IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

MASIMO CORPORATION,	:	
	:	
Plaintiff,	:	
	:	
v.	:	C. A. No. 09-80-LPS-MPT
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PHILIPS ELECTRONICS NORTH AMERICA CORPORATION, et al.,	:	
	:	
	:	
Defendants.	:	

REPORT AND RECOMMENDATION

I. Introduction

This is a patent infringement case. Masimo Corporation ("Masimo") sued Philips Electronics North American Corporation and Philips Medizin Systeme Böblingen GMBH (collectively "Philips") on February 3, 2009 alleging infringement of multiple U.S. Patents. Masimo and Philips manufacture competing products in the field of pulse oximetry, which allows for non-invasive measurement of the oxygen levels in a person's hemoglobin. Pulse oximetry equipment is commonplace in most clinical settings as either stand-alone devices or as components of multi-parameter patient monitors.

II. Background

Masimo's initial complaint on February 3, 2009 alleged infringement of a number of Masimo's pulse oximetry-related patents.[1] Masimo filed an amended complaint on

[1] D.I. 1.

May 12, 2009.[2] In the amended complaint, Masimo alleges 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. Masimo seeks monetary damages and injunctive relief against Philips.

Philips answered the amended complaint on June 15, 2009, denying all allegations and citing twelve defenses.[3] In addition, Philips concurrently filed counterclaims against Masimo alleging infringement of Philips' patents through the production, use, and sale of various Masimo's monitors, boards, sensors, and oximeters using patented Philips' technology. Philips also requests monetary damages and injunctive relief against Masimo.

This opinion addresses the motions filed by the parties requesting the striking or exclusion of various experts' opinions and testimony

III. Governing Law

Evidentiary Standard for Expert Testimony

The admissibility of expert testimony is governed by Federal Rule of Evidence ("FED. R. Evid.") 702, which states in relevant part:

> 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.

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

In *Daubert v. Merrell Dow Pharma., Inc.*, the Supreme Court interpreted FED. R. EVID. 702 to "confide[] to the judges some gatekeeping responsibility in deciding questions of the admissibility of proffered expert testimony."[4] The Third Circuit has analyzed Rule 702 as "embodying three distinct substantive restrictions on the admission of expert testimony: qualifications, reliability and fit."[5] Important facts to consider in evaluating the reliability of a particular scientific or technical methodology include:

> (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.[6]

"In *Paoli*, [the Third Circuit] explained that even if the judge believes 'there are better grounds for some alternative conclusion,' and that there are some flaws in the scientist methods, if there are 'good grounds' for the expert's conclusions, it should be admitted."[7] The question of whether an expert's testimony is admissible based on his qualifications, reliability, and fit is committed to the court's discretion.[8]

The trial judge has broad latitude in determining whether the *Daubert* factors are

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[4] 509 U.S. 579, 600 (1993) (Rehnquist, J., concurring in part and dissenting in part).

[5] *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000) (explaining *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741-43 (3d Cir. 1994)).

[6] *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 n. 8 (3d Cir. 1994).

[7] *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 152-53 (3d Cir. 1999) (quoting *In re Paoli*, 35 F.3d at 744).

[8] *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d at 749.

reasonable measures of reliability.[9] *In re Paoli*, the Third Circuit found that proffers of expert testimony do not have to "demonstrate . . . by a preponderance of evidence that the assessments of their experts are *correct*, they [need] only . . . demonstrate by a preponderance of evidence that their opinions are reliable."[10] *Daubert* recognized "vigorous cross examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence,"[11] and further emphasized the trial court must "focus" solely on principles and methodology, and not on the conclusions generated.[12] A trial judge, however, is to scrutinize whether such methods have been properly applied to the facts of the case.[13]

As previously stated, the determination of whether to exclude expert evidence is at the court's discretion.[14] The Third Circuit has noted, however:

> While evidentiary ruling are generally subject to a particularly high level of deference because the trial court has a superior vantage point to assess the evidence . . . , evaluating the reliability of scientific methodologies and data does not generally involve assessing the truthfulness of the expert witness and thus is often not significantly more difficult on a cold record. Moreover, here there are factors that counsel in favor of a hard look at (more stringent review of) the district court's exercise of discretion. For example, because the reliability standard of [FED. R. Evid.] 702 and 703 is somewhat amorphous, there is significant risk that district judges will set the threshold too high and will in fact force plaintiffs to prove their case twice. Reducing this risk is particularly important because the Federal Rules of Evidence display a preference for admissibility.[15]

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[9] *See Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 139 (1999)
[10] *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d at 744.
[11] *Daubert*, 509 U.S. at 596.
[12] *Id.* at 580.
[13] See *id.*
[14] *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d at 149.
[15] *Id.* at 749-50.

The Third Circuit has identified several factors for the court to consider in determining whether to exclude expert testimony:[16]

> (1) the prejudice or surprise in fact of the party against whom the excluded witness would have testified, (2) the ability of the 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.[17]

Additionally, the "'importance of the excluded testimony should be considered."

1. Masimo's Motion to Exclude the Expert Testimony of Drs. John H. Eichhorn, Thomas L. Higgins, and Edward A. Ochroch Pursuant to FED. R. EVID. 702[18]

Drs. Eichhorn, Higgins and Ochroch (Philips' Experts)

As part of its damages, Masimo seeks lost profits on certain of Philips' sales of FAST and a reasonable royalty on the remainder of FAST sales. To recover lost profits, Masimo must establish, *inter alia*, the absence of acceptable non-infringing substitutes that may have permitted Philips to retain some or all of its revenues.[19] Philips contends Nonin PureSAT ("PureSAT") is an available acceptable alternative that precludes Masimo from recovering lost profits and supports a low royalty rate. Philips offered expert testimony to support its claim that PureSAT is an acceptable alternative. Masimo now seeks to preclude testimony offered by Philips' experts, Drs. John H. Eichhorn ("Eichhorn"), Thomas L. Higgins ("Higgins"), and Edward A. Ochroch ("Ochroch") pursuant to Rule 702.[20]

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[16] *Inline Connect. Corp. v. AOL Time Warner Inc.*, 470 F. Supp. 2d 435, 438 (D. Del. 2007).
[17] *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d at 791.
[18] D.I. 385. The briefs addressing Masimo's motion to exclude are found at D.I. 386 (Masimo's opening brief), D.I. 491 (Philips' answering brief) and D.I. 581 (Masimo's reply brief).
[19] *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1156 (6th Cir. 1978).
[20] D.I. 385.

Parties' Positions

A. Masimo

Masimo moves to preclude Drs. Eichhorn, Higgins, and Ochroch from testifying that PureSAT was an available acceptable alternative to FAST, because the data on which they base their testimony is unreliable, specifically (1) the clinical observations of Eichhorn and Ochroch have no reliable methodological bases;[21] (2) similarly, the technical bulletins from Nonin contain no reliable methodological basis;[22] and (3) the Food and Drug Administration ("FDA") approval is an inappropriate foundation to show clinical acceptance.[23]

Masimo contends Drs. Eichhorn and Ochroch failed to create an acceptable methodology for their clinical observations of PureSAT,[24] because neither doctor operated with a standard protocol, and they failed "to control for motion, perfusion, or any other part of [their] evaluation[s]."[25] Dr. Eichhorn's study did not include control for time or measure specific levels of perfusion, such as patient desaturation. Masimo points out while Dr. Eichhorn's study involved a side-by-side comparison of PureSAT and Masimo's SET, Dr. Ochroch's study did not involve other pulse oximeters for immediate comparison.[26] Dr. Higgins, who performed no study, relies on the comments of a colleague's observations in an exercise lab. Masimo maintains the experts' investigations followed no standard protocol, and are qualitatively different in setting and

[21] D.I. 386 at 5-8.
[22] *Id.* at 8-10.
[23] *Id.* at 11-12.
[24] *Id.* at 6-7.
[25] *Id.*
[26] *Id.*

function, than the use of pulse oximetry equipment on a high acuity hospital floor.[27]

Masimo claims the Nonin technical bulletins are methodologically unreliable under Rule 702, because the tests were performed by Dr. Philip Bickler, who is neither an expert nor witness for either party. Drs. Higgins and Ochroch base part of their expert opinions on those bulletins and peer review teleconferences with Dr. Bickler, where they interviewed Dr. Bickler regarding his testing protocol.[28] Masimo argues such a review is inadequate, because it is performed "in a vacuum, without context for whether the results were based on reliable generally accepted test methodology."[29] Masimo further states the Bickler interviews do not demonstrate appropriately reliable methodology, by failing to identify controls, types of motion, instructions to patients, or the length of each test.[30]

Masimo contends Drs. Higgins and Ochroch unreasonably relied on FDA documents as evidence of acceptable performance for motion-tolerant pulse oximeters, and neither is purportedly adequately familiar with these standards and practices to assume reliability based on FDA approval. Specifically, Masimo argues neither expert is familiar with what standard, if any, the FDA uses for approval of a motion-tolerant pulse oximeter.[31]

B. Philips

Philips maintains the testimony of all three experts is admissible, as the underlying data upon which they base their opinions is reliable. Philips argues the

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[27] *Id.* at 7-8.
[28] *Id.* at 8.
[29] *Id.* at 9.
[30] *Id.*
[31] *Id.* at 11.

reliability of Drs. Eichhorn and Ochroch's opinions is confirmed when the data is reviewed in the aggregate; the Nonin technical bulletins are founded on reliable methodology; and the FDA approval speaks to the general acceptance of the methodology. Philips agrees, since Dr. Higgins is unfamiliar with FDA requirements as to approval its provisions for medical equipment, not to proffer any opinion from him regarding the significance of FDA approval or clearance concerning the performance of PureSAT.[32]

Philips contends Masimo's portrayal of Dr. Eichhorn's observations as casual review is misleading. Rather, his study "recorded times, medical conditions, gender, ages, and state of motion of each of the 13 patients."[33] The patients also represented a variety of different ages, medical conditions, oxygen saturations and states of motion.[34] Philips points out Masimo's expert, Dr. Timothy J. Quill ("Quill"), favors hands-on, personal experience with the equipment as an important part of the evaluation process.[35] To demonstrate acceptability of Eichhorn and Ochroch's methods, Philips points to Quill's testimony to show its experts' modes are often the basis for a hospital's decision to select a particular type of pulse oximeter.[36] Philips argues its experts have

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[32] D.I. 491 at 19, n.7.

[33] *Id.* at 14, Ex. 132 at ¶¶ 8-16.

[34] *Id.* at 14.

[35] *Id.* at 15 (citing Ex. 128 (Quill Depo.) at 68:8-69:12 ("Q. In your opinion, is it - is it necessary to have this kind of personal experience with a technology to be able to evaluate it? A. I think having a broad range of experience with the technology gives you a perspective that's important so that you know what to expect, what the state of the art is, and how well the unit that you are examining corresponds to that. So, in that sense, it is important.")).

[36] D.I. 526, Ex. 128 at 46:6-47:22 ("Q. Have you personally conducted any studies of pulse oximeters? A. Only as part of product evaluations for purchase. Q. All right. And when have you done that? A. The last time we did this, and I might be a year off or so, was when we - when we looked at monitors in about - must have been about 2004, to compare our monitors that we were using at that time, which were various Nellcor technologies, you know, the gamut of Nellcor technologies, versus Masimo's technology at that time. And my hospital ended up choosing Masimo's technology. . . .

experience determining what technology may act as an acceptable or outperforming alternative, a required element of the lost profits analysis.[37] Philips confirms that during his study, Dr. Ochroch's patient base was "awake, responsive, breathing on their own, moving around. We ask them to cough and deep-breathe, et cetera, et cetera, during this transport period."[38] Philips also contends Dr. Higgins' reliance on his colleagues' observations while in the exercise lab is appropriate, since it is the same type of data and information employed by hospitals when making purchasing decisions and is therefore reliable.[39]

While Masimo presents the Nonin technical bulletins as merely promotional materials, Philips argues their testing information is scientifically valid. Philips notes Dr. Bickler, who ran the studies contained in the Nonin bulletins, is a world-renowned expert in the field of pulse oximetry, and his laboratory, the University of San Francisco Hypoxia Laboratory ("Hypoxia Lab") is held in equal regard.[40] Philips maintains the Nonin technical bulletins are not only reliable, but have been adequately peer-reviewed by Drs. Ochroch and Higgins after extensively interviewing Dr. Bickler. Dr. Ochroch specifically stated he is more comfortable with Dr. Bickler's studies than he is with most

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Q. So, in your opinion, it's the people who are actually using the technology in the clinical setting who are most able to evaluate it? A. That's correct. And in most evaluations I've been involved in, they have a large voice, if not the largest voice.").

[37] D.I. 491 at 17.

[38] D.I. 526, Ex. 130 (Ochroch Depo.) at 82:3-20.

[39] *Id.*, Ex. 128 (Quill Depo) at 47:1-16 ("We did a clinical comparison and gave out a series of questions to the users, that were preformatted questions: What did you think of this monitor? And then ask them, you know: What did you think of the accuracy? And various questions. And then had a free text thing at the bottom, where they could simply make comments: Do you like this better or worse than the alternative technology? Et cetera? So, in that sense, we did that. And this is commonly done in the hospital. We value the opinions of the people that actually use the equipment, at least as much as our own. So you then gather a, you know, a bunch of comments, and then you sit down together, and you hash out a decision as to which to choose.").

[40] D.I. 491 at 6-7.

articles he peer reviews, because of the extensive data Dr. Bickler provided regarding his methodology, his standards employed, and the bases for his conclusions.[41] Philips also offers Dr. Higgins' years of peer-review experience as additional evidence of Dr. Bickler's acceptable methodology.[42] Philips points out Dr. Bickler did not publish the results of his studies because he understood Nonin owned those results and publishing rights.[43]

Regarding Masimo's criticism that the Nonin technical bulletins lacked standard protocols, Philips notes the substantial and detailed knowledge Drs. Higgins and Ochroch testified to regarding the procedures Dr. Bickler followed as learned through their interviews with him. Dr. Higgins was intimately familiar with Dr. Bickler's motion testing and perfusion protocols.[44] Dr. Ochroch testified in detail about Dr. Bickler's

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[41] D.I. 526, Ex. 130 at 207:20-208:10 ("I'm an expert reviewer for certain journals. And from Dr. Bickler, I got so much more data, so much more background, so much more detail in his methodology and what he did and how he did it and how he drew his conclusions and what he considers to be standards that he met and appropriate standards and - that, I mean, I personally feel like I was a peer reviewer for his Nonin bulletins. And he asked - I mean, I asked and he answered all of the tough questions that I try to keep in the back of my mind when I review any of those data, when I look at stuff for peer review.").

[42] D.I. 491 at 9, Ex. 129 (Higgins Decl.) at ¶4 ("I serve as a peer reviewer for numerous professional journals, and I am a member of the editorial boards of Critical Care Medicine and the Journal of Cardiothoracic and Vascular Anesthesia.").

[43] D.I. 491 at 9, Ex. 130 (Ochroch Depo.) at 167:22-168:15 ("Q. Did you talk to Dr. Bickler whether he tried to publish the results of his testing of the Nonin devices? A. I specifically asked him about that, and he says it's his standard and seems to always have been the UCSF hypoxia lab standard that they're paid for testing. They do not consider that their own domain, that they use the paid-for testing as a way to support their lab, to ask and answer their own questions. And so they collect the data specifically for the company. Should the company want to publish it, that's fine, well, and good. But he does not on his own publish the data. And the data are specifically the property of the company purchasing them.").

[44] D.I. 526, Ex. 131 (Higgins Depo.) at 83:2-86:6 ("[Bickler] said that he had a machine that basically the patient's forearm would rest on the machine and the elbow was kept relatively stable while the hand was moved up and down at various frequencies, and that they could put a block under the fingers to make it a tapping motion or a scraping motion in order to simulate the motion that they found clinically. I asked him how he came about this method of doing it and he said that they had done a lot of testing with actual motion and this came closest to simulating what they saw in terms of changes with pulse oximetry. . . . He said that the machine causes the arm to move up and down, and the rate at which it could be moved up and down could be steady or irregular. The height could be varied, and, again, whether there - it could be designed to mimic a tapping motion or a scraping motion of the fingers. . . . [The frequence of motion] was somewhere between a half and five cycles per second and [the laboratory]

protocols for motion testing,[45] to induce hypoxia,[46] and to test low perfusion.[47] Philips contends the level of detail provided by these experts satisfies the reliability element under Rule 702.

While Philips will not proffer Dr. Higgins on FDA clearance, it maintains Dr. Ochroch's consideration of PureSAT's FDA clearance is "appropriate, reasonable, and reliable."[48] Philips claims Dr. Ochroch has previous experience working with the FDA approval process.[49] Dr. Ochroch also relies on his interviews with Dr. Bickler

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had done some previous studies to show that that best represented normal human motion."). *Id.* at 106:5-10 (Higgins testifying perfusion was controlled through the use of a heating pad).

[45] D.I. 526, Ex. 130 at 158:22-161:16 ("[I]n order to standardize the tapping, [Bickler] built a - a platform that the hand with the test pulse oximeters rests on. And the platform linearly elevates both the hand and the forearm approximately an inch and decelerates at a set rate - I can't remember exactly how many inches per second it decelerates - to tap. And I believe it's at one tap a second that this very repetitive motion occurs. And that's the tapping protocol. And the rubbing protocol is they set a metronome to give the patient the timing. And they describe an arc for the patient to rub the fingertip with the monitor or monitor - fingertips with the monitors through an arc at that set rate, which I also believe is one sweep a second. . . . [H]e does both the rubbing and the tapping for each subject as we described before for - to get the mean and the error measurements as we described before.").

[46] *Id.* at 163:20-164:21 ("[A]s he described it to me and as is described in the technical bulletins, the UCSF hypoxia lab uses a very standardized stereotyped hypoxic event where they will bring them down using the devices I've already described to preset desaturations and maintain them there, and they will do that with and without motion, with and without brachial artery clamped, decrease perfusion. They do it - they've done it to compare subjects with different skin pigmentations, essential [sic] Caucasians versus African Americans, and I'm not sure if he also looked at somewhere in the middle like Hispanics at times. So there are a number of very stereotyped protocols laid out in those technical bulletins that he takes the subjects through. . . . I believe that it's the series of hypoxic challenges which is repeated and the two motion challenges that are repeated and the brachial artery clamp that's repeated. So four major interventions he described to me.").

[47] *Id.* at 181:2-15 ("[B]asically what they do is they put a clamp on the brachial artery and bring down the arterial waveform in certain standard plateaus because with the arterial waveform, it's pretty much the area under the curve that looks at the pulse, no just the absolute peak. And so you have to do essentially what's called I believe a Fourier's - Fourier's analysis to look at the change in the volume of the arterial waveform as you're applying this clamp to then start to step down the perfusion going to the hand and then seeing how the pulse oximeter deals with this drop in perfusion.").

[48] D.I. 491 at 19.

[49] *Id.* at 20, Ex. 130 (Ochroch Depo.) at 223:9-224:13 ("There is a member of my department who is seeking FDA approval for a device that measures central compartment stuff through the endotracheal tube, for lack of a better term. . . . There's another member of my department who is trying to get FDA approval for a new endotracheal tube that allows you to do a number of things through it, including jet ventilation.

So I've been variously involved in various FDA issues, and I was involved in the FDA process for several drugs before. So I've been - I've gotten bits and pieces, different pictures of different FDA application process.").

concerning the Nonin studies, that detail Dr. Bickler's methodology, which is consistent with FDA requirements.[50]

Discussion

The Third Circuit has found excluding relevant 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."[51] No such showing has been demonstrated by Masimo. The qualifications of Drs. Eichhorn, Ochroch and Higgins are uncontested. Their individual skills, education, training, and specialized knowledge are clearly adequate to qualify each as an expert.

Masimo suggests the underlying data upon which the experts base their respective opinions is unreliable and fails to meet the standards of Rule 702. For the following reasons, the court agrees with Philips that the requisite indicia of reliability are present, and the testimony of all three experts is admissible.

A. Personal Experience

Masimo's argument concerning the personal observations by Drs. Eichhorn and Ochroch is inaccurate. While Masimo claims no standard protocols and no controlled variables were applied, it ignores the nature of the studies. Drs. Eichhorn and Ochroch were not in the laboratory creating an experiment to test a specific hypothesis. Rather, they performed their studies in a clinical setting, working with actual patients.[52] The

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[50] D.I. 491 at 20, Ex. 130 at 226:3-10 ("Q. Do you know the specific test that the FDA has that the FDA relies on to determine if a pulse oximeter is accurate or reliable through motion? A. I believe we've already discussed that. There may be many things that the FDA will consider acceptable, but the only one I know in detail is what Dr. Bickler has done and has had accepted as appropriate for the FDA.").

[51] *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 791-92 (3d Cir. 1994) (quotations omitted).

[52] D.I. 491 at 14-17.

studies involved a wide range of patient ages and conditions, with regular observations and note-taking.[53] Dr. Eichhorn's study elicited side-by-side results between Nonin PureSAT and Masimo's SET, the latter which has been frequently used in hospital settings for some time. Dr. Ochroch's clinical observations involved active, conscious, patients during transport, which inevitably invites movement.[54] The studies employed by Philips' experts are consistent with those employed in the field of medical technology. Side-by-side comparisons allow instant assessment of a new product against an older, established device, while maintaining patient safety. As Dr. Quill testified, these types of studies are utilized by hospitals for purchasing decisions, with the "largest voice" given to doctors with hands-on experience.[55] Use of such techniques as purchasing factors speak directly to the methods' acceptance. As identified by the Supreme Court, the threshold for reliability is it be based on "good grounds", that is, scientific knowledge.[56]

Dr. Higgins' opinion is partially based on conversations with colleagues in the exercise lab at his hospital. Dr. Higgins testified patients in the lab were monitored via Nonin PureSAT pulse oximeters while exercising, and his colleagues unanimously reported being pleased with PureSAT's performance.[57] His investigation relied on the extensive experience of colleagues with whom Dr. Higgins works. As evidenced by hospitals use of different brands of pulse oximeters, the field of medical technology benefits from the continued assessment by comparison of multiple products'

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[53] *Id.* at 14, Ex. 132 at ¶¶ 8-16.
[54] *Id.* at 17, Ex. 130 at 82:3-20.
[55] D.I. 526, Ex. 128 at 47:20-22.
[56] *Daubert*, 509 U.S. at 590.
[57] D.I. 526, Ex. 129 (Higgins Decl.) at ¶6.

performance.[58] "*Daubert* explains that the language of Rule 702 requiring the expert to testify to *scientific knowledge* means that the expert's opinion must be based on the 'methods and procedures of science' rather than on 'subjective believe or unsupported speculation'; the expert must have 'good grounds' for his or her belief."[59] Years of training followed by extensive experience with relevant technology supports Dr. Higgins' reliance on fellow health care providers' opinions that PureSAT performs effectively in the presence of patient movement and under different levels of perfusion. Contrary to Masimo's argument, lack of direct personal experience is not fatal to the reliability of Dr. Higgins' testimony.[60]

B. The Nonin Technical Bulletins

Masimo classifies the Nonin technical bulletins as mere promotional materials based on three arguments.[61] Philips' evidence refutes Masimo's arguments.

Although Masimo is correct that the results of Dr. Bickler's studies were never published in an academic reference, when the studies were performed, Dr. Bickler was employed by the Hypoxia Lab, and came under contract with Nonin to perform the studies outlined in the technical bulletins. Because of that arrangement, Dr. Bickler believed the results were solely owned by Nonin. Dr. Bickler did not fail to publish the results due to some failure in form or procedure. Rather, he understood Nonin, as the

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[58] *Id.*

[59] *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d at 742 (citing *Daubert*, 509 U.S. at 590).

[60] *Kumho Tire Co., Ltd.*, 526 U.S. at 152 ("The objective of [the gatekeeping] requirement is to ensure the reliability and relevancy of expert testimony. It is to make certain that an expert, whether basing testimony upon professional studies *or* personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of the expert in the relevant field.") (emphasis added).

[61] Masimo's contentions are: (1) the results were never published; (2) the experiments were never peer-reviewed; and (3) there was no standard protocol.

contracting party, had the publishing rights to the data he gleaned from the experiments it funded. While part of the court's analysis includes whether scientific results are published, absence of publication alone does not establish the findings are inadmissible.[62]

Masimo contends the studies were never subject to peer-review, making them unreliable and inadmissible. Drs. Ochroch and Higgins, however, thoroughly investigated the standards and procedures utilized by Dr. Bickler in the studies.[63] Dr. Ochroch testified as an expert reviewer for a number of medical journals, he was satisfied with the caliber of scientific rigor that Dr. Bickler employed in the Nonin studies.[64] Dr. Higgins testified he has engaged in peer review of hundreds of articles during his career,[65] and he spent the same amount of time interviewing Dr. Bickler as he does for other peer reviews.[66] Based on the interview, Dr. Higgins concluded Dr. Bickler substantively met the requirements of acceptable methodology of the field.[67] When an experienced researcher thoroughly examines the methodology, protocol, and data from a study, and subsequently judges the reliability of that study, then the experiment has been appropriately peer-reviewed. That the method of peer-review relies on discussions with the researcher does not negate the reliability of the study results or the methodology of the review.

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[62] *Daubert*, 509 U.S. at 593 ("Publication (which is but one element of peer review) is not a *sine qua non* of admissibility; it does not necessarily correlate with reliability, . . . and in some instances well-grounded but innovative theories will not have been published[.]) (citations omitted).

[63] D.I. 491 at 10-13.

[64] D.I. 526, Ex. 130 (Ochroch Depo.) at 207:22-208:10.

[65] *Id.*, Ex. 131 (Higgins Depo.) at 41:9-14.

[66] *Id.* at 42:20-43:3; 15:14-20.

[67] *Id.* at 91:19-92:1 ("[H]e conducted the study as he would any of his other peer-reviewed studies with the same methods, the same sampling rate, and the same data collection and analysis[.]")

Masimo claims Drs. Ochroch and Higgins were entirely unfamiliar with the testing protocol employed in the Nonin technical bulletins. The court disagrees. Their interviews with Dr. Bickler discussed in great detail the protocols utilized. Dr. Higgins testified to the specifics of motion[68] and low perfusion testing protocols applied by Dr. Bickler.[69] Dr. Ochroch's deposition further clarifies the reliability of the protocols Dr. Bickler used for motion,[70] inducement of hypoxia,[71] and low perfusion.[72] Drs. Ochroch and Higgins gained significant knowledge of the protocols from their interviews with Dr. Bickler, and were able to assess and examine the nature of the data obtained. Both doctors are comfortable with the scientific validity and form of the experiments performed by Dr. Bickler. In determining reliability, the court looks at the totality of the research, rather than merely evaluating the elements in a piecemeal fashion. Philips' experts are qualified to peer-review and analyze the Nonin studies, and they confirm the protocols and methodology applied were consistent with those employed by one skilled in the art. Therefore, the court finds the Nonin technical bulletins are reliable bases for Philips' experts' opinions.

C. FDA Clearance

Masimo argues Dr. Ochroch's reliance on FDA approval standards renders his opinion unreliable.[73] Although Philips maintains Dr. Ochroch's reliance is "perfectly

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[68] D.I. 526, Ex. 131 at 83:2-86:6.
[69] *Id.* at 104:20-105:5.
[70] D.I. 526, Ex. 130 at 158:22-161:16.
[71] *Id.* at 163:20-164:21.
[72] *Id.* at 181:2-15.
[73] Masimo's original argument included Dr. Higgins' reliance on FDA approvals, but Philips subsequently agreed not to proffer any testimony from Dr. Higgins concerning FDA standards due to his lack of knowledge and unfamiliarity with said standards.

appropriate, reasonable and reliable,"[74] it fails to sufficiently demonstrate his familiarity with FDA standards. Dr. Ochroch repeatedly states that he is unfamiliar with tests implemented by the FDA to approve a pulse oximeter for motion tolerance[75] or intended use.[76] Philips' claim that Dr. Ochroch is adequately experienced in the FDA approval process for medical devices is further undermined by his admissions that he is only familiar with the process "in vague terms"[77] and has "never been part of a formal application process for a device as of yet."[78]

Philips correctly observes Dr. Ochroch's testimony is primarily based on his personal observations, discussions with Dr. Bickler and the Nonin technical bulletins and limitedly relies on FDA approval. Because the foundation for Dr. Ochroch's opinion and testimony does not rest on FDA approval standards for medical devices, reliance on FDA approval does not destroy the reliability of his entire opinion. Philips is precluded from offering testimony or opinion by Dr. Ochroch concerning FDA approval standards and the implications of FDA approval as evidence of clinical acceptance of motion tolerant pulse oximeters.

Conclusion

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[74] D.I. 491 at 19.

[75] D.I. 526, Ex. 130 at 226:3-10 ("Q. Do you know the specific test that the FDA has that the FDA relies on to determine if a pulse oximeter is accurate or reliable through motion? A. I believe we've already discussed that. There may be many things that the FDA will consider acceptable, but the only one I know in detail is what Dr. Bickler has done and has had accepted as appropriate for the FDA.").

[76] *Id.* at 234:22-235:6 ("Q. Do you know what test the FDA put in place - whether the FDA has a test in place in order to be able to say that your device is intended for this use? A. I believe we've already discussed that. And I do not know if the FDA has an absolute test for such a parameter or will accept various submissions.").

[77] *Id.* at 223:4-8 ("Q. Are you familiar with the procedures for getting a medical device approved by the FDA? A. Only in vague terms, in terms of what I discussed with Dr. Bickler of how those data are collected for what the FDA wants.").

[78] *Id.* at 224:12-13.

For the foregoing reasons, Masimo's motion to exclude the expert testimony of Drs. John H. Eichhorn, Thomas L. Higgins and Edward A. Ochroch pursuant to FED. R. EVID. 702[79] is granted in part and denied in part. Since Dr. Ochroch, like Dr. Higgins, is unfamiliar with FDA requirements as to its approval process of medical equipment, specifically pulse oximeters, any testimony and opinion rendered by him concerning the significance of FDA approval or clearance regarding the performance of PureSAT is excluded. As to the remaining testimony of Drs. Eichhorn, Higgins, and Ochroch, Masimo's motion to exclude is denied.

2. Philips'Motion to Exclude the Testimony of Timothy J. Quill.

Dr. Quill (Masimo's Expert)

In the present motion, Philips seeks to exclude portions of Masimo's expert testimony and report,[80] Dr. Timothy J. Quill ("Dr. Quill").

Parties' Positions

A. Dr. Quill's opinion addressing PureSAT as not an acceptable alternative.

In requesting Dr. Quill's opinion that PureSAT is not an acceptable alternative, be excluded, Philips points to his deposition[81] as evidence he has no basis to opine about "what would or would not be acceptable to Philips' customers."[82] In his deposition, when questioned whether Phillip's customers are satisfied with its FAST technology, Dr. Quill responded that he has not discussed, nor spoken with any customers about the

[79] D.I. 385.

[80] D.I. 420 (addressing D.I. 432, Ex. 31). Briefing on Philips' motion to exclude is as follows: D.I. 421 (Philips' opening brief), D.I. 486 (Masimo's answering brief) and D.I. 596 (Philips' reply brief).

[81] D.I. 432, Ex. 34 (Quill's Depo.).

[82] D.I. 421 at 4.

FAST technology.[83] On further questioning, Dr. Quill speculates about the technology which would satisfy Philips' customers.[84] In light of his responses, Philips maintains Dr. Quill's testimony of what is an acceptable alternative should be excluded.

Masimo points out that Dr. Quill is a Philips' customer, and because of his position on the Anesthesiology Equipment Committee at Dartmouth Hitchcock Medical Center, he has evaluated several brands of hospital monitors,[85] and therefore, has personal knowledge of the requirements needed by practitioners for pulse oximeters.[86] Masimo contends Philips' challenge to his testimony goes to weight, rather than admissibility under Rule 702, which is a jury determination.[87]

Philips counters that "because . . . Dr. Quill's opinion is based entirely on speculation, the court should exclude it,"[88] relying on *Laser Dynamics, Inc. v. Quanta Computer*,[89] where the Federal Circuit excluded testimony concerning royalty rates because the expert opinion was not tethered to facts in the record.[90]

B. Dr. Quill's testimony that PureSAT is an unacceptable alternative based on lack of evidence.

Philips opposes Dr. Quill's opinion that PureSAT is an unacceptable alternative technology because he improperly relies on the lack of peer-reviewed studies on PureSAT technology as evidence, which he concludes demonstrates the technology is

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[83] *Id.* at 33:12-20.
[84] *Id.* at 33:21-34:9.
[85] D.I. 486 at 4.
[86] *Id.*
[87] *Id.*
[88] D.I. 596 at 2.
[89] 694 F.3d 51 (Fed. Cir. 2012).
[90] *Id.* at 81.

not an acceptable substitute.[91] Philips contends "[t]he absence of evidence is not evidence,"[92] and points to Dr. Quill's deposition,[93] where he agrees lack of evidence only proves an absence of evidence, and is not proof of unacceptability.[94]

Masimo reiterates "Philips' criticisms . . . goes [sic] to the weight of the evidence supporting Dr. Quill's testimony and not admissibility."[95] Masimo argues the "absence of peer-reviewed data is compelling,"[96] because "more than 100 independent and objective studies"[97] have been performed on Masimo's technology, implicitly arguing none have been done on PureSAT. Masimo concludes "the lack of peer-reviewed literature is positive evidence of unacceptability."[98]

Philips counters that "Masimo's attempt to transform Dr. Quill's lack of evidence into affirmative evidence is simply an improper lawyer argument that contradict's Dr. Quill's own testimony."[99]

C. Dr. Quill's Supplemental Expert Report.

Because Dr. Quill's supplemental report[100] "was served on July 16, 2012-more than two months after the parties were required to serve expert reports,"[101] Philips maintains it should be excluded as untimely. Philips further explains "there [was] no reason [Dr. Quill] could not have presented [the information in his supplemental report]

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[91] D.I. 432, Ex. 31(Quill's Open. Rpt.) at ¶51.
[92] D.I. 421 at 6 (citing *Thompson v. Sullivan*, 987 F.2d 1482, 1491 (10th Cir. 1993)).
[93] D.I. 432, Ex. 34 (Quill's Depo.) at 43:5-45:4.
[94] Dr. Quill further testified "Nonin . . . doesn't market to the . . . in-hospital – in-patient population, which is what I deal with." *Id.* at 45:15-21
[95] D.I. 486 at 5.
[96] *Id.* at 6.
[97] *Id.* (citing D.I. 489, Ex. AA at MASP0579193).
[98] *Id.*
[99] D.I. 596 at 3 n.3.
[100] D.I. 432, Ex.33 (Quill's Supp. Rpt.)
[101] D.I. 421 at 6.

in his opening report."[102] Moreover, according to Philips, even if Dr. Quill's supplement report is not stricken on a timeliness basis, it should be excluded because the report suffers from the same absence of competent evidence as his initial report.[103]

Masimo maintains Dr. Quill's supplemental report "merely identifies additional support to confirm his previously-rendered opinions."[104] It notes when Dr. Quill submitted his opening report, "Philips had not disclosed the extent of its reliance on Nonin PureSAT,"[105] and Masimo did not know nor could have known "that Philips' entire rebuttal to Masimo's lost-profits case would be based solely on Nonin PureSAT."[106] Masimo insists upon learning of Philips' purported "brand new theory," it diligently conducted testing on PureSAT, and Dr. Quill promptly supplemented his report.[107] Masimo claims Philips has not been prejudiced by the timing of Dr. Quill's supplemental report, and the exclusion of the report would severely prejudice Masimo.[108]

Philips counters the burden rests on Masimo to present evidence that PureSAT is not an acceptable technology. Philips states Dr. Quill admits there was no reason why he could not have included the additional information contained in his supplemental report in his original opinion.[109] In countering Masimo's argument that Nonin PureSAT is a new theory, Philips notes that Dr. Quill addresses Nonin PureSAT in his initial report,[110] and therefore, his supplemental report should be excluded.[111]

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[102] *Id.*
[103] *Id.* at 7.
[104] D.I. 486 at 10.
[105] *Id.*
[106] *Id.*
[107] *Id.* at 11.
[108] *Id.* at 11-12.
[109] D.I. 596 at 7.
[110] *Id.* (referencing D.I. 432, Ex. 31 (Quill's Open. Rpt.) at 21-23).
[111] *Id.* at 8.

D. Dr. Quill's opinion on Masimo's commercial success as due to its advanced technology.

Philips maintains Dr. Quill fails to establish a nexus between the patents-in-suit and Masimo's commercial success.[112] Philips, citing *Rambus Inc. v. Hynix Semiconductor, Inc.*,[113] propounds Dr. Quill mere conclusory assertion that Masimo's products are successful, is insufficient to establish the required nexus between commercial success and the claimed inventions.

Masimo responds "Philips is incorrect that Dr. Quill must establish that nexus entirely by himself."[114] Masimo contends Dr. Gail Baura ("Dr. Baura" Masimo's expert on infringement and invalidity) provides the technical background and foundation for Dr. Quill's opinion. Dr. Quill also has personal knowledge of the performance and superiority of Masimo's pulse oximeter equipment, and why customers chose its technology. Masimo concludes Dr. Baura's opinions in conjunction with Dr. Quill's testimony form the basis for its commercial success.[115]

Philips observes that although Dr. Quill may rely on a technical expert, he did not rely upon Dr. Baura or any technical expert. Emphasizing Dr. Quill's deposition,[116] Philips points out that because he does not know which patents cover Masimo's products, he lacks any basis to opine on the commercial success of those products.

Discussion

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[112] D.I. 432, Ex. 34 (Quill's Depo.) at 119:10-17.

[113] 254 F.R.D. 597, 605 (N.D. Cal. 2008) ("[I]t is clear from Mr. Murphy's report that he did no analysis. His reasoning appears to be: the Manufacturers' products incorporate Rambus's claimed inventions; those products have been successful; ergo Rambus's inventions caused the products' success. Rule 702(2) demands more.").

[114] D.I. 486 at 12.

[115] *Id.* at 12-13.

[116] D.I. 596 at 9 (citing D.I. 432, Ex. 34 at 110:12-21).

A. Exclusion of Dr. Quill's testimony that PureSAT is not an acceptable alternative.

Dr. Quill's testimony with regard to what would be acceptable to Philips' customers is inadmissable; however, he may testify as to what is acceptable to other medical professionals and hospitals.

When questioned regarding the standards required by Phillip's customers, Dr. Quill speculated "they would be satisfied with the best performance, but they may not be aware that other monitors outperform the one that they have."[117] Dr. Quill, however, further testified that he has "never specifically spoken to any customers who use Philips' FAST technology,"[118] making him unqualified to opine on what would be acceptable to Philips' customers.[119]

Dr. Quill has served on the Dartmouth Hitchcock Medical Center's Anesthesiology Equipment Committee for more than 20 years, as well as several other hospital medical equipment committees in his 30 year career.[120] His extensive familiarity through medical conferences, discussions with health care providers, and his experience teaching medical students and residents, qualifies him to testify about the type of medical equipment which meets the needs of medical professionals and hospitals.

As a result, Dr. Quill may not testify about what is or is not acceptable to Phillip's

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[117] D.I. 432, Ex. 34 at 33:21-34:9.

[118] *Id.* at 33:15-18.

[119] Dr. Quill stated in his deposition that "in a recent evaluation, we chose Philips' monitors because of their quality." D.I. 488, Ex. A at 20:16-21:11. Despite his recent selection of Philips' equipment, it does not qualify him to speak regarding what is acceptable to all Philips' customers, because he admittedly does not have an adequate basis in this regard, and would be speculating on the bases for satisfaction with the product by other Philips' customers. D.I. 432, Ex. 34 at 33:21-34:9.

[120] D.I 432 at Ex. 31 at 2.

customers, but may testify about the requirements of medical professionals and hospitals.

B. Dr. Quill's opinion and testimony that PureSAT is an unacceptable alternative, based on a lack of evidence, is excluded.

Dr. Quill may testify there is lack of peer reviewed studies on Nonin PureSat showing that it is an acceptable alternative, but cannot opine or testify that Nonin PureSAT is unacceptable alternative due to the lack of such studies.

During his deposition, Dr. Quill agreed that "lack of evidence . . . of the acceptability of technology is not the same thing as proving [the technology] is not acceptable."[121] In other words, he admitted the absence of studies does not equate to a negative conclusion.

At issue is whether PureSat is an unacceptable alternative because of the lack of peer review studies demonstrating it is an acceptable alternative. The Supreme Court in *Daubert* stated "[t]he subject of an expert's testimony must be 'scientific . . . knowledge. . . '" where the "word 'knowledge' connotes more than subjective belief or unsupported speculation."[122] As noted previously, Dr. Quill admitted the absence of evidence demonstrating acceptability of a medical device does not prove the device is unacceptable.

To allow Dr. Quill to opine contrary to his deposition testimony,[123] would interject unsupported speculation that the Nonin PureSAT device is an unacceptable alternative,

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[121] *Id.* at Ex. 34 at 44:13-16.
[122] 509 U.S. at 589-90 (citing FED. R. EVID. 702).
[123] D.I. 432, Ex. 34 at 43:18-45:4.

thereby substituting mere subjective belief as opinion.

In exercising the court's gatekeeping role,[124] Dr. Quill may only testify there is a lack of peer reviewed studies which show Nonin PureSat is an acceptable alternative.

C. Dr. Quill's Supplemental Expert Report is excluded as untimely.

Dr. Quill's Supplemental Expert Report is excluded as untimely.

Masimo cites *Stecyk v. Bell Helicopter Textron, Inc.*[125] arguing that delay alone is insufficient to exclude expert opinion.[126] There, the Third Circuit upheld the lower court's decision to admit video tape evidence, because the "record reflect[ed] that plaintiffs had the videotapes five months prior to trial and that their own experts had viewed the videotapes."[127] The trial judge also gave the plaintiffs "additional opportunities to depose the defense witnesses and consult with their own experts," which the plaintiffs declined.[128]

Philips relies on *Praxair, Inc v. ATMI, Inc.* which excluded an expert report in the "absent substantial justification for the delay."[129] In *Praxair*, the court excluded an expert's supplemental report because the scheduling order did not authorize such reports, the report contained new testing, conclusions, and theories of invalidity not addressed in the original report, and it was filed ten days before summary judgment motions were due, thereby denying the opposition any rebuttal discovery before the filing of case dispositive motions.[130] The court recognized, although such "prejudice

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[124] *Daubert*, 509 U.S. at 600 (Rehnquist, J., concurring in part and dissenting in part).
[125] 295 F.3d 408 (3d Cir. 2002).
[126] D.I. 486 at 11**.**
[127] 295 F.3d at 413.
[128] *Id.*
[129] 231 F.R.D. 457, 464 (D. Del. 2005), *rev'd on other grounds* 543 F.3d 1306 (Fed. Cir. 2008).
[130] *Id.*

may be cured by allowing . . . additional expert discovery, this would . . . disrupt the trial process."[131]

The scheduling order in the instant matter did not provide for supplemental expert reports; it only provided for initial and rebuttal reports.[132] According to the final amended scheduling order, the deadline for filing opening expert reports was May 2. 2012; it did not modify the limitation on the number of expert reports, nor provide for supplemental reports.[133] Masimo does not contest that Dr. Quill's supplemental report was not served until July 16, 2012. In addition, the supplemental report contains new testing results of three pulse oximeters, which occurred on July 12, 2012.[134] When asked whether the testing could have been completed and included in his initial report, Dr. Quill responded "No. There's no reason why I couldn't have done it . . . I could have."[135] Further, the scheduling order has been modified at the request of the parties *several* times, and none permit supplemental reports. If either party desired the option of supplemental reports, the matter could have been addressed in the numerous changes to the scheduling order, or requested of the court long before discovery ended.

Masimo's argument that Philips reliance on the PureSat device introduces a purported "new theory" is unpersuasive. Although Masimo contends it was unaware of the *extent* of Philips' reliance,[136] it obviously knew of Philips' intent to depend on this device since Dr. Quill discussed Nonin PureSat in his initial report.[137] Additionally,

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[131] *Id.*
[132] D.I. 104 at 3-4.
[133] D.I. 326.
[134] D.I. 432, Ex. 33 at 2.
[135] *Id.*, Ex. 34 at 149:22-150:4.
[136] D.I. 486 at 10.
[137] D.I. 432, Ex. 31 at ¶¶ 47-51.

Philips identified in its responses to Masimo's interrogatories on June 2, 2011, that "Nonin SpO2 technology (including but not limited to PureSat . . .)"[138] was one of several non-infringing alternatives on the market. Masimo's "brand new theory" argument is unconvincing.

As noted by the Fifth Circuit in *Geiserman v. McDonald*:

> Regardless of [the litigant's] intentions, or inattention, which led to the flouting of discovery deadlines, such delays are a particularly abhorrent feature of today's trial practice. They increase the cost of litigation, to the detriment of the parties enmeshed in it; they are one factor causing disrespect for lawyers and the judicial process; and they fuel the increasing resort to means of non-judicial dispute resolution. Adherence to reasonable deadlines is critical to restoring integrity in court proceedings.[139]

Consistent with the reasoning in *Praxair* and *Geiserman*, there is no substantial justification for the delay in producing the additional information in Dr. Quill's supplemental report,[140] and the report will be excluded.

D. Dr. Quill's opinion that Masimo's commercial success is due to its advanced technology is allowed.

Dr. Quill may opinion that Masimo's medical professional customers chose its products because they have the ability "detect motion and reject the signal during motion,"[141] in accordance with his expert report.[142]

The commercial success of a patented invention may include evidence addressing long felt unsolved needs and the failure of others to produce alternatives to

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[138] D.I. 601, Ex. 165 at 11-12.
[139] 893 F.2d 787, 792 (5th Cir. 1990).
[140] "Flouting of discovery deadlines causes substantial harm to the judicial system" *Praxair*, 231 F.R.D. at 463 (internal citations omitted).
[141] D.I. 432, Ex 31 at ¶20.
[142] *Id.* (Quill Open. Rpt.).

the patented invention."[143] A proponent for commercial success "must establish a nexus between the evidence and the merits of the claimed invention."[144] In order to establish a prima facie case of nexus "'the patentee [must show] both that there is commercial success, and that the thing (product or method) that is commercially successful is the invention disclosed and claimed in the patent.'"[145]

Demonstrating secondary considerations does not require a single expert witness[146] to establish both commercial success of the product, and such success is due to the invention disclosed. Dr. Baura has opined regarding the inventions disclosed and claimed in the patents. As evidenced from his qualifications, his familiarity with practitioners and institutional needs, his experience in evaluating pulse oximeters in hospital settings, and his reliance on Dr. Baura's opinion, Dr. Quill is qualified to opine on the bases why Masimo's products are selected, linking the desired features of Masimo's products to the invention disclosed and claimed in the patents. The combined opinions and testimony of both experts demonstrate the required nexus and bases for commercial success.

To the extent Dr. Quill's testimony is based upon technical expertise of Dr. Baura, he is allowed to opine on the commercial success of Masimo's products.

Conclusion

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[143] *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995) (quoting *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966)).

[144] *Id.* (citing *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F. 2d 1530, 1539 (Fed. Cir. 1983)).

[145] *Id.* (quoting *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988)).

[146] *See Carnegie Mellon Univ. v. Marvell Tech. Group, Ltd.,* 286 F.R.D. 266, 271 (W.D. Pa. 2012) ("[I]t is well settled that one expert may rely upon another expert's opinion in formulating his own."). *See also Dura Auto. Sys. of Indiana, Inc. v. CTS Corp.*, 285 F.3d 609, 613 (7th Cir. 2002).

For the foregoing reasons, Philips' motion to exclude the expert testimony of Dr. Quill pursuant to FED. R. EVID. 702 is granted in part and denied in part.[147] Philips' motion to exclude Dr. Quill's supplemental expert report is granted.

3. Masimo's Motion to Exclude Portions of the Testimony of Michael C. Keeley, Ph.D. pursuant to FED. R. EVID. 702;[148]

Dr. Keeley (Philips' Expert)

On June 15, 2012, Philips' damages expert, Dr. Michael C. Keeley ("Dr. Keeley"), submitted his rebuttal expert report[149] against Masimo's claim for damages. Masimo moves[150] to exclude certain portions of Dr. Keeley's testimony under FED. R. EVID. 702.

Parties' Positions

Masimo advances three arguments in support of its motion to exclude.[151] The first argument is composed of three sub-arguments. Philips has the burden to show by a preponderance of the evidence that the opinions of the Dr. Keeley are reliable. Masimo's arguments will be addressed *seratim*.

A. Dr. Keeley should be precluded from opining that Nonin PureSAT is an acceptable alternative to Philips' FAST.

Masimo seeks damages for lost profits on "some of Phillip's sales of its accused FAST pulse oximetry technology and a reasonable royalty on the remainder of Phillip's FAST sales"[152] Masimo correctly notes it must establish "the absence of acceptable

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[147] D.I. 420.
[148] D.I. 388.
[149] D.I. 391, Ex. B.
[150] D.I. 388. Briefing on this motion is as follows: D.I. 389 (Masimo's opening brief), D.I. 490 (Philips' answering brief), and D.I. 583 (Masimo's reply brief).
[151] D.I. 389.
[152] *Id.* at 3.

noninfringing substitutes" as one element for lost profits.[153] Masimo asserts Dr. Keeley's opinion on available acceptable alternatives is fatally flawed and unreliable, warranting exclusion,[154] by advancing the following arguments.

1. Dr. Keeley cannot rely on the opinions of Drs. Eichhorn, Higgins, and Ochroch.

Masimo contends because Drs. Eichhorn, Higgins, and Ochroch opinions are unreliable, any opinion by Dr. Keeley based upon their opinions is equally unreliable.

Previously in this opinion, Masimo's motion to exclude the testimony of Drs. Eichhorn, Higgins, and Ochroch has been addressed.[155] Therefore, consistent with that decision, to the extent Dr. Keeley's opinion and testimony does not depend upon on the portions of Dr. Higgins and Ochroch's opinions that were excluded, Dr. Keeley may rely on the findings and conclusions of Drs. Eichhorn, Higgins, and Ochroch.

2. Dr. Keeley has no expert qualifications to offer an independent opinion of the acceptability of Nonin PureSAT.

The crux of Masimo's argument is Dr. Keeley is "an economist with no personal familarity with pulse oximetry, and . . . has no particular knowledge, training, or skill to pass expert judgment on the performance or acceptability of pulse oximetry technology."[156] Masimo asserts Dr.Keeley purportedly "offered his own opinion that

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[153] *Panduit Corp. v.* Stahlin Bros. Fibre Works, Inc.*,* 575 F.2d 1152, 1156 (6th Cir. 1978).

[154] D.I. 389 at 3.

[155] *See* at 16-17 *supra*. Only the opinions of Drs. Ochroch and Higgins regarding the significance of FDA approval or clearance were excluded: "Since Dr. Ochroch, like Dr. Higgins, is unfamiliar with FDA requirements as to its approval process of medical equipment, specifically pulse oximeters, any testimony and opinion rendered by him concerning the significance of FDA approval or clearance regarding the performance of PureSAT is excluded. As to the remaining testimony of Drs. Eichhorn, Higgins, and Ochroch, Masimo's motion to exclude is denied."

[156] D.I. 389 at 5.

Nonin PureSAT was acceptable,"[157] beyond the opinions of Philips' other technical experts, as well as opining on Dr. Quill's supplemental report.[158]

The court has previously granted Philips' motion to exclude the supplemental report of Dr. Quill,[159] and to the extent Dr. Keeley references that report, it is excluded.

With respect to Masimo's argument that Dr. Keeley offered his own opinion on the acceptability of Nonin PureSAT, Philips counters that Dr. Keeley may rely on the opinions of Drs. Eichhorn, Higgins, and Ochroch that Nonin PureSAT is an acceptable noninfringing alternative. Philips further defends that "Masimo [is not] argu[ing] that damages experts are prohibited from relying on the opinions of technical experts; rather Masimo [is] argu[ing] that the opinions of Drs. Eichhorn, Ochroch, and Higgins are unreliable."[160]

3. Dr. Keeley's opinion is unreliable because he assumes Philips would have substituted PureSAT for FAST.

Masimo's claims that in order for Dr. Keeley to assume Nonin PureSAT is an acceptable noninfringing alternative, Philips must have recognized it as such. Masimo insists this underlying assumption is "unsupported and contradicted by the only evidence on the matter,"[161] that is, Philips "never used Nonin PureSAT in any of its hospital monitors, defibrillators, or telemetry devices."[162] Masimo further contends there is "no evidence that Philips ever would have considered adding Nonin PureSAT to its

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[157] *Id.* (referencing D.I. 391, Ex. B (Keeley's Rebuttal Rpt.) at ¶¶ 13, 92).

[158] *Id.* (referencing D.I. 391, Ex. C (Keeley Depo.) at 52:16-57:22). It is not lost on the court that Masimo's argument against Dr. Keeley is the opposite argument they advanced for their expert, Dr. Quill.

[159] *See* at 25-27 *supra*.

[160] D.I. 490 at 13.

[161] D.I. 389 at 6.

[162] *Id.*

already existing technology lineup including Masimo and Nellcor's options."[163]

Philips counters Masimo is inventing "new legal requirements for determining what are acceptable noninfringing alternative[s]."[164] Philips cites *Grain Processing Corp. v*. *Amer. Maize-Prod. Co.*,[165] which found that to refute a claim for lost profits, only an acceptable noninfringing alternative must be proven; there is no requirement that the infringer actually used or considered the alternative.[166]

Masimo responds that contrary to Philips' experts, in a "but-for" world, PureSAT is not an acceptable noninfringing substitute. Masimo also counters that under *Grain Processing Corp.,* the court considers "'whether and to what extent [PureSAT] was acceptable as a substitute in the relevant market,'"[167] that is, the market of multi-parameter hospital monitors, and there is no evidence that PureSAT "has ever been used" in lieu of a multi-parameter monitor.[168]

B. Dr. Keeley's opinion which limits Masimo's incremental profit margins is based on an unreliable regression analysis.

Masimo argues Dr. Keeley "conducted a flawed regression analysis to estimate [its] incremental profit margins,"[169] which resulted in an improper lost profits calculation and conclusion. Specifically, Masimo disputes with Dr. Keeley "directly correlat[ing] Masimo's actual revenue and actual selling expenses, in order to predict the incremental cost that would have been incurred . . . to achieve . . . lost sales."[170]

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[163] *Id.*
[164] D.I. 490 at 14.
[165] 185 F.3d 1341 (Fed. Cir. 1999).
[166] D.I. 409 at 14-15.
[167] D.I. 583 at 2 (citing *Grain Processing Corp.*, 185 F. 3d at 1355).
[168] D.I. 389 at 7.
[169] *Id.*
[170] *Id*. at 8.

Masimo further contends his analysis assumes "revenue is the only variable that affects selling, general and administrative ("SG&A") expenses,"[171] which fails to account for "any variable that affect[s] . . . cost and revenues in the real world."[172]

Masimo claims Dr. Keeley incorrectly applied the methods described in the LITIGATION SERVICES HANDBOOK ("the HANDBOOK"), because he neglected to identify "activities or variables that generated costs, and blindly assumed that revenue has a linear relationship with all of Masimo's SG&A costs."[173] In sum, Masimo maintains Dr. Keeley's regression analysis is "overly simplistic, ignores real-world facts, and offers an unreliable measure of Masimo's true incremental operating margin."[174]

Phillips counters that Masimo's damages expert, Micheal J. Wagner ("Wagner"), relied on the HANDBOOK and has used regression analysis, and further contends Dr. Keeley's method is generally consistent with the HANDBOOK.[175] Specifically, Philips points to Wagner's deposition where he states that Dr. Keeley's method was appropriate and correct.[176]

Philips contends Masimo incorrectly argues that Dr. Keeley's analysis improperly deviates from the HANDBOOK because purportedly there is better available information, which is merely data gathered by Masimo's personnel and conclusions drawn by Wagner's staff.[177] Philips maintains Masimo has no more valid or appropriate information to claim that Dr. Keeley's analysis is inconsistent with the HANDBOOK.

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[171] *Id*.
[172] *Id.*
[173] *Id*. at 9.
[174] *Id*. at 10.
[175] D.I. 526, Ex. 116 at 232:16-233:13
[176] *Id*. at 233:14-18.
[177] D.I. 490 at 4.

Philips further maintains that in its criticism of Dr. Keeley, Masimo misapplies the Seventh Circuit case, *ATA Airlines, Inc. v. Federal Express Corp.*[178] Philips contends *ATA Airlines* did not criticize the methodology employed by an expert, but faulted the expert's application of the methodology,[179] because the expert predicted cost would decline with the increase in revenue, contrary the model applied by Dr. Keeley.[180]

Philips submits that Dr. Keeley's regression analysis is corroborated by a "non-regression check analysis that examines real-world data,"[181] by reviewing the actual amount (real-world data) that Masimo's "SG&A costs increased when its sales and revenue increased year-over-year during the damages window."[182] Philips, thus, maintains Dr. Keeley's real-world approach confirms the appropriateness of his regression analysis.[183] Because Masimo does not include research and development ("R&D") costs in its SG&A expenditures, Dr. Keeley's real- world approach using Masimo's data is not affected by R&D costs.[184] Therefore, Dr. Keeley's non-regression check analysis using real-world information corroborates his regression analysis.

Philips contends Masimo fundamentally misunderstands Dr. Keeley's regression

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[178] 665 F. 3d 882 (7th Cir. 2011) (rehearing and rehearing en banc denied).
[179] D.I. 490 at 5.
[180] *Id*. at fn. 3.
[181] *Id.* at 7.
[182] *Id.*
[183] *Id.* at 8. Philips notes Wagner admitted during his deposition that his cost estimates were not checked against real-world figures because Philips is a customer of Masimo, and such a check would not be helpful. Since the present matter involves selling additional products to Philips, he concluded there would be "zero incremental SG&A" for such added sales. Wagner did admit, however, the additional sales in his lost profits analysis are not to Philips–rather they are sales to Philips' "ultimate customers," who are not "'existing Masimo customers.'" *Id.* at 8 (referencing D.I. 526, Ex. 116 at 224:13-225:12; 258:9-13; 259:20-260:8).
[184] *Id.* at 9. Wagner claimed a real-world check analysis was not necessary because real-world SG&A includes R&D, which is not relevant in a but-for analysis. He was unable to recall whether R&D is a component of Masimo's SG&A expenses (citing D.I. 526, Ex. 116 at 258:15-20; *id.* at 261:4-6). Philips points out R&D is not an included expenditure in Masimo's SG&A costs. (referencing *Id.*, Ex. 119 at MASP0633202).

analysis,[185] and notes "the goal of [his] analysis is to determine how much SG&A costs rises when product revenue increases."[186] Dr. Keeley's objective was not to determine how much each variable contributed to cost increases, but to ascertain the "total SG&A costs increase associated with product revenue increases."[187]

Contrary to Masimo's criticism, Philips maintains Dr. Keeley was not required to amortize capital expenses because they are not costs related to sales, but usually long term expenditures. Philips contends Dr. Keeley's analysis regarding foreign sales is conservative, because it does not distinguish them from U.S. sales,[188] which benefits Masimo by lowering its SG&A costs, resulting in higher profits.[189] Finally, Masimo's allegation that Dr. Keeley failed to consider all of its product revenue, is incorrect because it has not demonstrated other products have different SG&A costs.

Masimo initially counters that Wagner does not endorse Dr. Keeley's application of regression analysis because of its unreliability in this matter.[190]

Next, Masimo asserts the HANDBOOK does not support the use of a simple regression analysis in this case.[191] Masimo denies it selectively quoted from the HANDBOOK, but rather identified relevant sections that an economist uses to determine the circumstances when regression analysis is appropriate. It further argues Philips attack on Wagner's method is irrelevant to the analysis employed by Dr. Keeley.

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[185] *Id.*
[186] *Id.*
[187] *Id.*
[188] *Id.* at 10.
[189] D.I. 490 at 11
[190] D.I. 583 at 4.
[191] *Id.*

Masimo criticizes Philips' interpretation of the *ATA Airlines* decision[192] because the damages in that case, like the instant matter, are "based on lost sales, not increased revenue with no change in sales quantity."[193] It also contends Dr. Keeley's analysis is contrary to *ATA Airlines*, since it fails to "match costs with revenues and consider real world explanations for fluctuations in profit margins,"[194] and ignores that court's warning against "modeling the relation between costs and revenue as a straight line."[195] Because Dr. Keeley "blindly assumes that revenue has a simple linear relationship with all of Masimo's SG&A costs,"[196] his report simply divides the data into two separate linear relationships that are split in time.[197]

Masimo further claims Dr. Keeley never supports his assumption that the revenue costs across its entire product line is the same as the revenue costs for its lost sales to Philips.

Masimo denies that Dr. Keeley's regression analysis is confirmed by real-world data,[198] by noting Phillips employs a circular argument of "merely us[ing] the same set of data-points . . . of costs and revenue . . . use[d] for [Dr. Keeley's] regression analysis."[199]

Lastly, Masimo reasons Dr. Keeley's regression analysis oversimplifies its business by assuming linear correlations between costs and revenue, and ignores the absence of any evidence that SG&A costs for the products at issue are the same as

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[192] *Id.* at 5.
[193] *Id.*
[194] D.I. 583 at 5 (referencing *ATA Airlines*, 665 F.3d at 893-96)
[195] *Id.* at 6.
[196] *Id.*
[197] *Id.*
[198] *Id.*
[199] *Id.*

SG&A costs for the rest of Masimo's product line.

C. Dr. Keeley should be precluded from relying on the 2001 Nonin/Respironics Agreement[200] as a basis for the reasonable royalty rate for Masimo's patents.

Masimo opposes Dr. Keeley's application of the 2001 Nonin/Respironics agreement ("Agreement") as a basis for calculating a reasonable royalty since it is not comparable to a hypothetically negotiated license for Masimo's patents-in-suit.[201]

According to Masimo, that Agreement does not relate to the technology at issue which "measures blood oxygen saturation and pulse rate in the presence of motion and/or low perfusion,"[202] because "Nonin had no motion-tolerant pulse oximetry technology in 2001."[203]

Masimo contends the Agreement is a software license, not a patent license, and under *ResQNet.com, Inc. v. Lansa, Inc.*,[204] software licenses cannot be used to establish a reasonable royalty,[205] because they "provide too narrow of a patent right to provide substantial evidence of [a] . . . royalty rate."[206] Masimo further asserts no nexus has been shown between the Agreement and the patents-in-suit.

Because Dr. Keeley acknowledges the Agreement is a software license and not a patent license; the technologies involved are different; and the Agreement is not

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[200] D.I. 392, Ex. J. (Nonin/Repironics Licensing Agreement).
[201] D.I. 389 at 11.
[202] *Id.*
[203] *Id.* at 12.
[204] 594 F.3d 860 (Fed. Cir. 2010).
[205] D.I. 389 at 11.
[206] *Id.* (citing *Lucent Tech., Inc. v. Gateway, Inc.*, 509 F. Supp. 2d 912 (S.D. Cal. 2007).

comparable to the hypothetical negotiation in this matter,[207] Masimo contends Dr. Keeley should be excluded from relying on the Agreement for his reasonable royalty calculation.[208]

Philips claims that Masimo mischaracterizes Dr. Keeley's opinion concerning the Agreement. Philips notes Dr. Keeley's opines that in the hypothetical negotiation between the parties, a factor for Philips would be available noninfringing alternatives, such as the Nonin product, as limiting the negotiation price.[209] Philips represents Wagner similarly acknowledged that a patent owner cannot seek a higher price for its patents than the next best alternative.[210] Since Wagner's testimony is consistent with Dr. Keeley's analysis, Philips contends the Agreement is comparable to the hypothetical negotiation, if the Nonin product is found to be acceptable noninfringing alternative.

Philips contends the Agreement evidences that Nonin intended to allow Respironics to use future technology developed by Nonin, including PureSAT, during the entire relevant damages period in the present matter.[211]

Philips denies the Agreement is a software license, that it contains any mention of software, or that Dr. Keeley agrees it is a software license.[212] Contrary to Masimo's analysis, Philips argues *ResQNet.com* found a reasonable royalty cannot be based upon a bundled license which includes both technology and services,[213] to avoid a

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[207] Masimo states that because the Agreement was limited to the homecare market and Philips' products are sold in the hospital market, it cannot be comparable to the relevant hypothetical negotiation which would have involved the hospital market. D.I. 389 at 13.

[208] D.I. 389 at 13.

[209] D.I. 490 at 16 (referencing D.I. 526, Ex. 117 (Keeley Depo.) at 85:7-17)).

[210] *Id.*

[211] *Id.* at 18. It

[212] *Id.*

[213] *Id.*

plaintiff from inflating "its reasonable royalty by relying on licenses that cover more than the technology at issue."[214] Although Philips concedes the Agreement covers more than technology, it maintains this favors Masimo because "it militates [against] a rate lower than $75 per unit."[215]

Finally, Philips takes issue with Masimo's argument that because Philips' products are sold in hospitals and the Agreement addresses the homecare market, it is not comparable and irrelevant. Philips points out the language of the Agreement is not limited to the homecare market; rather, Respironics' business was limited to that market.[216] Because the Agreement licensed a direct competitor in the same homecare market, it evidences Nonin's willingness to license an indirect competitor, such as Philips.[217]

Masimo responds that because Nonin PureSAT cannot read through motion, its technology is irrelevant. Masimo further claims the Agreement does not relate to the technology at issue,[218] because: it was executed at least two years before PureSAT was commercialized; Dr. Keeley admitted he was uncertain whether the Agreement covered motion-tolerant pulse oximetry technology; and he relied on hearsay statements about a hypothetical agreement that Nonin would be willing to enter, rather than the Agreement.[219]

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[214] *Id.* at 19.

[215] *Id.* (Philips also disagrees with Masimo's reading of *Lucent Tech.* arguing court "simply explained that the scope of the software license must be sufficiently comparable to the license of the hypothetical negotiation. In the present case, the . . . [A]greement provided all the technology necessary to produce PureSAT SpO2 and is therefore relevant to the damages analysis." D.I. 490 at 19.)

[216] *Id.* at 20.

[217] *Id.*

[218] D.I. 583 at 8.

[219] *Id.*

In addressing Philips' contention that the Agreement is not a software license, Masimo states Philips "acknowledges 'that the agreement granted rights to use Nonin's algorithm' which is synonymous with . . . software.

Masmio disputes Philips' characterization of the scope of the Agreement, maintaining it only relates to the homecare market, not the hospital market. Masimo also claims that Wagner did not admit that the Agreement was relevant, and only "acknowledged that the cost of switching to an acceptable noninfringing alternative is relevant to the damages analysis."[220]

Discussion

A. To the extent Dr. Keeley relies on the opinions of Drs. Eichorn, Higgins and Ochroch that Nonin PureSAT is an available acceptable alternative to Philips' FAST, his opinion is allowed.

1. Dr. Keeley may rely on the opinions of Drs. Eichorn, Higgins, and Ochroch.

As found previously herein, Dr. Keeley may rely on the opinions of Drs. Eichorn, Higgins, and Ochroch to the extent that their opinions were not excluded.

2. Dr. Keeley may not give an independent opinion of the acceptability of Nonin PureSAT.

Dr. Keeley is an economist, not a medical professional, and is unqualified to provided an independent opinion on the acceptability, or lack thereof, of pulse oximetry devices. Dr. Keeley, however, may rely on the opinions of Philip's technical experts, that is, the opinions of Drs. Eichorn, Higgins, and Ochroch, that Nonin PureSAT is an acceptable noninfringing alternative, for calculating damages.

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[220] *Id.* at 9-10.

Since Dr. Quill's supplemental report has been previously excluded, any part of Dr. Keeley's opinion relying upon this report is likewise excluded.

3. Dr. Keeley's opinion is not unreliable because he assumes Philips would have substituted PureSat for FAST.

The Federal Circuit in *Grain Processing Corp. v. American Maize-Products Co.*, stated: "'to be an acceptable non-infringing substitute, the product or process must have been available *or* on the market at the time of infringement.'"[221] The court continued "[t]his statement is an apt summary of [Federal Circuit] precedent, which permits available alternatives - including but not limited to products on the market - to preclude lost profits damages."[222] In the absence of exact equivalent product to the patented invention, courts may allow "its next-best alternative(s) - regardless of whether the alternative(s) were actually produced and sold during the infringement."[223] In so finding, a court is allowed to "discern the market value of the patent owner's exclusive right, and therefore his expected profit or reward."[224] Whether a product or process is an acceptable substitute in the relevant market, factors for consideration include: "consumers' intended use for the patented product, similarity of physical and functional attributes of the patentee's product to alleged competing products, and price."[225] Thus, the focus is what a hypothetical consumer at the time of the alleged infringement would

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[221] 185 F. 3d 1341, 1349 (Fed. Cir. 1999) (quoting *Grain Processing Corp. v. American Maize-Products Co.*, Nos. 95-1506, 95-1507, 1997 WL 71726, at *2,(Fed. Cir. Feb. 20, 1997)).

[222] *Id.*

[223] *Id*. at 1351.

[224] *Id.*

[225] *Id* at 1355.

deem to be an acceptable alternative.[226]

Masimo misapplies the analysis in *Grain Processing*. The focus is not what Philips would or would not consider to be an acceptable alternative, but rather, what a consumer would or would not consider to be an acceptable alternative. Dr. Keeley, therefore, in his opinion on damages, is allowed to rely upon Philips' technical experts, and their opinions as to the acceptability of Nonin PureSAT to consumers of pulse oximetry devices.

B. Dr. Keeley is not precluded from opining on Masimo's incremental profit margin

Wagner states "[i]n order to calculate Masimo's incremental profitability on its lost sales, it is necessary to differentiate between fixed and incremental costs."[227] He continues, "[i]ncremental costs are costs that do increase with sales, like direct materials, and direct labor."[228] Wagner "determined three areas of incremental costs: cost of goods (COGS), other cost of sales (OCOS) and incremental operating expenses."[229] Further, "profits are calculated as revenues less incremental costs."[230] Thus, Masimo's incremental profit is determined by taking incremental revenue and subtracting incremental costs, as shown in the equation below.[231]

$$I_p = I_R - (COGS + OCOS + I_{OE})$$

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[226] *See id.* (The term "consumer" as used in *Grain Processing* refers to the end-user of the product.).

[227] D.I. 392, Ex. E (Wagner's Rpt.) at ¶251.

[228] *Id.*

[229] *Id.* at ¶253.

[230] D.I. 392, Ex. E at ¶251.

[231] I_P = incremental profit; I_R = incremental revenue; I_{OE} = incremental operating expense.

Dr. Keeley, in his rebuttal report,[232] calculates incremental profit by "taking the difference between incremental revenue and incremental costs,"[233] which is a similar general formula used by Wagner. Dr. Keeley calculates incremental costs using "the cost of goods sold ("COGS") and costs other than direct product cost that an entity must incur in order to make additional sales."[234] Dr. Keeley identifies these other expenditures as sales, general, and administrative costs or SG&A costs.[235] As a result, Dr. Keeley's equation for incremental profit is:

$$I_p = I_R - (COGS + SG\&A)$$

In comparing Wagner and Dr. Keeley's equations for incremental profits the issue is whether Dr. Keeley's SG&A costs equate to Wagner's OCOS and incremental operating expenses (I_{OE}),[236] which is an appropriate issue for the jury.

The court's role is to determine whether Dr. Keeley's methodology is scientifically acceptable, not which calculation or opinion is more correct. As evidenced from the analysis above, the approach by Dr. Keeley is reasonable and substantially equivalent to Wagner's methodology.

In *ATA Airlines*, the Federal Circuit criticized an expert correlating revenue with total costs, both fixed and variable. The Federal Circuit stated "revenue does not

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[232] D.I. 391, Ex B. (Keeley Rebut. Rpt.).
[233] *Id.* at ¶185.
[234] *Id.*
[235] *Id.*
[236] Dr. Keeley similarly concludes when he noted: "Mr. Wagner fails to explain whether the 'incremental operating costs' included incremental general or administrative costs." D.I. 391, Ex. B at ¶188.

influence [total] costs;"[237] but, an increase in revenue may be correlated with an increase of cost, if the increase in cost is related to an increase of sales.[238] Here, contrary to Masimo's argument, both Wagner and Dr. Keeley performed a substantially similar analysis by correlating the incremental revenue with its corresponding incremental cost of additional sales.

The court's role as a gatekeeper is to assure the methods employed by experts are scientifically sound, with the finder of fact to decide whose expert's analysis is more credible. Masimo's arguments regarding Dr. Keeley's regression analysis address weight. Therefore, Dr. Keeley's opinion in this regard is allowed.

C. Dr. Keeley is precluded from relying on the 2001 Nonin/Respironics agreement to inform the reasonably royalty rate for Masimo's patents.

In *ResQNet.com v. Lansa, Inc.*,[239] the Federal Circuit held:

> the district court erred by considering . . . re-bundling licenses to significantly adjust upward the reasonable royalty without any factual findings that accounted for the technological and economic differences between those licenses and the [ ] patent.[240]

Further, the Federal Circuit "has long required district courts performing reasonable royalty calculations to exercise vigilance when considering past licenses to technologies other than the patent in suit."[241] Here, the court must determine if the 2001 Nonin/Respironics Licensing Agreement[242] concerns technology substantially similar to the patents-in-suit. If the court is unable to ascertain this nexus, then the Agreement

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[237] 665 F.3d at 893.
[238] *Id.*
[239] 594 F.3d 860 (Fed. Cir. 2010).
[240] *Id.* at 873.
[241] *Id.* at 869.
[242] D.I. 392, Ex. J.

cannot be used in calculating a reasonable royalty.

The Agreement does not identify any specific products covered, and only generally specifies "products identified by Resprionics and agreed to by Nonin."[243] Low profusion or motion measurement technology is also not directly addressed, but the Agreement does provide Respironics will compensate Nonin seventy-five dollars for each Respironics devise sold with Nonin pulse oximetry technology. Dr. Keeley could not answer if Nonin or Respironics contemplated or anticipated that the agreement would cover future low perfusion or read through motion technology.[244]

The Agreement is not comparable to a hypothetical negotiated license for the patents-in-suit. Although the Agreement generally references "pulse oximetry technology," it does not specifically identify the technology, nor address the patents-in-suit through other descriptions, such as read through motion or low perfusion.[245] Further, nothing in the Agreement suggests Respironics or Nonin intended to include such technology.[246] The Agreement does not contemplate comparable technology to the patents-in-suit.[247] Therefore, the Nonin/Respironics agreement cannot be used in calculating a reasonable royalty rate.

Conclusion

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[243] *Id*.

[244] Q. "Do you know whether the potential availability of Nonin's pulse oximetry technology to read through motion or be motion-tolerant had any impact on Respironic's interest in entering into this license agreement?" A. "I don't know specifically." D.I. 526, Ex. 117, (Keeley Depo.) at 92:8-13. *See also*, *id.* at 91:15-92:2

[245] See *ResQNet*, 594 F.3d at 870 ("Notably, none of these licenses even mentioned the patents in suit or showed any other discernible link to the claimed invention.").

[246] The fact that the Agreement can "be renewed by mutual agreement" does not provide the necessary intent.

[247] Similar to the license in *ResQNet*, the Agreement contains services unrelated to the patents-in-suit, such as technical support, advice on continuing product enhancements, and marketing support. 594 F. 3d at 870.

For the foregoing reasons, Masimo's motion to exclude the expert testimony of Dr. Keeley pursuant to FED. R. EVID. 702[248] is granted in part and denied in part. Specifically, Masimo's motion to exclude Dr. Keeley from relying on the 2001 Nonin/Resperionics agreement is granted.

4. Philips' Motion to Exclude the Testimony of Michael J. Wagner;[249]

Michael J. Wagner (Masimo's Expert)

Philips moves to preclude the testimony of Michael J. Wagner ("Wagner") on nine different topics: (1) the percentage of FAST sockets that use Masimo, Nellcor and Philips' sensors; (2) lost sales on stand-alone units; (3) the appropriateness of a $1000 per unit reasonable royalty rate; (4) future damages; (5) Masimo's profit margin; (6) the division of FAST sales in the but-for world; (7) lost profits recoverable if only the '984 patent is infringed; (8) "concluded royalty rates"; and (9) Nonin PureSAT as not an acceptable non-infringing alternative.

Discussion

A. Wagner's opinion on the percentage of FAST sockets using Masimo, Nellcor and Philips' sensors is admissible.

Philips maintains Wagner's conclusions regarding the percentage of FAST sockets utilizing Masimo, Nellcor and Philips' sensors are baseless and should be excluded. Philips specifically disputes Wagner's conclusions that 70% of FAST sockets have Philips' sensors, while only 5% are Masimo's sensors and 25% use Nellcor sensors.[250] Philips proffers three arguments. First, it contends Wagner based his entire

[248] D.I. 388.
[249] D.I. 422.
[250] D.I. 432, Ex 26 (Wagner Rpt.) at ¶¶265-267.

opinion on a single spreadsheet that showed worldwide multi-parameter unit sales and the brand of sensors shipped with the unit at the time of the sales. Philips claims this document is inapposite because it shows worldwide data rather than U.S. data, only lists the sensors shipped with the unit rather than any sensors sold thereafter,[251] and is contrary to other evidence. Second, Philips argues Wagner's opinion ignores certain testimony of Rick Fishel,[252] the President of Masimo's Worldwide OEM Business and Corporate Development, and David Heckendorn,[253] Philips' Product Manager for Pulse Oximetry Sensors and Cables, which indicated a much higher Masimo's sensor usage and a lower Philips' sensor usage. Finally, Philips contends a rough check performed by Dr. Keeley explicitly demonstrates Wagner vastly overstates Philips' actual sensor sales, and does not support Wagner's 70% figure.[254]

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[251] *Id*., Ex 30 (Wagner Depo.) at 24:22-25:10 ("A. If I had [ongoing sensor usage] information, again, I would have used that in addition to this information to inform my opinion. But I don't have that information.").

[252] D.I. 433, Ex 46 (Fishel Depo.) at 99:15-100:15 ("A. So what is my understanding of the percentage of Philips' FAST sockets using a Masimo's sensor today in the U.S.? Q. Yes. A. Okay. It's a guesstimate. Q. Of course. A. I would guess it is 20 percent. 15 percent to 20 percent. Q. And do you have any idea what the percentage of Philips' sensors is being used with the FAST sockets in the U.S. today? A. Another guesstimate. I would guess it's similar, but maybe 10 to 15 as opposed to 15 to 20. Maybe 10 percent. Q. And is it your understanding that most of the rest are Nellcor sensors? A. Yes. Q. Is it your understanding that all the rest are Nellcor sensors? A. No. They're compatible with generic. So most of the rest was your question. Q. Yes, that's right.")

[253] D.I. 489, Ex M (Heckendorn Depo.) at 145:17 to 146:18 ("Q. We were talking about the percentage of total sensors used with the AO1 with FAST, and what is your best estimate as far as the percentage of Philips' sensors? A. 1 to 2 percent. Q. And what is your best estimate as to the percentage of Masimo's sensors? A. Let's say 30 to 40 percent. Q. And what is your best estimate of Nellcor sensors? A. 50 to 60 percent. Q. And then just to make sure we've got this all clear, when we were talking about the percentage of monitors and their sensor usage, what percent of monitors use Philips' sensors? A. Yeah, so I would say for Philips, 8 percent. Q. And what percent of monitors use Masimo's sensors? A. I'll give the same answer I did just a minute ago, 30 to 40 percent. Q. And what percent of monitors use Nellcor sensors? A. 50 to 60 percent.")

[254] *Id.* at ¶173 ("Multiplying the 2011 annual $602.20 sensors revenue per device by 228,151 FAST devices (i.e., the number of FAST sockets Mr. Wagner's analysis implies use Philips' sensors in 2011) results in total implied 2011 Philips' sensor revenues of $137.39 million. But in 2011, Philips' actual sensor revenue was only $8.47 million, one sixteenth of what Mr. Wagner says it should have been. That is, Mr. Wagner overstated Philips' sensor sales by a factor of sixteen.")

Masimo submits Wagner's methodology was appropriate under the circumstances. It argues Wagner does not base his opinion entirely on the Philips' spreadsheet. Rather, he uses the document as a starting point. Masimo claims because Philips created the spreadsheet outside the context of litigation, it is more reliable. Wagner acknowledged the document shows worldwide sales rather than U.S. sales,[255] but relied on it as the only available business record offered by Philips. Masimo maintains Wagner's use of the spreadsheet as a starting point for his analysis was reasonable. Further, Masimo argues Wagner's application of fact-based assumptions, when conducting a reasonableness check, bolsters the reliability of his method.[256] Lastly, Masimo asserts Wagner was aware of Fishel and Heckendorn's estimates, but excluded them as unreliable.[257] Masimo defends Wagner's approach by noting that Heckendorn defined his analysis as a "ballpark estimate,"[258] and Fishel only offered percentages when pressed to do so.[259]

When determining damages, "any adverse consequences must rest on the infringer when the inability to ascertain lost profits is due to the infringer's own failure to

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[255] D.I. 432, Ex 26 at ¶266 ("The analysis includes a spreadsheet on *worldwide sensors sales* that appears to estimate the Nellcor sensors share of its sockets[.]) (emphasis added).

[256] *Id.* 432, Ex 29 (Wagner Supp. Rpt.) at ¶¶8-11.

[257] D.I. 489, Ex P (Wagner Depo) at 14:2-16 ("Q. Would you look with me at table 3. It's on page 16. Do you see that this is what Dr. Keeley has set forth as the estimates of David Heckendorn and Rick Fishel? A. It is. Q. So let's look at – let me first ask, do you have any reason to doubt Mr. Fishel's estimates of sensors being used with FAST sockets? A. Yes. Q. What is that? A. He has no information to base his judgment. I know he's clearly a knowledgeable person in this industry, as is Mr. Heckendorn. But my understanding, both of them testified in their depositions they really just don't know, but this is their best guess.").

[258] *Id.*, Ex M at 147:2-6 ("Q. Okay. Now, how confident are you in those percentages? A. I wouldn't bet my life on them, but I think – I think they're pretty good ballpark estimates.")

[259] D.I. 489, Ex X (Fishel Depo) at 98:9-11 ("Q. Do you have any idea how many Philips' FAST sockets are being used with Masimo's sensors? A. No.")

keep accurate or complete records."[260] Under the guise of criticizing Wagner's methodology, Philips argues because no available records exist for U.S. sensors sales, Masimo should be precluded from offering evidence of the types of sensors used with the allegedly infringing sockets. Lack of sufficient business records is construed against the infringer.

Philips oversimplifies Wagner's analysis as based on a single spreadsheet, while ignoring other relevant testimony.[261] Wagner analyzed the only available record evidence, and did not ignore the testimony of Fishel and Heckendorn. He felt their depositions were inaccurate because both admitted their figures were estimates based on their experience.[262] He applied fact-based assumptions extrapolated from other evidence to perform a reasonableness check of his figures. He further limited his analysis to open-socket units, since AO2 units were compatible only with Nellcor sensors.[263] Wagner also assumed customers would standardize technology, concluding

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[260] *Lam, Inc. v. Johns-Manville Corp.*, 718 F.2d 1056, 1065 (Fed. Cir. 1983).

[261] D.I. 423 at 4-8.

[262] D.I. 432, Ex 30 at 27:12-28:19 ("Q. So do you think, now that you know about Mr. Fishel's testimony and Mr. Heckendorn's testimony, that it would have been prudent to take that into account in your analysis? A. I think – I'm a fact-based witness, and any facts that are relevant, I would like to take into consideration. But I have considered it since I received Dr. Keeley's rebuttal report, and I've rejected the information as being probative based on both this table you're showing me as Exhibit 5, and the analysis I've done in my updated report, which is very inconsistent with those two best estimates of people with no information. Q. Well let's backtrack a little on that. You said they have no information. That's not quite true, is it? A. I think, if you show me the right pages from Mr. Heckendorn's deposition, I think he says he has no information. Q. Other than his experience in the industry; correct? A. Sure. I mean, clearly, he's got experience in the industry. Q. And the same with Mr. Fishel. He has experience in the industry. A. He does. Q. So it wouldn't be quite right to say they don't have any information. A. 'Any documentary information' is probably a better way of saying it.").

[263] D.I. 489, Ex M at 128:17-129:18 ("Q. Okay. So aside from AO1 with FAST, SureSigns, and telemetry, are there any other pulse oximeters that Philips sells that are compatible with Philips, Masimo and Nellcor sensors? A. I think not. Q. The AO2 with FAST, is it your understanding that those are compatible only with Nellcor sensors? A. Today that's the case, yes. Q. Was there a time in which the AO2 with FAST was compatible with sensors other than the Nellcor sensors? A. Yes. Q. When was that? A. From about 2004 to mid 2007, we supplied Philips reusable sensors that were compatible with the FAST technology in the AO2 socket. Q. Are there any Nellcor sensors that are compatible with AO2 with FAST that are not compatible with AO1 with FAST? A. Yes. Q. Are all of the Nellcor sensors

those who purchased a monitor with Masimo's SET would use Masimo's sensors. In light of the deposition of Andreas Bindszus, Philips' Director of Marketing for General and Emergency Care, who testified the compatibility of generic sensors with FAST sockets is the primary reason customers choose FAST,[264] Wagner adjusted his figures appropriately.[265] Philips argues Wagner's conclusions are incorrect, but fails to explain how his methodology is inappropriate or unreliable. Therefore, Wagner's opinion on sensor sales is admissible.

B. Wagner's findings on lost sales of stand-alone units is admissible.

Philips contends Wagner's calculation of lost sales of stand-alone units is arbitrary, and therefore, inadmissible because he simply uses an existing ratio of board sales and stand-alone unit sales and applies them to the but-for world, creating a loss that Masimo did not actually realize.[266] Philips claims Wagner can only state Masimo "might be" losing sales, and fails to show any direct competition between Philips and Masimo in stand-alone units.[267] In support, Philips points to Wagner's comparison of two unrelated products, which he admits could be misleading.[268] Because Philips interprets Wagner's comment as a possible arbitrary application of the sales ratio, it

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compatible with AO2 with FAST? A. I believe they are.")

[264] *Id.*, Ex N (Bindszus Depo) at 230:17-231:2 ("Q. What are the reasons that a customer purchasing an IntelliVue monitor would choose the Philips' FAST SpO2 option over the other options available? A. The availability of generic sensors, so not being bound to one sensor. Q. Is that the top reason? A. Yes.").

[265] D.I. 485 at 9.

[266] D.I. 423 at 8.

[267] *Id.*, Ex. 30 (Wagner Depo) at 103:7-15 ("Q. And are you saying then that there's competition in the sense that Philip's FAST boards and Masimo's SET boards compete within IntelliVue? A. Yes, there's competition there. There's also indirect competition for standalones to the extent that through Philip's behavior, that they have made Nellcor a stronger competitor who does sell standalones, there is some competition there that Masimo might be losing sales, but it's not direct with Philips.").

[268] *Id.* at 156:4-7 ("Q. My point is that you can always calculate the ratio and argue from that there have been lost sales of some other product. A. Sure, that's true.").

moves to exclude his opinion.

Masimo argues direct competition is not a factor in determining lost sales; rather a "causal relation" between Philips' infringement and Masimo's lost profits on stand-alone sales is required.[269] Masimo states this causal relationship is easily shown because of the tendency by hospitals to standardize pulse oximetry technology.[270] Due to the interchangeable nature of Philips' sockets, it claims Nellcor is now a stronger competitor in stand-alone units, which supports Wagner's analysis.[271]

Philips relies on *BIC Leisure Prods., Inc.* to demonstrate Wagner's opinion on lost sales of stand-alone units is contrary to law because the parties are not direct competitors in stand-alone units. Direct competition, however, is not a required factor for lost sales. Rather, "[t]o recover lost profits as opposed to royalties, a patent owner must prove a causal relation between the infringement and its loss of profits."[272] Wagner offers multiple sources showing standardization of pulse oximetry technology within hospitals.[273] He testified the interchangeability of FAST sockets has strengthened Nellcor as a competitor. His reasoning is that the compatibility of FAST sockets with Nellcor products may have influenced hospitals to standardize to Nellcor products rather than Masimo's devices. Wagner's reasoning is not speculative, and credibility is left to

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[269] D.I. 485 at 11; citing *BIC Leisure Prods., Inc. v. Windsurfing Int'l, Inc.*, 1 F.3d 1214, 1218 (Fed. Cir. 1993).

[270] D.I. 432, Ex. 26 (Wagner Rpt.) at ¶219 ("Furthermore, many hospitals prefer to standardize on one technology.").

[271] *Id.*, Ex. 30 at 103:7-15; *Id.*, Ex. 26 at ¶225 ("This testimony indicates that standardization to a single pulse oximetry technology satisfies the functional need of the hospital to provide effective care. When viewed as an entire hospital providing care to patients, the combination in a hospital of Philips' accused products with Masimo's SET pulse oximetry technology and Masimo's stand-alone monitors provide enhanced pulse oximetry function to a hospital's patients. Therefore, it is appropriate to include the convoyed sales of stand-alone monitors in the lost profits calculation.")

[272] *BIC Leisure Prods., Inc.*, 1 F.3d at 1218.

[273] D.I. 432, Ex. 26 at ¶¶219-25.

the jury.

Philips further argues Wagner's application of the ratio between board sales and stand-alone sales in but-for world sales is arbitrary, misleading, and purposefully creates sales that did not occur,[274] as evidenced by his deposition[275] which demonstrates the impropriety of his method.

Philips' argument is without merit. In his testimony, Wagner emphasizes the close relationship among the products on which his ratio is based.[276] Contrary to Philips' contention, Wagner's ratio is grounded on testimony from multiple sources, the relatedness of the compared products, and customer standardization of pulse oximetry technology. Predicting lost sales is not an exact science, and the patent owner must show "a reasonable probability that, absent the infringement, it would have made the infringer's sales."[277] Philips' argument goes to the weight of Wagner's opinion; his methodology satisfies Rule 702 and *Daubert*.[278]

C. Wagner's testimony on reasonable royalty rate is based on acceptable methodology and admissible.

Philips criticizes Wagner's reliance on three sources for his $1000/unit royalty rate, the Masimo/Nellcor license, the Masimo/Draeger agreement, and the

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[274] D.I. 423 at 8.

[275] D.I. 432, Ex. 30 at 155:14-18 ("Q. For example, suppose Masimo also sold baseball hats. You could do a calculation of the ratio of their baseball hat sales to their board sales, couldn't you? A. I could, but you're giving me a counterfactual assumption.").

[276] *Id.* at 155:19-22 ("A. Here I'm talking about products that are clearly related, that would use the same sensors, types of sensors, that there's standardization in a hospital. That is very different from selling baseball caps.").

[277] *BIC Leisure Prods., Inc.,* 1 F.3d at 1218 (citing *Water Technologies Corp. v. Calco Ltd.*, 850 F.2d 660, 671 (Fed. Cir. 1988), *cert. denied*, 488 U.S. 968 (1988)).

[278] *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589-90 (1993); *see i4i Ltd. Partnership v. Microsoft Corp.*, 598 F.3d 831, 852 (Fed. Cir. 2010) ("When the methodology is sound, and the evidence relied upon sufficiently related to the case at hand, disputes about the degree of relevance or accuracy (above this minimum threshold) may go to the testimony's weight, but not its admissibility.") .

Masimo/Respironics agreement, contending none provide a valid basis for a per unit royalty rate in that amount. Philips argues the Masimo/Nellcor license is not relevant because it uses a percentage royalty, not a dollar amount, which is applicable to all Nellcor oximeter and sensor revenues, that is the entire revenue Masimo will receive over the life of a Nellcor closed socket.[279] Wagner's translation of that percentage into a dollar amount is inconsistent with the compatible nature of Philips' FAST open sockets. Wagner interprets the agreement to be a $1000/unit royalty rate by adding the percentage royalty from the actual sale of the socket to the percentage royalty received from every Nellcor sensor sale associated with that socket over its lifetime, and concludes that amount in royalties is paid by Nellcor for every sale of its closed-socket unit. Philips argues Masimo's expectations from Nellcor is not the proper measure of the reasonable royalty under the *Georgia-Pacific* hypothetical negotiation.[280] It contends the Nellcor license proves Masimo was willing to accept a *total* revenue of $1000/per unit or socket, even though it could make more revenue through its direct sales of pulse oximeters and sensors. Because Philips' FAST is an open socket, that is, it is compatible with sensors made by other manufacturers, such as Masimo and Nellcor, it purports Masimo would charge Philips less. Thus, for Masimo to realize a $1000 from each sale of a Philips' FAST socket, the royalty charged to Philips would be less than this amount because Masimo's profits would primarily be realized from sales of Masimo or Nellcor sensors for use with a FAST socket.[281] Accordingly, Wagner's translation to a

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[279] D.I. 423 at 11.

[280] *Georgia-Pacific Corp. v. United States Plywood Corp.*, 318 F. Supp. 1116, 1121 (S.D.N.Y. 1970).

[281] D.I. 423 at 11-12.

dollar amount dramatically overcompensates Masimo.[282]

Philips further complains the Draeger and Respironics agreements provide no rationale for a $1000/unit royalty rate.[283] The Draeger agreement has no royalty, merely a liquidated damages provision which operates only when Draeger fails to sell a minimal amount of Masimo's products. Philips' criticism of the use of the Respironics agreement is that $1000/unit rate is not a royalty, and Masimo agreed not to use this amount as evidence of a royalty. For these reasons, Philips concludes Wagner's opinion in this regard should be excluded.

Masimo argues Wagner's conversion of the Masimo/Nellcor percentage to a dollar amount was not only appropriate, but necessary[284] due to the different business models of the Masimo/Nellcor license and Philips' FAST open-socket products. Philips could sell its FAST socket and thereafter sell only its accompanying sensors, ultimately yielding less than an acceptable amount to Masimo from the hypothetical negotiation.[285] By translating to a dollar figure, that situation is avoided, because Masimo would receive the lifetime value on the socket, although its other products, such as sensors,

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[282] D.I. 432, Ex 30 at 111:15-112:2 ("Q. Let's say that Philips sells a FAST board, and they have to pay Masimo $1000 for that unit. Masimo will then get that $1000, plus continue to benefit even more during the life of that FAST socket from selling sensors into that socket; right? A. If Masimo sells the sensor, yes. Q. Or if Nellcor sells some sensors into that FAST socket; right? A. They're not going to make $1000, but they're going to make something, yes.").

[283] D.I. 423 at 12-13.

[284] D.I. 485 at 12-14.

[285] D.I. 432, Ex. 26 at ¶348 ("I adjust for one difference between the Nellcor Agreement and the hypothetical license in this section. As demonstrated by Nellcor's royalty reports, the Nellcor license fees are largely driven by its sensor sales. In comparison, Philips sells multi-parameter monitors that often work with other monitoring solutions that are sold for thousands of dollars. In addition . . . Philips' sales of the accused products have grown throughout the time period, which results in an understatement of lifetime sensors related to a socket when a framework is applied such as that used in the Nellcor Agreement.").

are not convoyed.[286] Masimo contends Philips' arguments regarding the Masimo/Nellcor license involve weight, not admissibility, of Wagner's opinion.

Masimo states the Draeger and Respironics agreements are appropriate because the negotiations occurred after infringement accusations were raised by Masimo, and both licenses require payment of $1000 per unit when contractual minimums are not met.[287] The Draeger agreement is comparable to a royalty rate because the liquidated damages provision is only activated when Draeger sells more of its infringing products than authorized.[288] Masimo points out in the Respironics agreement that its promise to not use the license as evidence of a royalty rate was made only to Respironics, and not to any third party.[289] Masimo concludes reliance on the agreements and Wagner's opinion is consistent with Rule 702 and case law.

The *Georgia-Pacific* factors are widely accepted to calculate a reasonable royalty rate.[290] Wagner's report applies those factors to comprehensively determine the appropriate royalty rate from a hypothetical negotiation.[291] His prior application of the *Georgia-Pacific* factors has been affirmed by the Federal Circuit.[292] Several *Georgia-Pacific* factors relate to profitability of the patented products, and Wagner's analysis of the business models of Masimo and Philips are consistent with those factors. In translating the percentage royalty applied to closed-socket products by Nellcor to a

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[286] D.I. 485 at 13.
[287] *Id.* at 14.
[288] *Id.* at 15.
[289] *Id.* at 16.
[290] *Lucent Technologies, Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1324-5 (Fed. Cir. 2009); *see also Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1554 n.13 (Fed.Cir.1995) (en banc); *Radio Steel & Mfg. Co. v. MTD Prods., Inc.*, 788 F.2d 1554, 1557 (Fed.Cir.1986)
[291] D.I. 432, Ex 26 (Wagner Rpt.) at ¶¶352-489.
[292] *i4i Ltd. Partnership v. Microsoft Corp.*, 598 F.3d 831 (Fed. Cir. 2010).

dollar royalty on open-socket technology sold by Philips, Wagner's analysis comports with the hypothetical negotiation between Philips and Masimo. In such negotiations, representatives of both companies would consider in their royalty analysis various scenarios regarding the type of board and the type of sensors sold.

Philips' criticisms of the Masimo/Nellcor license are directed to Wagner's conclusion and the weight, not admissibility, of his findings.

Wagner's application of the Draeger and Respironics agreements is also appropriate. In the hypothetical negotiation, both parties would consider existing licensing agreements. Wagner determined the Masimo/Nellcor license establishes a royalty of approximately $1000 per socket sold by Nellcor. That same unit price is also found in the Draeger and Respironics agreements, although neither specifically address a unit price royalty rate. Both Draeger and Respironics, however, are required to pay that per unit price if they sell an amount of infringing units in excess of their respective contractual limitations. Because Wagner's analysis of the Nellcor, Draeger, and Respironics agreements is methodologically appropriate and reasonable under the *Georgia-Pacific* factors, it is admissible.

D. Wagner's opinion on future damages is admissible.

Philips contends Wagner's testimony on future damages fails to meet the legal standard for admissibility. To be admissible, Philips argues the standard is "commensurately greater" because of future unknowns.[293] Projections for future damages must not be speculative.[294] Philips claims Wagner's analysis is speculative

[293] *Oiness v. Walgreen, Co.*, 88 F.3d 1025, 1031 (Fed. Cir. 1996).
[294] *Id.*

due to various unknown factors, including increased sales. Philips points to Wagner's deposition as demonstrating that an increasing trend in Masimo's sales would decrease the amount of damages.[295] Because Wagner ignored this trend, Philips purports his opinion is unreliable.[296]

Masimo contends Philips' argument addresses weight, and not the foundation of Wagner's opinion. It argues Wagner recognized an increasing sales trend that ended in 2008, although this trend was not included in his future damages calculations.[297] Masimo argues Wagner fully considered all available information, and compiled an opinion that satisfies Rule 702.

Philips' argument is misplaced, insomuch as it relies on *Oiness v. Walgreen* to support a "commensurately greater" standard for the admissibility of Wagner's testimony.[298] The *Oiness* court overturned a jury verdict because its finding on future damages was inconsistent with the record. There, the court held all experts who testified on lost projected sales failed to perform a credible economic analysis to support their conclusions. In absence of that required analysis, there was no reasonable support for the jury's excessive damages award. The commensurately greater

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[295] D.I. 432, Ex. 30 (Wagner Depo.) at 18:4-13 ("Q. So would you agree that if Masimo does begin to sell a much higher proportion of the sensors into that FAST socket, that would have an effect on future convoyed sales damages? A. I agree that it would. Q. In fact, it could have a dramatic effect, couldn't it? A. You'd have to give me facts, but certainly if it's a significant increase, it would have a significant impact on the future damages.").

[296] D.I. 423 at 14.

[297] D.I. 432, Ex 30 at 13:6-16 ("Q. But the number of Masimo's sensors being used with Philips' sockets is increasing; is that correct? A. It is, and as you can see in that calendar year 2008, it's up to 6 percent by that period of time. Q. So is there an increasing trend? A. There is an increasing trend. Q. And in the future, is it your estimate that would continue to increase? A. I don't have enough information to know. It seems pretty stable, but it is increasing. I should say, the rate of the increase is significantly declining.").

[298] D.I. 423 at 14.

standard, however, applies to the burden of proof the patentee must meet to justify future damages, which has no bearing on the admissibility of expert testimony, if Rule 702 is satisfied.

Since Wagner failed to account for an increasing trend in sales that could substantially affect damages, Philips maintains his methodology is unreliable. Philips points to Wagner's recognition of an increasing trend in Masimo's sales between 2004 and 2008, and extrapolates that continued increases would dramatically decrease the amount of damages.[299] Wagner, however, determined the increase in sales rapidly declined from 2007 to 2010,[300] which negated consideration of past increases in the future. Wagner used Philips' sales data, analyzed the percentage of FAST monitors using Masimo's sensors,[301] and applied his experience to determine a reasonable estimate as to future damages. Because Philips' arguments address weight, and not admissibility, and Wagner's underlying methodology is reliable, its motion on future damages is denied.

E. Wagner's testimony regarding Masimo's profit margin is excluded.

Philips alleges Wagner's opinion on Masimo's profit margin is not consistent with his book, the LITIGATION SERVICES HANDBOOK, a widely recognized publication on methodologies for damages analyses, and thus unreliable.[302] Philips accuses Wagner of not employing a standard accepted methodology, that is regression analysis, as set

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[299] D.I. 432, Ex. 30 at 13:6-16.

[300] *Id.*, Ex. 29 (Wagner Rpt.) at ¶11("For the years 2007-2010, I estimate that the percentage of customers that use Masimo's sensors are 1.5%, 5.8%, 1.7%, and 1.3%, respectively.").

[301] *Id.*

[302] D.I. 432, Ex. 30 (Wagner Deposition) at 232:16-20 ("Q. Is this book, the Litigation Services Handbook, wisely relied upon by damages experts, to your knowledge? A. It is. And it's one of the few authoritative pieces in my industry.").

forth in his book.[303] Philips further claims the information on which he relies, consists of data collected and findings developed by his staff that he does not understand,[304] and he is uncertain about the bases for his staff's conclusions.[305] Since Wagner is unfamiliar with the underlying facts for his conclusions, Philips maintains he cannot know whether that information is reliable, and his opinion on profit margin should be excluded.

Masimo argues a standard regression analysis is not appropriate because this analysis is too simplistic and unreliable for this matter.[306] Since Wagner did not consider increased costs incurred by Masimo in his opinion, his methodology is accurate.[307]

The Supreme Court recognized expert opinion must be on "good grounds, based on what is known."[308] Experts are required to be more knowledgeable and experienced

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[303] *Id*. at 234:1-3 ("Q. . . . But when you have superior information, you may want to reject this approach.").

[304] *Id*. at 234:12-20 ("Q. So the – and then as we've talked about, the assumptions that you relied upon as a reason for departing from chapter 5 of the Litigation Services Handbook are assumptions that your staff confirmed with Masimo's personnel; is that right? A. That is correct. But based on my experience and judgment and doing a lot of work in this industry, the conclusions reached are eminently reasonable, in my experience and opinion.").

[305] *Id*. at 227:7-228:6 ("Q. And there's a reference in here that your staff has discussed the operating expense analysis with Masimo to confirm that the assumptions are reasonable. And in particular, does that mean Julie Nakata at Masimo? A. And Rick Fishel. Q. Who at your staff had those discussion? A. I believe it was two people, it would be Greg Pinsonneault and also Carson Li. Q. What assumptions did they confirm are reasonable? A. They went through the entire spreadsheet to try and understand the basis for the judgments made by the financial people at Masimo, and based on their descriptions, found them to be reasonable. Q. Did your staff then communicate all of that information to you? A. No, only their judgment or their opinion based on what they had heard, not the details. Q. So you're not aware of the details of the conversations with Julie Nakata or Rick Fishel? A. No. And that would be double hearsay, and I wouldn't want to offer that as the basis of my opinion.").

[306] D.I. 485 at 18.

[307] *Id.*

[308] *Daubert*, 509 U.S. at 590.

in a specialized area than the average person.[309] To insure only accurate findings are admitted, the opinions and testimony of an expert must be reliable.[310] The expert should, at a minimum, have a basic understanding of the data that forms the basis of his opinion.[311] Wagner's testimony evidences a lack of familiarity with the underlying data for his conclusions on profit margin.

In evaluating Masimo's profit margin, Wagner delegated work to his staff. As shown in his deposition, Wagner was unfamiliar with the supporting documents[312] and other details for his assumptions.[313] His analysis, therefore, fails to "withstand the basic test of reliability."[314] An expert is obligated to know and understand the facts upon which his assumptions rely.[315] Blind reliance on projections created by third parties absent a review and understanding of the underlying data means the expert is merely parroting conclusions by non-testifying individuals. Therefore, Wagner's opinion and testimony on this issue is excluded.

F. Wagner's division of FAST sales in the but-for world satisfies Rule 702 and is admissible.

Philips also moves to exclude Wagner's testimony on the division of FAST sales

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[309] FED.R.EVID. 702 advisory committee's notes ("[T]he text of Rule 702 expressly contemplates that an expert may be qualified on the basis of experience. In certain fields, experience is the predominant, if not sole, basis for a great deal of reliable expert testimony.").

[310] *Daubert*, 509 U.S. at 590.

[311] *Id.*

[312] D.I. 432, Ex 30 (Wagner Depo.) at 226:20-227:3 ("Q. This comes from the Excel spreadsheet bearing Bates No. MASP0636810. It's from Masimo's 2011 income statement. You don't remember having seen this? A. I personally don't recall seeing this document. My staff may have, but no one brought this document to my attention that I recall.")

[313] *Id.* at 227:21-228:5 ("Q. Did your staff then communicate all of that information to you? A. No, only their judgment or their opinion based on what they had heard, not the details. Q. So you're not aware of the details of the conversations with Julie Nakata or Rick Fishel? A. No.")

[314] *Chemipal Ltd. v. Slim-Fast Nutritional Foods Int'l, Inc.*, 350 F. Supp. 2d 582, 590 (D. Del. 2004).

[315] *Id.* at 592 ("Essentially, his 'lack of familiarity with the methods and the reasons underlying ... [his staff's] projections virtually precluded any assessment of the validity of the projections through cross-examination.'") (quoting *TK–7 Corp. v. Estate of Barbouti*, 993 F.2d 722, 732 (10th Cir.1993)).

in the but-for world. Wagner uses market shares to determine the percentage of FAST sockets that would have been Masimo's sockets under the but-for analysis. Philips argues Wagner should have used sensor sales as a more appropriate reference. Wagner recognizes purchasers of a FAST socket with a Nellcor sensor would also buy a Nellcor board, while customers who bought a FAST socket with a Masimo sensor would purchase a Masimo SET board.[316] Wagner opines hospitals often standardize their equipment to a specific brand determined by sensor choice.[317] Those assumptions, Philips argues, demonstrate that Wagner's conclusions lack any factual foundation, and should be excluded.

Masimo claims Philips' arguments address only weight. It characterizes Philips' criticisms as directed to Wagner's use of algorithm market shares rather than sensor market shares, and Wagner sufficiently explains why sensor market shares are less reliable.[318]

Philips fails to explain why Wagner's methodology is unreliable, and does not

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[316] D.I. 432, Ex 30 at 161:18-162:5 ("Q. [I]sn't it logical to assume that a FAST board being used with Nellcor sensors becomes a Nellcor board in the but-for world? A. Yes. Q. And is it also true that a customer using FAST with Masimo sensors has some preference for Masimo sensors? A. If they've proven, based on their behavior, they use Masimo sensors, clearly, yes.").

[317] *Id*. at 165:19-166:2 (A. My understanding is that yes, that it would be more both technically appropriate and economically appropriate for the hospital to standardize, based on what [Rick Fishel] told me in this paragraph. Q. Based on sensors? A. Yes.").

[318] *Id.* at 162:10-163:14 (Q. So doesn't it, then, make more sense to divide the FAST sockets in the but-for world according to sensor percentages as opposed to industry market shares of the boards? A. No. Q. And why not? A. Because there's a confounding event if you do it that way that would be hard to control for. And the sensor market share is not only driven by new sales, but by historical sales. And that causes a problem with the accuracy of the measurement. If you talk about the actual sales of a board during the damage period, that's more timely and is a better indicator for that particular board whose sensors will be used. Q. . . . Did you say there's a historical effect or something like that? A. Yeah, that a lot of the sensor sales overall, if you calculate the market share, is really driven on past behavior, whose boards and sensors someone used way in the past earlier than this damage period. And clearly, again, there are apparently trends here where Masimo is increasing their market presence and market share over time, but if you base it on sensor sales, it's a much slower increase, because there's a lot of people that are locked into their old technology or old decision that use Nellcor.").

dispute Wagner's application of a specific factor, algorithm sales, to determine market split in the but-for world. Rather, Philips' criticism is Wagner used the wrong factor, which may be addressed during cross examination. Therefore, Philips' motion is denied.[319]

G. Wagner's testimony on lost profits for only the '984 patent if infringed is admissible.[320]

Philips argues Wagner's assessment of lost profits for the '984 patent is baseless, because he concludes a 10% loss in Philips' sales automatically correlates to a 10% increase in Masimo's sales in the but-for world. Wagner theorizes had Philips designed around by removing the time-domain algorithm in 2004, technology would have rendered Philips' design-around an unacceptable alternative, resulting in an initial loss of 10% in sales in the first year of the design-around which would have continued each succeeding year. According to Philips, these decreases are unsupported by any facts.

Masimo denies Wagner's opinion is mere speculation, because he relied on the opinion of Dr. Quill, which demonstrates the unacceptability of Philip's technology prior to its infringing products.[321] Therefore, Wagner's opinion under the Rule 702 analysis is reasonable and admissible.[322]

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[319] *State Industries, Inc. v. Mor-Flow Industries, Inc.*, 883 F.2d 1573, 1578 (Fed. Cir. 1989.

[320] Although the '984 has been found non-infringed, the court includes this discussion in light of the objections filed by both parties.

[321] D.I. 432, Ex. 31 (Quill's Open. Rpt.) at ¶36 ("[T]he Philips' FFT only FAST algorithm sold between 1999 and 2003 would have become an increasingly unacceptable substitute for a technology with the ability to accurately measure in the presence of motion and during low perfusion, that did not have the delay and pulse rate problems inherent with the early version of FAST that relied only on the FFT algorithm.").

[322] D.I. 485 at 19.

Philips' argument focuses on Wagner's conclusion, and misstates how it is applied. It claims Masimo uses Wagner's 10% figure to prove it is entitled to 10% annually in lost profits.[323] Rather, Wagner applies that percentage as a cap on the maximum amount of Masimo's lost profits assuming the '984 patent is the only patent found valid and infringed.[324] Despite his personal opinion that the loss in sales would resemble a cliff rather than a gradual decline,[325] Wagner applied an average loss because "most experts use averages in this situation."[326]

In determining the 10% figure, Wagner relied on Dr. Quill's evaluation of Philips' technology prior to infringement. Dr. Quill concluded without FAST, Philips' lack of read-through-motion technology would have lead to declining sales in pulse oximetry. Wagner incorporated Dr. Quill's findings to determine lost profits. Philips' argument with Wagner's percentage calculation is an issue that may be effectively addressed through cross examination. Wagner's opinion and testimony regarding lost profits of the '984 patent is admissible.

H. Wagner's testimony regarding "concluded royalty rates" is admissible.

Philips points to a purported lack of any support for Wagner's "concluded royalty rates," which are determined by combinations of the patents found to be infringed. The

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[323] D.I. 423 at 17.

[324] D.I. 432, Ex. 30 at 147:22-148:14 ("Q. Well, if, for example, Philips is only found to infringe the '984 patent, then Masimo's lost sales are simply the 10 percent per year that builds by year? Is that right? A. I don't think so. Q. Well, if Philips were to eliminate the time-domain algorithm from FAST, it could continue to make the same sales it's making for some small period of time, and then it starts to lose 10 percent per year? A. I think that would be a reasonable assumption given the facts as I've described them in my report. Q. So Masimo certainly cannot have lost any more sales than that 10 percent loss per year, correct? A. If only the '984 patent's infringe, that's correct.")

[325] *Id.* at 148:18-20.

[326] *Id.* at 154:20-21.

table attached to his expert report uses a $1000 per unit as the maximum reasonable royalty, and a percentage of this amount depending on the combination of infringed patents.[327] Philips argues Wagner's percentage valuation for each combination is based solely on his judgment absent any underlying facts or evidence, and should be excluded as speculative.

Masimo contends Wagner's apportionment is founded on his experience and judgment, the distinction between foundational and non-foundational patents, and the terms of the Nellcor/Masimo license.[328] Masimo claims Wagner's well-analyzed approach of combining those factors into a reasonable apportionment system is consistent with Rule 702.[329]

When evaluating reliability of an expert, the court considers all sources on which the expert relies. Wagner has long and respected history as a damages expert, and is published in the field.[330] His experience and judgment are entitled to some weight.[331] Wagner relied on the Nellcor/Masimo license which differentiated the value of certain

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[327] D.I. 432, Ex. 26 at ¶492, Fig. 57.

[328] D.I. 485 at 20.

[329] D.I. 489, Ex P (Wagner Depo.) at 241:15-243:8 ("A. . . . [T]here are two, my understanding is, basically different groups of patents being asserted here. One is the read-through motion patents and one is the parallel engine, as described here, the robustness patent, the '984. And again, based on my starting line baseline agreement of the Masimo/Nellcor agreement, that when you are licensing both these groups of patents together in a license agreement, about 25 percent of the value is placed on the parallel engines technology. And I've used that same assumption here. So if you end up proving this patent's invalid, or my client not proving that '984 is infringed, then the maximum amount of possible damages for the read-through motion would be 75 percent of the 100 percent. My understanding is the '222 is a truly foundational patent, and I do agree with, in that context, that you'd give basically 100 percent of the value to whether you have one patent, two patents, or three patents. It's like you have all the value for read-through motion to '222, whether that's the only patent you infringe or you also infringe the '272 and '194 as well. Q. . . . Considering all four of Masimo's patents together, you're saying that the '984 represents about 25 percent of it? A. Yes . . . I used the Masimo/Nellcor agreement, that if this particular functionality was taken out by Nellcor, they could reduce their royalty rate from 13 percent to 10 percent, which is a reduction of 23 percent. I've rounded it to 25 percent.).

[330] D.I. 423 at 15.

[331] *See* n.62 *supra*.

patents by reducing the amount of the royalty in the event of a design around.[332]

An expert's damages analysis must be based on "sound economic and factual predicates".[333] Wagner's past experience, professional judgment and reasoned assumptions, which includes weighing the valuable nature of foundational patents versus the incremental value of an improvement patent, and the pre-existing licensing Masimo/Nellcor agreement corroborates his opinion.[334] Philips' argument focuses on Wagner's conclusions on royalty rates. Therefore, Philips' motion on this issue is denied.

I. Wagner's opinion on Nonin PureSAT as an unacceptable non-infringing alternative is excluded.

Philips argues Wagner's reliance on Dr. Quill's report is the sole basis for his conclusion that PureSAT is an unacceptable non-infringing alternative.[335] Wagner relies heavily on Dr. Quill's opinion on this issue, commenting "[i]f he's wrong, then I'm wrong."[336] Philips contends the exclusion of Dr. Quill's testimony mandates also excluding Wagner's opinion in this regard.

Masimo points to other sources that support Wagner's understanding of

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[332] D.I. 485 at 20, n. 9. ("The Masimo/Nellcor Agreement explicitly provides that, if Nellcor designs around Masimo's '984 Patent, [Nellcor] may reduce its royalty rate by three percent. Mr. Wagner relied on this in-part to determine a relative value of Masimo's '984 Patent separate from Masimo's other asserted patents.").

[333] *Integra Lifesciences I, Ltd. v. Merck KGaA,* 331 F.3d 860, 870-72 (Fed. Cir. 2003).

[334] D.I. 432, Ex. 30 (Wagner Depo.) at 243:20-244:9 ("A. . . . I understand the '272 and '194 are considered to be real important to read-through-motion, they're not quite the level of foundational as the '222 is. And so they by definition should have a lower value. So whether one or both of them are infringed, those would be the only two infringed, I assume 50 percent value, which is taking away 25 percent value for the '222 and the 25 percent of the value for the '984 out of the total of 100 percent.")

[335] D.I. 423 at 20.

[336] D.I. 432, Ex. 30 at 138:22-139:1.

PureSAT's acceptability as a non-infringing alternative, which include Joe Kiani[337] and David J. Baker.[338] Masimo, therefore, reasons exclusion of Dr. Quill's testimony on this issue does not preclude Wagner's opinion. Contrary to Masimo's argument, it is the sources Wagner found significant and relied upon in forming his opinion, not what other sources may be available.[339] Wagner explicitly states he relies *solely* on Dr. Quill's findings whether Nonin PureSAT is an acceptable non-infringing alternative.[340] As previously determined herein, Dr. Quill's opinion was limited in that regard. To the extent Dr. Quill's testimony was limited on this issue, and Wagner relied on any analysis and conclusions of Dr. Quill's that were not allowed, Wagner's opinion and testimony are similarly excluded.

VI. Order and Recommended Disposition

Consistent with the findings contained in the Report and Recommendation,

IT IS RECOMMENDED that:

1. Masimo's Motion to Exclude the Expert Testimony and Opinions of Drs. John H. Eichhorn, Thomas L. Higgins, and Edward A. Ochroch Pursuant to FED. R. EVID. 702 (D.I. 385) is denied in part, and granted in part.

2. Philips' Motion to Exclude the Testimony and Opinion of Timothy J. Quill (D.I. 420) is denied in part, and granted in part.

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[337] D.I. 494 at ¶6 ("In order to confirm that Nonin PureSAT could not measure through motion, I tested Nonin PureSAT myself. I put on a Nonin monitor with PureSAT and ran it through motion conditions. My test confirmed that Nonin PureSAT did not work at all during motion conditions.").

[338] D.I. 493 at ¶¶1-3.

[339] *Daubert*, 509 U.S. at 590.

[340] D.I. 432, Ex. 30 (Wagner Depo) at 138:9-16 ("Q. Do you rely on Dr. Quill for your assertions about whether there are noninfringing alternatives that are acceptable in this case? A. I do, and I don't have the technical qualification to reach that conclusion. That is an assumption that I make to do my analysis. I assume the assumption is correct. But I'm *completely relying* upon Dr. Quill for that assumption.") (emphasis added).

3. Masimo's Motion to Exclude Portions of the Testimony and Opinion of Michael C. Keeley, Ph.D. pursuant to FED. R. EVID. 702 (D.I. 388) is denied in part, and granted in part.

4. Philips' Motion to Exclude the Testimony and Opinion of Michael J. Wagner (D.I. 422) is denied in part, and granted in part.

Pursuant to 28 U.S.C. § 636(b)(1)(B), FED. R. CIV. P. 72 (a), and D. DEL. LR 72.1, any objections to the Report and Recommendation shall be filed within fourteen (14) days limited to fifteen (15) pages after being served with the same. Any response shall be limited to fifteen (15) pages.[341]

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.)

May 20, 2013

/s/ Mary Pat Thynge
UNITED STATES MAGISTRATE JUDGE

[341] FED. R. CIV. P. 72(a).