and pulse rate measurements."[466]

Masimo argues its accused Signal IQ software cannot literally infringe the '074 patent because the code relied upon by Philips is merely designed to calculate an

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[461] D.I. 523 at 2.
[462] D.I. 528, Ex. 150 (fuzzy TECH Manual at 170-72).
[463] '074 patent, claim 1 (refer to n.13, *supra*. for construction of fuzzy logic).
[464] *See generally* D.I. 415. Part of Masimo's argument rests on its motion that Dr. Turner is not a qualified expert. Since Masimo's motion to exclude was denied, Dr. Turner's opinions will be considered.
[465] Signal Extraction Technology.
[466] D.I. 528, Ex. 134 MASP0028034-037.

average of numbers which is arithmetic and not fuzzy logic.[467] Philips points to several lines of code in Masimo's Signal IQ software as evidence of infringement of claim 1 of the '074 patent; Masimo responds that code is simply "conventional logic and math,"[468] and because fuzzy logic deals with "maybes" and degrees of true, such "precise calculation[s]," cannot be representative of fuzzy logic.[469] Masimo argues Philips has produced no evidence identifying use of fuzzy logic in the Signal IQ software.[470]

The lines of code in the Signal IQ software on which Philips relies as proof of infringement are "fTDDensity," "fHarmMagRatio," "fEquivalentWidth," and "fRawConf."[471] Philips maintains these lines of code represents fuzzy logic,[472] because they are membership functions which interlink factors relevant to the measurement signal in pulsoximetry devices, and thus read on claim 1 of the '074 patent. In support, Philips points to the testimony of its expert witness, Dr. Turner, and the deposition of Dr. William Melek.[473]

Dr. Turner opines the Signal IQ software uses precise calculations and creates a quality variable labeled "fRawConf."[474] Specifically, the factors in the Signal IQ source code–fTDDensity, fHarmMagRation and fEquivalent Width–are "used to

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[467] D.I. 589 at 10-11.
[468] D.I. 415 at 10.
[469] *Id.* at 11.
[470] Masimo also complains Dr. Turner interjected new bases for infringement during his deposition. It argues such "change" in his opinion should be stricken. Philips denies any such modification occurred. *See* D.I. 523 at 6. Masimo's complaint is a bit contrived, particularly in light of certain expert declarations it submitted in support of or in opposition to the various summary judgment motions filed in this matter, and thereby effectively augmented its experts' reports and depositions. Further, Dr. Turner specifically addressed and denied this accusation in his deposition. *See* D.I. 416, Ex. 3 at 248:13-251:19.
[471] D.I 415 at 6.
[472] D.I. 523 at 9-10.
[473] *Id*. at 9-14.
[474] D.I. 528, Ex. 139 (Turner Depo.) at 239:10-11.

determine the set membership in the set called high confidence, which is denoted in the code by the variable raw confidence" or fRawConf.[475] This variable represents the measurement signal data to be communicated to the device user. Therefore, the "fRawConf" variable is calculated based on membership functions, that is, fTDDensity, fHarmMagRatio, and fEquivalentWidth,[476] factors having a degree of membership in the set of high confidence (as expressed by the "fRawConf" variable).[477] According to Dr. Turner, this method, which uses precise calculations, results in the interlinking of factors to create a value expressed numerically between 0 and 1 and represents fuzzy logic in Signal IQ.[478]

Masimo's exhibits support Dr. Turner's position.[479] First, as noted by Philips, "averages and mathematical equations are commonly used to implement fuzzy logic."[480] The Altrock text, for example, notes "fuzzy logic operators . . . can mathematically be represented,"[481] and fuzzy logic rules may be "computed" in some instances.[482] The text also teaches a "singleton membership" method can be used to defuzzify the representation of the linguistic value represented by a number between 0 and 1.[483] Each of these examples use precise mathematic equations to manipulate the data being processed via fuzzy logic. Moreover, the Altrock text provides, "[f]uzzy

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[475] *Id.* at 222:1-4; *see also* D.I. 527, Ex. 134A (Turner Inf. Rpt.) at ¶¶ 87-106.
[476] D.I. 528, Ex. 139 at 222:1-4.
[477] *Id*.; Id. Ex. 139A at ¶¶ 87-106.
[478] *Id.* Ex. 139 at 239:10-11.
[479] D.I. 417, Ex. 10 at MASP0579042-69.
[480] D.I. 523 at 8, which, contrary to Masimo's argument, specifically references pages 10-14 of Philips' brief and all supporting analyses, including citations to expert reports and expert depositions.
[481] D.I. 417, Ex. 10 at MASP0579066. Using AND-OR-NOT operators, "OR can be mathematically represented by the max operator." *Id.*
[482] *Id*. at MASP0579065.
[483] *Id*. at MASP0579068.

logic has been developed as . . . a mathematical model."[484] Therefore, although equations by themselves may not be fuzzy logic, if used in a certain manner, they become part of and implement fuzzy logic.

Philips cites to several equations it contends represent fuzzy logic membership functions, for example, from Masimo's Signal IQ source code, an example from the Altrock text, and the Bosque patent.[485] Masimo responds Philips only demonstrated "superficial similarity between the linear scaling equations in Signal IQ and an example of a segregated membership function in Altrock and Bosque."[486]

Philips, however, references evidence showing equations, like those contained in Signal IQ, as operating as fuzzy logic membership functions. In addition to Dr. Turner's testimony, Philips points to the testimony of Masimo's expert witness, Dr. Melek.[487] During deposition, Dr. Melek was asked to plot the membership functions for one of the fuzzy sets found in the Bosque patent[488] and Signal IQ software. Specifically, he was instructed to plot the relationship in Masimo's code between the factors fTD Density and fHarmMagRatio and the variable fRawConf, to demonstrate that fRawConf is fuzzy logic because it represents a partial degree of membership in a set.[489] These membership functions, when plotted separately, created graphs showing a line of positive incline from left to right. Dr. Melek also drew certain fuzzy logic

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[484] Id. at MASP0579052. As noted in Altrock, to implement human logic in engineering solutions, a mathematical model is need. Fuzzy logic serves in that capacity because it "allows the representation of human decision and evaluation process in algorithmic form." *Id.*

[485] D.I. 523 at 10-14. The Bosque patent, U.S. Patent No. 5,803,135, or the '135 patent is relied on by Masimo as prior art to the '074 patent, discussed later in this opinion.

[486] D.I. 589 at 3.

[487] D.I. 528, Ex. 140 at 10.

[488] Both parties agree the Bosque patent addresses fuzzy logic.

[489] D.I. 528, Ex. 141(Melek Depo.) at 271:283:12; Ex. 149 Hand drawn Exhibit 3012 of fTDDensity; Ex. 151 Hand drawn Exhibit 3013 of fHarmMagRatio.

membership functions of the Bosque patent.[490] The shapes created on Dr. Melek's graphs, according to Philips, show how Masimo's "code uses fuzzy logic," because the graphs of the membership functions in Signal IQ and Bosque are identical.[491] As further noted by Philips, these figures also have an "**identical** shape to Figure 2.3,"[492] of Altrock in describing the fever example Masimo "cited repeatedly as demonstrating fuzzy logic."[493] According to Philips, such demonstrative evidence shows a genuine issue of material fact.

Masimo refers to the lines of source code on which Philips relies as "equations," "precise calculation[s]," "scaling equations," and "scaling functions,"[494] which Masimo's expert, Dr. Melek, opines are mathematic calculations and not fuzzy logic.[495] Obviously, Dr. Melek disagrees with Dr. Turner's analysis.

Masimo argues because the graphs drawn by Dr. Melek per Philips' assumptions during his deposition do not depict overlap, they cannot represent fuzzy logic. Overlap is the area on a graph shared by at least two membership functions.[496] In the Altrock text, one such graph plots the membership functions in a fuzzy logic system used to evaluate fevers.[497] The fuzzy logic membership functions are titled "low," "normal," "raised," and "strong fever." When plotted on the same graph, the

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[490] D.I. 528, Ex. 152, Hand drawn Exhibit 3009.

[491] D.I. 523 at 14. These examples were used by Philips to show that Signal IQ uses fuzzy logic, which Masimo denies.

[492] *Id.* at 12 (emphasis in original).

[493] *Id.*; D.I. 528, Ex. 148 (Melek Reb. Rpt.) at 38.

[494] D.I. 415 at 10, 11, 12.

[495] D.I. 528, Ex. 140, at 13-14.

[496] Based on the parties' arguments and the evidence on record, the overlap region on a graph represents the numerical values of a membership function, the result of mathematic equations. The values within an area of overlap represent values that belong to separate membership functions to a degree between 0 and 1. Thus, it appears that membership functions-the equations-are part of fuzzy sets.

[497] D.I. 417, Ex. 10 at MASP0579056.

"normal" and "raised" functions each create triangular shapes which overlap to some degree. Without such similar overlap, Masimo contends the graphs cannot represent fuzzy logic; rather, they merely represent membership functions, and not fuzzy logic.[498]

However, Altrock provides that "[t]he degree of membership can also be represented by a continuous function" and references Figure 2.3 as plotting such a membership function.[499] This particular graph is the one referenced in Philips' brief, and apparently omitted in Dr. Melek's declaration.[500] When the membership function in Figure 2.3 is plotted, it creates a graph identical to those drawn by Dr. Melek.[501] This example suggests that overlap is not required to graphically represent membership functions in fuzzy logic. Dr. Turner confirmed during his deposition that a membership function, as evidenced in the Signal IQ source code, could be plotted to correspond to the partial membership set as demonstrated in the Altrock text.[502] He further confirmed and identified in the Signal IQ source code the fuzzy set RawConf.[503]

As previously noted, fuzzy logic was construed as "multivalued (as opposed to binary) logic developed to deal with imprecise or vague data. Fuzzy logic allows for partial membership in a set, values between 0 and 1, shades of gray and maybe; it introduces the concept of the 'fuzzy set.'"[504] The Altrock text provides:

Note, that fuzzy sets are a true generalization of conventional sets. The

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[498] D.I. 589 at 3 (wherein Masimo accuses Philips' logic by use of those depictions as "fuzzy").
[499] D.I. 517, Ex. 10 at MASP0579055.
[500] D.I. 523 at 10-14.
[501] D.I. 417, Ex. 10 (Altrock Text) at MASP0579055; D.I. 523 at 13.
[502] D.I. 528, Ex.139 (Turner Depo) 235:7-239:16.
[503] D.I. 416, Ex. 3 (Turner Depo) at 244:8-251:19.
[504] *Masimo v. Philips Elec. N. Am. Corp.*, C.A. No. 09-80-LPS-MPT, 2011 WL 678447, at *14 (D. Del. Feb. 18, 2011), *adopted in part Masimo v. Philips Elec. N. Am. Corp.*, C.A. No. 09-80-LPS-MPT, 2012 WL 125759, at *1 (D. Del. Jan. 17, 2012).

> cases of μ=0 and μ=1of the conventional indicator function are just special cases of the fuzzy set. The use of fuzzy sets *defined by membership functions* in logical expression is called "fuzzy logic." Here, the degree of membership in a set becomes the degree of truth of a statement.[505]

Therefore, membership functions define the use of fuzzy sets which is fuzzy logic.

As the previous discussion shows, genuine issues exist regarding whether the contested lines of source code in the Signal IQ software are fuzzy logic. The parties' experts dispute the functionality of the source code in the Signal IQ software, and how fuzzy logic is used in the Bosque patent, the Signal IQ software (as well as whether it is used at all in Masimo's product), and the '074 patent. For these reasons, the issue of literal infringement should be left to the jury.

B. Doctrine of Equivalents

1. Prosecution History Estoppel

Philips argues if Masimo's Signal IQ software does not literally infringe the '074 patent, then it infringes under the doctrine of equivalents and none of the exceptions to the doctrine apply. Masimo raises two legal grounds as eliminating application of the doctrine of equivalents: prosecution history estoppel and ensnaring prior art.[506]

Masimo points out Philips amended its application during prosecution, thereby creating a presumption it surrendered certain subject matter.[507] The amendment was made after the PTO rejected certain claims of the '074 patent as anticipated by the

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[505] D.I. 417, Ex. 10 at MASP0579056 (emphasis added).

[506] D.I. 415 at 13-16. Masimo cites the Nellcor N-400 as a prior art reference and argues application of the doctrine of equivalents will cover this prior art.

[507] *Id.* at 13; D.I. 589 at 4. Specifically, [a] patentee's decision to narrow his claims through amendment may be presumed to be a general disclaimer of the territory between the original claim and the amended claim." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 740 (2002).

Bosque patent. The original claims 1 and 5 provided "interlinking the factors thus determined by means of an uncertain logic, *preferably fuzzy logic*." After the rejection, Philips, according to Masimo, narrowed the claimed "uncertain logic" to only fuzzy logic by changing the word "preferably" to "including."[508] Because Philips surrendered subject matter by purportedly narrowing the claim to fuzzy logic, Masimo argues it cannot now use that subject matter to prove infringement under the doctrine of equivalents.[509]

Philips disagrees contending the doctrine of equivalents is applicable because: (1) the amendment to change "preferable fuzzy logic" to "including fuzzy logic" during prosecution was not made for patentability;[510] and (2) the doctrine will not ensnare prior art.[511] Philips argues, therefore, that the prosecution history estoppel exception to the doctrine of equivalents is inapplicable.

During prosecution, the PTO rejected Philips' application finding claims 1 through 12 as anticipated by the Bosque patent.[512] In response, Philips amended its patent application.[513]

Claim 1 originally read:

> A method of determining a quantitative statement concerning the quality of a measurement signal, preferably a medical measurement signal, such as

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[508] *Id.* at 14. *See* D.I. 417, Ex. 2 at MASP0022486, MASP0022595.

[509] Philips and Masimo agree the '074 patent and the Bosque patent use fuzzy logic. They disagree on *how* each of the patents use fuzzy logic.

[510] D.I. 523 at 15.

[511] *Id*. at 14-16.

[512] D.I. 416, Ex. 2 at MASP0022588. In rejecting the twelve claims as anticipated by Bosque, the examiner noted "Bosque discloses a method to determining the quality of a pulse oximetry signal using fuzzy logic." *Id.* Regarding claim 1, the examiner found "[t]he method includes determining factors relevant to the measuring signal by performing a signal evaluation by examining artifacts, the saturation value and the rate of change of the saturation value," referencing col. 4, lines 6-17 of the Bosque patent. The examiner further held [t]he method also includes interlinking the factors by using fuzzy logic to provide a quality indicator," referencing col. 4, lines 18-47. *Id.*

[513] D.I. 589 at 4.

in pulsoximetry, comprising the steps of: (a) determining factors relevant to the measuring signal, preferably relating to the signal recording, signal processing, and/or signal evaluation, and (b) interlinking the factors thus determined by means of an uncertain logic, preferably fuzzy logic, into a quality indicator which quantitatively describes the quality of the determined measurement value.[514]

The amended claim 1 now provides:

A method of determining a quantitative statement concerning the quality of a medical measurement signal [, preferably a medical measurement signal, such as] in pulsoximetry, said method comprising the steps of: (a) determining factors relevant to the [measuring] measurement signal, [preferably] the factors relating to [the] combinations selected from the group consisting of signal recording, signal processing, [and/or] and signal evaluation; and [, and] (b) interlinking the factors [thus determined] by means of an uncertain logic,[preferably] including fuzzy logic, into a quality indicator [which] wherein the quality indicator quantitatively describes [the] a quality of [the] a determined measurement value of the measurement signal.[515]

In amending claim 1, the applicant provided the following arguments to the examiner regarding why the claim was allowable over Bosque:

> Claims 1-12 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent 5,830,135 to Bosque, et. al.
>
> The PTO provides in MPEP § 2131 that "*to anticipate a claim, the reference must teach every element of the claim . . . .*"
>
> Therefore, with respect to claim 1, to sustain this rejection the Bosque patent must contain all of the above claimed elements of claim 1. However, contrary to the examiner's position that all elements are disclosed in the Bosque reference, the latter reference does not disclose a method including the step of determining factors relevant to a measurement signal, the factors relating to combinations selected from the group consisting of *signal recording*, *signal processing*, *and* *signal evaluation*. In contrast, Bosque discloses a pulse oximeter alarm system

[514] D.I. 416, Ex. 2 at MASP0022486.

[515] *Id.* at 2 at MASP0022595. Language added to the amendment is underlined, while deleted language is bracketed.

> based on fuzzy logic that simply differentiates between false alarms, caused by artifacts, from true alarms. Bosque further differs in that it only teaches using separate fuzzy sets of oxygen saturation, rate of change of oxygen saturation, and artifact.[516]

Because Bosque undisputedly relates to fuzzy logic, Philips maintains "the presence of fuzzy logic could not have been the basis on which the applicants' distinguished Bosque."[517]

In determining the scope of estoppel, the "court must look to the specifics of the amendment and the rejection that provoked the amendment to determine whether estoppel precludes the particular doctrine of equivalents argument being made."[518] As evidenced by the prosecution history, the applicant did not distinguish amended claim 1 of the '074 patent from Bosque by the reference of fuzzy logic in the claim.

Contrary to Masimo's argument that claim 1 was narrowed by only changing the claim from *preferrably* fuzzy logic to *including* fuzzy logic, a reading of the amendment as a whole demonstrates other modifications were made to the claim narrowing its scope. For instance, the preamble was changed from being directed to "a method of determining a quantitative statement concerning the quality of a measurement signal, preferably a medical measurement signal such as pulsoximetry" to limit the claim to be directed at "a method of determining a quantitative statement concerning the quality of a *medical* measurement signal *in pulsoximetry*." Thus, the amended claim only applies to medical measurements in pulse oximetry. Further, claim 1(a) originally provided the steps of "determining factors relevant to the measuring signal, preferably relating to the

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[516] D.I. 527, Ex. 134B at ¶ 49 (emphasis in original); D.I. 416, Ex. 2 at MASP0022600-01 (emphasis in original).

[517] D.I. 523 at 15.

[518] *Intervet Inc. v. Merial Limited*, 617 F.3d 1282, 1291 (Fed. Cir. 2010).

signal recording, signal processing and/or signal evaluation." It now requires steps of "determining factors relevant to the *measurement* signal, *the factors* relating to *combinations selected from the group consisting of* signal recording, signal processing, *and* signal evaluation." Therefore, in the amended claim, the factors must relate from a group that includes signal processing, signal recording *and* signal evaluation; whereas prior to the amendment, the "and/or" indicated all three of those elements were not required. As a result, the preamble and claim 1(a) were narrowed.

In contrast, claim 1(b) did not only require "uncertain logic." Rather, the original claim provided "uncertain logic, *preferably* fuzzy logic,[519] while the amended claim now reads "uncertain logic, *including* fuzzy logic.[520] Therefore, Masimo's motion that prosecution history estoppel prevents the application of the doctrine of equivalents is denied.

2. Encompassing Prior Art

Masimo contends application of the doctrine of equivalents to expand claims 1 and 5 as covering Signal IQ would encompass subject matter existing in the prior art, specifically the Nellcor 400 ("N-400") device. In support, Masimo compares its Signal IQ device with the N-400, noting that both pulse oximeters contain a quality indicator, which is quantitative.[521] According to Masimo, both devices use math and conventional logic to calculate a quality indicator, with the N-400 combining up to 27 variables that

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[519] Preferably means more desirable; like better. *Random House Webster's College Dictionary* 2d Ed. 1997.

[520] Include or including means to contain as a part or member of a whole. *Random House Webster's College Dictionary* 2d Ed. 1997.

[521] D.I. 415 at 14-16, referencing D.I. 419 (Melek Decl.) at ¶¶ 67-68. The N-500 was scaled to a value between 0-100. *Id.* at ¶ 75.

relate to the quality of the signal.[522] By calculating these variables, a quantitative, multi-parameter confidence indicator of signal quality is displayed.[523] According to Dr. Melek, the equations of the N-400 are similar to and more complex than those calculations (scaling equations) accused by Philips in the Signal IQ algorithm as fuzzy logic.[524] Dr. Melek compares from the Signal IQ what he describes as scaling equations, and what Philips asserts is fuzzy logic, to the N-400 equations, and concludes the calculations of signal quality are indistinguishable.[525] Because Dr. Turner agrees the N-400 satisfies every limitation of claim 1, except for fuzzy logic,[526] and the calculations of the Masimo and Nellcor devices are identical, Masimo argues Philips cannot maintain Masimo's Signal IQ calculations are fuzzy logic without covering the N-400.[527]

Philips counters that application of the doctrine of equivalents does not expand the scope of claim 1 and dependent claim 5 to cover prior art because the differences between Masimo's code and claim 1 are insubstantial, in that, like the '074 patent, the Signal IQ algorithm uses various factors derived from stages of processing of the signal to derive its statement of signal quality.[528] Philips criticizes Masimo's analysis as pure abstract because it merely extracted two mathematical equations–one from the N-400 and another from Signal IQ–absent any context. Using Masimo's example $SignalQuality = \frac{SignalQuality+50}{100}$, Philips argues the equation just adjusts the

[522] D.I. 416, Ex. 14 (N-400 Software Spec.) at COV 1743; D.I. 419 at ¶ 71.
[523] *Id.*, Ex. 12 (N-400 1993 Manual) at COV 1018; D.I. 419 at ¶¶ 66-67, 71-75.
[524] D.I. 419 at ¶¶ 75-76.
[525] *Id.* at ¶¶ 61, 75-76.
[526] D.I. 416, Ex. 3 at 283:3-6.
[527] D.I. 419 at ¶¶ 61, 75-76.
[528] D.I. 527, Ex. 134A at ¶¶ 108-110.

SignalQuality variable because the "input is SignalQuality and the output is SignalQuality," making the equation merely a mathematical equation not related to the same functions as the graphs drawn by Dr. Melek during his deposition.[529]

Masimo suggests this distinguishment by Philips to be pure attorney argument. Before its analysis, Philips, however, referenced Dr. Turner's deposition wherein he explains why the N-400, as compared to Masimo's SignalQuality IQ and the '074 patent, does not use either uncertain or fuzzy logic by comparing variables to threshold logic. In N-400, the result of that comparison leads to a "definitive adding up of points or branching," rather that "a definition of a membership in a partial set," because the former is used to produce the eventual outcome in a logical tree and does not implement fuzzy operators in the decision process. As noted by Dr. Turner, unlike Masimo's algorithm and the '074 patent, the N-400 uses a conventional mathematical branching software; Masimo's implementation, like the '074 patent, of the RawConf values, occurs in a manner in which "they are adjusted for set membership, the way in which they are interlinked, constitutes fuzzy logic."[530] Thus, as Philips counters, the Signal Quality equation in N-400 on which Masimo's drawing relies "does not relate a *signal factor* (like fTDdensity or fHarmMagRatio) to a variable representing the degree of confidence in the measurement value."[531]

As previously discussed under the infringement analysis, the parties disagree, for example, regarding whether conventional logic implements fuzzy logic, whether the

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[529] D.I. 523 at 16.

[530] D.I. 416, Ex. 3 at 276:8-286:16.

[531] *Compare* D.I. 523 at 16 (equation analysis) to D.I. 589 at 6 (N-400 graph showing Signal Quality as both measurements, while the graph of Masimo's Signal IQ shows fRawConf and fTDDensity, which Philips maintains are signal factors and part of fuzzy logic) (emphasis added).

graphs relied on by Philips comparing Masimo's code to examples of fuzzy logic in the Bosque patent and the Altrock text means SignalQuality IQ uses fuzzy logic, and whether fTDDensity, fHarmMagRatio, fEquivalentWidth, fRawConf are fuzzy sets or partial membership sets, rather than precise calculations involving a binary analysis, such as a scaling function, which uses conventional math, has no uncertainty, no shades of gray, no maybes and no determination that a pulse reading is partially good to a degree. These and other disagreements regarding the application and implementation of fuzzy logic, as well as the analysis herein, raise genuine issues not amenable to summary judgment.

C. Validity of the '074 Patent

Masimo argues claims 1 and 5 of the '074 patent are anticipated by the Bosque patent because the inventor developed her system in the early 1990's and published a Dissertation in November 1993, which was more than one year before the '074 patent application filed on June 10, 1999, and Bosque describes each and every step of the claimed methods.[532]

During prosecution, the PTO rejected Philips' application finding claims 1 through 12 as anticipated by the Bosque patent.[533] In response, Philips amended its patent application, including claim 1.[534]

The parties agree the Bosque patent uses fuzzy logic; rather their dispute focuses on *how* Bosque and the '074 patent apply and implement fuzzy logic.

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[532] D.I. 415 at 16-17.
[533] D.I. 416, Ex. 2 at MASP0022588.
[534] D.I. 589 at 4. *See* at 105 of this opinion for the original and amended claim 1.

Masimo contends the amended language covers Bosque, because the claim language teaches combinations of fuzzy sets required to implement the method disclosed in the '074 patent,[535] which are relevant to the measurement signal, and the Bosque patent teaches this method.[536]

Philips argues fuzzy logic, as applied in Bosque, is used "to analyze previously saved oxygen saturation values - not factors relevant to the measurement signal,"[537] that is, the values analyzed using fuzzy logic in the Bosque patent are not "factors relating to combinations selected from the group consisting of signal recording, signal processing, and signal evaluation,"[538] and those elements are not interlinked to "a quality indicator." Thus, the Bosque system as described in the Bosque patent "does not determine a quantitative statement concerning the quality of a medical measurement signal in pulsoximetry."[539] According to Dr. Turner, the "Bosque system determines whether or not certain thresholds are met to trigger varying audible alarm conditions."[540] Therefore, under Philip's analysis, Bosque does not teach the same method as the '074 patent.

Masimo contends Philips' argument during prosecution for allowance of the '074 patent over Bosque was limited to only claim 1's requirement of "combinations of

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[535] D.I. 589 at 7-8.

[536] *Id*. Masimo also criticizes Philips' citation practice, claiming it merely reaches a conclusion without support. D.I. 589 at 8 (criticizing Philips conclusion at D.I. 523 at 19). A review, however, of Philips' answering brief shows that before a conclusion, it referenced materials which support its conclusion (*See* D.I. 523 at 18-19 (citing Turner Valid. Rpt., at Appx. A and the Bosque Dissertation which explains the Bosque system of the '135 patent)).

[537] D.I. 523 at 19-20.

[538] *Id*. at 20.

[539] D.I. 416, Ex. 5 (Turner Valid. Rpt.) at Appx. A at 1, Appx. D. at 1. Masimo referenced these appendices in its arguments. D.I. 415 at 17.

[540] *Id.*

factors" while Bosque used "separate fuzzy sets." Despite Masimo's paraphrase, the actual argument reads:

> However, contrary to the examiner's position that all elements are disclosed in the Bosque reference, the latter reference does not disclose a method including the step of determining factors relevant to a measurement signal, the factors relating to combinations selected from the group consisting of *signal recording*, *signal processing*, *and* *signal evaluation*. In contrast, *Bosque discloses* a pulse oximeter alarm system based on fuzzy logic that simply differentiates between false alarms, caused by artifacts, from true alarms. Bosque further differs in that it only teaches using *separate fuzzy sets of oxygen saturation, rate of change of oxygen saturation, and artifact.*[541]

Masimo ignores the response that the claimed method determines "factors relevant to the measurement signal, the factors relating to combinations selected from the group consisting of signal recording, signal processing and signal evaluation."

As opined by Dr. Turner, the Bosque system, as described in both the Bosque Dissertation and the Bosque patent, "uses previously calculated saturations values from a pulse oximeter [which does not employ fuzzy logic for calculating SpO2, a measurement signal or value] and then transmits and saves these values to a file . . . for further analysis by the fuzzy logic program."[542] Thus, because Bosque starts with the measurement value SPO2, which is the final value and not a factor relevant to the measurement signal, Bosque cannot teach "using factors relevant to the measurement signal that relate to the signal recording, signal processing, or signal evaluation" nor "teach determining or combining the underlying signal factors relevant to the measurement signal (e.g. SPO2) during the course of patient monitoring."[543]

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[541] D.I. 527, Ex. 134B at ¶ 49 (emphasis in original) (emphasis added); D.I. 416, Ex. 2 at MASP0022600-01 (emphasis in original) (emphasis added).

[542] D.I. 416, Ex. 5, Appx. A at 1-2, Appx. D at 1-2.

[543] *Id.*

Dr. Melek opines Bosque uses combinations of fuzzy sets, determines factors relevant to the measurement signal, uses combinations of the recited factors in the claim, and points to Bosque's RATE and DESAT fuzzy sets as factors relating to signal processing and oldARTIFACT fuzzy set as a factor relating to signal evaluation.[544] Dr. Turner disagrees these variables are signal factors relevant to the measurement signal; rather they are derived from the final SPO2 value, that is the measurement signal, and not related to signal recording, signal processing or signal evaluation.[545]

Masimo criticizes Dr. Turner's use of the word "intermediate factors" or "intermediate data" as misapplying the language of claim 1, and thereby fails to show a genuine issue of material fact.[546] Rather, the full colloquy cited by Philips reads:

> Q. And what is your basis for that? (which follows a series of questions related to why the requirements of the '074 patent are not invalidated by the Bosque system, the Bosque Dissertation and the Bosque patent–referenced as the Bosque prior art).[547]
>
> A. Because the–Bosque–or the Bosque patent was in front of the patent examiner and was determined that the '074 patent, but requiring intermediate data from the processing, was distinctly different from a scenario where you use the *final values of the measurement signal*, the measurement value. In this case being the saturation values, the oxygen saturations values [SpO2] from an existing oximeter. The patent office determined that–that '074 was differentiated from that prior art.[548]

Regarding Dr. Turner's invalidity report, he clearly differentiated why starting with the ultimate SpO2 measurement value, which is not a factor relevant to the measurement signal, as the Bosque patent does, did not teach "determining or

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[544] D.I. 419 at ¶¶ 81-85.
[545] D.I. 416, Ex. 5 at Appx. A at 2, Appx. D. at 2.
[546] D.I. 589 at 8-9.
[547] *See* D.I. 416, Ex. 3 at 292:8-295:4.
[548] *Id*. at 295:5-16 (emphasis added).

combining the underlying signal factors relevant to the measurement value."[549] Unlike the '074 patent, the Bosque patent and its system or method begin with the final value (SpO2), the analysis of which does not involve fuzzy logic, and "then feeds that final value into the fuzzy logic program for further analysis."[550]

When Dr. Turner's opinion is reviewed as a whole, rather than picking out phrases in isolation, it does demonstrate a genuine issue of how fuzzy logic is used in the methods of each patent.

Masimo, by again selecting a comment by Dr. Turner in isolation on the issue of quality indicator, claims the comment is equivocal and insufficient to create a genuine issue of material fact.[551] Masimo also argues Philips and Dr. Turner fail to respond to Dr. Melek's conclusion that the Bosque patent includes a "quality indicator that quantitatively describes a quality of a determined measurement value of the measurement signal."[552] The relevant section of Dr. Turner's opinion in its entirety provides:

> Further, Dr. Melek has not shown that the Bosque system discloses a quantitative quality indicator; rather, Dr. Melek points to the "ARTIFACT" variable and *concludes that is a quality indicator* even though it appears to merely decide whether an artifact is present, and if so, to trigger the audible alarm and display a color indicator of saturation status (Ex. 53, Melek Report, at pages 43-44). Acknowledging again that the Bosque system does not include factors, Dr. Melek has not shown how any measurement signal factors contributing to the "ARTIFACT" variable are combined, determined, or interlinked at all let alone by means of fuzzy logic. In addition, the Bosque system does not generate a quantitative

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[549] D.I. 416, Ex. 5 at Appx. A at 1-2 (under analysis of claim 1(a) of the '074 patent). *See also*, D.I. 4126, Ex.5 at Appx. D at 1-2.

[550] *Id.*

[551] D.I. 589 at 9 (specifically the language cited by Masimo is "***appears*** to merely decide whether artifact is present" (emphasis in original)).

[552] *Id.* at 10.

quality indicator which is a quantitative description of the quality of the SpO2 value.[553]

Further, as discussed previously, Dr. Turner does address the variables discussed by Dr. Melek in the Basque Dissertation, and disagrees with his analysis.[554] Therefore, contrary to Masimo's suggestion, a genuine issue of material fact remains whether the Bosque patent invalidates the '074 patent.

Claim 5

As previously noted, claim 5 is dependent on claim 1 and reads:

The method as claimed in claim 1, further comprising:

controlling an alarm function in dependence on the quality indicator in response to the measurement signal deviating from at least one of a given limit value and range.[555]

Because summary judgment is denied for independent claim 1, and claim 5 is dependent of claim 1, summary judgment is necessarily inappropriate as to claim 5.

5. Philips' Motion for Summary Judgment of Invalidity of U.S. Patent No. 6,669,194;[556]

Masimo contends Philips infringes claims 1-6, 8, 10-12, and 14-22 of the '194 patent.[557] Philips filed counterclaims for non-infringement, invalidity, and unenforceability of the claims of the '194 patent. Philips contends the asserted claims of the '194 patent are invalid for failure to meet the written description requirement, lack

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[553] D.I. 416, Ex. 5 at Appx. A at 2 (under analysis of claim 1(b) of the '074 patent) (emphasis added).

[554] *Compare* Turner Valid. Rpt. at D.I. 416, Ex. 5 at Appx. A, referencing Melek Inv. Rpt. at 42-44 and Bosque Dissertation at MASP0547111-119 and MASP0547173-178 with D.I. 589 at 10, referencing Melek Inv. Rpt at 44, citing Bosque Dissertation at MASP0547174.

[555] D.I. 416, Ex. 1.

[556] D.I. 406.

[557] Claims 1, 3-5, 8, 10, and 14-17 are independent claims.

of enablement, and/or anticipation by European Patent No. 0645117A ("EP '117").[558]

The '194 Patent (Masimo Patent)

In describing the "Field of the Invention," the '194 patent recites:

> The present invention relates to the field of signal processing. More specifically, the present invention relates to the processing of measured signals, containing a primary signal portion and a secondary signal portion, for the removal or derivation of either the primary or secondary signal portion when little is known about either of these components. The present invention is especially useful for physiological monitoring systems including blood oxygen saturation systems and pulserate measurement systems. The present invention further relates to a method and apparatus for signal processing of signals in order to compute an estimate for pulserate.[559]

Parties' Positions[560]

Philips contends the asserted claims of the '194 patent are invalid for failure to meet the written description requirement, lack of enablement, and/or anticipation .[561]

According to Philips, the '194 patent describes a specific three-step process to estimate pulse rate: 1) ensure the spectrum is clean by scrubbing any noise out of the signal, if present; 2) classify the clean spectrum into one of five categories; and 3) estimate the pulse rate from the classified clean spectrum.[562] Philips contends the asserted claims are much broader, giving as an example, the lack of a requirement that the signal be scrubbed, and instead covering classification of a spectrum that is clean *or* unclean.[563] Philips maintains Masimo did not invent or disclose any method of

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[558] D.I. 406.
[559] '194 patent, 1:11-22.
[560] The briefs addressing Philips' motion of invalidity (D.I. 406) are found at: D.I. 407 (Philips' opening brief), D.I. 506 (Masimo's answering brief), and D.I. 594 (Philips' reply brief).
[561] D.I. 407 at 1.
[562] *Id.* at 1.
[563] *Id.* at 1-2.

estimating pulse rate from an unclean spectrum and that the inventor admits as much.[564] For this reason, Philips contends the asserted claims invalid for failure to meet the written description requirement.

Philips also contends at deposition of one of the named inventors of the '194 patent, Rex McCarthy admitted "he would have to conduct extensive experiments to determine whether and how to change the disclosed algorithm to work on unclean spectral data," therefore, the specification of the '194 patent does not enable asserted claims and they are invalid for that reason as well.[565]

Philips notes claims 11, 14, and 16 also recite estimating the pulse rate by using a center of mass calculation.[566] Philips states the specification contains no disclosure of estimating pulse rate using a center of mass; such calculation is described only as part of the scrubbing operation.[567] Philips concludes those claims are invalid as lacking written description as well.

Finally, Philips argues some claims are so broad that they are anticipated by EP '117 as that reference purportedly discloses on its face all elements of many of the asserted claims.[568]

Masimo disputes the assertion that the '194 patent does not disclose any method of estimating pulse rate from an "unclean" spectrum.[569] It maintains the rules-based method of the '194 patent may work without any scrubbing and that even when

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[564] *Id.* at 2.
[565] *Id.* at 13.
[566] *Id.* at 2.
[567] *Id.* at 2.
[568] *Id.* at 2. Philips has not moved for summary judgment of anticipation on claims 11, 14, and 16 which each include a "center of mass" limitation.
[569] D.I. 506 at 1.

scrubbing is applied, the '194 patent teaches the scrubbing just provides a waveform with a better signal-to-noise ration.[570] Masimo contends in all of these embodiments, noise due to motion artifact is never entirely removed.[571] Masimo argues, therefore, the '194 patent discloses classifying/sorting both scrubbed and unscrubbed spectral data in order to estimate a pulse rate.[572]

Masimo states Philips' enablement argument relies on a single excerpt from the deposition testimony of a Masimo inventor about hypothetical changes to his development work to support its argument it would take undue experimentation to classify an "unclean spectrum."[573] Masimo argues that testimony does not change the '194 patent's actual disclosure of classifying/sorting both scrubbed and unscrubbed spectral data.[574] Masimo also alleges the inventor testified that, during development, many "combinations of things were evaluated" and confirmed the '194 patent discloses a rules-based method without scrubbing.[575] Consequently, Masimo maintains Philips has not carried its burden on the issue of undue experimentation to prevail on its enablement argument.[576]

Masimo also contends Philips' written description argument directed at the claims reciting the "center of mass" limitation also lacks merit as the '194 patent purportedly discloses use of a center-of-mass calculation for estimating a pulse rate.[577]

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[570] *Id.*
[571] *Id.*
[572] *Id.*
[573] *Id.* 1.
[574] *Id.* at 1-2.
[575] *Id.* at 2.
[576] *Id.*
[577] *Id.*

Finally, Masimo insists EP ‘117 does not anticipate any of the claims of the ‘194 patent as EP ‘117 allegedly does not provide any disclosure of the inventions of the ‘194 patent, i.e., classifying/sorting of fundamental frequency and harmonic frequency peaks to estimate pulse rate.[578] Specifically, EP ‘117 purportedly does not teach classifying or sorting spectral data into a fundamental and one or more harmonics of the fundamental (claims 1-6, 8, 10, 12), classifying spectral data based on ratios (claims 4-6, 10, 12, 17-22), estimating pulse rate from the fundamental and one or more harmonics of the fundamental/additional spectral peaks (claims 1, 2, 8, 10, 12, 17-22), identifying then classifying or sorting three or more spectral peaks (claims 1-3), classifying spectral lines corresponding to a fundamental and two or more harmonics of the fundamental (claim 8), selecting a portion of the spectral data based on one or more rules (claim 15), confidence factors (claims 12, 18), and one or more rules comparing relative magnitudes of one or more spectral peaks (claims 2, 20).[579]

Because Philips can not demonstrate by clear and convincing evidence that each and every limitation of the allegedly anticipated claims is disclosed by EP ‘117, Masimo urges the court to deny summary judgment of anticipation.[580]

A. Written Description and Enablement

Philips correctly notes, although the written description and enablement requirements arise from the first paragraph on. 35 U.S.C. § 112, each is a separate and

[578] *Id.*
[579] *Id.* at 2-3.
[580] *Id.* 3.

distinct requirement for patentability.[581] Masimo points out, however, Philips' argument co-mingles the two requirements.[582] As did Masimo, the court separately addresses these distinct requirements.

1. Unclean Spectrum

Philips maintains although the asserted claims encompass classifying, sorting, or selecting both clean and unclean spectral data to estimate a pulse rate, the '194 patent does not disclose or enable classifying, sorting, or selecting *unclean* spectral data.[583] Philips argues the asserted claims are invalid for failure to meet the written description requirement because the specification does not disclose any method of estimating pulse rate from an unclean spectrum.[584] Its lack of enablement argument rests on inventor testimony purportedly admitting that undue experimentation would be required to use the claimed invention on an unclean signal.[585]

With regard to its written description argument, Philips maintains the claims of the '194 patent broadly cover classifying both clean and unclean spectral data, but the specification only discloses classifying clean spectral data.[586] It contends the specification emphasizes the importance of obtaining a clean spectrum and describes the removal of motion artifacts from the signal prior to estimating the pulse rate.[587]

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[581] *See Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*) ("Since its inception, this court has consistently held that § 112, first paragraph, contains a written description requirement separate from enablement . . . .").

[582] D.I. 506 at 5 n.4.

[583] D.I. 407 at 9.

[584] *Id.* at 2.

[585] *Id.* at 11.

[586] *Id.* at 9 (citing D.I. 429, Ex. 14A (Stone Inv. Rpt) at ¶ 405) (Dr. Stone opines "[t]he '195 Patent does not disclose the determination of the pulse rate in a spectrum that has not been 'scrubbed' of noise. Nor does it disclose the application of the 'Rule Based Pulserate Detection' to a spectrum that has not been 'scrubbed' of noise.")).

[587] *Id.* at 9.

Philips points to the specification's statement that "'[i]dentification and removal of . . . motion artifacts is often a *prerequisite* to any signal processing used to obtain blood oxygen saturation, pulserate, or other physiological data.'"[588] Philips states figure 12 illustrates the detected signal being subjected to a scrubbing operation to remove those artifacts.[589] According to Philips, the only input to the rules based method is described as the "scrubbed spectrum."[590] Next, a set of specific rules is applied to classify the spectrum and estimate the pulse rate.[591]

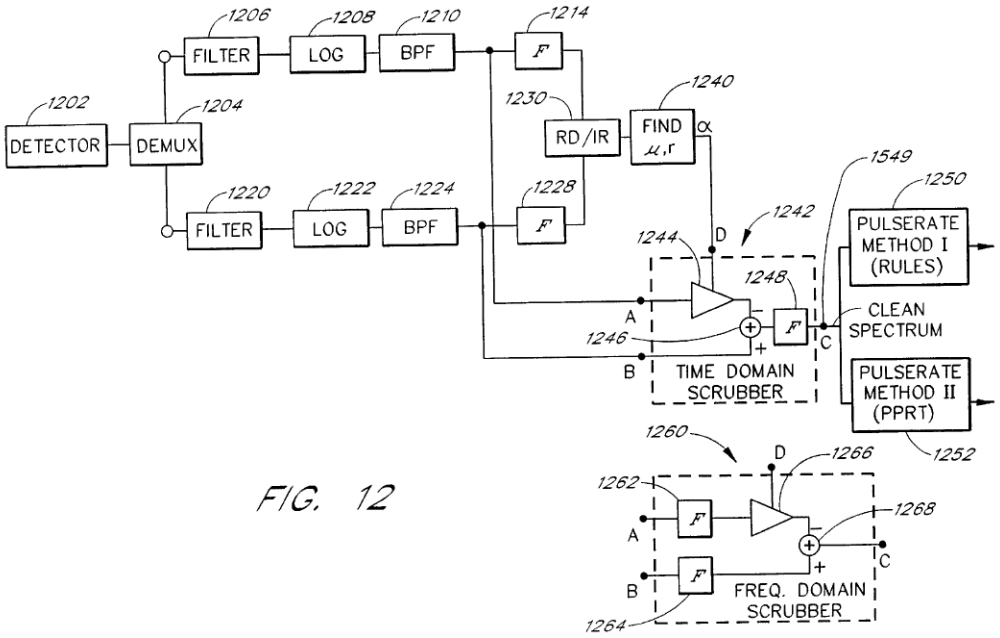

FIG. 12

[588] *Id.* at 9 (quoting '194 patent, 12:26-29 (emphasis added by Philips)).

[589] *Id.* at 10 (citing '194 patent, 15:39-42 ("FIG. 12 shows a block diagram of a signal processing system that implements the motion detection and spectrum scrubbing operations in accordance with one aspect of the present invention.")).

[590] *Id.* at 10 (citing '194 patent, 17:16-19 ("[T]he scrubbed spectrum present at the terminal 1250 in FIG. 12 contains some of the information that would be found in the Fourier spectrum of an electrocardiograph (EKG).")).

[591] *Id.* at 10 (citing '194 patent at 19:5-16 and D.I. 429, Ex. 14A (Stone Inv. Rpt.) at ¶¶ 404-05).

Philips points out that figure 12 shows the output of the scrubber, and the input to the rules-based pulse rate method, is a "CLEAN SPECTRUM."[592]

Additionally, Philips contends the following testimony by McCarthy is an admission that the patent does not disclose providing to the rules based method an unclean spectrum, and that it does not provide any description of how to classify an unclean spectrum.

> Q. All right. And there's no input to the rules-based algorithm in Figure 12 other than a clean spectrum; correct?
>
> A: That's correct.
>
> Q. And there's no description in Columns 17 to 20 . . . that suggest feeding the rules-based algorithm anything other than a clean spectrum; correct?
>
> A. Correct.[593]

Philips also alleges McCarthy admitted the specification only describes, and Masimo only invented, rules that would classify a clean spectrum:

> Q. Mr. McCarthy, you talked about the fact earlier that the rules set forth in Figure 18 in this patent are disclosed to operate on a signal that has been scrubbed of noise; right?
>
> A. Yes.
>
> Q. Did you develop with Mr. Diab any set of rules that were intended to operate on a signal that had not been scrubbed of noise and still yield the correct pulse rate?

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[592] *Id.* at 10 (citing '194 patent, 16:27-35 ("Regardless of whether the time domain scrubber 1242 or the frequency domain scrubber 1260 is used, the scrubber output C is a plethysmographic waveform in the frequency domain at terminal 1249. Ideally, the waveform at terminal 1249 is cleaner (e.g., has a better signal to noise ratio) than the waveform at either scrubber input A or scrubber input B. The waveform at terminal 1249 can be displayed on a display (not shown) or sent to a rule based pulserate detector 1250 and/or a transform based pulserate detector.")).

[593] D.I. 407 at 10 (quoting D.I. 433, Ex. 44 (McCarthy Depo.) at 230:13-20).

A. I don't recall doing that, no.[594]

Finally, McCarthy purportedly admitted he did not know if the disclosed rules could be used to classify an unclean spectrum because that is not what he invented:

> Q. Okay. Now, my question is this: Would the rules be as effective if the signal was not subjected to the scrubber?
>
> A. Yeah, I would have to run the experiment. I don't know off the top of my head what its performance would be.[595]

Based on those alleged admissions, Philips argues there is no dispute that the inventors did not invent or disclose a method to classify an unclean spectrum.[596]

Masimo maintains the '194 patent discloses estimating pulse rate from an unscrubbed signal; the named inventors testified they did develop techniques to classify and apply rules to unclean data; and Dr. Baura opines the specification is adequate to convey Masimo's possession of the claimed invention.[597]

Masimo states the '194 patent discloses a preferred embodiment that "disables the scrubber" for data that does not meet a threshold value.[598] It also points to other descriptions of situations where "no scrubbing is necessary."[599] The patent teaches this

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[594] *Id.* (quoting D.I. 433, Ex. 44 at 254:9-18).

[595] *Id.* at 10-11 (quoting D.I. 433, Ex. 44 at 276:22-277:7). Masimo's counsel objected to this question as calling for speculation.

[596] *Id.* at 11.

[597] D.I. 506 at 5-10.

[598] *Id.* (citing '194 patent, 16:52-55 ("In a preferred embodiment, the threshold value is 0.5. In the process block 1310, the value of α is set to 0, which essentially disables the scrubber.")).

[599] *Id.* (citing '194 patent, 16:49-50 ("[I]f in the process block 1308, the delta d is less than the threshold value, then no scrubbing is necessary and the process advances to a process block 1310."); '194 patent, 3:43-47 ("The need for waveform scrubbing can be determined by comparing the largest ratio line to the smallest ration line. If the difference does not exceed a threshold value, the[n] no scrubbing is needed."); '194 patent, 15:18-27 (describing an embodiment where certain ratios whether motion artifacts are present and, if so, "the spectrum must be scrubbed . . . ."); '194 patent, 15:28-38 (describing a preferred embodiment where determination of whether a threshold value has been crossed determines whether scrubbing is required); D.I. 508 (Baura Decl.) at ¶ 8 (Baura opining, in reliance of the previously cited portions of the specification, that "the '194 patent discloses embodiments where the signal is not scrubbed.")).

unscrubbed data is then classified or sorted in order to estimate pulse rate.[600]

Masimo also notes Philips' acknowledgment that the '194 patent discloses classifying a scrubbed signal, but accuses Philips of ignoring that the scrubbed signal is not "clean."[601] Masimo states the '194 patent teaches the waveform scrubber merely provides a better signal-to-noise ratio before classifying and estimating pulse rate.[602] According to Dr. Baura, one of skill in the art understands that because pulse oximetry signals always include some level of noise, due to motion or other sources, those signals are neither clean nor unclean.[603] Philips concludes, therefore, the '194 patent discloses estimating pulse rate date from classifying unscrubbed data, or scrubbed data that has some level of noise.[604]

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[600] *Id.* (citing '194 patent, 16:36-20:42; Figs. 12 and 13).

[601] *Id.* at 7.

[602] *Id.* (citing '194 patent, 16:30-32 ("Ideally, the waveform at terminal 1249 is cleaner (e.g., has a better signal to noise ratio) than the waveform at either scrubber input A or scrubber input B.").

[603] D.I. 508 (Baura Decl.) at ¶ 6 ("Persons of ordinary skill in the art understand that pulse oximetry signals are not either clean or unclean. All signals contain varying amounts of noise due to patient movement or other sources. Describing a signal as clean or unclean is understood to be a rough approximation of the amount of noise in the signal, commonly referred to as the signal-to-noise ratio. Even 'clean' signals will have some level of noise present."); *see also* D.I. 507, Ex. 3 at 276:3-8 (McCarthy responded to the question "what would you have to do to determine whether this would work well on a spectrum that hadn't been cleaned" by stating "[y]ou're speaking cleaned as if [the spectrum is] binary cleaned or uncleaned, and it's not."); *id.*, Ex. 2 (Diab Depo.) at 211:6-212:2 (Diab testified that he must have performed analysis to determine whether the rules would work in the presence of motion "because that's part of the analysis of the algorithm. . . . [W]hen we developed the algorithm we subjected [it] to a lot of test data that we collected in the field. And part of that testing would require looking at those conditions. Another issue might be that when you determine whether there is a motion or no motion, you may be ambiguous right there. And there might be cases where you think there is no motion, and it is motion, and it has to be subjected to these rules. So probably part of the analysis involved that, although I don't have a clear recollection of that."); *id.* 2 at 212:20-:214:6 (Diab testified "although you try to get the reduction in the motion, you don't completely remove the motion. What you do, you reduce the magnitude of the motion. . . . [W]hen we suspected that there is motion in the data, we attempted to reduce that effect of the motion, and then provided it to the rules. But there is no question that that cannot be done hundred percent. And what you end up with is a spectrum that has reduced motion, but it is not gone completely, and therefore, for these rules to work, they have to work under that condition as well, when there is still some motion present."); *id.*, Ex. 3 at 230:6-9 (Q. "And, in fact, the input to the rules-based method that you and [Diab] invented was a spectrum that had been cleaned of motion artifact; correct? [McCarthy] A. to some extent, yes.").

[604] D.I. 506 at 7.

With regard to the inventor testimony cited by Philips, Masimo states the issue is what is disclosed in the '194 patent, not what Masimo reduced to practice.[605] Masimo contends, however, that Diab testified techniques were developed to classify and apply rules to unclean data,[606] and McCarthy likewise testified the input to the rules-based method that was invented, had been cleaned of motion artifacts "[t]o some extent."[607]

Masimo also characterizes McCarthy's testimony that he did not recall having developed with Diab any set of rules that were intended to operate on a signal that had not been scrubbed of noise, and still yield the correct pulse rate, as vague recollections of his development work occurring many years earlier.[608] Masimo emphasizes that McCarthy's testimony does not alter what is disclosed in the '194 patent.[609]

In response to Philips' argument that Dr. Baura has not adequately supported her opinion that the '194 patent discloses classifying an unclean signal, Masimo states she cited the specification where it discusses conditions "when no scrubbing is necessary."[610] Masimo disputes Philips' contention that Dr. Baura's citation is insufficient because the scrubber is "disabled only when no noise is present, i.e., when the signal is already clean.'"[611] Masimo maintains that is not what the patent says, rather, the patent states no scrubbing is necessary if "the delta d is less than the threshold value," not that the signal is "already clean" because there is "no noise."[612]

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[605] *Id.*

[606] *Id.* at 7-8 (citing D.I. 507, Ex. 2 at 210:8-19, 210:20-212:2 (Diab describing developing rules that could identify peaks when it was possible there was motion present), 212:20-214:6 (see description of testimony, above)).

[607] *Id.* at 8 (citing D.I. 507, Ex. 3 at 230:6-9).

[608] *Id.* at 8.

[609] *Id.*

[610] *Id.* (citing D.I. 431, Ex. 23 at ¶ 342 (citing '194 patent at 16:50-55)).

[611] *Id.* (quoting D.I. 407 at 11).

[612] *Id.* (citing '194 patent, 16:45-51.

According to Masimo, this disclosure does not "emphasize[ ] the importance of having a clean spectrum" as Philips alleges.[613]

Masimo does not contest Philips' assertion that the asserted claims cover classifying, sorting, or selecting both clean and unclean spectral data to estimate a pulse rate. Indeed, it argues the patent does disclose such actions. The court, however, determines the specification does not disclose classifying, sorting or selecting unclean spectral data, i.e., spectral data containing motion artifacts. The patent states "[p]atient movement introduces motion artifacts to the composite signal as illustrated in the plethysmographic waveform illustrated in FIG. 2B. These motion artifacts distort the measured signal."[614] Contrary to Masimo's assertion, the patent does emphasize the necessity that motion artifacts be removed from the signal:

> Persons skilled in the art know that the data obtained during, pulse oximetry measurements using red and infrared light art often contaminated due to motion. Identification and removal of these motion artifacts is often a prerequisite to any signal processing used to obtain blood oxygen saturation, pulserate, or other physiological data.[615]

Masimo argues the specification discloses estimating pulse rate from classifying clean spectra based on its contention that no signal is ever completely "clean," e.g., that all signals have some level of noise. In support, it notes the scrubber produces a signal that "has a better signal to noise ratio."[616]

As the patent makes clear, the identification and removal of motion artifacts is necessary to practice the claimed inventions. For instance, the specification recites:

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[613] *Id.* at 8-9.
[614] '194 patent, 3:6-9.
[615] *Id.*, 12:24-29.
[616] *Id.*, 16:30-32.

> The need for waveform scrubbing can be determined by comparing the largest ratio line to the smallest ratio line. If the difference *does not* exceed a threshold value, then no scrubbing is needed. If the difference *does* exceed a threshold value, then the waveform *must be scrubbed*, and the scrubbing coefficient corresponds to the magnitude of the largest ratio line.[617]

The patent reiterates the "threshold value" indicates whether motion artifacts are present that must be removed from the signal:

> If, in the decision block 1308, the delta d is *greater than* a threshold value, *then motion artifacts are present* and the process advances to a decision block 1312 to continue the calculation of α. Otherwise, if in the process block 1308, the delta d is *less than* the threshold value, then *no scrubbing is necessary* and the process advances to a process block 1310.[618]

The specification does not disclose, and no evidence of record suggests, estimating a pulse rate where the algorithm determines motion artifacts are present, i.e., when the threshold value is exceeded. Masimo's assertion that the patent discloses estimation of pulse rate on "unclean" spectra relies on the single citation in Dr. Baura's expert report,[619] and each of those in her declaration,[620] to the patent's description of processing data that *does not* exceed the threshold value.

Moreover, although inventor McCarthy testified the input to the rules-based method was a spectrum that had been clean of motion artifacts "to some extent," he acknowledged the spectrum "had been subjected to an algorithm designed to clean it of motion."[621] McCarthy also testified he did not know if the rules would be effective if the signal was not subjected to the scrubber, and would have to experiment to make that

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[617] *Id.*, 3:43-49 (emphasis added).
[618] *Id.*, 16:45-51 (emphasis added).
[619] D.I. 431, Ex. 23 at ¶ 342 (citing '194 patent, 16:50-55).
[620] D.I. 508 at ¶ 8 (citing '194 patent, 3:43-47, 15:18-27, 15:28-38; 16:49-55).
[621] D.I. 507, Ex. 3 at 230:6-12.

determination.[622] Although Diab testified he "must have" performed analysis to determine whether rules would work in the presence of motion, because "there might be cases where you think there is not motion, and [there] is motion," he further acknowledged "probably part of the analysis involved that, although I don't have a clear recollection of that."[623]

The court determines the specification of the '194 patent does not disclose possession of an invention that can estimate pulse rate utilizing a signal determined to contain motion artifacts. Consequently the asserted claims, which would cover such estimation, are invalid for lack of adequate written description.

With regard to lack of enablement, the extent of Philips' argument is: "Mr. McCarthy . . . admitted that it would take significant experimentation to determine whether and how he would have to change his invention to make it classify unclean spectrum."[624] In support, Philips relies solely on the last, italicized, question and answer in the following exchange:

> Q. And if you determined that the rules were ineffective, you'd have to come up with some way of modifying the rules in that circumstance?
>
> A. You're asking me to continue to develop the algorithm by changing some component of it, and I can't tell you what the result would be without doing it.
>
> Q. Understood.
>
> A. I'm not that smart.

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[622] *Id.* at 276:22-277:7.
[623] *Id.*, Ex. 2 at 211:6-212:2.
[624] D.I. 407 at 11; *see also id.* at 13 ("[S]ince the inventor himself admits that he would have to conduct extensive experiments to determine whether and how to change the disclosed algorithm to work on unclean spectral data, the claims are . . . not enabled by the specification of the '194 patent.").

Q. Whether and how you'd have to change the algorithm if you didn't subject the signal to a scrubber first is something that you don't know until you experiment and find out; right?

A. Today I don't know that; that's true.[625]

Philips also contends Dr. Baura's enablement argument is a conclusory statement that "[a] person of ordinary skill in the art would . . . understand how to make and use the inventions of the asserted claims of the '194 Patent without undue experimentation."[626]

Masimo asserts McCarthy's testimony was not an admission that "significant experimentation" would be required to classify unclean data.[627] It maintains Philips asked McCarthy a series of hypothetical questions about the performance of rules on unscrubbed data, and asked McCarthy to assume the rules were "ineffective" on unscrubbed data.[628] Masimo notes the above-quoted testimony was part of that discussion.[629] Masimo states McCarthy testified that, although not having specific recollection of Masimo's development work, he did recall "many architectures and combinations of things were evaluated,"[630] and ultimately relied on the '194 patent to describe Masimo's work.[631]

Philips' reply brief does not specifically address Masimo's position on the enablement of the '194 patent, other than to reiterate its position that the claims are invalid for lack of enablement, but notes the court can grant summary judgment of no

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[625] D.I. 433, Ex. 44 (McCarthy Depo.) at 277:18-278:14. Masimo's counsel objected to the first and last questions as asking an incomplete hypothetical and calling for speculation.

[626] D.I. 407 at 12 (quoting D.I. 431, Ex. 23 (Baura Valid. Rpt.) at ¶ 342).

[627] D.I. 506 at 11.

[628] *Id.* at 12.

[629] *Id.*

[630] *Id.* (citing D.I. 507, Ex. 3 at 278:16-12).

[631] *Id.* (citing D.I. 507, Ex. 3 at 279:20-22 ("I think our best understanding at the time is what we disclosed in the patent, and I don't have any other detailed recollection.")).

written description without reaching the enablement question.[632]

The court determines Philips has failed to demonstrate, by clear and convincing evidence, that the claims are invalid for failing to "enable one of ordinary skill in the art to practice the claimed invention without undue experimentation."[633] McCarthy was asked "*if* you determined that the rules were ineffective, you'd have to come up with some way of modifying the rules in that circumstance?"[634] In response to that hypothetical question, McCarthy testified "I can't tell you what the result [of changing some component of the algorithm] would be without doing it."[635] McCarthy was then asked "*[w]hether* and how you'd have to change the algorithm if you didn't subject the signal to a scrubber first is something that you don't know until you experiment and find out; right?"[636] The court disagrees with Philips that the response to that question, "[t]oday I don't know that; that's true,"[637] is an admission "that it would take significant experimentation to determine whether and how he would have to change his invention to make it classify unclean spectrum."[638] McCarthy stated *if* he determined the rules were ineffective, he would have change some component of the algorithm and determine what the result of that change was. There was no testimony indicating the extent of experimentation that might be required. He also stated he did not know *whether* the algorithm might have to be changed without experimenting to find out.

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[632] D.I. 594 at 2 n.2.
[633] *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc.*, 617 F.3d 1296, 1305 (Fed. Cir. 2010).
[634] D.I. 507, Ex. 3 at 277:18-20 (emphasis added).
[635] *Id.* at 278:1-4.
[636] D.I. 507, Ex. 3 at 278:8-11 (emphasis added).
[637] *Id.* at 278:13-14.
[638] D.I. 407 at 11.

Again, the court does not view that statement as an admission McCarthy "would have to conduct extensive experiments to determine whether and how to change the disclosed algorithm to work on unclean spectral data."[639] Consequently, Philips motion for summary judgment of invalidity for lack of enablement is denied.

2. Center of Mass Calculation

Asserted claims 11, 14, and 16, recite using a center of mass calculation to estimate pulse rate. For example, claim 11 recites "[t]he method of claim 10, wherein said *pulserate is estimated according to a center of mass* of at least a portion of said series of spectral peaks."[640] Claim 14 of the '194 patent recites:

> In a physiological monitor attached to a living organism having a pulserate, said monitor having a detector responsive to physiological properties related to a pulserate, a method comprising *the steps of*:
>
> > transforming a time-domain plethysmograph waveform into a spectral domain waveform;
> >
> > classifying one or more spectral values obtained from said spectral domain waveform; and
> >
> > using results from a *center of mass calculation* of at least a portion of said spectral values to *estimate said pulserate*.[641]

Philips contends the "center of mass" claims fail the written description requirement because the '194 patent provides no description for using a center of mass calculation

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[639] *Id.* at 13.

[640] '194 patent, claim 11.

[641] D.I. 428, Ex. 4, '194 patent (emphasis added). Claim 16 also contains similar limitations as claim 14: transforming a "first time-domain representation" into a "first spectral-domain representation" and transforming a "second time-domain representation" into a "second spectral-domain representation"; classifying "*said* first spectral-domain representation and *said* second spectral-domain representation . . . to identify a series of spectral peaks"; and estimating pulse rate "from *said* series of spectral peaks as a function of a center of mass type calculation." '194 patent, claim 16 (emphasis added).

to estimate pulse rate.[642]

Philips states it is undisputed that the specification only describes using a center of mass calculation to generate a clean signal by scrubbing a signal of noise.[643] According to Philips, because the inventors did not disclose possession of the invention using a "center of mass" to estimate pulse rate, claims 11, 14, and 16 are invalid for lack of written description.[644]

Philips further contends that although the sequence of steps recited in those claims demonstrates the center of mass calculation is used to estimate pulse rate *after* classification of the spectral peaks, the specification does not disclose estimating pulse rate according to a center of mass *after* the peaks have been classified.[645]

Philips states the inventor and Dr. Baura admit the center of mass calculation is used only for scrubbing the signal; the claims do not include the waveform scrubber and, therefore, there can be no dispute that the claimed use of "center of mass" for estimating pulse rate cannot refer to the center of mass calculation used in the scrubber.[646]

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[642] D.I. 407 at 13-14 (citing D.I. 429, Ex. 14A (Stone Inv. Rpt.) at ¶ 410 ("Claims 11, 14, and 16 of the '194 Patent require estimation of a pulse rate using a 'center of mass' calculation. The specification discloses only a single specific 'center of mass' calculation which is not utilized for calculating the pulse rate, but rather the calculation of a ratio threshold for use in the scrubbing operation. . . . The specification of the '194 Patent does not disclose how to compute such a 'center of mass' in 'estimating' a pulse rate . . . .")).

[643] *Id.* at 14 (citing D.I. 429, Ex. 14A ¶ 410; D.I. 431, Ex. 25 (Baura Depo.) at 469:14-470:11 (Dr. Baura agreeing that one use of the center of mass calculation is to initiate the waveform scrubber), 472:13-22 (Dr. Baura agreed "the waveform scrubber that the center of mass is used to initialize" is depicted in figure 12 as within the "1240 bock," not the 1250 block; "1250 is the pulse rate method." Block 1250 is labeled "PULSERATE METHOD I (RULES)".)); *see also*, D.I. 433, Ex. 44 (McCarthy agreeing that the center of mass calculation described in columns 14 and 15 of the '194 patent "is used as part of the waveform scrubber operation").

[644] *Id.* at 14.

[645] *Id.* (citing D.I. 429, Ex. 14A (Stone Inv. Rpt.) at ¶ 410).

[646] *Id.* at 14-15.

Philips states the specification makes clear the scrubber operation, which is purportedly the only disclosed "center of mass" calculation, takes pace *before* the claimed classification of the spectrum.[647] Philips maintains the specification states the clean spectrum resulting from the scrubbing operation is classified, and pulse rate is estimated by applying a single set of specific rules.[648]

Philips contends Dr. Baura's only rebuttal is a conclusory statement that "a person of ordinary skill in the art would understand how to estimate a patient's pulse rate in accordance with Claims 11, 14, and 16 of the '194 Patent without undue experimentation, and would also recognize that the inventors had possession of this subject matter."[649] Philips contends those purportedly conclusory statements are insufficient to defeat summary judgment.[650]

Philips concludes the "center of mass" claims do not satisfy the written description requirement because the '194 patent provides no description the conveys to one of skill in the art that the inventors were in possession of estimating a pulse rate according to a center of mass calculation.[651]

Masimo argues Philips assertion that the claims require estimating a pulse rate according to a center of mass *after* the spectral peaks have been classified is incorrect because the claims do not require a temporal restriction.[652] As an example, Masimo

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[647] *Id.* at 15.
[648] *Id.* (citing '194 patent, Figs. 12 & 18A-C).
[649] *Id.* (citing D.I. 431, Ex. 23 (Baura Valid. Rpt.) at ¶¶ 345-46).
[650] *Id.* at 15 (citing *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) (affirming summary judgment of obviousness because statements by patentee's expert were conclusory and failed to raise a genuine issue of material fact); *Lemelson v. U.S.*, 752 F.2d 1538, 1551 (Fed. Cir. 1985) (giving "no weight to the series of conclusory statements offered by [plaintiff's] expert witness")).
[651] *Id.* at 15.
[652] D.I. 506 at 13.

points out claim 14 merely recites "using results *from* a center of mass calculation of at least a portion of said spectral values to estimate pulse rate," and "classifying one or more spectral values obtained from said spectral domain waveform."[653] Masimo contends that language provides no restriction on when the spectral values are classified, and provides no restriction on when the center of mass calculation must be used.[654] It argues the center of mass calculation is one of the many aspects of the pulse rate algorithm disclosed in the '194 patent.[655] Citing figure 12, Masimo states there are many disclosed aspects of the invention that are claimed to estimate pulse rate, giving as examples acquiring red and infrared signals, and the transformation of those signals into the frequency domain.[656] According to Masimo, as set forth in claim 14, the estimation of pulse rate is performed based on all of those earlier steps.[657] It contends, like the signal acquisition and transformation, the center of mass calculation is used on classified frequency peaks to determine whether motion is present and that the claimed physiological monitor to estimate the pulse rate includes all of those steps.[658]

The court disagrees with Masimo's analysis. The result of claims 11, 14, and 16 is that the pulse rate is estimated, but those claims require using a center of mass calculation for that estimation: the pulse rate to be "estimated *according to a center of mass* of at least a portion of said series of spectral peaks";[659] "*using results from a*

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[653] *Id.* (emphasis added by Masimo).
[654] *Id.* at 13.
[655] *Id.* at 14.
[656] *Id.*
[657] *Id*.
[658] *Id.*
[659] '194 patent, claim 11 (emphasis added).

center of mass calculation of at least a portion of said spectral values *to estimate said pulserate*";[660] and estimating the pulse rate "from said series of spectral peaks *as a function of a center of mass type of calculation* of at least a portion of said series of spectral peaks."[661]

Moreover, Masimo's contention that the claims do not require a temporal restriction is incorrect as the claims set forth sequential steps, each utilizing the results of the previously performed steps. Taking claim 14 as an example, the claim recites "a method comprising the *steps of*: transforming a time-domain plethysmograph waveform into *a spectral domain waveform*." The next step uses that transformed spectral domain waveform: "classifying one or more *spectral values* obtained from *said spectral domain waveform.*" The final step estimates pulse rate using results from a center of mass calculation of the previously classified spectral values: "using results from a center of mass of at least a portion of *said spectral values* to estimate said pulserate." Thus, "the sequential nature of the claim steps is apparent from the plain meaning of the claim language and nothing in the written description suggests otherwise."[662]

At deposition, Dr. Baura agreed with the sequential requirement Philips suggests. For instance, with regard to claim 11, Dr. Baura testified as follows:

> Q. Claim 11 says, "Pulse rate is estimated according to a center of mass of at least a portion of said series of spectral peaks." Do you see that?
>
> A. Yes.

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[660] *Id.,* claim 14 (emphasis added).
[661] *Id.*, claim 16 (emphasis added).
[662] *Mantech Envtl. Corp. v. Hudson Envtl. Servs., Inc.*, 152 F.3d 1368, 1376 (Fed. Cir. 1998) Similar to the claims at issue here, the *Mantech* court examined a claim in which each step in the sequence utilized the product of previously performed steps. *See id.* & *id.* n.13.

* * * * *

Q. Does the said series of spectral peaks in Claim 11 refer to the series of spectral peaks that result from the classify step of Claim 10?

A. Yes. It refers to the series of spectral peaks that comprise a fundamental peak and at least one harmonic of said fundamental peak.

Q. And that series of spectral peaks is the result of the classify step in Claim 10; correct?

A. Yes.[663]

Dr. Baura testified similarly with regard to claim 16:

Q. Can you look at claim 16 . . . [t]he last limitation says, "Estimate said pulse rate from said series of spectral peaks as a function of a center-of-mass-type calculation of at least a portion of said series of spectral peaks." Do you see that?

A. Yes.

* * * * *

Q. The said series of spectral peaks referred to in the last limitation of Claim 16 refers to the series of spectral peaks that are identified by the classify step of Claim 16; correct?

A. Yes.

Q. Okay. So in Claim 16 you've got to transform, then classify, then estimate; right?

A. Yes.[664]

Masimo does not explain how the '194 patent describes estimating a pulse rate using a center of mass calculation. Indeed, Masimo states "the center-of-mass calculation is used on classified frequency peaks to determine *whether motion is present*," not to

[663] D.I. 431, Ex. 25 at 458:15-459:11.
[664] D.I. 431, Ex. 25 at 459:12-460:12.

estimate a pulse rate.[665] Consequently, the court determines the '194 patent's description of a modified center of mass that Masimo cites does not disclose estimating a pulse rate using a center of mass calculation.

Masimo also argues, however, the patent discloses a "Transform Based Pulserate Detection" embodiment where two Fourier transforms are used to estimate the pulse rate.[666] It contends one of skill in the art would understand the second transform is another example of a center-of-mass calculation to estimate pulse rate.[667]

Philips contends this additional argument should be rejected because the dual-transform embodiment is unrelated to the claims.[668] It also notes Dr. Baura did not rely on that disclosure during expert discovery.[669] Moreover, Phillips maintains the section of the '194 patent cited by Masimo does not describe a center of mass calculation of any kind.[670]

The court first notes Philips asserts "[t]he patent . . . discloses [an] embodiment called a 'transform based pulserate detection method (PPRT)' 1252. It is undisputed that the claims of the '194 patent are not directed to that alternative embodiment."[671] The basis of the assertion that the claims are not directed to that embodiment is unclear. Describing figure 12, the patent states "[t]he waveform at terminal 1249 can be

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[665] D.I. 506 at 13 (emphasis added); *see also* D.I. 508 at ¶ 9 (Dr. Baura states "I understand that Philips also contends that the '194 Patent does not disclose a center of mass calculation to estimate pulse rate. However, the '194 Patent teaches that a modified center of mass is used after peaks are initially classified *to determine whether motion artifact is present*." (citing '194 patent, 13:45-15:17) (emphasis added)).

[666] *Id.* at 14 (citing '194 patent at 21:15-56).

[667] *Id.* (citing D.I. 508 at ¶ 10; D.I. 507, Ex. 2 (Diab. Depo.) at 271:6-274:6 (explaining development of a second transform center-of-mass calculation to estimate pulse rate)).

[668] D.I. 594 at 6.

[669] *Id.* (citing D.I. 431, Ex. 23 at ¶¶ 345-46).

[670] *Id.* (citing '194 patent, 21:15-56).

[671] D.I. 407 at 3 n.3.

displayed on a display (not shown) or sent to a rule based pulserate detector 1250 and/or *a transform based pulserate detector 1252*."[672] During his 2011 deposition, inventor Diab discussed development of a technique to estimate pulse rate via "a two transformation to the frequency domain."[673] He described the second transformation as a center of mass calculation to estimate a pulse rate: "[a]nd when you are done with the double transformation you end up with a pulse rate that analyzed the harmonics can came up with the–as if it is a center of mass for the frequency. Because it multiplies the magnitude, and it takes account–it weighs the frequency by the magnitude."[674] In her declaration submitted in support of Masimo's opposition to Philips' motion, Dr. Baura explains her opinion that the "Transform Based Pulserate Detection" embodiment would be understood by one of skill in the art as "this technique is a type of center-of-mass calculation to estimate pulse rate," and cites Diab's testimony as further support.[675]

Philips contends the "dual-transform embodiment [is] completely unrelated to the claims. . . [and] the section Masimo cites never describes a center of mass calculation of any kind–it is simply not disclosed."[676] Other than merely citing the section of the specification cited by Masimo, Philips provides no support for its contentions. It also does not suggest why Diab's testimony and Dr. Baura's opinion that the dual-transform embodiment discloses estimation of pulse rate utilizing a center of mass calculation is

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[672] '194 patent, 16:33-35 (emphasis added).

[673] D.I. 507, Ex. 2 at 271:6-274:6.

[674] Id. 272:6-11; *see also id.* at 272:13-273:3 ("So you take the first one, that is the first figure, that's the fundamental. That would be the first transformation. When you do the second transformation, you are analyzing the repetitiveness of the harmonics. That is what it does. And the way it does it, it weighs each frequency by its magnitude and where it is, and it looks at all of them and come up with a frequency. So the largest peak in the second transform will correspond to a frequency that is like a calculation of center of mass . . . .").

[675] D.I. 508 at ¶ 10.

[676] D.I. 594 at 6.

incorrect. Consequently, the court determines a question of fact exists as to that issue and denies Philips' motion for summary judgment that claims 11, 14, and 16 of the '194 patent are invalid for lack of adequate written description.

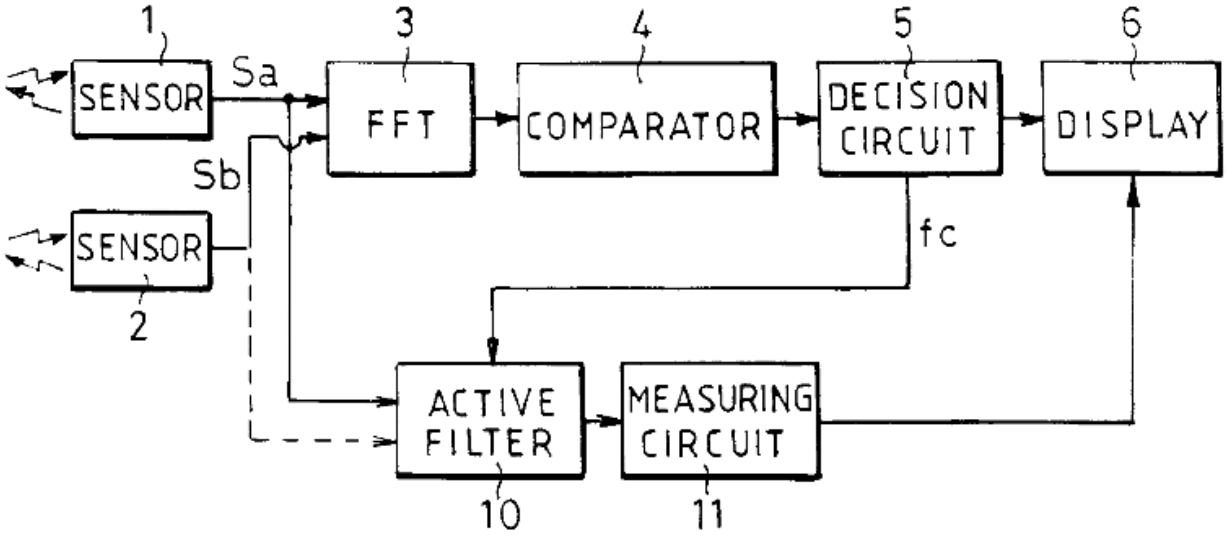
B. Anticipation

Philips argues European Patent No. 0645117A ("EP '117") anticipates each of the asserted claims other than those reciting a "center of mass," specifically, claims 1-6, 8, 10, 12, 15, and 17-22.[677] EP '117 was published on March 29, 1995 and Philips contends it is thus prior art to the '194 patent under 35 U.S.C. § 102(b). According to Philips, EP '117 was not cited during prosecution of the '194 patent.

EP '117 discloses an "apparatus for detecting pulse waves and motion intensity of a living body in motion."[678] Similar to the '194 patent, Philips contends EP '117 "estimates pulse rate by classifying the frequency domain peaks into fundamentals and harmonics using a plurality of rules based on magnitudes and ratios of the various peaks."[679] Figure 1 of EP '117 illustrates the apparatus for detecting pulse rates:

[677] D.I. 407 at 16.
[678] D.I. 432, Ex. 38, EP '117 at Abstract.
[679] D.I. 407 at 16.

FIG.1.



The detected light signals Sa and Sb are transformed into the frequency domain.[680] The peaks are identified and classified into fundamentals or harmonics.[681] Thereafter, the pulse rate is estimated.[682] Thus, Philips' expert, Dr. Stone, opines EP '117 discloses all of the steps of claims 1-6, 8, 10, 12, 15 and 17-22 including: (a) transforming the signal into the frequency domain, (b) identifying three or more peaks, (c) classifying those peaks into a fundamental and harmonics, and (d) estimating the

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[680] D.I. 432, Ex. 38, EP '117 at 14:3-11.

[681] *Id.* at 14:14-16 (stating, in reference to Fig. 1, "[t]he comparator 4 stores the frequency spectra temporarily, and compares the magnitudes of major lines included in the spectra with one another"); *id.* at 12:7-11 (referring to Figs. 10(a) and 10(b) and stating "S1 denotes a fundamental frequency of arm strokes (body motion), S2 denotes the second-order harmonic of the arm strokes, and M1 denotes the fundamental frequency of blood pulses (that is, the pulse rate)"); *id.* at 14:25-30 (referring to Fig. 9 and stating "if the amplitudes a, b, c, and d of frequency components f_1 and f_2 . . . satisfy the relationship (a/b) < (c/d) or (c/a) > (d/b), then it is decided that frequency f_1 corresponds to arterial blood pulses, and that frequency f_2 corresponds to arm strokes"); *id*. at 15:44-53 (stating the comparator "may also compare for example the fundamental wave of a pulse wave to the second-order harmonic of body motion, or compare the second-order harmonic of the pulse wave to the fundamental wave of body motion").

[682] *Id.* at 14:20-24 (stating, in reference to Fig. 1, "[t]he comparison results are supplied to a decision circuit 5. Referring to comparison result patterns stored in advance, the decision circuit 5 determines which frequency responds to pulses and which one corresponds to body motion"); *id.* at 14:46-53, 15:4-9 (stating the frequency corresponding to blood pulses are extracted and the pulse rate is displayed).

pulse rate.[683]

Masimo states the '194 patent addresses the problem of calculating pulse rate when the pulse rate and noise overlap in the frequency domain.[684] To address that problem, the '194 patent teaches classifying and sorting the frequency spectrum to identify a pulse rate peak and corresponding harmonic peaks of the pulse rate."[685]

In contrast, Masimo maintains EP '117 does not disclose classifying or sorting frequency peaks, much less fundamental frequency peaks and associated harmonics to estimate pulse rate, and does not disclose how frequency peaks are selected for use in the disclosed comparator circuit.[686]

Masimo states asserted claims 1-6, 8, 10, and 12 each require classifying or sorting signal peaks into a fundamental and one or more harmonics of the fundamental to estimate pulse rate. According to Masimo, the fundamental referred to in the claims is the fundamental frequency of the pulse rate and that, in the frequency domain, harmonics are multiples of the fundamental frequency of the pulse rate.[687] For instance, claim 1 recites:

> *sort* said three or more spectral peaks according to one or more rules into one or more spectral peaks corresponding to *a fundamental frequency and one or more harmonics of said fundamental frequency*, and estimate a

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[683] D.I. 407 at 18-20 (discussing, as examples, claims 1 and 15 of the '194 patent); D.I. 429, Ex. 14A (Stone Inv. Rpt.) at 80-82, ¶¶ 306-10; D.I. 431, Ex. 25 at 429:21-430:17, 443:3-18 (admitting Fig. 10 of EP '117 discloses identifying three or more peaks in the spectral domain and a portion of the spectrum is selected for calculation of pulse rate); D.I. 210 at 13 (finding "one or more rules" means "guidelines"); D.I. 432, Ex. 38, EP '117 at 14:25-36, 15:44-16:7 (describing selection of peaks using guidelines); *id.* at 14:46-53, 15:4-9 (noting pulse rate is calculated from fundamental frequency and displayed); *id.* at 15:20-26 (noting the "amplitudes of major frequency components are compared to one another" to discriminate "the pulse wave and the body motion").

[684] D.I. 506 at 15 (citing '194 patent, 1:24-44).

[685] *Id.* (citing '194 patent, 17:10-20:42).

[686] *Id.* (citing D.I. 508 (Baura Decl.) at ¶ 15).

[687] *Id.* at 16 (citing D.I. 508 at ¶ 14).

> pulserate from said fundamental frequency and said one or more harmonics.[688]

Masimo contends EP '117 does not disclose classifying/sorting peaks into a fundamental and one or more harmonics of that fundamental.[689] In response, Philips points to figures 10 and 9, and the associated descriptions of those figures, to argue of EP '117 does disclose that limitation.[690]

Although three peaks are labeled in figure 10, those peaks are not described as representing a fundamental and one or more harmonics of that fundamental. EP '117 recites: "[i]n Figures 10(a) and 10(b), S1 denotes a fundamental frequency of arm strokes (body motion), S2 denotes the *second-order harmonic of the arm strokes*, and M1 denotes the fundamental frequency of blood pulses (that is, the pulse rate)."[691] Next, the fundamental frequency is compared to body motion, not one or more harmonics of the fundamental frequency of the pulse rate: "[i]f the ratio of M1 to S1 is compared between the ratio shown in Figure 10(a) and the ratio shown in Figure 10(b), it is concluded from the above relationships that M1 represents pulses."[692]

Figure 9 illustrates comparing frequency components f_1 and f_2 to determine which corresponds to blood pulses and which corresponds to arm strokes (body motion), not one or more harmonics of the fundamental frequency:

> [A]s shown in Figure 9, when amplitudes of components at frequencies f_1 and f_2 are a and b, respectively for the wavelength of 660 nm, and c and d, respectively, for the wavelength of 940 nm, if (a/b) < (c/d) or (c/a) > (d/b),

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[688] '194 patent, claim 1 (emphasis added). Independent claims 3-5, 8, and 10 each contain a similar requirement. Claims 2, 6, and 12 depend from independent claims 1, 5, and 10, respectively.
[689] D.I. 506 at 16-19.
[690] D.I. 594 at 8-9; D.I. 407 at 19-20.
[691] D.I. 432, Ex. 38, EP '117 at 12:7-11 (emphasis added).
[692] *Id.* at 12:12-15

> then it is concluded that f_1 is the frequency corresponding to arterial blood pulses, and f_2 is the frequency corresponding to arm swinging. Once the frequency which corresponds to arterial blood pulses has been detected, the pulse rate can be determined by converting the frequency to a number of pulses per minute. In this way, the pulse rate of a living body in motion can be detected.[693]

EP '117 also recites comparing "the fundamental wave of a pulse wave and the fundamental wave of body motion"; "the fundamental wave of a pulse wave to the second-order harmonic of body motion"; or "the second order-harmonic of the pulse wave to the fundamental wave of body motion."[694] Although EP '117 states "any waves which can be discriminated clearly can be designated to be used in comparison,"[695] the court determines there is a question of fact as to whether that statement is clear and convincing evidence that EP '117 discloses classifying/sorting spectral data.[696] Consequently, Philips' motion for summary judgment that EP '117 anticipates claims 1-6, 8, 10, and 12 of the '194 patent is denied.

Masimo also notes claim 1, 2, 8, 10, and 12 require estimating pulse rate from the fundamental and one or more harmonics of that fundamental, and that claims 17-22 recite that the monitor estimate pulse rate from the fundamental and an additional spectral peak at an additional spectral peak at a higher frequency.[697] Masimo argues

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[693] *Id.* at 11:43-56.
[694] *Id.* at 15:44-53.
[695] *Id.* at 15:53-55.
[696] Philips also notes EP '117 recites: "[a]n active filter 10 extracts the frequency fc considered to correspond to blood pulses and its harmonics (for example, up to fifth- or sixth-order harmonics) from the output signal Sa or Sb outputted by the sensor 1 or 2."). D.I. 594 at 9 (citing EP '117, 14:46-49). According to Dr. Baura, however, "[t]his excerpt . . . does not teach the sorting of a fundamental frequency of the pulse rate, and one or more harmonics or the fundamental frequency, or estimating pulse rate from such sorting. Rather, EP '117 teaches that the pulse rate has already been determined and displayed by the decision circuit 5 before the active filter 10 extracts these frequencies." D.I. 508 at ¶ 21 (comparing EP '117, 14:46-15:9 with EP '117, 14:25-36).
[697] D.I. 506 at 18. Claim 17 is an independent claim from which claims 18-22 depend.

'EP '117 does not disclose using both the fundamental, and its harmonics or additional higher frequencies, to estimate the pulse rate. As support, Masimo cites several statements in EP '117 in support of its contention that reference teaches calculating a pulse rate from only the fundamental corresponding to the blood pulses.

> [A]s shown in Figure 9: . . . . Once the frequency which corresponds to arterial blood pulses has been detected, the pulse rate can be determined by converting the frequency to a number of pulses per minute. In this way, the pulse rate of a living body in motion can be detected.[698]
>
> According to the decision made by the decision circuit 5, a display unit 6 . . . converts the frequency fc, which has been considered to correspond to the pulse rate, into a frequency per minute, and displays it on the display element.[699]
>
> According to the comparison result, the decision circuit 5 discriminates the pulse wave and the body motion. The display unit 6 displays a pulse rate corresponding to the fundamental frequency of the pulse wave.[700]
>
> In some cases, body motion of a person under examination does not have periodicity. In this case, since major frequency components obtained by the Fourier transformation all result from blood pulses, it is much easier to discriminate the pulse wave. In the comparator 4 of this embodiment, when the output signal of the fast Fourier transformation circuit 3 contains only one fundamental wave and its harmonics, it is concluded that only blood pulse wave are detected, and its fundamental wave is regarded as blood pulses.[701]

Dr. Baura again opines Philips' reliance on citation to the description of filter 10 is misplaced based on her assertion "EP '117 teaches that the pulse rate has already been determined and displayed by the decision circuit 5 before the active filter 10 extracts these frequencies."[702]

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[698] D.I. 432, Ex. 38, EP '117, 11:43-56.
[699] *Id.* at 14:30-36.
[700] *Id.* at 15:22-16.
[701] *Id.* at 15:55-16:7.
[702] D.I. 508 at ¶ 21.

Because there is a question of fact as to whether using both the fundamental, and its harmonics or additional higher frequencies, to estimate the pulse rate is disclosed, Philips' motion for summary judgment that EP '117 anticipates claims 1, 2, 8, 10, 12, and 17-22 of the '194 patent is denied.

Dependent claims 12 and 18 also each require a "confidence factor" that Masimo contends is not disclosed by EP '117.[703] Philips' claim chart for claims 12 and 18 provides citations to EP '117, but those citations do not mention a confidence factor.[704] Dr. Baura opines EP '117 does not disclose a confidence factor.[705] Moreover, in his invalidity report, Dr. Stone does not opine EP '117 anticipates claims 12 and 18 through disclosure of estimating pulse rate using a confidence factor, instead, he opines "[i]t would have been *obvious* to a person of ordinary skill in the art *to modify EP '117* to associate the pulse rate calculation with the motion intensity calculation in order to obtain a confidence factor associated with the pulse rate."[706] Consequently, Philips' motion for summary judgment that EP '117 anticipates claims 12 and 18 of the '194 patent is denied.

The remaining claim of the '194 patent Philips contends is anticipated by EP '117 is claim 15, which recites:

> 15. A physiological monitor for monitoring comprising a signal processor configured to:
>
> > transform a time-domain representation of a plethysmograph waveform into a spectral-domain representation having at least three spectral peaks at non-zero frequencies;

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[703] D.I. 506 at 19.
[704] D.I. 407, Appx. A at 26, 36.
[705] D.I. 431, Ex. 23 (Baura Valid. Rpt.) at ¶¶ 262-63, 281-82; D.I. 508 at ¶¶ 58, 71.
[706] D.I. 429, Ex. 14A (Stone Inv. Rpt.) at ¶¶ 354, 372 (emphasis added).

> select a selected portion of said spectral-domain representation based on one or more rules relating to characteristics of spectral lines in said selected portion and one or more harmonics of spectral lines in said selected portion; and
>
> estimate said pulserate from said selected portion of said spectral-domain representation.[707]

Masimo only argues the second and third elements are not disclosed by EP '117.[708]

With regard to the third element, "estimating said pulserate from said selected portion of said spectral-domain representation," i.e., the portion "relat[ed] to characteristics of spectral lines in said spectral portion *and* one or mor harmonics of spectral lines in said selected portion," Masimo makes the same argument it did challenging the disclosure of EP '117 as to claims 1, 2, 8, 10, 12, and 17-22; "EP '117 teaches calculating a pulse rate from only the fundamental corresponding to the blood pulses."[709] For the same reason the court denied Philips' motion as to those claims, as it pertained to the estimating a pulse rate limitation, the court again denies Philips motion for summary judgment that EP '117 anticipates claim 15 of the '194 patent.

6. Masimo's Motion for Summary Judgment of Noninfringement and Invalidity of U.S. Patent No. 6,122,535;[710]

The '535 Patent (Philips Patent)

Philips contends Masimo infringes claim 1 of the '535 patent. Masimo moves for summary judgment of non-infringement and invalidity of that claim.[711] Masimo argues it

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[707] '194 patent, claim 15.

[708] *See* D.I. 506 at 20; D.I. 508 at ¶¶ 61-62. In its claim chart, Philips cites the disclosure by EP '117 of "a physiological monitor for monitoring comprising a signal processor configured for" and the first element of the claim. *See* D.I. 407, Appx. A at 28-30.

[709] D.I. 508 at ¶ 62.

[710] D.I. 393.

[711] D.I. 393. The briefs are found at D.I. 396 (Masimo's opening brief), D.I. 521 (Philips' answering brief), and D.I. 585 (Masimo's reply brief).

is entitled to summary judgment of non-infringement because its accused Fast Saturation Transform ("FST") algorithm does not literally infringe, the doctrine of equivalents cannot be applied, and the FST algorithm has never been used to calculate a patient's oxygen saturation. Masimo further maintains summary judgment of invalidity is warranted because claim 1 is anticipated by U.S. Patent No. 5,575,284 ("the '284 patent") and Masimo's '272 patent.

A. Literal Infringement

The Abstract of the '535 patent recites the invention is directed at:

> A method of determining at least the concentration of a component from the intensity of electromagnetic waves with at least two selected wavelengths which are reflected by human tissue or transmitted through human tissue comprises firstly the step of converting the intensities of the received electromagnetic signals into at least one first and one second time-dependent electric signal. Then a time-discrete transformation of the first and of the second electric signal into the frequency domain is performed to determine first and second spectral values of the first and of the second signal. Complex combinatorial values are formed from said first and second spectral values and physiologically relevant combinatorial values are selected by evaluating the complex combinatorial values according to given criteria for the physiological relevance thereof. Finally, the concentration of the component is calculated by using the selected combinatorial values or by using the frequencywise-associated spectral values.[712]

Claim 1 of the '535 patent recites:

> 1. A method of determining at least the concentration of a blood component from the intensity of electromagnetic waves with at least two selected wavelengths which are reflected by a patient's tissue or transmitted through the patient's tissue, said method comprising the following steps:
>
> (a) converting the intensities of received electromagnetic signals into at least one first and one second time-dependent electric

[712] '535 patent, Abstract.

signal;

(b) time-discretely transforming the first and the second time-dependent electric signal into the frequency domain for determining first and second spectral values of the first and of the second signals;

(c) selecting physiologically relevant first and second spectral values by evaluating said first and second spectral values according to criteria selected in accordance with the patient's physiological parameters; and

(d) calculating the concentration of the blood component making use of the selected first and second spectral values.[713]

The first two limitations of claim 1 of the '535 patent require converting "received electromagnetic signals" into "one first and one second time-dependent electric signal," and "transforming the first and second time-dependent electric signal into the frequency domain for determining first and second spectral values."[714] According to Masimo, Philips alleges the FST algorithm uses a first chirp-Z function to transform an infrared time-domain signal into the frequency domain to obtain first spectral values, and a second chirp-Z function to transform a red time-domain signal into the frequency domain to obtain second spectral values.[715] Masimo states, therefore, that Philips' identifies the first spectral values as infrared spectral values and the second spectral values as red spectral values.[716] Philips does not appear to challenge Masimo's position.

Masimo's non-infringement argument focuses on step (c): "selecting

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[713] '535 patent, claim 1.
[714] *Id.*
[715] D.I. 396 at 5 (citing D.I. 399, Ex. 9 (Stone Depo.) at 113:6-114:8; 121:1-1213:12; 132:3-134:10).
[716] *Id.* at 5.

physiologically relevant first and second spectral values by evaluating said first and second spectral values according to a patient's physiological parameters."[717] Masimo argues its FST algorithm does not infringe because its does not "*evaluat[e]* said *first and second* spectral values according to criteria selected in accordance with the patient's physiological parameters" as required by step (c).[718] Masimo maintains its FST algorithm never evaluates second, or red, spectral values as required by the claim.[719] Masimo states Philips' expert acknowledges Masimo's products do not evaluate red spectral values[720] and that the portions of the FST algorithm Philips relies upon only evidence an evaluation of a transformed infrared signal.[721]

Much of Philips' counter-argument is that Masimo incorrectly interprets the claim as requiring individual, or separate, evaluations of the red and infrared signals.[722] Masimo responds it has never argued the claim requires such separate evaluations, and agrees that under the plain and ordinary meaning, the claim does *not* require separate evaluations of the red and infrared spectral values.[723]

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[717] *Id.* at 4.

[718] The court construed the phrase "selecting physiologically relevant first and second spectral values" to mean "selecting first and second spectral values that are determined to have physiological relevance based on criteria selected in accordance with characteristics of the specific patient being monitored." D.I. 210 at 15-17; D.I. 319 at 2. The parties did not ask for a construction of "evaluating said first and second spectral values."

[719] D.I. 396 at 6.

[720] *Id.* at 6 (citing D.I. 399, Ex. 9 at 161:6-16 ("Q. So what red information is evaluated? A. There is no red information. The data set of the red an infrared information is evaluated. Q. And so according to your interpretation, b[y] evaluating first and second spectral values, you're saying you only have to evaluate the first spectral value and you don't have to evaluate the second spectral value? A. That is what I'm saying.")).

[721] D.I. 396 at 6; D.I. 585 at 2 (citing D.I. 398, Ex. 8 (Stone Infr. Rpt.) at ¶¶ 24, 57, 59-60, 67); *id.* at 3 (citing D.I. 398, Ex. 8 at ¶¶ 59-60, 67-68).

[722] *See, e.g.*, D.I. 521 at 8 ("Masimo interprets this claim limitation[, step (c) of claim 1,] as requiring the evaluation of both red and infrared values individually, rather than collectively as a set of data. In other words, Masimo would require two evaluations: one evaluation of first spectral values and another evaluation of second spectral values.").

[723] D.I. 585 at 2, 2 n.3.

Nevertheless, Philips maintains the FST algorithm does perform the requirement of step (c) of "evaluating said first and second spectral values" under its interpretation of the claim. Dr. Stone opines claim 1 requires evaluating the data set comprising the red and infrared values:

> Q. Okay. So what you pointed to here, finding the peak would be evaluating the first spectral values by looking at the infrared magnitudes; right?
>
> A. That's correct.
>
> Q. The claim also says evaluating second spectral values. Can you show me where that is performed?
>
> * * * * *
>
> A. It says evaluating the first and second. I don't have to thoroughly go through both, there is a data set that are combined. I evaluate a data set that includes both. I may look at only one, but I've evaluated the data set including both the red and infrared.[724]

Philips notes Dr. Baura's non-infringement report acknowledges Masimo's algorithm generates a data set containing red and infrared spectral values: "pastFST_PI contains the frequency of the transformed values at each peak, the magnitude of the transformed infrared values at each peak, and the ratio of *red over infrared* magnitude values at each peak."[725] Philips reasons the data set "pastFST_PI" is, therefore, calculated from red and infrared spectral values.[726] Dr. Stone opines Masimo's algorithm evaluates that data set by finding the peak that has the highest magnitude within 5 beats per minute of the patient's hear rate.[727] He also opines when the peak is selected, its ratio, which

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[724] D.I. 525, Ex. 91 (Stone Depo.) at 159:4-20.
[725] D.I. 521 at 10 (citing D.I. 525, Ex. 109 (Baura Non-Infr. Rpt.) at ¶ 32 (emphasis added)).
[726] *Id.* at 10.
[727] D.I. 398, Ex. 8 at ¶¶ 69-71.

includes red and infrared spectral values, is also selected.[728] Philips concludes this demonstrates the FST algorithm selects red and infrared values by evaluating the data set that includes the red and infrared spectral values, as required by claim 1.[729]

The court agrees with Philips that the evidence presented demonstrates there is a genuine issue of material fact as to whether the FST algorithm performs the required "evaluating said first and second spectral values." Consequently, Masimo's motion for summary judgment of no literal infringement is denied.

B. Doctrine of Equivalents

Philips also argues Masimo is not entitled to summary judgment of non-infringement because it purportedly infringes claim 1 of the '535 patent at least under the doctrine of equivalents.[730] According to Philips, evaluation of only infrared spectral values is not substantially different from evaluation of both red and infrared spectral values because when the accused functionality is utilized, peaks in the infrared and red spectra will be highly correlated.[731] As a result, Philips argues evaluation of one peak in the infrared is equivalent to evaluation both peaks, as in conditions of no motion, the peaks will be aligned in both spectra.[732]

Masimo, however, maintains Philips cannot rely on the doctrine of equivalents to prove infringement pointing to vitiation of claim elements, prosecution history estoppel,

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[728] *Id.*, Ex. 8 at ¶ 57 ("The FST algorithm includes a function called FMR. . . . The FMR function is called and used to find peaks in the transformed infrared magnitude spectrum. Once the peaks are found, the FMR function extracts and stores in an array of structures . . . the (a) frequency of the transformed infrared values at each peak; (b) magnitude of the transformed infrared values at each peak; and (c) the ratio of *red over infrared* magnitude values at each peak . . . .") (emphasis added).

[729] D.I. 521 at 10.

[730] *Id.*

[731] *Id.* at 10 (citing D.I. 99B (Stone Suppl. Rpt.) at ¶ 13).

[732] *Id.* (citing D.I. 99B at ¶ 13).

and the disclosure-dedication rule.[733] The determination of whether a legal limitation precludes the application of the doctrine of equivalents is appropriate for summary judgment.[734]

1. Vitiation

The doctrine of equivalents cannot be used to vitiate an element from the claim in its entirety.[735] Claim 1 recites evaluating "first and second spectral values."[736] Masimo argues Philips' infringement contentions would eliminate the requirement of evaluating second spectral values. Dr. Stone testified:

> Q: And so according to your interpretation, b[y] evaluating first and second spectral values you're saying you only have to evaluate the first spectral value and you don't have to evaluate the second spectral value?
>
> A: That is what I'm saying.[737]

Masimo contends, however, "Philips cannot use the doctrine of equivalents to vitiate the requirement of evaluating second spectral values from the claim."[738]

Philips counters, under the doctrine of equivalents, if only infrared spectral values were evaluated, "the accused products would still perform a step equivalent to each claim limitation, and no steps [would be] removed, or vitiated."[739] It argues Masimo's algorithm "selects red and infrared spectral values based on an evaluation of those

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[733] D.I. 396 at 7-10.

[734] *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39 n.8 (1997).

[735] *Id*. at 29 ("Each element contained in a patent claim is deemed material to defining the scope of the patented invention, and thus the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole.").

[736] '535 patent, claim 1.

[737] D.I. 399, Ex. 9 at 161:11-16.

[738] D.I. 396 at 7 (citing *Am. Calcar, Inc. v. Am. Honda Motor Co., Inc.*, 651 F.3d 1318, 1339 (Fed. Cir. 2011) (rejecting a doctrine of equivalents theory because "finding a signal from one source to be equivalent to 'signals from a plurality of sources' would vitiate that claim limitation by rendering it meaningless")).

[739] D.I. 521 at 11 (citing D.I. 525, Ex. 99B at ¶¶ 11-12).

values."[740] Philips additionally notes the Federal Circuit held if an accused device performs a step that is slightly different than the claimed step, the claimed step is not necessarily vitiated.[741] Thus, Philips contends "the selection step of claim 1(c) is still undeniably performed by Masimo . . . products, even if only infrared signals are evaluated."[742]

The court disagrees with Philips. Philips states Masimo argues "that evaluating only infrared spectral values would vitiate *step (c)* of claim 1."[743] Masimo's argument, however, is that if the claim were to cover evaluating only infrared spectral values, that would vitiate the requirement of "evaluating . . . second spectral [red] values."[744] Dr. Stone opines there is an insubstantial difference between evaluating only infrared spectral values and evaluating both red and infrared spectral values,[745] stating:

> The evaluation of *only infrared values* would still cause a pulse oximeter to: convert the intensities of electromagnetic signals into time-dependent electric signals, time-discretely transform electric signals into the frequency domain to determine spectral values, select and evaluate physiologically relevant spectral values according to criteria selected in accordance with the patient's physiological parameters, and calculate the concentration of a blood component making use of spectral values, as required by claim 1. Consequently, evaluating only red or only infrared

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[740] *Id.* (citing D.I. 401 (Baura Decl.) at ¶ 22 (stating first and second spectral values are selected, but arguing only infrared spectral values are evaluated)).

[741] *Primos, Inc. v. Hunter's Specialties, Inc.*, 451 F.3d 841, 850 (Fed. Cir. 2006) ("There is no set formula for determining whether a finding of equivalence would vitiate a claim limitation, and thereby violate the all limitations rule. Rather, courts must consider the totality of the circumstances of each case and determine whether the alleged equivalent can be fairly characterized as an insubstantial change from the claimed subject matter without rendering the pertinent limitation meaningless.") (citation omitted).

[742] D.I. 521 at 11-12. Philips argues this is not a case where there is vitiation when removal of a second source effectively negates the claimed ability to select between two different sources. *Id.* (distinguishing *Am. Calcar*, 651 F.3d at 1339).

[743] *Id.* at 11 (emphasis added); D.I. 521 at 12 ("*[T]he selection step* of claim 1(c) is still undeniably performed by Masimo SET products, even if only infrared signals are evaluated.") (emphasis added).

[744] D.I. 396 at 7; D.I. 585 at 4.

[745] D.I. 525, Ex. 99B at ¶ 11.

spectral values would not effectively eliminate any limitations of claim 1.[746]

In *Primos*, relied upon by Philips, the defendant argued a finding of equivalence was erroneous because "the substitution of the accused dome for the claimed 'plate' would vitiate the 'plate' limitation and thereby violate the all limitations rule."[747] The Federal Circuit disagreed: "because Primos's theory of equivalence (*i.e.*, that a dome is equivalent to the claimed 'plate') does not 'effectively eliminate . . . [the 'plate' limitation] in its entirety,' it does not violate the all limitations rule."[748] Here, Philips does not suggest a substitution for the claim's requirement of "evaluating . . . second spectral values." Stone opines "[t]he evaluation of *only infrared spectral values* would still cause a pulse oximeter to . . . select and evaluate physiologically relevant spectral values."[749] He likewise testified it was his interpretation that by "evaluating first and second spectral values . . . you only have to evaluate the first spectral value and you don't have to evaluate the second spectral value."[750]

Because Philips' equivalency argument effectively eliminates "evaluating . . . second spectral values," that argument violates the all limitations rule. The court, therefore, grants Masimo's motion for summary judgment that Philips infringement contentions fail as a matter of law under the doctrine of equivalents for violation of that rule.

2. Prosecution History Estoppel

Masimo also argues prosecution history estoppel precludes Philips' reliance on

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[746] *Id.* at ¶ 12 (emphasis added).
[747] *Primos, Inc.*, 451 F.3d at 850.
[748] *Id.*
[749] D.I. 525, Ex. 99B at ¶ 12 (emphasis added).
[750] D.I. 399, Ex. 9 at 161:11-16.

the doctrine of equivalents.

When a patentee is unable to explain why a limiting element was added by amendment during prosecution, "prosecution history estoppel would bar the application of the doctrine of equivalents as to that element."[751] The patentee "bear[s] the burden of showing that the amendment does not surrender the particular equivalent in question."[752] The application of prosecution history estoppel, a legal limitation on the application of the doctrine of equivalents, is appropriately decided by the court.[753]

With prosecution history estoppel, "a patentee is unable to reclaim through the doctrine of equivalents what was surrendered or disclaimed in order to obtain the patent."[754] Thus, even where no amendments are made to the claims, "statements made . . . during the prosecution history [can] constitute a surrender of [the] claims."[755]

During prosecution, claim 1 of the '535 patent was rejected as anticipated by U.S. Patent No. 5,553,614 (the "'614 patent").[756] Philips distinguished claim 1 from the '614 patent by arguing:

> [The '614 patent] discloses a blood oxygenation system wherein real and imaginary portions of two signals are used to determine saturation. A frequency domain analysis is used by [the '614 patent], but the determination of the saturation level involves no selection activity from the derived complex measurement values. [*The '614 patent*] *considers just one signal* and uses the magnitude and phase *thereof* to render his

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[751] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 740 (2002) (citation and internal quotation marks omitted).

[752] *Id.* at 741.

[753] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 344 F.3d 1359, 1368 (Fed. Cir. 2003) (*en banc*).

[754] *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 107 F. Supp. 2d 489, 492 (D. Del. 2000) (citation omitted).

[755] *Id.* at 494 (listing examples including "(i) amendments made to overcome patentability rejections or (ii) arguments made during prosecution that show a 'clear and unmistakable surrender of subject matter.'" (citation omitted)).

[756] D.I. 396 at 8.

measurement.

> *By contrast*, Applicants make adaptive selections from among *a plurality of complex values* to assure that artifacts and noise are reduced or eliminated from the measurement quantities.[757]

Masimo contends that passage demonstrates Philips argued to the PTO that the '614 patent "considers just one signal," and in contrast, the claimed invention requires evaluating a plurality of values, i.e., both first and second spectral values.[758]

Philips argues the '614 patent was not distinguished based on claim 1 of the '535 patent's selection of both red and infrared spectral values, as Masimo contends.[759] Rather, Philips maintains the '614 patent was distinguished based on a lack of selection activity and evaluation in any form in that reference.[760]

The court again disagrees with Philips. Philips responded to the PTO's rejection stating "[the '614 patent] discloses a blood oxygenation system wherein real and imaginary portions of two signals are used to determine saturation."[761] It continued by noting "[a] frequency domain analysis is used by [the '614 patent] but the determination of the saturation level involves no selection activity *from the derived complex measurement values*."[762] Again, these complex values are a combination of the first and second spectral values and, as Philips points out, the '614 patent discloses red and infrared values.[763] Philips then distinguished the '614 patent from claim 1 of the '535

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[757] D.I. 399, Ex 10 ('535 Patent File History) at MASP0022425 (emphasis added).

[758] D.I. 396 at 9. Masimo states the complex values described in the '535 patent, also referred to as "complex combinatorial values" in the patent, are a combination of the first and second spectral values. D.I. 396 at 9 n.3. Philips does not dispute that statement.

[759] D.I. 521 at 12.

[760] *Id.* at 13.

[761] D.I. 399, Ex 10 at MASP0022425.

[762] *Id.* (emphasis added).

[763] D.I. 521 at 12 (citing '614 patent at 6:43-51 ("a ratio circuit divides the I and R terms and the angle is computed")).

patent by stating "[the '614 patent] *considers just one signal* and uses the magnitude and phase *thereof*[, i.e., the magnitude and phase of that one signal,] to render [its] measurement."[764] "*By contrast*, Applicants make adaptive selections from *among a plurality of complex values* [, i.e., a combination of first and second spectral values,] to assure that artifacts and noise are reduced or eliminated from the measurement quantities."[765] Philips distinguished the '614 patent based on its consideration of "just one signal" to make its measurement, whereas claim 1 of the '535 patent selects "from a plurality of complex values" to make its measurement. Consequently, Philips' surrendered its present argument that evaluation of only infrared values is equivalent to evaluation of both red and infrared values. Masimo's motion for summary judgment based on prosecution history estoppel is granted.

3. Disclosed But Unclaimed Embodiments

"[A] patentee cannot narrowly claim an invention to avoid prosecution scrutiny by the PTO, and then, after patent issuance, use the doctrine of equivalents to establish infringement because the specification discloses equivalents."[766] "The disclosure-dedication rule requires an inventor who discloses specific matter to claim it, and to submit the broader claim for examination. Otherwise, that matter is dedicated to the public and may not be recaptured under the doctrine of equivalents."[767]

Masimo asserts the '535 patent discloses evaluation of the red spectrum *or* the

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[764] D.I. 399, Ex 10 at MASP0022425 (emphasis added).
[765] *Id.* (emphasis added).
[766] *Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co., Inc.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002).
[767] *PSC Computer Prods., Inc. v. Foxconn Int'l, Inc.*, 355 F.3d 1353, 1360 (Fed. Cir. 2004).

infrared spectrum to determine peaks,[768] and this embodiment is an alternative to the preferred embodiment that uses both red *and* infrared spectrums to determine complex combinatorial values, which are then used to identify peaks.[769] Philips claimed the preferred embodiment evaluating both "first and second spectral values." Because Philips did not claim the broader embodiment that uses the red spectrum *or* the infrared spectrum to determine peaks, Masimo argues that disclosure has been dedicated to the public, and Philips cannot recapture that subject matter under the doctrine of equivalents.[770]

Philips contends Masimo's argument is an attempt to read the specific algorithm disclosed in column 12 of the '535 patent as a generic disclosure of all methods utilizing separate infrared and red values.[771] Based on that reading, Philips accuses Masimo of asserting any algorithm that uses only red or infrared values would be disclaimed.[772] Such assertion is purportedly contrary to precedent which holds a disclaimer only as to the precise species described in the specification.[773]

The Federal Circuit has held:

> if one of ordinary skill in the art can understand the unclaimed disclosed teaching upon reading the written description, the alternative matter disclosed has been dedicated to the public. This "disclosure-dedication" rule does not mean that any generic reference in a written description necessarily dedicates all members of that particular genus to the public.

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[768] D.I. 396 at 10 (citing '535 patent, 12:15-17 ("It is, for example, possible to determine the above-described peek [sic] determination in the red and/or infrared spectrum separately.")).

[769] D.I. 396 at 10 (citing '535 patent, 12:12-14 ("In the following further developments of and *alternatives to* the above-described special embodiment of the method according to the present invention are described."(emphasis added)), 7:6-8:38).

[770] D.I. 396 at 10.

[771] D.I. 521 at 13.

[772] *Id.*

[773] *Id.* at 13-14.

> The disclosure must be of such specificity that one of ordinary skill in the art could identify the subject matter that had been disclosed and not claimed.[774]

Additionally, "the public notice function of patents suggests that before unclaimed subject matter is deemed to have been dedicated to the public, that unclaimed subject matter must have been identified by the patentee as an alternative to a claim limitation."[775]

Philips argues the algorithm described in column 12 of the '535 patent is not described as a method of "evaluating" spectral values, but, rather as a peak determination algorithm: "it is, for example possible to describe peek [sic] determination in the red and/or infrared spectrum separately."[776] With regard to that alternative method, Philips states the specification describes the peak determination process in which peaks are eliminated and remaining peaks are used to calculate an average saturation.[777] Philips contends to the extent any subject matter was dedicated to the public, it was that peak detection algorithm in its entirety, including the use of all of its steps.[778] It insists it did not dedicate to the public every algorithm that happens to use red and infrared values separately.[779]

Masimo disputes its argument is that any algorithm that uses only red or infrared values would be disclaimed; rather, its argument was directed to the disclosed embodiment that evaluates only the red *or* infrared spectral values to determine

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[774] *Pfizer, Inc. v. Teva Pharms., USA, Inc.*, 429 F.3d 1364, 1378 (Fed. Cir. 2005) (quoting *PSC Computer Prods., Inc. v. Foxconn Int'l, Inc.*, 355 F.3d 1353, 1360 (Fed. Cir. 2004)).
[775] *Pfizer*, 429 F.3d at 1379.
[776] D.I. 521 at 14 (quoting '535 patent, 12:15-17).
[777] *Id.* (citing '535 patent, 12:18-41).
[778] *Id.* at 14.
[779] *Id.*

peaks.[780] Masimo maintains the specification belies Philips' position that the alternative method does not concern any "method of 'evaluating spectral values, but instead is a peak determination algorithm."[781] The majority of the '535 patent specification describes the embodiment of claim 1 that selects relevant peaks by evaluating complex combinatorial values (a combination of the red *and* infrared spectral values).[782] The final two paragraphs describe "further developments of and alternatives to the *above-described* special embodiment of the method according to the present invention are described. It is, for example, possible to determine the *above-described peek [sic] determination* in the red and/*or* infrared spectrum separately."[783] Masimo points out that Dr. Stone relied on this section to opine claim 1 covers Masimo's algorithm, testifying:

> Q. . . . So is there any other support for your interpretation that the evaluating first and second spectral values only requires evaluating the first spectral values?
>
> A. Not to my knowledge.
>
> Q. And so you're relying entirely on column 12, lines 15 to where?
>
> * * * * *
>
> A. 15 through 17.
>
> Q. Okay. That's the entire support for your interpretation that evaluating said first and second spectral values only requires evaluating said first spectral values; right?
>
> A. That and my contention that evaluating a data set that includes both of them is the same as evaluating them.[784]

The court agrees with Masimo that the specification indicates the "further development

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[780] D.I. 585 at 5.
[781] *Id.* (quoting D.I. 521 at 14).
[782] *Id.* (citing '535 patent, 4:29-12:11).
[783] '535 patent, 12:12-18 (emphasis added).
[784] D.I. 586, Ex. 21 (Stone Depo.) at 170:2-19.

of alternatives *to the above-described special embodiment*" is the same as the claimed algorithm except for the use of red or infrared spectra separately. Therefore, the court grants Masimo's motion for summary judgment that the disclosed but unclaimed embodiment precludes Philips' doctrine of equivalents argument.

C. Direct Infringement

Masimo also argues it is entitled to summary judgment of non-infringement of claim 1, a method claim, because Philips has not presented evidence that the code at issue has ever been used to calculate a patient's oxygen saturation.

A "patentee bears the burden of proving infringement by a preponderance of the evidence."[785] "To infringe a method claim, a person must have practiced all steps of the claimed method."[786] "Just as anticipation can be found by a single prior art use, a finding of infringement can rest on as little as one instance of the claimed method being performed during the pertinent time period[,]"[787] however, it is insufficient that the accused product is merely capable of performing the claimed method.[788] "A patentee may rely on either direct or circumstantial evidence to prove infringement."[789] To prove "'direct infringement, a patentee must either point to specific instances of direct infringement or show that the accused device necessarily infringes the patent in suit.'"[790]

Masimo's products utilize multiple algorithms and techniques to calculate oxygen

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[785] *Laitram Corp v. Rexnord, Inc*., 939 F.2d 1533, 1535 (Fed Cir. 1991) (citation omitted).

[786] *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1317 (Fed. Cir. 2009) (citing *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 775 (Fed. Cir. 1993)).

[787] *Id.*

[788] *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311 (Fed. Cir. 2006) ("Method claims are only infringed when the claimed process is performed, not by the sale of an apparatus that is capable of infringing use.").

[789] *Lucent Techs., Inc. v. Gateway, Inc.*, 543 F.3d 710, 723 (Fed. Cir. 2008) (citing *Liquid Dynamics Corp. v. Vaughan Co.*, 449 F3d. 1209, 1219 (Fed. Cir. 2006)).

[790] *Id.* (quoting *ACCO Brands, Inc. v. ABA Locks Mfr. Co.*, 501 F.3d 1307, 1313 (Fed. Cir. 2007)).

saturation, including time-domain and frequency-domain algorithms.[791] Within the frequency-domain processing, there are three different ratios calculated for possible use in determining oxygen saturation.[792] Philips accuses only one of those three ratios of infringement.[793] The accused ratio can only be used if three conditions are met: 1) the pulse rate must have dropped at least 20 beats per minute ("bpm") below the long-term average; 2) the pulse rate must be below 30-50 bpm; and 3) the patient must be motionless.[794]

According to Masimo, Philips has no evidence of the accused code being executed to calculate a patient's oxygen saturation under those conditions.[795] It also contends even if those conditions have occurred, its algorithm may still not use the accused code to calculate oxygen saturation instead of ratios from other algorithms.[796]

Philips contends there is ample evidence of direct infringement and notes circumstantial evidence can establish direct infringement.[797] Philips also contends evidence in the form of Masimo's own documents and numerous clinical studies

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[791] D.I. 401 (Baura Decl.) at ¶ 8.

[792] *Id.* at ¶ 8.

[793] *Id.* at ¶¶ 8-9.

[794] *Id.* at ¶ 9 ("[T]he third-frequency domain ratio can be used only when the pulse rate has dropped at least 20 beats per minute from the long-term average ***and*** the pulse rate is below a corner frequency of 30-50 beats per minute.") (emphasis in original); D.I. 398, Ex. 8 at ¶ 67 ("The DR2 function calls the FDNM_CalcPR function, a function that calculates a patient's pulse rate under conditions of *no motion*.") (emphasis added).

[795] D.I. 396 at 12.

[796] D.I. 401 at ¶ 9 ("[E]ven if such circumstances exist, there is no guarantee that this particular ratio will be used to calculate oxygen saturation instead of ratios from Masimo's many other algorithms."), ¶ 16 ("Even if the two conditions discussed above were somehow met in Masimo's products, those products may still report a saturation value from another algorithm instead of the frequency domain algorithm.").

[797] D.I. 521 at 14-16 (citing *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1318 (Fed. Cir. 2009); *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., Ltd.*, 449 Fed. Appx. 923, 928-29 (Fed. Cir. 2011); *Symantec Corp. v. Computer Assocs. Int'l, Inc.*, 522 F.3d 1279, 1293 (Fed. Cir. 2008); *Oracle Corp. v. Parallel Networks, LLC*, 778 F. Supp. 2d 527, 543-44 (D. Del. 2011)).

demonstrate acts of direct infringement.[798] Although Masimo argues it would be rare for a patient to exhibit the conditions required for use of the accused ratio, Philips maintains such conditions are satisfied with some regularity.[799] Philips gives as an example, sudden or acute bradycardia, a condition where a patient with a normal long-term heart rate has a sudden decrease in heart rate.[800]

Philips contends several pieces of evidence provide direct and circumstantial evidence of infringement.[801] This evidence consists of the testimony of Dr. Stone regarding when the required conditions would be met, the testimony of Dr. Edward Andrew Ochroch, an anesthesiologist, regarding the frequency of such conditions occurring in anesthetized patients, and Masimo's own studies and internal documents showing numerous instances of these conditions occurring in patients monitored by Masimo pulse oximeters.[802]

According to Dr. Stone, several cardiac conduction abnormalities cause the required conditions to be met in hospital floor environments, including ventricular "auto-pacing" and periodic blocks of alternate heart beats.[803] Dr. Stone opines "[i]t is hard for me that these circumstances have never occurred in a patient being monitored by a

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[798] *Id.* at 15.

[799] *Id.*

[800] D.I. 521 at 15 (citing D.I. 522 (Ochroch Decl.) at ¶¶ 6-9 (describing acute or sudden bradycardia)).

[801] *Id.* 16.

[802] *Id.* at 16-18.

[803] D.I. 524 (Stone Decl.) at ¶ 12 ("Sudden or acute bradycardia . . . can be caused by a variety of chemical and physiological triggers particularly in an operating room environment with anesthetized patients; Cardiac conduction abnormalities. Failures of the conductive system of the heart can result in ventricular 'auto-pacing', a condition in which the natural contraction frequency of the myocardium results in a 'regular' heartbeat rate of 15 to 20 beats per minute. . . . Similarly, conductive conditions which periodically block alternate beats or even 2 out of 3 beats exist which may trigger the conditions required for execution of the infringing algorithm.").

Masimo pulse oximeter."[804]

Dr. Ochroch avers the required conditions "occur in operating room environments when a patient experiences acute or sudden bradycardia. Acute bradycardia is not uncommon in anesthetized patients, and can have a variety of chemical physical triggers. Additionally, anesthetized patients typically do not exhibit motion."[805] Dr. Ochroch states he has personally "observed bradycardia to occur in patients numerous times. I have also witnessed patients being monitored with several pulse oximeters, including Masimo pulse oximeters, experience acute bradycardia."[806]

Philips also argues Masimo's own studies and internal documents demonstrate numerous instances of these conditions occurring in patients being monitored by Masimo pulse oximeters.[807]

The court agrees with Masimo that Philips does not present evidence that each and every step of method claim 1 of the '535 patent has actually been performed.[808] First, Masimo is not a direct infringer, which requires a showing that Masimo "performed

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[804] *Id.* at ¶ 16.

[805] D.I. 522 at ¶ 6.

[806] *Id.* at ¶ 8. Dr. Baura acknowledges having seen these conditions, albeit only once, in an operating room environment. D.I. 401 at ¶¶ 14, 17.

[807] D.I. 521 at 17 (citing D.I. 526, Ex. 111 (abstract describing study where Masimo oximeters were used to recognize pulse rates of less than 50 bpm); *id.*, Ex. 112 (article citing two examples of Masimo pulse oximeters giving erroneous audible alarms on anesthetized patients experiencing profound bradycardia); *id.*, Ex. 113 at MASP0406249-52 (study showing results of Masimo oximeter monitoring a patient with an obstructive sleeping disorder); *id.*, Ex. 110 (email from Joe Kiani, a Masimo employee, noting testing of Masimo's products on patient(s) with bradycardia); *id.*, Ex. 114 (showing study evaluating ability of Masimo products to identify bradycardic events in patients); D.I. 526, Ex. 115 (article stating "data gathered during the three-month evaluation, covering 2,587 total patient days, showed that the Masimo Patient SafetyNet system supported the early identification of patients with . . . acute bradycardia needing atropine")).

[808] *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1317 (Fed. Cir. 2006) ("A method or process consists of one or more operative steps, and, accordingly, "[i]t is well established that a patent for a method or process is not infringed unless all steps or stages of the claimed process are utilized.") (quoting *Roberts Dairy Co. v. United States*, 208 Ct. Cl. 830, 530 F.2d 1342, 1354 (Ct. Cl. 1976)).

all of the steps in the claimed methods."[809] The only evidence of Masimo's purported performance of all the steps of claim 1 of the '535 patent is a 2003 internal email from a Masimo employee noting he has "occasional acute bradycardia to the 20s. Engineering has collected a lot of data on me to help with the 'pulse beep' algorithm."[810] Masimo represents the email does not concern the algorithm at issue here when it states: "the email discusses helping with the 'pulse beep algorithm,' not the saturation algorithm at issue here."[811] It also notes the email does not articulate that each of the conditions required for the accused ratio to run.[812] Therefore, the court determines Philips has not presented evidence to support its infringement contention that Masimo is a direct infringer of claim 1 of the '535 patent.

The court also agrees with Masimo that it is not an indirect infringer. Philips recognizes that to show indirect infringement, "the performance of the claimed method is required . . . ."[813] Philips presents evidence purportedly demonstrating infringing use by others of Masimo products. Philips describes each of the exhibits cited as: using Masimo oximeters to recognize acute bradycardia (<50 bpm) in certain patients; citing two examples of a Masimo pulse oximeter giving erroneous audible alarm on anesthetized patients experiencing profound bradycardia in an operating room; reporting the results of Masimo oximeter monitoring a patient experiencing a pronounced bradycardia; a study evaluating Masimo products' ability to identify hypoxic

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[809] *Mirror Worlds, LLC v. Apple Inc.*, 692 F.3d 1351, 1359 (Fed. Cir. 2012) (citing *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1317 (Fed. Cir. 2009)).

[810] D.I. 526, Ex. 110 at MASP0410630.

[811] D.I. 585 at 6.

[812] *Id.*

[813] D.I. 521 at 15 (citing *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1308 (Fed. Cir. 2009) & *O2 Micro Int'l Ltd v. Beyond Innovation Tech.*, 449 F. Appx. 923, 928-29 (Fed. Cir. 2011)).

and bradycardic events in patients; and findings where data gathered over three months, covering 2,587 total patient days showed a Masimo product supported the early identification of acute bradycardia needing atropine.[814] Each of these documents reference bradycardia, but Philips does not explain how, or why, any of them demonstrate the Masimo products were used under the conditions required by the accused frequency-domain ratio. Masimo provides a useful example of acute bradycardia that would not meet the first two required conditions. Consider that an acute bradycardia would occur with a pulse rate quickly dropping from 70 to 52 bpm.[815] That example would not meet the requirements of a drop of 20 bpm or a pulse rate below 50.[816] That Masimo's products may be capable of performing the claimed method is not enough to support Philips' allegation of infringement.[817]

The two cases Philips primarily relies upon regarding circumstantial evidence are likewise unavailing. In *Lucent Technologies, Inc. v. Gateway, Inc.*, there was testimony from an actual user (the plaintiff's expert) that he and his wife had used the accused software in an infringing manner, and the expert commented "[i]t's hard to imagine that we're the only two people in the world that ever used it."[818] The court also noted "Microsoft not only designed the accused products to practice the claimed invention, but *instructed it customers to use the accused products in an infringing way*."[819] The court

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[814] D.I. 521 at 17-18 (citing D.I. 526, Exs. 111, 112, 113, 114, 115, respectively).
[815] D.I. 585 at 7.
[816] *Id.* at 7.
[817] *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311 (Fed. Cir. 2006) ("Method claims are only infringed when the claimed process is performed, not by the sale of an apparatus that is capable of infringing use.").
[818] 580 F.3d 1301, 1318 (Fed. Cir. 2009).
[819] *Id.* (emphasis added).

further remarked "the jury reviewed evidence relating to the extensive sales of Microsoft products and the dissemination of instruction manuals for the Microsoft products."[820] That court additionally determined "[t]he circumstantial documentary evidence, supplementing the experts' testimony, was *just barely sufficient* to find direct infringement by a preponderance of the evidence."[821] Here, Philips has not provided evidence Masimo instructed its customers, or anyone else, to perform the accused steps, nor that anyone has performed those steps.

In *Symantec Corporation v. Computer Associates International, Inc.*, the court noted "the specific intent necessary to induce infringement 'requires more than just intent to cause the acts that produce direct infringement. . . . [T]he inducer must have an affirmative intent to cause direct infringement.'"[822] The court continued "[t]his is not a case where the customers may be using the product in either an infringing way or a non-infringing way; [defendant's] customers *can only use the [plaintiff's] products in an infringing way*."[823] Here, in contrast, Masimo's products are normally used in a non-infringing way.[824]

Because Philips has not produced evidence that each of the steps of method claim 1 of the '535 patent has actually been performed, Masimo's motion for summary judgment of non-infringement is granted.

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[820] *Id.*

[821] *Id.* (emphasis added).

[822] 522 F.3d 1279, 1292 (alteration and omission in original) (quoting *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) relevant section (*en banc*)).

[823] *Id.* at 1292 (emphasis added).

[824] D.I. 401 at ¶ 8 (Baura stating "[t]he two ratios not accused of infringement come from statistics determined by the FST algorithm, which is Masimo's *primary frequency-domain algorithm*.") (emphasis added); D.I. 522 at ¶ 9 (Stone stating "[w]hile acute bradycardia *is not a common occurrence*, it does occur with some regularity in operating room environments.").

D. Invalidity

Masimo contends claim 1 of the '535 patent is invalid because it is anticipated by U.S. Patent No. 5,575,284 ("the '284 patent") and Masimo's '272 patent.

1. The '284 Patent

"A claim is anticipated and thus invalid if each and every limitation of a claim is found, expressly or inherently, in a single prior art reference."[825] Further, "[a]nticipation may be resolved on summary judgment if there is no genuine issue of material fact."[826]

Masimo alleges its '284 patent is prior art to the '535 patent under 35 U.S.C. §§ 102(a) and (e).[827] Masimo states that although the '284 patent was not before the USPTO during the prosecution of the '535 patent, "Philips knew of the '284 patent when it was identified by the European Patent Office as being 'particularly relevant' to the claims as originally filed."[828]

Masimo notes there is no dispute that the '284 patent discloses limitations (a), (b), and (d) of claim 1 of the '535 patent.[829] The parties' dispute is whether the '284 patent discloses limitation (c) of that claim.

Limitation (c) of claim 1 of the '535 patent recites:

> (c) selecting physiologically relevant first and second spectral values by evaluating said first and second spectral values according to criteria

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[825] *Planet Bingo, LLC v. Game Tech Int'l, Inc.*, 472 F.3d 1338, 1346 (Fed. Cir. 2006) (citation omitted).

[826] *Zenith Elecs. Corp. v. PDO Commc'n Sys., Inc.*, 522 F.3d 1348, 1356-57 (Fed. Cir. 2008) (citation omitted).

[827] D.I. 396 at 15.

[828] *Id.* at 15, 15 n.6.

[829] D.I. 396 at 15 (citing D.I. 399, Ex. 13 (Philips' response to Masimo's invalidity contentions) at 121-22 (claim chart listing Philips' validity contentions and including no argument concerning the lack of disclosure of limitations (a), (b), and (d) of claim 1 by the '284 patent). In briefing, Philips does not argue the '284 patent lacks disclosure of limitations (a), (b), and (d).

selected in accordance with the patient's physiological parameters . . . .[830]

Masimo argues the '535 patent specification makes clear that "criteria" includes verifying that a frequency is in the probable pulse range.[831]

According to Masimo, the '284 patent discloses obtaining red and infrared spectral values using a Fast Fourier Transform ("FFT"),[832] and discloses that red and infrared "time-domain data is . . . converted into the frequency domain."[833] "For both the red and IR values, the AC component is determined by the magnitude of the highest spectral peak found at from 0.5 to 2.5 Hz [or cycles per second], and represents the pulsatile, or AC component, of the oximetry waveform."[834] Masimo states the "0.5 to 2.5 Hz" value corresponds to a pulse rate from 30 to 150 beats per minute ("bpm").[835] Thereafter, the identified red and infrared pulsatile components are then used to calculate a ratio to determine saturation.[836] Masimo acknowledges the pulse rate will vary from patient to patient, but argues selecting the largest pulsatile between 30 to 150 bpm permits identification of the pulse rate of the specific patient being monitored.[837] Masimo contends the '284 patent evaluates red and infrared values by criteria selected in accordance with the patient's physiological parameters, e.g., verifying the highest value, which corresponds to the pulse of the specific patient, is within an acceptable

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[830] '535 patent, claim 1. The court construed the phrase "selecting physiologically relevant first and second spectral values" from this limitation as meaning "selecting first and second spectral values that are determined to have physiological relevance based on criteria selected in accordance with characteristics of the specific patient being monitored." D.I. 210 at 15-17, 31.

[831] D.I. 396 at 14 (citing '535 patent, 10:27-34 (describing "knockout" criteria, such as when a peak does not correspond to a "pulse rate between 30 and 360 bpm")).

[832] *Id.* at 16 (citing '284 patent, 10:57-11:10).

[833] *Id.* at 16 (citing '284 patent, 10:57-62).

[834] *Id.* at 16-17 (citing '284 patent, 10:66-11:2).

[835] *Id.* at 17.

[836] *Id.* at 17 (citing '284 patent, 11:5-11:10).

[837] *Id.* at 17.

range between 30 to 150 bpm.[838]

Masimo concludes, therefore, that the '284 patent discloses "selecting physiologically relevant first and second spectral values" (which the court construed to mean "selecting first and second spectral values that are determined to have physiological relevance based on criteria selected in accordance with characteristics of the specific patient being monitored"), and thus anticipates the '535 patent.[839]

Philips focuses on the court's construction requiring "selection in accordance with the *specific patient* being monitored," in arguing the '284 patent does not anticipate because it does not disclose use of the physiological parameters of the "specific patient" to select spectral values.[840] Philips contends Masimo's position confuses the concepts of "physiological parameters," as recited in claim 1, with what Philips describes as the broader concept of "physiologically relevant" criteria.[841] Accordingly, physiological parameters are parameters associated with a specific patient being monitored.[842] Philips states examples of physiological parameters in the '535 patent include previously calculated pulse rate (frequency), saturation, and perfusion.[843]

Philips contends the '284 patent's assumption that the highest peak between 0.5 and 2.5 Hz corresponds to the patient's pulse rate, is not evidence that spectral values are selected in accordance with a patient's physiological parameters.[844] Philips argues

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[838] *Id.*
[839] *Id.*
[840] D.I. 521 at 19.
[841] *Id.* at 19.
[842] *Id.*
[843] *Id.* (citing '535 patent, 10:48-54) ("The peaks and the associated needles can also be evaluated on the basis of tendency variations with regard to a reference value that was ascertained in a preceding run. In so doing, e.g. +20 points can be awarded to a respective peak for small frequency variations (<10% rel), small perfusion variations (<10% rel) or small saturation variations (<5% abs).").
[844] *Id.* at 19.

because this criteria is identical for every patient, and the selection range or rules are not modified in accordance with characteristics of the specific patient being monitored, it does not meet the court's claim construction.[845] Philips argues, therefore, the '284 patent does anticipate claim 1 of the '535 patent.[846]

Masimo's response to Philips' anticipation argument with regard to the '284 patent relies on arguments made by Philips' during claim construction.[847] It does not dispute Philips' argument in opposition to this motion that the criteria recited in the '284 patent is identical for every patient, or the selection range or rules are not modified in accordance with characteristics of the specific patient being monitored. Consequently, the court finds Masimo has not established, as a matter of law, that the '284 patent discloses limitation (c) of claim 1 of the '535 patent and its motion for summary judgment that the '284 patent anticipates that claim is denied.

2. The '272 Patent

Masimo alleges its '272 patent is prior art to the '535 patent under 35 U.S.C. §§ 102(a) and (e).[848] According to Masimo, the '272 patent discloses using a complex FFT to provide a frequency domain representation of the red and infrared signals for determining oxygen saturation and pulse rate.[849]

Masimo states there is no dispute that the '272 patent discloses limitations (a)

[845] *Id.* (citing D.I. 525, Ex. 99C (Stone Valid. Rpt.) at ¶¶ 66-70).
[846] *Id.* at 19-20.
[847] D.I. 585 at 8-9.
[848] D.I. 396 at 13.
[849] *Id.* (citing '272 patent, 55:14-58:45, Figs. 25A-C).

and (b) of claim 1 of the '535 patent.[850] The parties' dispute focuses on whether the '272 patent discloses limitations (c) and (d) of that claim.

Again, limitation (c) of claim 1 of the '535 patent recites:

> (c) selecting physiologically relevant first and second spectral values by evaluating said first and second spectral values according to criteria selected in accordance with the patient's physiological parameters . . . .[851]

Masimo reiterates the '535 patent specification makes clear that "criteria" includes verifying that a frequency is in the probable pulse range.[852] Masimo states the '272 patent discloses selecting frequencies from 20 to 500 beats per minute to include the heart rate and harmonics of the heart rate.[853] Thus, Masimo contends the '272 patent discloses the requirements of limitation (c).[854]

Masimo also states the '272 patent discloses using the maximum red FFT value to provide a threshold for other red values that can be used, and the maximum infrared FFT value to provide a threshold for other infrared values that can be used.[855] The '272 patent discloses an embodiment using 1% of the maximum magnitude as the

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[850] *Id.* (citing D.I. 399, Ex. 13 at 121-22 (claim chart listing Philips' validity contentions and including no argument concerning the lack of disclosure of limitations (a) and (b) of claim 1 by Masimo's PCT Publication No. WO 96/12435). The '272 patent has the same specification as Masimo's PCT Publication No. WO 96/12435. *Compare* D.I. 398, Ex. 7 ('272 patent), D.I. 399, Ex. 14 (PCT Publication No. WO 96/12435). In briefing, Philips does not argue the '272 patent lacks disclosure of limitations (a) and (b).

[851] '535 patent, claim 1.

[852] D.I. 396 at 14 (citing '535 patent, 10:27-34 (describing "knockout" criteria, such as when a peak does not correspond to a "pulse rate between 30 and 360 bpm")).

[853] *Id.* (citing '272 patent, 56:31-48).

[854] *Id.* at 14.

[855] *Id.* (citing '272 patent, 56:47-54 ("The threshold modules 660, 662 examine the sample points, on a point-by-point basis, to select those points where the magnitude of an individual point is above a particular threshold which is set at a percentage of the maximum magnitude detected among all the remaining points in the snapshots. In the present embodiment, the percentage for the threshold operation is selected as 1% of the maximum magnitude"), 57:10-12 ("6. the red sample must pass the red threshold 660; 7. the infrared sample must pass the infrared threshold 662") & Fig. 25B).

threshold.[856] The maximum red and infrared values correspond to the "modulation degree or approximately to the perfusion."[857] Masimo maintains the maximum red and infrared values are criteria selected in accordance with the patient's physiological parameters, and, therefore, this is another example of the '272 patent disclosing limitation (c).[858]

Philips responds by alleging Masimo again erroneously conflated the concepts of physiological parameters and physically relevant information.[859] Dr. Stone opines a range between 20 and 500 bpm is not a physiological parameter of the specific patient, as that frequency range applies to every patient.[860] Masimo again responds by reiterating arguments made by Philips during claim construction, and does not dispute the range between 20 and 500 bpm applies to every patient.[861] The court again determines that criteria does not establish the '272 patent discloses limitation (c).

With regard to Masimo's contentions based on the '272 patent's disclosure of certain other criteria, e.g., phase and thresholding, Dr. Stone opines those criteria "are merely parameters of the red and infrared signals . . . but none of these parameters are selected in accordance with the characteristics of the specific patient being monitored. Instead, they apply to every patient . . . ."[862]

Masimo responds the '272 patent discloses using a threshold of 1% of the

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[856] *Id.* (citing '272 patent, 56:47-54).
[857] *Id.* (citing '535 patent, 9:3-5 ("absH [norm.]: Absolute height of the peak as normalized after the preprocessing; corresponds to the modulation degree or approximately to the perfusion").
[858] *Id.* at 14.
[859] D.I. 521 at 20
[860] D.I. 525, Ex. 99C at ¶ 93.
[861] D.I. 585 at 9.
[862] D.I. 525, Ex. 99C at ¶ 93.

maximum red or infrared values for each individual patient.[863] It argues that because maximum red or infrared values changes for each patient, so would any percentage of those values and, therefore, the value to which the percentage is applied varies with each specific patient.[864]

Because the same threshold of 1% is applied to every patient, the court determines there is a question of fact as to whether any resulting variance to which the percentage is applied due to changes in maximum red or infrared values among individual patients is an example of the '272 patent disclosing limitation (c).

Masimo also presents two additional reasons Philips is incorrect that the threshold criteria is not a "physiological parameter." First, it notes the court's construction requires the criteria be "selected in accordance with *characteristics* of the patient being monitored," not in accordance with physiological parameters, and maximum red and infrared values are characteristics of the specific patient being monitored.[865] Second, Masimo contends, even if the criteria needed to be in accordance with a "physiological parameter," the '535 patent explains the maximum red and infrared values correspond to perfusion, and Philips admits, and the '535 patent explains, that perfusion is a physiological parameter.[866]

Neither argument is convincing. First, as noted above, the '272 patent discloses selecting maximum red and infrared values based on the same 1% threshold for all

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[863] D.I. 585 at 9.
[864] *Id.*
[865] *Id.* at 10.
[866] *Id.* (citing D.I. 521 at 19 (Philips stating "the examples of physiological parameters in the '535 patent include previously calculated pulse rate (frequency), saturation, and *perfusion*" (citing '535 patent, 10:48-54) (emphasis added))).

patients, whether or not those values vary among patients. Second, Masimo maintains the *'535 patent* explains maximum red and infrared values correspond to perfusion. It states the *'535 patent* explains perfusion is a physiological parameter, which Philips acknowledges. Masimo concludes "[t]hus, the criteria (perfusion) that sets the threshold for each patient is a physiological parameter according to Philips and the *'535 patent*."[867] Masimo does not, however, demonstrate how the *'272 patent* discloses using perfusion to set the threshold for each patient. As a result, the court denies Masimo's motion for summary judgment that the '272 patent discloses limitation (c) of claim 1 of the '535 patent.

Finally, the parties disagree on Masimo's assertion that the '272 patent discloses limitation (d) of the '535 patent. Limitation (d) requires:

> calculating the concentration of the blood component making use of the selected first and second spectral values.[868]

Masimo states, for each selected red and infrared pair, the '272 patent discloses taking a ratio and providing it to a saturation equation module.[869] As a result, saturation values are provided from which arterial and venous saturation can be selected.[870] Additionally, Masimo contends the final saturation value displayed is based on the known past physiological value for the patient being monitored.[871] Thus, Masimo argues the '272 patent discloses limitation (d).[872]

Philips contends this limitation is not disclosed by the '272 patent because it does

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[867] *Id.* (emphasis added).
[868] '535 patent, claim 1.
[869] D.I. 396 at 15.
[870] *Id.* (citing '272 patent, 57:16-48).
[871] *Id.* (citing '272 patent, 46:61-47:3).
[872] *Id.* at 15.

not base the calculation of an SpO2 value on a patient's physiological parameters.[873] It states the '272 patent calculates an SpO2 value and *after* calculating it, determines whether to display the value based on historical SpO2 values.[874] Philips maintains at no point is a previous SpO2 value actually used in the selection process.[875]

Masimo's only response to Philips' argument is that the claim language recites "calculating concentration of the blood component making use of the selected first and second spectral values," and that language does not require the calculation be based on the patient's physiological parameters.[876] That claim language requires "making use of *the selected first and second spectral values*." Those spectral values are the spectral values selected in limitation (c), which selection the court determined was "based on criteria selected in accordance with characteristics of the patient being monitored." The court, therefore, rejects Masimo's argument that the language of limitation (d) demonstrates the '272 patent anticipates that limitation claim 1, and denies Masimo's motion for summary judgment on that issue.

7. Philips' Motion for Summary Judgment on Laches with Respect to U.S. Patent Nos. 5,632,272, 6,263,222, and 6,999,194;[877]

Presently before the court is Philips' motion for summary judgment on laches

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[873] D.I. 521 at 20.

[874] *Id.* (citing D.I. 525, Ex. 99C at ¶¶ 94-95 (Dr. Stone opines Dr. Baura's assertion that the final saturation value displayed is based on the known past physiological value for the patient being monitored is incorrect. The passage relied upon by Dr. Baura "refers only to the display of a final SpO2 calculation. The spectral values were selected earlier in the algorithm based only on parameters related to the red and infrared signals. The decision of whether to display SpO2 values calculated from spectral values is different from the steps recited in claim 1 of the '535 patent, which recite 'selecting values in accordance with characteristics of the specific patient being monitored.' The claims require more than merely selecting whether to display an SpO2 value calculated from spectral values previously selected with other parameters.")).

[875] *Id.* (citing D.I. 525, Ex. 99C at ¶¶ 94-95).

[876] D.I. 585 at 10.

[877] D.I. 397.

with respect to the '272 patent",the '222 patent, and '194 patent against Masimo.[878] For the reasons discussed herein, Philips' motion will be denied.

Laches (Philips Motion)

Philips argues summary judgment should be granted because pre-suit damages are unavailable due to the operation of laches on the '272, '222 and '194 patents.[879] The parties differ substantially on the facts. The court sets out the facts not disputed or absent the parties' interpretation of them.

Masimo's communicated regarding the technology at issue with Hewlett Packard ("HP") in 1999, because HP released its Fourier Artifact Suppression Technology ("FAST").[880] Masimo was surprised to learn of FAST, which purportedly was quite similar to the SET technology.[881] Masimo wrote to HP on May 3, 1999, notifying of its '272 patent (among others), and offered a license to incorporate SET into HP's products.[882] In a follow up letter dated June 18, 1999, Masimo asserted FAST contained its algorithm or one similar to it, and suggested HP was ignoring Masimo's proprietary rights.[883] Masimo again offered HP a license to incorporate SET.[884] On the same day, HP responded that Masimo's offer was under consideration.[885] In a letter dated July 2, 1999, HP provided a more comprehensive response, and emphasized it

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[878] *Id.* The briefs are found at D.I. 400 (Philips' opening brief), D.I. 495 (Masimo's answering brief), and D.I. 592 (Philips' reply brief).

[879] D.I. 400 at 2.

[880] *Id.* at 3.

[881] D.I. 495, (Joseph Kiani Decl. Chief Executive Officer ("CEO") of Masimo) at 2.

[882] *Id.* at 2-3; D.I. 504 at 5; D.I. 400 at 3-4; D.I. 496 Ex. 8. Masimo wanted HP to replace FAST with SET. Neither the '272 nor the '194 patents had issued, so no notification of those two patents could have been provided.

[883] *Id.* at 4; D.I. 496 Ex. 9.

[884] D.I. 400 at 4.

[885] *Id.*; D.I. 496 Ex. 10.

did not use Masimo's algorithm.[886] Masimo then responded by letter on July 13, 1999, confirming its willingness to grant HP a license and requested a meeting.[887] HP responded in writing on October 1, 1999, concluding Masimo's '272 patent did not cover HP's products and declined the offer for a license.[888]

In October 1999, while Masimo was negotiating with Philips and others to integrate SET in their products, Masimo sued industry leader Nellcor for patent infringement.[889] That litigation lasted until January 17, 2006, when Nellcor executed a settlement agreement with Masimo to discontinue sales of its infringing products.[890] The Nellcor litigation involved the '222 patent, not the '272 or '194 patents.[891]

In 1999, HP spun off its medical division to form a new corporation, Agilent Technologies, which was acquired by Philips in late 2000.[892] As part of the parties' discussions, in early 2001, Philips provided Masimo with a copy of its '535 patent,[893] which disclosed the FAST algorithm along with Philips' white paper discussing the '535 patent and the FAST algorithm.[894] On March 12, 2001, Masimo provided a claim chart identifying its infringement contentions of the '272 patent.[895] On July 25, 2001, Philips responded by denying any infringement of the '272 patent and offered to meet to further explain its views.[896] On August 22, 2001, during the parties' meeting, Philips explained

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[886] *Id.*; D.I. 496 Ex. 11.
[887] *Id.*; D.I. 496 Ex. 12.
[888] *Id.*; D.I. 496 Ex. 13.
[889] D.I. 495 at 6-8; D.I. 504 at 19.
[890] *Id.*; D.I. 498 Ex. 87; D.I. 499 Ex.134-41.
[891] D.I. 499 Ex. 144; D.I. 500 Ex. 145.
[892] D.I. 400 at 5; D.I. 495 at 3.
[893] U.S. Patent No. 6,122,535 ("the '535 Patent"); D.I. 428, Ex. 5.
[894] D.I. 400 at 11; D.I. 433, Ex. 47 at 171:22-174:21.
[895] *Id.* at 5; D.I. 496 Ex. 14.
[896] *Id.*; D.I. 494 at 3; D.I. 434 Ex. 74. Agilent/Philips stated "Masimo's assertions are misplaced and that Agilent's technology does not infringe any of the claims of those patents." *Id.*

why FAST did not infringe Masimo's patents.[897] Only the '272 patent, not the '222 patent, was addressed at that time.[898]

Following the August 2001 meeting, Philips and Masimo discussed a business partnership, which involved transitioning from FAST to SET.[899] On April, 3, 2003, the parties executed a Binding Letter of Intent,[900] which expressly reserved Masimo's right to sue Philips for patent infringement.[901] In December 2003, the parties negotiated and signed a Development, Manufacture and Distribution Agreement ("OEM Agreement"), that reserved Masimo's right to sue.[902] From 2004 through 2006, Masimo continued to negotiate with Philips to facilitate Philips' implementation of SET.[903] These negotiations resulted in two amendments to the 2003 OEM Agreement, the first in July 2004 and the second in March 2005.[904] During these negotiations, Masimo identified the '222 patent to Philips, which was part of the Nellcor litigation.[905]

In 2006, Masimo again expressed its infringement concerns to Philips,[906] and subsequently provided infringement claim charts on December 5, 2006 addressing the '222, '272 and '194 patents.[907] On January 8, 2007, the two parties met to discuss

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[897] D.I. 400 at 5; D.I. 494 at 3; D.I. 433 Ex. 49 at 70:18-77:16.

[898] *Id.*

[899] D.I. 495 at 3-6. Masimo asserts the parties continually met or discussed potential agreements and term sheets that would effectively resolve their patent dispute by substituting SET for FAST, primarily relying on the Kiani declaration. *Id*. Philips disagrees the discussions related to licensing of Masimo's patents at issue relying on the OEM Agreement, admissions in depositions and emails. *See* D.I. 433, Ex. 47 at 210:4-6, 212:6-21, 215:16-217:4, 220:3-9, Ex. 49 at 18-89; D.I. 435, Ex.76, 77, 79.

[900] D.I. 497, Ex. 64.

[901] *Id.*

[902] *Id.*, Ex. 65. The OEM Agreement did not resolve Masimo's patent issues nor address a license to its patents. D.I. 400 at 6; D.I. 435, Ex. 79.

[903] D.I. 495 at 6.

[904] D.I. 495 at 6; D.I. 497 Ex. 66-67.

[905] D.I. 504 at 13.

[906] D.I. 400 at 6, Ex. 76, 77; D.I. 495 at 8; D.I. 504 at 24.

[907] *Id.*; D.I. 495 at 8; D.I. 504 at 24-25.

those concerns.[908] Philips again insisted it did not infringe, and no resolution or agreement was reached.[909] Masimo continued to negotiate with Philips until January 2009 for a business agreement to phase out FAST and implement SET, but those efforts failed.[910] Despite the parties disagreements over the purpose and content of their conversations throughout their negotiations, it is clear Masimo believe Philips infringed the three patents under consideration in this motion.[911] On February 3, 2009, Masimo filed this action.[912]

Legal Standards:

A. Laches

Laches is an equitable defense to a claim for patent infringement. "In a legal context, laches may be defined as the neglect or delay in bringing suit to remedy an alleged wrong, which taken together with lapse of time and other consequences, causes prejudice to the adverse party and operates as an equitable bar."[913] Laches will bar recovery of damages for any infringement committed more than six years prior to the filing of the complaint or a counterclaim for infringement. The law on laches is rooted in the equitable principle that courts will not assist one who has "slept on his rights."[914]

To establish laches, a party must prove: (1) the patentee delayed in bringing suit

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[908] *Id.*

[909] *Id.*

[910] Again the parties dispute the focus of the discussions after the January 2007 meeting, including Philips' purported "misrepresentations" regarding the FAST algorithm. D.I. 400 at 7; D.I. 495 at 8-11; D.I. 504 at 25-30.

[911] *See generally*, D.I. 504 (Kiani Decl.).

[912] D.I. 400 at 7; D.I. 495 at 11.

[913] *See A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020, 1028-29 (Fed. Cir. 1992).

[914] *Crown Packaging Tech., Inc. v. Rexam Beverage Can Co.,* 679 F. Supp. 2d 512, 519 (D. Del. 2010).

for an unreasonable and inexcusable length of time from the time the patentee knew or reasonably should have known of the defendant's allegedly infringing activity; *and* (2) material prejudice to the defendant resulted from the delay.[915] Material prejudice may be either evidentiary prejudice or economic prejudice. Evidentiary prejudice arises when the infringer cannot present a full and fair defense on the merits due to the loss of records, death of witnesses, or the dimming of memories, thereby undermining the court's ability to judge the facts.[916] Economic prejudice arises when an infringer suffers the loss of monetary investments or incurs damages that would likely have been prevented by an earlier suit,[917] and not merely monetary losses related to a finding of liability for infringement.[918] Rather, the court must look for a change in the economic position of the alleged infringer during the period of delay.[919]

The equitable nature of laches does not follow hard and fast rules with regard to the level of actual knowledge required to trigger laches. The period from which the delay is measured begins at "the time the patentee knew, or in the exercise of reasonable diligence should have known, of the allegedly infringing activity."[920] It is "more than a mere suspicion but less than absolute assurance of [the] alleged infringement in order to activate the laches clock."[921] Thus, courts impose a duty on

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[915] *Id.* at 1032.

[916] *Id.* at 1033.

[917] *Id.* Any monetary loss claimed by the defendant must have a proven "nexus" to the patentee's delay in filing suit. *Gasser Chair Co., Inc. v. Infanti Chair Mfg. Corp.*, 60 F.3d 770, 774 (Fed. Cir. 1995).

[918] *A.C. Aukerman Co.*, 960 F.2d at 1033; *see also Jenn-Air Corp. v. Penn Ventilator Co.*, 464 F.2d 48, 49-50 (3d. Cir. 1972).

[919] *Id; see also Crown Packaging Tech., Inc. v. Rexam Beverage Can Co.,* 679 F. Supp. 2d 512, 526 (D. Del. 2010). Change must be a result of the delay, not simply a business decision to capitalize on a market opportunity. *Id.*

[920] *Adelberg Labs., Inc. v. Miles, Inc.*, 921 F.2d 1267, 1270 (Fed. Cir. 1990).

[921] *Rockwell Int'l Corp. v. SDL, Inc.*, 103 F. Supp. 2d 1192, 1197 (N.D. Cal. 2000).

patentees to police their patent rights and will impose constructive knowledge based on the required reasonable, diligent inquiry.[922] A patentee must investigate "'pervasive, open, and notorious activities' that a reasonable patentee would suspect were infringing."[923] "For example, sales, marketing, publication, or public use of a product similar to or embodying technology similar to the patented invention . . . give rise to a duty to investigate whether there is infringement."[924] "Furthermore, constructive knowledge of the infringement may be imputed to the patentee even where he has no actual knowledge of the sales, marketing, publication, public use, or other conspicuous activities of potential infringement if these activities are sufficiently prevalent in the inventor's field of endeavor."[925]

An alleged infringer can establish a presumption of laches by showing that more than six years elapsed between the time the patentee knew or should have known of the alleged infringing activity and the time of filing suit.[926] Such a delay raises a presumption that the delay is unreasonable, inexcusable, and prejudicial.[927] The period does not begin, however, prior to the issuance of a patent.[928] Where the presumption is

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[922] *See Wanlass v. Gen. Elec. Co.,* 148 F.3d 1334, 1338 (Fed. Cir. 1998).

[923] *Id. (*quoting *Hall v. Aqua Queen Mfg., Inc.*, 93 F.3d 1548, 1553 (Fed. Cir. 1996)).

[924] *Id.* (internal citations omitted).

[925] *Id.*

> If a patentee knows of the existence of a product or device that (i) embodies technology similar to that for which he holds a patent and (ii) uses that similar technology to accomplish a similar objective, he has a duty to examine the product or device more closely to ascertain whether it infringes his patent. If he shirks this duty, he does so on peril of triggering the laches period and perhaps ultimately losing his right to recover damages for the infringement.

Odetics, Inc. v. Storage Tech. Corp., 919 F. Supp. 911, 918 (E.D. Va. 1996), *on remand* 14 F. Supp. 2d 800 (E.D. Va. 1998), *aff'd in part, rev'd in part*, 185 F.3d 1259 (Fed. Cir. 1990).

[926] *A.C. Aukerman Co.*, 960 F.2d at 1037.

[927] *Id.* at 1035–36.

[928] *Id.* at 1032 (citations omitted).

established, the burden shifts to the patentee to produce sufficient evidence to "put the existence of a presumed fact into genuine dispute" with regard to the reasonableness of the delay or the alleged prejudice.[929]

"Importantly, where the patentee does not meet this burden of production by failing to come forward with *either* affirmative evidence of a lack of prejudice *or* a legally cognizable excuse for its delay in filing suit, the two facts of unreasonable delay and prejudice '*must* be inferred.'"[930] The presumption, however, is not evidence.[931] Where the "patentee presents a sufficiency of evidence which, if believed, would preclude a directed finding in favor of the infringer," the "presumption evaporates and the accused infringer is left to satisfy its burden of persuasion with actual evidence" of unreasonable delay and material prejudice.[932] "[T]he defendant bears the ultimate burden of persuasion," and the "burden of persuasion does not shift by reason of the patentee's six-year delay."[933]

"Ultimately, the establishment of the factors of undue delay and prejudice, whether by actual proof or by the presumption, does not mandate recognition of a laches defense in every case. Laches remains an equitable judgment of the trial court in light of all circumstances."[934] "A court must look at all of the particular facts and circumstances of each case and weigh the equities of the parties."[935] "[W]here there is

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[929] *Id.* at 1038.

[930] *Hall v. Aqua Queen Mfg., Inc.*, 93 F.3d 1548, 1554 (Fed. Cir. 1996) (emphasis in original) (quoting *A.C. Aukerman Co.*, 960 F.2d at 1037).

[931] *A.C. Aukerman Co.*, 960 F.2d at 1037.

[932] *Id.* at 1037-38.

[933] *Id.* at 1032.

[934] *Abbott Diabetes Care, Inc. v. Roche Diagnostics Corp.*, 2007 U.S. Dist. LEXIS 31193, at *8 (N.D. Cal. Apr. 24, 2007) (internal citation omitted) (citing *A.C. Aukerman Co.*, 960 F.2d at 1036).

[935] *A.C. Aukerman Co.*, 960 F.2d at 1032.

evidence of other factors which would make it inequitable to recognize the defense despite undue delay and prejudice, the defense may be denied."[936] Thus, "[e]ven if unable to overcome the presumption, a patentee may be able to preclude application of the laches defense with proof that the accused infringer was itself guilty of misdeeds towards the patentee."[937] This concept flows from the maxim, "[h]e who seeks equity must do equity."[938]

B. Unclean Hands

The unclean hands doctrine, rooted in the historical concept of the court as a "vehicle for affirmatively enforcing the requirements of conscience and good faith," requires the parties "have acted fairly and without fraud or deceit as to the controversy in issue."[939] The unclean hands doctrine works as a bar to the application of laches and "closes the doors of a court of equity to one tainted with inequitableness or bad faith relative to the matter in which he seeks relief, however improper may have been the behavior of the defendant."[940] The doctrine "stems from the belief that an equitable defense, such as laches, cannot be used to reward a party's inequities or to defeat justice."[941] To invoke the doctrine, "a mere showing of inequitable conduct on the part of the infringer, however, does not suffice to negate the effect of laches."[942] Instead, the patentee bears the burden of producing sufficient evidence proving that "the infringer

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[936] *Id.* at 1036.
[937] *Id.* at 1038.
[938] *Id.*
[939] *Crown Packaging Tech., Inc.*, 679 F. Supp. 2d at 521 (quoting *Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 814-15 (1945)).
[940] *Id.* at 521 (quoting *Precision Instrument Mfg. Co.*, 324 U.S. at 814).
[941] *Id*. (quoting *Hot Wax, Inc. v. Turtle Wax, Inc.*, 191 F.3d 813, 825 (7th. Cir. 1999)).
[942] *Odetics, Inc., v. Storage Tech. Corp.,* 14 F. Supp. 2d 800 (E.D.Va. 1998).

has engaged in particularly egregious conduct [that] would change the equities significantly in the plaintiff's favor."[943] Further, "willful infringement, by itself, is not sufficient to preclude the application of the laches defense."[944]

ANALYSIS

Philips argues the laches clock was triggered for ten years on the '272 patent and eight years on the '222 patent, and is therefore entitled to a presumption that Masimo's delay in bringing this suit on these two patents was both unreasonable and prejudicial.[945] Although not asserting the presumption, Philips contends Masimo's five year delay in bringing suit on the '194 patent was likewise unreasonable and

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[943] *Crown Packaging Tech., Inc.*, 679 F. Supp. 2d at 521 (quoting *A.C. Aukerman Co.,* 960 F.2d at 1033). *See, e.g., Odetics, Inc.,* 14 F. Supp. 2d at 806 (many of the cases in which the laches defense was not allowed involved conduct more egregious than willful infringement alone); *Bott v. Four Star Corp*, 807 F.2d 1567, 1576 (Fed. Cir. 1986) (egregious conduct consisted of (i) copying the claimed invention and (ii) "inexcusably accelerating infringing sales after [the Federal Circuit] had affirmed the district court's decision on liability"); *A.C. Aukerman Co. v. R.L. Chaides Constr. Co.,* 1993 WL 379548, at *5 (defendant's construction of new infringing product after litigation commenced, failure to investigate patent's validity, and knowledge that there was only one license constituted "particularly egregious" conduct).

[944] *Crown Packaging Tech., Inc.*, 679 F. Supp. 2d at 521-22 (quoting *Odetics, Inc.* 14 F. Supp. 2d at 806); *see also Western Elec. Co., Inc. v. Piezo Tech.,*1990 WL 126269, at *10 (M.D. Fla. Mar. 22, 1990) ("Although a showing of egregious conduct may persuade a court that the equities do not lie with the defendant, a plaintiff's allegations of 'willful infringement' do not automatically bar the alleged infringer from asserting the laches and estoppel defenses; this is a matter for the court to determine in its equitable discretion"); *Loral Corp. v. B.F. Goodrich Co.*, 1989 U.S. Dist. LEXIS 16865, at *127 (S.D. Ohio Jan. 27, 1989) ("Although BFG's infringement was willful . . . . the court is of the opinion that BFG's willfulness during this time period was not characterized by egregious conduct . . . . Thus, BFG is not precluded from asserting laches . . . ."), *rev'd on other grounds*, 899 F.2d 1228 (Fed. Cir. 1990); *Stambler v. Diebold, Inc.*, 1988 U.S. Dist. LEXIS 10132, at *18 (E.D.N.Y. Sept. 27, 1988) ("[T]he Court is aware of no case that stands for the proposition that willful infringement, without proof of deliberate, calculated plagiarism, constitutes such egregious conduct as to defeat a laches defense."), *aff'd*, 878 F.2d 1445 (Fed. Cir. 1989); *cf. TruePosition Inc. v. Andrew Corp.,* 568 F. Supp. 2d 500, 517-18 (D. Del. 2008) (deciding not to bar the defendant's equitable claims because the plaintiff failed to point to any particular actions on the part of the defendant that could bridge the gap between willfulness and particularly egregious conduct). In *TruePosition*, dismissing plaintiff's argument to the contrary, the court declined to find (as a matter of first impression) that "the Federal Circuit's 'new tougher' standard set forth in *In re Seagate Tech., LLC,* 497 F.3d 1360 (Fed. Cir. 2007)" for willfulness "raised the bar so high so as to render 'objective recklessness' and 'egregiousness' virtually indistinguishable." *Id.*

[945] D.I. 400 at 1.

prejudicial.[946] Masimo denies it slept on its rights with respect to the '272, '222 and '194 patents, and argues it persistently pursued its patent claims against Philips.[947] Masimo further contends its delay in bringing suit was not unreasonable and is excused due to litigation with Nellcor, continuous negotiations with Philips, and diligent enforcement of its patents throughout the industry.[948] Moreover, Masimo asserts Philips was not prejudiced by the timing of this lawsuit because Philips always understood Masimo would sue if the parties ultimately failed to resolve their differences.[949] Even if Philips did suffer material prejudice, however, Masimo argues the laches defense fails because the required "nexus" between such prejudice and any alleged delay has not been shown.[950] Lastly, Masimo maintains Philips' attempt to bar Masimo's claims in equity is defeated by the doctrine of unclean hands.[951] Philips disputes Masimo's arguments regarding no material prejudice and unclean hands.[952]

A. Presumption of Laches

Philips may establish the presumption by showing more than six years elapsed between the time Masimo knew or should have known of the alleged infringing activity and the time of filing suit.[953] Masimo filed this action on February 3, 2009. Thus, to trigger the presumption, Philips must show Masimo knew or should have known of the alleged infringement for the '272 and '222 patents on or before February 3, 2003. More

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[946] *Id.*
[947] D.I. 495 at 1.
[948] *Id.*
[949] *Id.* at 2.
[950] *Id.* at 18.
[951] *Id.* at 20.
[952] D.I. 593 at 7, 10.
[953] *A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020, 1037 (Fed. Cir. 1992).

specifically, because Philips raises laches on summary judgment, it must show an absence of genuine issues of material fact as to whether Masimo had such knowledge before the crucial 2003 date on each patent.[954] The laches period does not begin, however, prior to the issuance of a patent.[955]

The '272 patent issued on May 27, 1997.[956] Philips contends laches began to run for this patent as early as May 3, 1999, when Masimo first became aware of FAST and determined it may infringe.[957] Masimo knew of the FAST algorithm in May 1999 when it learned of HP's Viridia M3, which contained that purportedly infringing algorithm.[958] Masimo wrote to HP in May 1999 raising its belief that FAST used its intellectual property, because HP was characterizing its new product as containing "Masimo's algorithm."[959] HP denied infringement and Masimo's offer for a license.[960] Philips did not acquire Agilent, HP's former medical division, until late 2000.[961] In early 2001, Masimo received Philips' '535 patent along with Philips' white paper discussing the '535 patent and the FAST algorithm.[962] In March 2001, Masimo provided Philips with a claim chart and its infringement contentions on the '272 patent, and discussed how a business partnership could resolve their issues.[963]

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[954] *Rockwell Intern. Corp. v. SDL, Inc.*, 103 F. Supp. 2d 1192, 1196 (N.D. Cal. 2000).
[955] *A.C. Aukerman Co.*, 960 F.2d at 1032.
[956] D.I. 400 at 2.
[957] *Id*. at 10.
[958] *Id.*
[959] *Id.*; D.I. 433 Ex. 47 at 142:22-144:2, 154:20-155:7. Masimo's CEO, Joe Kiani, was shocked to learn about the introduction of FAST. D.I. 495 at 2. The May 3, 1999 letter touted the importance of Masimo's SET technology, identified the '272 patent, and asserted HP's Viridia M3 patient monitor contained pulse oximetry processing "quite similar to Masimo SET." *Id.* at 3-4.
[960] D.I. 400 at 4; D.I. 496, Ex. 13.
[961] D.I. 495 at 3; D.I. 400 at 5.
[962] D.I. 400 at 11; D.I. 433, Ex. 47 at 171:22-174:21.
[963] *Id.* at 5; D.I. 496, Ex. 14.

Philips argues Masimo's belief in 1999 that FAST infringed triggered the obligation to examine the HP Viridia M3 to ascertain whether it actually infringed the '272 patent.[964] Masimo, however, contends it made no accusations of infringement in any correspondence with HP in 1999.[965] Prior to its purchase of Agilent, Philips was not involved in any infringement discussions on the '272 patent with Masimo until March 2001. Masimo's 1999 letters merely notified HP of its '272 patent and encouraged HP to enter into a license.[966] It was not until March 2001, that Masimo reached out to Philips concerning its infringement allegations on the '272 patent.[967]

For laches on the '272 patent to apply, Masimo's actual or constructive knowledge of Philips' infringement had to exist by February 3, 2003. For Philips to meet this burden, it must show that Masimo "had more than a mere suspicion but less than an absolute assurance of [Philips'] alleged infringement in order to activate the laches clock."[968] A patentee needs to, however, provide some formal notice of claimed infringement in order to be imputed with actual knowledge.[969] Evidence of Masimo's required knowledge of infringement of the 272 patent is its receipt of Philips' white paper and '535 patent describing the FAST algorithm in early 2001 and its letter in March 2001, with infringement charts. Thus, the laches period for the '272 patent begins at the latest by March 2001, and Masimo's seven year and eleven month delay before suing on the '272 patent triggers the presumption of laches.

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[964] *Id.* at 10.
[965] D.I. 495 at 3.
[966] *Id.*; D.I. 496 Ex. 8-9.
[967] D.I. 496 Ex. 13, 14.
[968] *Rockwell Intern. Corp.*, 103 F. Supp. 2d at 1198.
[969] *Id.*; *see also Naxon Telesign Corp. v. Bunker Ramo Corp.*, 517 F. Supp. 804, 806 (N.D. Ill. 1981).

Philips also contends the presumption applies to the '222 patent, which issued on July 17, 2001.[970] Philips maintains Masimo's knowledge of its alleged infringing activity on the '222 patent existed at the time of the parties' meeting in August 2001, when the parties discussed their respective positions on infringement.[971] According to Philips, the '222 patent was not addressed at the August 2001 meeting or in any correspondence or later discussion until December 5, 2006,[972] when Masimo provided claim charts asserting infringement on the '272, '272 and '194 patents.[973] Masimo, however, contends the parties discussed the '222 patent before December 2006 during their business negotiations.[974] Notably absent in Masimo's argument is any reference that the '222 patent was discussed during the August 2001 meeting.

As with the '272 patent, the operative date for laches on the '222 patent is February 3, 2003. Since Masimo was provided Philip's '535 patent and white paper regarding the FAST algorithm in early 2001, it should have known of Philips' alleged infringement on the '222 patent when it issued in July 2001. Although Masimo did not expressly claim infringement until December 2006, it admits discussing the '222 patent with Philips before the December 2006 letter. Therefore, Masimo knew or should have reasonably known of Philips' alleged infringement on the '222 patent as early as July 2001. Because Masimo's delay in bringing suit on the '222 patent is for a period of seven years and five months, the presumption of laches arises.

The '194 patent was not issued until March 2, 2004, four years and ten months

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[970] D.I. 400 at 2.
[971] *Id* at 11.
[972] D.I. 400 at 6; D.I. 496, Ex. 17.
[973] D.I. 434, Ex. 76.
[974] D.I. 495 at 4-5; D.I. 504 9-19, 24-25.

prior to the filing of this action. Because any purported delay was less than six years, the presumption does not apply,[975] Philips must prove Masimo's delay in filing suit on the '194 patent was unreasonable from which Philips suffered material prejudice.

When the presumption applies, unreasonable delay and prejudice is inferred, absent rebuttal evidence.[976] The presumption is, however, a "bursting bubble" which completely vanishes by the production of sufficient evidence to support a finding of the nonexistence of a presumed fact.[977] Accordingly, the presumption shifts the burden to Masimo to demonstrate its delay in bringing suit on the '222 and '272 patents was reasonable, that Philips did not suffer any material prejudice as a result of the delay, or Philips had unclean hands.[978]

B. Reasonableness of the Delay

As noted previously, when the presumption of laches regarding the '272 and '222 patents applies, an inference of unreasonable delay arises which may be overcome by a legally justified excuse that the delay was reasonable under the circumstances.[979] Such evidence need only be sufficient to raise a genuine issue on the reasonableness of the delay.[980]

Masimo propounds three bases why its delay in bringing suit on the '222, '272 and '194 patents was reasonable: 1) the parties engaged in extensive negotiations from 1999 to 2009 to resolve their differences regarding these patents; 2) Masimo was

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[975] D.I. 400 at 11.
[976] *A.C. Aukerman Co.*, 960 F.2d at 1037.
[977] *Id.*
[978] *Crown Packaging Tech., Inc. v. Rexam Beverage Can Co.*, 679 F. Supp. 2d 512, 526 (D. Del. 2010).
[979] *A.C. Aukerman Co.*, 960 F.2d at 1038.
[980] *Id.*

involved with other litigation concerning its patent rights with Nellcor from 1999 to 2006; and, 3) Philips repeatedly caused delay.[981]

Other litigation may establish a legally cognizable excuse for delay.[982] Patent actions are inherently expensive and time consuming; requiring a patentee to engage in multiple litigation at the same time may be unfair.[983]

Masimo relies on litigation with Nellcor between 1999 to 2006 as a basis that any delay in filing suit against Philips on the '222 patent was excused, and the laches period should be tolled.[984] Of the three patents involved herein, the validity, enforceability and ownership of only the '222 patent was at issue in the Nellcor litigation.[985] Until completion of that litigation, those issues regarding the '222 patent remained unresolved, which provides justification for Masimo not pursing Philips on that patent while the Nellcor action was pending. Furthermore, the evidence demonstrates Philips knew of the Nellcor litigation, which was widely reported throughout the industry.[986] Masimo discussed with and provided updates about the Nellcor litigation to Philips, and reserved its right to sue on the '222, as evidenced by its letters accompanied with claim infringement charts in March 2001 and December 2006, by meeting with Philips in August 2001 and January 2007 to discuss infringement, and by the OEM Agreement.[987]

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[981] D.I. 495 at 12-16.
[982] *A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020, 1033 (Fed. Cir. 1992).
[983] 6-19 CHISUM ON PATENTS § 19.05 [2][b][i].
[984] D.I. 495 at 6-8, 15-16.; D.I. 498 Ex. 87; D.I. 499 Ex. 134-41.
[985] D.I. 499 Ex. 144; D.I. 500 Ex. 145, 146.
[986] D.I. 495 at 7; D.I. 500 Ex. 154-163.
[987] D.I. 400 at 5; D.I. 495 at 3, 8; D.I. 496 Ex. 14; D.I. 434, Ex. 76; D.I. 500, Ex. 148-53; D.I. 504 at 20-21, 25.

Philips relies on *Jamesbury Corp. v. Litton Indus. Products, Inc.*[988] to support its position that Masimo failed to affirmatively notify Philips it was the next entity to be sued. *Jamesbury*, however, is distinguishable from the present matter. There, although the parties unsuccessfully attempted to settle their patent dispute, after negotiations ended, the patentee remained silent for eight years before commencing a lawsuit.[989] No such period of silence occurred in the instant matter.[990]

Further, contrary to Philips' position, notice of other litigation is not required where a defendant is aware of such litigation from other sources.[991] Nor does prior contact mandate notice of intent to sue.[992]

Similar to the facts in *Cover v. Hyramatic Packaging Co.*,[993] in the instant matter, Masimo has presented evidence that Philips not only knew of the Nellcor litigation, but was also monitoring that litigation.[994]

As a result, Masimo's delay in filing suit against Philips on the '222 patent while the Nellcor litigation was pending was not unreasonable.[995]

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[988] 839 F.2d 1544 (Fed. Cir. 1988).

[989] *Id.* at 1553.

[990] As noted previously herein, the parties dispute whether their business discussions served as a remedy for their patent issues. What is clear from the miles of exhibits submitted, is that throughout the period of the Nellcor litigation, concerns regarding the '222 patent remained.

[991] *Aukerman*, 960 F.2d at 1039.

[992] *Id.* (noting "overall equities *may* require appropriate notice," but "such notice requirement is not to be rigidly imposed) (emphasis added).

[993] C.A. No. 93-6400, 1994 WL 396423 at *3 (E.D. Pa. July 27, 1994) (finding plaintiff gave no indication he approved of defendant's alleged infringement, was justified in not proceeding against defendant until patent ownership in the other litigation was established, and notice of that litigation was not required).

[994] D.I. 499, Ex. 132; D.I. 500, Ex. 150, 153-64.

[995] The Federal Circuit issued its opinion upholding the validity and enforceability of the '222 patent on September 7, 2005. Remand of the '222 patent to the district court was limited to entering a permanent injunction on that patent. *See* D.I. 499, Ex. 144. Thereafter, Masimo and Nellcor entered into an agreement settling their disputes on January 17, 2006. D.I. 498, Ex. 87.

For genuine bilateral negotiations to excuse delay for filing suit,[996] the negotiations must be between the patentee and the alleged infringer.[997] Masimo claims, because it was engaged in negotiations with Philips until 2009, the presumption of laches on the '222 and '272 patents has been rebutted, and any purported delay in filing on the '194 patent was reasonable.

From the beginning of the negotiations with HP in 1999 through the August 2001 meeting with Philips, HP, then Philips denied infringement of the '272 patent. Thereafter, in 2003, the parties entered into an OEM Agreement, in which Masimo reserved its right to sue Philips for infringement.[998] Masimo presents evidence, mainly through the Kiani declaration, that the parties continued to negotiate the implementation of SET into Philips' products, but no agreement was ever reached. In response to Masimo's December 2006 letter accompanied by infringement charts on the three patents in suit, Philips continued to deny any infringement and no resolution occurred.[999]

A.C. Aukerman v. Miller Formless Co. provides "[f]or such tolling, the negotiations must ordinarily be continuous and bilaterally progressing, with a fair chance of success, so as to justify significant delays."[1000] In *Aukerman*, the parties engaged in eight years of correspondence regarding a license to resolve their patent dispute, during which defendant never took a license nor abandoned its position of noninfringement.[1001] Although neither party broke off communications, but continued to reiterate their

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[996] *A.C. Aukerman Co*., 960 F.2d at 1033.
[997] *Giese v. Pierce Chemical Co.,* 29 F. Supp. 2d, 33, 40-41 (D. Mass. 1998).
[998] D.I. 495 at 3-6; D.I. 504 at 17-18; D.I. 497 Ex. 66-67.
[999] D.I. 495 at 8-11; D.I. 504 at 25.
[1000] *A.C. Aukerman Co. v. Miller Formless Co., Inc.*, 693 F.2d 697, 700 (7th. Cir. 1982).
[1001] *Id.* at 701.

respective positions, the court found "there has to be something more than continued jousting, at least where there is no real possibility of success on the part of the patentee in obtaining the . . . . type of license it wants,"[1002] leading the court to find the delay unreasonable.[1003]

Philips maintains, as evidenced by correspondence between the parties, the various draft term sheets, the Binding Letter of Intent and the OEM agreement, it explicitly intended to "continue selling FAST technology along side Masimo's SET," and provide customer choice regarding SpO2 solutions, thereby evidencing the negotiations between the parties were not to eliminate FAST and resolve any patent issues.[1004]

Negotiations, however, do not have to exclusively regard a license in order to justify delay. "Negotiations that would have most likely resolved issues of infringement" will evince an intent to enforce its patents.[1005] Based on the present record, there are genuine factual issues as to whether Philips would phase out FAST and implement SET, which would thereby resolve issues related to the three patents involved in this motion.[1006]

Therefore, Masimo has demonstrated a legally sufficient basis to refute the presumption of laches on the '222 and '272 patents sufficient to raise genuine factual issues on the reasonableness element. Similarly, because the presumption of laches does not apply to the '194 patent, genuine issues of material fact on reasonableness

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[1002] *Id*.
[1003] *Id.*
[1004] D.I. 593 at 5-6.
[1005] *Metso Minerals, Inc. v. Powerscreen Int'l. Distribution Ltd.*, 833 F. Supp. 2d 321, 328-29 (E.D.N.Y. 2011).
[1006] *See generally* D.I. 504. *See also*, Ex. 64, 65, 82-86, 103-124.

remain as to that patent.

C. Material Prejudice

Since Masimo rebutted the presumption of laches by showing a reasonable excuse for its delay in filing suit on the '272 and '222 patents, Philips must produce evidence that it suffered material prejudice as a result of Masimo's delay in filing suit by demonstrating the absence of any genuine issue of material fact.[1007] Material prejudice may be either economic or evidentiary.[1008] If Philips satisfies its burden, Masimo must come forward with specific facts refuting material prejudice to defeat Philips' motion for summary judgment.[1009]

1. Evidentiary Prejudice

Philips does not argue it suffered any evidentiary prejudice, and therefore that factor is not a basis for laches.

2. Economic Prejudice

Economic prejudice arises when an infringer suffers the loss of monetary investments or incurs damages that would have likely been prevented by an earlier suit.[1010] "Economic prejudice is not a simple concept but rather is likely to be a slippery issue to resolve."[1011] The court must look for a change in the alleged infringer's economic position during the period of delay, such as investment in production of the

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[1007] *Adelberg Labs., Inc. v. Miles, Inc.*, 921 F.2d 1267, 1270 (Fed. Cir. 1990).

[1008] *A.C. Aukerman Co. v. R.L. Chaides Const. Co.*, 960 F.2d 1020, 1033 (Fed. Cir. 1992).

[1009] *Wanlass v. Gen. Elec. Co.*, 148 F.3d 1334, 1338 (Fed. Cir. 1998)(quoting *Hall v. Aqua Queen Mfg., Inc.*, 93 F.3d 1548, 1553 (Fed. Cir. 1996)).

[1010] *A.C. Aukerman Co.*, 960 F.2d at 1032.

[1011] *Id.* at 1033; *see also Crown Packaging Tech., Inc. v. Rexam Beverage Can Co.*, 679 F. Supp. 2d 512, 526 (D. Del. 2010).

allegedly infringing device.[1012] "The change must be *because of and as a result of* the delay, not simply a business decision to capitalize on a market opportunity."[1013] "An alleged infringer need not show economic prejudice due to reliance upon the patentee's delay, but rather must show economic prejudice that results from the patentee's delay."[1014]

Philips claims economic prejudice from Masimo's delay because it expanded the use of its FAST technology into several patient monitors and other product lines, including defibrillators.[1015] Philips further asserts the majority of its expansion occurred after the 2003 OEM Agreement with Masimo, because that agreement contemplated the continued sale of FAST.[1016] Masimo contends Philips showed no change in economic position as a result of Masimo's delay,[1017] and there is no nexus between any alleged prejudice suffered by Philips and Masimo's delay.[1018] As a result, Masimo argues Philips has failed to show economic prejudice from Masimo's delay.

Although Philips made significant investment in R&D to improve and upgrade, as well as expand FAST by integration into several product lines,[1019] it merely asserts the majority of its expansion occurred after the 2003 OEM Agreement with Masimo as evidence of the nexus between delay and economic prejudice.[1020] Masimo, however,

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[1012] *A.C. Aukerman Co.*, 960 F.2d at 1033.
[1013] *Hemstreet v. Computer Entry Systems Corp.*, 972 F.2d 1290, 1294 (Fed. Cir. 1992) (emphasis added); *see also Crown Packaging Tech.*, 679 F. Supp. 2d at 526.
[1014] *Meyers v. Asics Corp.*, 974 F.2d 1304, 1308 (Fed. Cir. 1992) (emphasis in original); *see also Crown Packaging Tech.*, 679 F. Supp. 2d at 526.
[1015] D.I. 400 at 11.
[1016] *Id.* at 11-12; D.I. 435 Ex. 79.
[1017] D.I. 495 at 17.
[1018] *Id.* at 18-20.
[1019] D.I. 400 at 11-12.
[1020] *Id.* at 12; D.I. 592 at 10.

has shown through statements from Philips' executives that an earlier lawsuit would not have affected Philips' business plans with respect to FAST, along with evidence of Philips' indifference to Masimo's detailed infringement allegations.[1021] Similar to *Meyers v. Asics Corp.*,[1022] the evidence in the instant matter "shows that none of the defendants [were] concerned that its products might infringe . . . . and [did] not show that any of the defendants would have acted differently had [the patentee] filed suit earlier."[1023] Masimo has demonstrated an earlier infringement action would not have forestalled Philips' research and development and marketing efforts.[1024] "The change must be because of and as a result of the delay, not simply a business decision to capitalize on a market opportunity."[1025] Masimo has raised genuine issues of material fact as to whether a nexus exists between Philips' economic change and Masimo's delay in filing suit.

In light of the findings on reasonableness and because Philips failed to satisfy its burden on material prejudice, its motion for summary judgment on laches is denied.

Since Philips' motion for summary judgment on laches is denied for failing to satisfy the elements of that defense, the court need not address Masimo's equitable arguments regarding unclean hands**.**

[1021] D.I. 495 at 18-19; D.I. 500, Ex. 187; *id.*, Ex. 166 at 167:7-168:13; *id.*, Ex. 147 at 235:19-241:18; D.I. 499, Ex. 131 at 189:12-192:9.

[1022] 974 F.2d 1304, 1308 (Fed. Cir. 1992).

[1023] *Id.*

[1024] *Hemstreet v. Computer Entry Sys. Corp.*, 972 F.2d 1290, 1293-94 (Fed. Cir. 1992); *see also Freeman v. Gerber Products Co.*, 466 F. Supp. 2d 1242, 1248 (D. Kan. 2006) ("The Federal Circuit has repeatedly emphasized the importance of the fact that the alleged infringer must have changed its position 'because of and as a result of the delay' . . . . [The defendant] did not prove that it did anything differently than it otherwise would have done had it not been for plaintiff's delay in filing suit" . . . . [The defendant] made a deliberate business decision to reject plaintiffs' suggestion that [the defendant] may be infringing plaintiffs' patent and to proceed with its original plan for product development, marketing and sales.") (internal citations omitted).

[1025] *Hemstreet*, 972 F.2d at 1294.

ORDER

Consistent with the findings contained in the Report and Recommendation,

IT IS RECOMMENDED that

1. Masimo's motion for summary judgment of infringement of claims 17 and 18 of the '222 patent (D.I. 405) be denied. Philips' motion for summary judgment of invalidity based on the written description requirement under 35 U.S.C. § 112 (D.I. 410) be granted, and Philips' motion for summary judgment of anticipation of the '379 or Hall patent (D.I. 410) be denied.

2. Philips' motion for summary judgment of invalidity of the '984 patent (D.I. 394) be denied. Philips' motion for summary judgment of noninfringement of the '984 patent (D.I. 394) be granted.

3. Philips' motion for summary judgment of non-infringement and invalidity of asserted claims of the '272 patent (D.I. 402) be denied.

4. Masimo's motion to exclude the testimony of Philips' expert John M. Turner (D.I. 381) be denied. Masimo's motion for summary judgment of noninfringement and invalidity of the '074 patent (D.I. 414) be denied.

5. Philips' motion for summary judgment of invalidity of anticipation of EP '117 (D.I. 406) be denied. Philips' motion of invalidity of written description (D.I. 406) be granted. Philips' motion for summary judgment of invalidity of lack of enablement (D.I. 406) be denied.

6. In light of the manner in which the parties' presented their arguments, Masimo's motion for summary judgment of no literal infringement of claim 1 of the '535 patent (D.I. 393) be denied. Masimo's motion for summary judgment of doctrine of

equivalents based on vitiation, prosecution history estoppel and disclosed but unnamed embodiment (D.I. 393) be granted. Masimo's motion for summary judgment of noninfringement of claim 1 (D.I. 393) be granted. Masimo's motion for summary judgment of invalidity of claim 1 of the '535 as anticipated by the '284 patent and the '272 patent (D.I. 393) be denied.

7. Philips' motion for summary judgment based on laches with respect to the '272, '222, and '194 patents (D.I. 397) be denied.

Pursuant to 28 U.S.C. § 636(b)(1)(B), FED. R. CIV. P. 72 (b)(1), and D. DEL. LR 72.1, any objections to the Report and Recommendation shall be filed within fourteen (14) days limited to forty (40) pages after being served with the same. Any response shall be limited to forty (40) pages.[1026]

The parties are directed to the Court's Standing Order in Non-Pro Se Matters for Objections Filed under FED. R. CIV. P. 72 dated November 16, 2009, a copy of which is found on the Court's website (www.ded.uscourts.gov.)

April 2, 2013

/s/ Mary Pat Thynge
UNITED STATES MAGISTRATE JUDGE

[1026] FED. R. CIV. P. 72(b)(2).