United States District Court,
C.D. California.

MALLINCKRODT, INC,
v.
MASIMO CORPORATION.

No. CV 00-06506-MRP

Feb. 27, 2003.

Owner of patents for pulse oximeter devices sued competitor for infringement. Competitor counterclaimed for infringement of its own patents. Construing claims, the District Court, Pfaelzer, J., held that: (1) "adaptive filters" were not limited to adaptive noise cancelers; (2) requirement that signal processor be able to calculate arterial oxygen saturation "without significant interference" meant that calculated amount was accurate enough for purposes for which calculation was being employed; (3) parts of "oximeter probe system" could reside on oximeter itself; (4) "known wavelength" had to be single value; (5) "translation circuitry" had to be part of sensor probe; "calibration code" had to have single value; and (6) requirement that tonal frequency vary "continuously" meant that tonal frequency changed constantly as quantity being measured changed.

Claims construed.

Court-Filed Expert Resumes

6,036,642. Cited.

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Memorandum of Decision and Order RE:

1. Claim Construction

2. Motion to Strike Masimo's Declarations

PFAELZER**, District Judge.**

I. Introduction

This is a patent infringement suit in which all the patents-in-suit relate to pulse oximetry. Plaintiffs/Counterdefendants Mallinckrodt Inc. and Nellcor Puritan Bennett, Inc. (collectively, "Nellcor") assert six separate patents. Defendant/Counterclaimant Masimo Corp. ("Masimo") asserts five patents. A list of these patents follows.

Masimo Patents

-> **6,206,830 B1** FN1-Signal Processing Apparatus and Method (Mar. 27, 2001)
FN1. For ease of reference, all patents will be referenced by their last three digits. I.e., Patent No. 5,769,785 will be cited to as the " '785 patent."

-> **6,157,850**-Signal Processing Apparatus (Dec. 5, 2000)
-> **6,263,222 B1**-Signal Processing Apparatus (Jul. 17, 2001)

-> **5,769,785**-Signal Processing Apparatus and Method (Jun. 23, 1998)

-> **5,490,505**-Signal Processing Apparatus (Feb. 13, 1996)

Mallinckrodt / Nellcor Patents

-> **4,621,643**-Calibrated Optical Oximeter Probe (Nov. 11, 1986)
-> **4,653,498**-Pulse Oximeter Monitor (Apr. 18, 1989)

-> **4,700,708**-Calibrated Optical Oximeter Probe (Oct. 20, 1987)

-> **5,078,136**-Method and Apparatus for Calculating Arterial Oxygen Saturation Based Plethysmographs Including Transients (Jan. 7, 1992)

-> **5,807,247**-Method and Apparatus for Facilitating Compatibility Between Pulse Oximeters and Sensor Probes (Sept. 15, 1998)

-> **Re. 36,000**-Adhesive Pulse Oximeter Sensor With Reusable Portion (Dec. 22, 1998)

Pulse oximetry FN2 is the non-invasive measurement of arterial blood oxygen saturation. The monitoring of oxygen saturation is a critical function, as a patient deprived of blood oxygen for even a short period of time can suffer brain damage or death.

FN2. The overview in this Section I has been prepared for the convenience of the reader and constitutes no part of the Order.

Pulse oximeter devices generally comprise two main elements. First, a sensor attaches to the patient to provide signal information. This sensor is typically a bandage-like component that is wrapped around the patient's finger. Light is sent by an emitter in the sensor through the patient's tissue, passing through the

oxygen carrying arteries. A detector in the sensor measures the amount of light that is transmitted through the finger or other tissue and creates signals. The amount of light absorbed is used to calculate the amount of blood constituent being measured. Second, a circuit board includes electronics that process the signal information from the sensor to calculate an oxygen level.

Oxygen level is derived using known properties of energy attenuation. Differing levels of oxygen in the blood alters the amount of light waves transmitted through the patient's tissue. Ideally, the information from the sensor would encompass only signals from the patient's arterial blood. In reality, the signal is often accompanied by "noise" generated from venous blood and/or patient movement. Patient movement, muscular movement, and vessel movement can cause the properties of energy attenuation to vary erratically. These motion artifacts may be caused by voluntary or involuntary movements on the patient's part (e.g., breathing, coughing, etc.) or by external forces (e.g., choppiness while the patient is being transported via helicopter). Hence, conventional pulse oximeters suffered from the inability to accurately monitor oxygen levels in the presence of noise.

To ameliorate this problem, filters are employed to eliminate the unwanted noise. Some products, for example, employ a processor that generates a noise reference which is then used by the processor to eliminate the noise. Others time-average a patient's signals and give less weight to signals not within the average. Regardless of the technique employed, the end goal is to derive consistently accurate readings under varying conditions.

II. Legal Standard

[1] [2] [3] The interpretation of patent claims is a matter of law reserved for the court. *See* Markman v. Westview Instruments, Inc., 517 U.S. 370, 372, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). "It is well-settled that, in interpreting an asserted claim, the court should look first to the intrinsic evidence of record, i.e., the patent itself, including the claims, the specification, and, if in evidence, the prosecution history." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). "In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such situations, it is improper to rely on extrinsic evidence." Id. at 1583. At its discretion, and if necessary, a court may turn to "extrinsic evidence" including "expert and inventor testimony, dictionaries, and learned treatises." *Markman,* 52 F.3d at 980. Such extrinsic evidence, however, "is to be used for the court's understanding of the patent, not for the purpose of varying or contradicting the terms of the claims." *Id.* at 981.

In construing claim terms, the Court makes decisions that may affect a host of other issues including invalidity; however, the claim construction process itself is not intended to resolve such questions.

III. Legal Issues and Analysis

In many cases, the differences in claim construction advanced by the Masimo and Nellcor rest on two fundamental disagreements over the law.

A. Means-plus-function Claim Terms

The Patent Act provides explicit guidelines for interpretation of claim elements expressed in means-plus-function terms:

An element in a claim for a combination may be expressed as a means or step for performing a specified

function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

35 U.S.C. s. 112, para. 6.

Throughout the claim construction process, the parties have disagreed on the proper way to identify the corresponding structure to a means-plus-function claim term. Masimo asserts that "the structure is the structure described in the patent specification, including any alternative structure, which is necessary to perform the claimed function." (Masimo Open. Mem. on Cl. Const. at 4.) Further, it asserts that where the structure disclosed in the specification for performing the function is a computer or microprocessor, the corresponding structure includes the computer or microprocessor and the specific algorithm in the specification. Nellcor argues that Masimo's component by component approach is in error; rather, it argues that the relevant inquiry is the overall structure corresponding to the claimed function. Essentially, Nellcor argues that it need only identify the general structure of a claim while Masimo argues that the claim is limited to the specific structures identified in the specification.

[4] Both parties's interpretations omit essential aspects of the law. If two products perform the same function, either structural identity or equivalence are sufficient to constitute infringement. *See Odetics,* 185 F.3d at 1267. Thus, in construing means-plus-function elements during the claim construction phase, the Court is preliminarily informed by the actual components and structures disclosed in the specification. *See, e.g.,* Unidynamics v. Automatic Products Intern., 157 F.3d 1311, 1320 (Fed.Cir.1998); Valmont Indus., Inc. v. Reinke Mfg. Co., Inc., 983 F.2d 1039, 1044 (Fed.Cir.1993). Ultimately, however, for the purposes of infringement neither the inquiry nor the claim's scope ends there; for under 35 U.S.C. s. 112, paragraph 6, equivalents of the disclosed structure are within the scope of the claim as well. Determining these so-called "statutory equivalents" requires examining the overall structure of the element, rather than the individual components comprising such element. *See Odetics,* 185 F.3d at 1268 ("The component-by-component analysis used by the district court finds no support in the law.").

[5] Although the claim encompasses both the exact structure and all statutory equivalents, only the exact structure is determined during the claim construction phase. While it may be practically possible for the Court to determine that a limited set of structures are equivalent to the disclosed structures, it is impossible for this Court to define the entire set of equivalent structures. Moreover, "whether an accused device infringes a s. 112, para. 6 claim as an equivalent is a question of fact," *Odetics,* 185 F.3d at 1268, not properly resolved at this time.

[6] Consistent with the foregoing, the Court identifies the specific structure(s) disclosed in the specification corresponding to the relevant means-plus-function elements. Whenever possible and applicable, the claim interpretations will also identify the specific algorithm disclosed in the specification with respect to a computer or a processor. *See* WMS Gaming, Inc. v. Int'l. Game Tech., 184 F.3d 1339 (Fed.Cir.1999). "In a means-plus-function claim in which the disclosed structure is a computer, or microprocessor, programmed to carry out an algorithm, the disclosed structure is not the general purpose computer, but rather the special purpose computer programmed to perform the disclosed algorithm." Id. at 1349 (citing In re Alappat, 33 F.3d 1526, 1545 (*en banc*) (Fed.Cir.1994)). These identified structures, however, may not (and likely do not) represent the universe of statutory equivalents that may be identified at trial.

B. Issue Preclusive Effect of '642 Patent **Interpretation**

1. Masimo I

In Masimo Corp. v. Mallinckrodt Inc., 18 Fed. Appx. 852 (Fed.Cir.2001) ("Masimo I"), the Federal Circuit was faced with the proper claim construction of the terms "adaptive filter" and "adaptive signal processor," as used in Masimo's U.S. Patent No. 6,036,642 (issued Mar. 14, 2000) (the " '642 patent"). The district court declined Masimo's invitation to interpret the "adaptive filter" limitation of claim 16 and "adaptive noise canceler" limitation of claim 28 claims to mean a generic adaptive filter; instead, it construed the term to mean "only one specific type of adaptive filter, an adaptive noise canceler." That being so, the court held that no reasonable juror could find either literal infringement or infringement under the doctrine of equivalents and granted summary judgment of non-infringement.

On appeal to the Federal Circuit, Masimo urged that the terms "adaptive filter" and "adaptive signal processor" are readily understood by those skilled in the art to be "devices that remove noise by monitoring their own performance and, in response, self-adjust their own parameters through closed loop action to improve their performance."Masimo I, 18 Fed. Appx. at 854-55.

The Federal Circuit also disagreed with Masimo; rather, in affirming the district court's decision, the Federal Circuit agreed that the terms are limited to a specific type of adaptive filter-an adaptive noise canceler. The Federal Circuit noted that the only type of adaptive filter disclosed in the '642 patent is of the adaptive noise canceler variety. This, it suggested, would lead one of ordinary skill in the art to assume that the term in the claim was meant to be limited to an adaptive noise canceler. Additionally, the Federal Circuit noted that in the prosecution history, there is evidence that Masimo used the terms interchangeably. Perhaps most importantly, though, the Federal Circuit found it telling that in the claims of the '642 patent, Masimo treated the terms synonymously. Claims 18, 19, and 21, which depend from claim 16, refer to "said adaptive canceler." Yet claim 16 itself refers only to an "adaptive filter."

2. Collateral Estoppel

Relying on the Federal Circuit's decision as well as the doctrine of collateral estoppel, Nellcor now urges this Court to hold as a matter of law that the only filters disclosed in Masimo's patents-in-suit are adaptive noise cancelers and that all relevant claims should be construed to include this limitation.

[7] "Collateral estoppel, also known as issue preclusion, shields a defendant from having to litigate issues that have been fully and fairly tried in a previous action and decided adversely to a party." Pharmacia & Upjohn v. Mylan Pharm., 170 F.3d 1373, 1379 (Fed.Cir.1999). The purpose of the doctrine is to "relieve parties of the cost and vexation of multiple lawsuits, conserve judicial resources, and, by preventing inconsistent decisions, encourage reliance on adjudication." Allen v. McCurry, 449 U.S. 90, 94, 101 S.Ct. 411, 66 L.Ed.2d 308 (1980). To foreclose relitigation of an issue under collateral estoppel: 1) the issue at stake must be identical to the one alleged in the prior litigation; 2) the issue must have been actually litigated in the prior litigation; and 3) the determination of the issue in the prior litigation must have been a critical and necessary part of the judgment in the earlier action. *See* Clark v. Bear Stearns & Co., 966 F.2d 1318, 1320 (9th Cir.1992). Because the application of collateral estoppel is not a matter within the exclusive jurisdiction of the Federal Circuit, the Court applies the law of the Ninth Circuit. *See* Bayer Ag v. Biovail Corp., 279 F.3d 1340, 1345 (Fed.Cir.2002).

[8] "The party asserting collateral estoppel must show that the estopped issue is identical to an issue actually litigated and decided in the previous action." Pool Water Prods. v. Olin Corp., 258 F.3d 1024, 1031 (9th

Cir.2001). "If there is doubt, however, collateral estoppel will not be applied." Davis & Cox v. Summa Corp., 751 F.2d 1507, 1518 (9th Cir.1985). Even where the requirements for collateral estoppel are met, the decision to apply the doctrine is within the Court's discretion. *See* id. at 1519.

The Court finds, and the parties seem to agree, that whether collateral estoppel applies here rests only on the "same issue" factor for there is little question that Masimo had a full and fair opportunity to litigate *Masimo I* and that the claim construction affirmed by the Federal Circuit was critical to the disposition of the prior case.

In turn, whether the issues in the Masimo patents-in-suit here are identical to those in *Masimo I* depends on how *Masimo I* is properly read. Of the three reasons articulated by the Federal Circuit to support the *Masimo I* holding-the patent'sspecification, claim language, and prosecution history-the specification is the only thing the '642 patent litigated in *Masimo I* and the Masimo patents-in-suit here share in common.FN3 Thus, Nellcor's collateral estoppel argument is necessarily predicated upon the notion that while the Federal Circuit in *Masimo I* articulated three reasons supporting its decisions, each of those three reasons independently supported the ultimate holding. If each reason were but a factor, and it was the combination of factors that led to the *Masimo I* holding, then the issues here could not possibly be the same issues litigated in *Masimo I*.

FN3. Even the specifications are different for two of the patents-in-suit. *See infra*.

That the specification alone supports the claim construction is not inconsistent with a literal reading of *Masimo I*. Nowhere in *Masimo I* does the Federal Circuit state that each of its three reasons were but "factors" supporting its affirmance of the district court. In fact, immediately after the discussion of the specification, the court "therefore conclude[d]" that one of ordinary skill in the art reading the specification would understand the term "adaptive filter" to be limited to an adaptive noise canceler. Masimo I, 18 Fed. Appx. at 855.

[9] On the other hand, this "independent support" reading would place the rationale of *Masimo I's* claim construction in substantial tension with the longstanding principle of claim construction that one should not read limitations into the claim from the specification. *See* SRI Intern. v. Matsushita Elec. Corp. of Amer., 775 F.2d 1107, 1121 (Fed.Cir.1985) ("[T]hat a specification describes only one embodiment does not require that each claim be limited to that one embodiment."); Bayer, 279 F.3d at 1348 ("[A] court may not read into a claim a limitation from a preferred embodiment, if that limitation is not present in the claim itself."). In using the '642 patent' s specification to support its holding, the Federal Circuit focused heavily on the fact that the only embodiment disclosed in the patent is an adaptive noise canceler. *See* Masimo I, 18 Fed. Appx. at 855.

[10] Hence, although Masimo I can literally be read either of two ways, the Court finds that it is more reasonable and accurate to read *Masimo I* to mean not that the specification alone supported the narrow claim construction ordered there, but that the specification, in light of the claim language and the prosecution history, supported the narrow claim construction. Reading *Masimo I* thus, it seems obvious that the doctrine of collateral estoppel is inapplicable.

Moreover, denial of application of the doctrine of collateral estoppel here is consistent with the underlying purposes of the doctrine. In dealing with collateral estoppel issues, "the problem involves a balancing of

important interests: on the one hand, a desire not to deprive a litigant of an adequate day in court; on the other hand, a desire to prevent repetitious litigation of what is essentially the same dispute." Restatement (Second) of Judgements s. 27, comment c (1980). The Court's decision does not open the floodgates to repetitious litigation. Only two of the Masimo patents in this suit (the '785 patent and the '830 patent) even share the same specification with the '642 patent. The argument against collateral estoppel gains additional force with respect to the '785 patent since it was filed nearly three years before the '642 patent was filed. This renders the prosecution history and the claim language of the '642 patent particularly inapplicable to the '785 patent since they were not around to "aid" one in reading the '785 patent for the first two years after issuance of the '785 patent.

Nor does litigation of the claims here prejudice Nellcor in any substantial manner. Unlike an issue that must ultimately be tried before a jury, claim construction is a legal question which would not have required extensive effort on the part of Nellcor's counsel to argue to the Court. Additionally, the intrinsic evidence, upon which much of claim construction turns, was readily available to the parties and to the Court. This, taken together with the fact that the present case involves different patents with varying specifications, claim language, and prosecution histories makes the doctrine inapplicable.

3. Construction of "Filter"

[11] Having determined that collateral estoppel does not bar Masimo from arguing a broad construction of the term "filter" or "adaptive filter," the Court declines to adopt any of Nellcor's interpretations for "filter" and all similar terms. In the absence of collateral estoppel, these narrow interpretations lose force since they rely exclusively on the fact that the specifications disclose only one embodiment-an adaptive noise canceler. As noted, *supra,* unless the sole embodiment is also accompanied by claim language, prosecution history, or any other intrinsic evidence, such a sole embodiment should not be construed to limit otherwise broad claim language. *See* Teleflex, Inc. v. Ficosa N. Amer. Corp., 299 F.3d 1313, 1326 (Fed.Cir.2002) ("Ficosa argues that where only one embodiment is disclosed in the specification, claim terms are limited to the embodiment disclosed.... A review of these cases and others demonstrates that our precedent establishes no such rule."). *Masimo I* is aligned with these precedents in holding that where the specification either explicitly suggests a limited claim, or where the specification, combined with some other evidence, suggests a limited claim, such a limited construction is to be taken. In this case however, Nellcor has not directed the Court's attention to, nor has the Court independently found, evidence in any of the patents-in-suit that would support the limited reading advanced by Nellcor.

For this reason, the Court also declines to provide the limiting constructions to claims such as the word "selecting" in claim 1 of the '222 patent. The pertinent portion of claim 1 is as follows:

determining arterial oxygen saturation during motion by filtering at least one of said intensity signals wit [sic] a *Kalman filter* to generate an approximation of arterial oxygen saturation during motion, and *selecting* a resulting arterial oxygen saturation based upon knowledge about oxygen saturation in body tissue and upon the approximation of arterial oxygen saturation

('222 patent, 73:12-18 (emphasis added).). Nellcor would have the Court construe "selected" to mean "selecting an output of an adaptive canceler with which to compute oxygen saturation by selecting a peak in the integrated adaptive canceler output." (Nellcor Open. Cl. Const. Br. at 18.) This construction seems to flow not from the ordinary meaning of "selecting," but from the meaning of "selecting" read in the context of a claim in which the "Kalman filter" is an adaptive noise canceler. The Court rejects Nellcor's proposed

construction initially because there is no evidence that "Kalman filter" only means an adaptive noise canceler. Even if Nellcor's "Kalman filter" construction were correct, the Court would still reject Nellcor's attempt to then re-inject the adaptive noise canceler limitation into "select." Whatever a Kalman filter might ultimately be held to mean, the jury will have no problem understanding that it is the output of that filter from which the "selecting" process will be made.

IV. Claim Term Construction

A. Masimo's '785 Patent Claim Terms

1. The word "SELECTED" (claim 29 FN4) requires no construction.

FN4. References to claims in which the claim terms are used are not an exhaustive list.

2. The word "COMBINING" (claim 29) requires no construction.

B. Masimo's '830 Patent Claim Terms

1. The phrase "TRANSFER FUNCTION" (claims 9, 10, 20, and 21) requires no construction.

2. The terms "PROCESSOR CALCULATOR" (claim 9) and "CALCULATING" (claim 20) require no construction.

C. Masimo's '505 Patent Claim Terms

[12] 1. The structure that corresponds to the "SIGNAL PROCESSOR MEANS" limitation (claim 19) is the signal processor (26) which generates an output that is either a secondary reference signal which is correlated to both of the secondary signal portions or a primary reference signal which is correlated to both of the primary signal portions. ('505 patent, 14:4-10, Figs. 4a and 4b.)

[13] 2. The term "SIGNIFICANT" (claim 19) requires no construction. Nellcor's argument that the term is indefinite is based on the erroneous notion that unless something can be quantified to an exact amount, it must be invalid. One of the main purposes of requiring patentees to set forth specific claims is to provide proper notice to the public. Where exactitude is possible, it clearly advances this goal. However, a patentee is not required to draw bright lines for the sake of clarity when those bright lines would obscure rather than enhance disclosure. *See* Exxon Research and Eng. Co. v. U.S., 265 F.3d 1371, 1377-80 (Fed.Cir.2001).

Here, the question of how much the signal must be a function of the primary or secondary signal defies an exact description. That the significance cannot be quantified by an absolute value does not render the notice function of the element meaningless. Lack of meaning is a determination reached only if Nellcor can demonstrate that as stated, the claim is indeterminate to those of ordinary skill in the art. The mere fact that a term cannot be quantified into an absolute value, even when taken in conjunction with the fact that the specifications do not provide examples of what is or is not significant, cannot be said to rise to the level of meeting the "clear and convincing standard to show that one of ordinary skill would not understand" what is included in claim 19. *N*. Amer. Vaccine v. Amer. Cyanamid Co., 7 F.3d 1571, 1579 (Fed.Cir.1993).

[14] 3. The phrase "EITHER ... OR" (claim 19) means that a minimal requirement of the signal is that a

significant component is derived from at least one or the other signal. Thus, the claim language requires at least one, but does not exclude the possibility of both.

4. The word "COMBINE" (claim 19) requires no construction.

D. Masimo's '222 Patent **Claim Terms**

1. The phrase "SELECTING A RESULTING ARTERIAL OXYGEN SATURATION" (claim 1) requires no construction.

2. The word "PROCESSOR" (claims 5, 7, and 16) requires no construction.

3. The term "SIGNAL PROCESSOR" (claim 17) requires no construction.

[15] 4. The term "MOTION" (claims 1 and 5) means movement of body tissue which causes erratic noise, that, in the absence of a filter, would cause the ratio of red to infrared signals to not accurately reflect the arterial oxygen saturation.

[16] 5. The phrase "WITHOUT SIGNIFICANT INTERFERENCE" (claim 17) means that the calculated oxygen saturation is accurate enough for the purposes of which the calculation is being employed.

E. Masimo's '850 Patent **Claim Terms**

[17] 1. The term "INDICATIONS" (claim 1) means something that represents the physiological parameters. Such a representation can be in the form of a number, a word, a symbol, or any other marker with established meaning.

2. The phrase "AT LEAST TWO ALTERNATIVE CALCULATIONS" (claim 1) requires no construction.

3. The phrase "ANALYZING ... TO DETERMINE A RESULTING INDICATION" (claim 1) does not require that the resulting indicator need be one of the two calculation results. It can, for example, be an average of the two results. Additionally, the process of analyzing includes, but is not necessarily limited to "studying, comparing, or breaking down." No further construction is required.

4. The term "QUALITY" (claim 22) requires no construction.

[18] 5. The phrases "AVERAGING THE RESULTING INDICATION ... OVER TIME" and "AVERAGING OVER A TIME WINDOW" (claims 23 and 24) simply mean that more than one resulting indication, each of which is derived at a different time, is averaged. Additionally, "TIME WINDOW" means a "period of time."

F. Nellcor's '643 and '708 Patent **Claim Terms**

[19] 1. The phrase "OXIMETER PROBE SYSTEM" ('643 claim 1) does not exclude the possibility that parts of the "oximeter probe system" reside on the oximeter itself.

[20] 2. The phrases "KNOWN WAVELENGTH VALUE" and "KNOWN WAVELENGTH" ('708 claims 1, 7, and 11) require that the known wavelength be a single value. However, more than one "known

wavelength" may share the signal to the oximeter which is indicative of that one specific wavelength. In other words, while, for example, 660 nanometers will always be associated with 150 ohms, 150 ohms can be associated with not only 660 nanometers, but also 661, 662, etc.

[21] 3. The corresponding structure to the "MEANS FOR DETACHABLY WIRING" limitation ('643 claim 1 and '708 claims 1, 7, and 11) includes the following: wires from the red and infrared LEDs, the photoelectric sensor, the coding element, and a ground wire that is attached to an eight-pin connector.

[22] [23] 4. The phrase "ENCODING MEANS FOR PROVIDING SIGNALS" ('708 claims 1-3, 7, and 11) requires that the encoding means provide one and only one value. This one value, however, can be indicative of a plurality of wavelengths. The corresponding structure is a resistor, capacitor or eight-pin connector on the probe assembly with one and only one known value.

[24] 5. The function of the "DECODING MEANS RESPONSIVE TO SAID ENCODED SIGNALS" ('643 patent claims 1 and 2) is "selecting appropriate calibration coefficients for use in calculating oxygen saturation based upon the known wavelength." Each encoded signal carries only one value and the encoded value is acted upon in only one way (i.e., by the oximeter employing a particular extinction coefficient). More than one wavelength, however, is capable of triggering the same encoded value. The correspondingstructure is a microprocessor (16), support circuitry (118-19, 123, 140-48, 150, 152, 154, 157), and associated wiring. The microprocessor is programmed to perform the algorithms disclosed in the specification. ('708 patent, 6:27-7:6.)

G. Nellcor's '247 Patent **Claim Terms**

[25] 1. The phrase "SENSOR PROBE" (claim 1) means a group of interrelated or interacting components directed towards providing information to a pulse oximeter required to compute a blood parameter which is attached to the tissue sample in some manner. The probe itself may comprise components other than those directed towards emitting and detecting light, but those components must reside on the sensor probe itself.

Masimo's argument that the sensor probe can only have components directed towards light emission and detection is in error. The initial application contained five distinct species of the claimed invention, represented by the embodiments of Figs. 2a, 3, 4, 5, and 9 in the original patent application. ('247 patent file history, Paper 1, Figs. 2a, 3, 4, 5, and 9.) Relevant here are the embodiments of Figs. 3, 4, 5, and 9, since each of those embodiments included a probe sensor. In response to a PTO action, Nellcor elected to pursue the species represented by the embodiment of Fig. 3. ('247 patent file history, Paper 5) Based on this election, Masimo now argues that the sensor probe cannot include, for example, adapter module (418) diagramed in Fig. 4, or probe adapter (930) diagramed in Fig. 9. Thus, it argues that Nellcor's sensor probe can only emit and detect light.

Masimo's construction is not well-founded. To begin with, the sensor probe diagramed in Fig. 3 includes more than the ability to emit and detect light. Specifically, Fig. 3, as well as claim 1, states that the sensor probe also comprises LED translation circuitry, RCAL translation circuitry, and Current translation circuitry. ('247 patent file history, Paper 1, Fig. 3) In that sense, Masimo's construction does not fully describe the sensor probe.

Masimo's construction also misunderstands what was foregone during the patent's prosecution. In the foregone embodiments, the sensor probe did not purport to include for example, adapter module (418) or

probe adapter (930); rather, those components were both described and illustrated as being distinct from the sensor probe. Hence, while Nellcor's election might possibly foreclose it from claiming an embodiment of the invention with both a sensor probe and a separate adapter module, it does not foreclose Nellcor from claiming a sensor probe with the functions of an adapter module built-in.

[26] 2. The term "REPRESENTATIVE" (claim 1) means that something includes the information from the second wavelength necessary for the pulse oximeter to compute a blood parameter.

3. The phrase "LIGHT OF A SECOND WAVELENGTH" (claim 1) requires that the light is different from the first wavelength of light.

4. The term "VALUE" (claims 1, 10, 13, and 21) refers to a single numerical quantity.

5. The term "MANIPULATING" (claims 1 and 13) requires no construction.

[27] 6. The phrase "TRANSFORMED SIGNAL HAVING A PREDETERMINED MATHEMATICAL RELATIONSHIP" (claims 1 and 13) means a signal representative of light of a second wavelength scattered by the tissue sample and that has a predetermined mathematical relationship to the first probe signal. There is no requirement that the transformation itself must be performed based on a predetermined mathematical relationship.

[28] 7. The term "TRANSLATION CIRCUITRY" (claim 6) means "electrical components that make the sensor and meter electrically and physically compatible." This translation circuitry must be a part of the sensor probe.

[29] [30] 8. The phrase "CALIBRATION CODE CIRCUITRY FOR TRANSMITTING A DESIRED CALIBRATION CODE" (claim 10) requires a calibration code that is a value that indicates known wavelength(s) of light. The value must be a single known quantity. Further, the calibration code circuitry must be a part of the sensor probe.

H. Nellcor's '000 Patent Claim Terms

[31] 1. The structure corresponding to the "CONDUCTING CABLE MEANS" limitation (claims 18 and 22) is a cable having a plurality of wires to connect the sensor to the external monitoring system. ('000 patent, 2:28-29, 3:40-42, 4:48-52, Figs. 1 and 3.)

[32] 2. There are two structures corresponding to the "MEANS FOR RELEASABLY CONNECTING" limitation (claim 18). The first set of components includes the following:

1. a tail on an elongated plastic substrate (42);

2. a series of conductive traces on the top surface of the tail (40);

3. a compressible foam member (44) on the tail (42);

4. a pair of tabs (46) extending from the top half of the tail (42);

5. a channel (48) on the bottom side of a rigid housing (16);

6. a series of electrical contacts (50) in the channel (48);

7. a bridge (52) extending across the housing (16) covering the series of electrical contacts (50); and

8. a pair of grooves (54) in the channel (48) that are slightly larger than the tabs (46).

('000 patent, 2:63-3:7; 4:8-47, and Fig. 3.) Additionally, the '000 patent also discloses that one could substitute bridge (52) with a spring action clip. ('000 patent, 5:10-17.)

[33] 3. The structure corresponding to the "MEANS FOR SECURING" limitation (claim 18) is an adhesive layer or velcro fastener on the flexible member. ('000 patent, 5:15-17.) The means for securing in the independent claim does not encompass the "adhesive on the substrate." Additionally, the "flexible arms that secure the flexible member to the patient" is not properly construed as part of this claim phrase. The question of whether the flexible arms are part of claim 18 involves a construction not of "securing means," but rather of "flexible member." This latter term was neither briefed nor argued by either party and the Court intimates no view on the construction of the "flexible member."

4. No structure is found that corresponds to the claimed function of "AN END" (claim 22).

I. Nellcor's '136 Patent **Claim Terms**

[34] 1. The term "HEART RATE" (claims 1, 6, and 11) means either a patient's heart rate or a number indicative of that heart rate.

2. The term "FUNDAMENTAL HEART RATE" (claims 1, 3, 6, and 8) has no meaning that is ascertainable from the intrinsic evidence. If the term has a meaning to those of ordinary skill in the relevant art, that meaning was not presented to the Court.

[35] 3. The corresponding structure to the "MEANS FOR RECEIVING" limitation (claims 1 and 6) is plethysmograph sensor (100), patient module (200), and saturation analog circuit (300).

[36] 4. The corresponding structure to the "FILTER MEANS" limitation (claims 1 and 6) is a multiplexer, a buffer, an offset amplifier, a programmable gain circuit, a sample/hold circuitry, a comparator, a buffer, a 16-bit microprocessor, RAM, ROM, system timing signals, and bus. The microprocessor is programmed to transform the detected optical signals into the frequency domain by use of the Fourier transform and eliminate frequency components of the detected optical signal other than those that have a frequency below the frequency of the fundamental heart rate; or the microprocessor is programmed to provide a digital filter to eliminate the frequency components of the detected optical signal other than those that have a frequency below the frequency of the fundamental heart rate.

[37] 5. The corresponding structure to the "DIVIDING MEANS FOR DIVIDING" limitation (claims 1 and 6) is a multiplexer, a buffer, an offset amplifier, a programmable gain circuit, sample/hold circuitry, a comparator, a buffer, a 16-bit microprocessor, RAM, ROM, system timing signals, and a bus. The microprocessor is programmed to divide the detected optical signal by the filtered signal in phase.

[38] 6. The corresponding structure to the "MEANS FOR DIGITIZING" limitation (claim 5) is the Analog to Digital Conversion Section (1000). ('136 patent, Fig. 1.)

J. Nellcor's '498 Patent **Claim Terms**

[39] 1. The corresponding structure to the "MEANS FOR DETECTING" limitation (claim 1) is preamplifier (40), amplifiers (41, 42), detectors (43, 44), low pass filters (45), offset amplifiers (47, 48), multiplexer (50), comparator (52), latch (23), clock generator (70), counter (172), binary counter (173), hold circuits (57) and microprocessor (16) and its peripherals (RAM, buses, enable port, write port, ROMs, address bus, ROM addressing, read enable, output data buses, memory select input, RAM enable, and counter) programmed to determine a pulsatile signal and compute blood oxygen saturation.

[40] 2. The corresponding structure to the "MEANS FOR GENERATING" limitation (claim 1) is microprocessor (16) and its peripherals (RAM, buses, enable port, write port, ROMs, address bus, ROM addressing, read enable, output data buses, memory select input, RAM enable, and counter) programmed using the algorithm disclosed in the '498 patent specification to control the volume, pitch, and repetition rate, a speaker (15) and associated circuitry (740-43), the volume control knob (10), and associated control circuitry (791-93).

[41] 3. The corresponding structure to the "MEANS ... FOR CONTROLLING" limitation (claim 1) is microprocessor (16) and peripheral circuitry (RAM, buses, enable port, write port, ROMs, address bus, ROM addressing, read enable, output data buses, memory select input, RAM enable, and counter) programmed using the algorithm disclosed in the '498 patent.

[42] 4. The corresponding structure to the "MEANS ... FOR CONTINUOUSLY VARYING THE TONAL FREQUENCY" limitation (claim 1) is microprocessor (16) and its peripheral circuitry (RAM, buses, enable port, write port, ROMs, address bus, ROM addressing, read enable, output data buses, memory select input, RAM enable, and counter) programmed using the algorithm disclosed in the specification to vary the voltage of the beep signal in response to changes in saturation.

[43] 5. The term "CONTINUOUSLY" (claim 1) means that the tonal frequency changes constantly as the quantity being measured changes.

[44] 6. The corresponding structure to the "MEANS FOR DECREASING" (claim 2) is microprocessor (16) and its peripheral circuitry (RAM, buses, enable port, write port, ROMs, address bus, ROM addressing, read enable, output data buses, memory select input, RAM enable, and counter) programmed to decrease the tonal frequency of the audible signal with decreasing oxygen saturation.

V. Motion to Strike

Nellcor, pursuant to Rules 16(f) and 37(b)(2)(B) of the Federal Rules of Civil Procedure, seeks to exclude evidence submitted by Masimo, Inc. ("Masimo") in support of Masimo's proposed claim constructions of the patents-in-suit.

On January 31, 2002, the Court entered a Joint Claim Construction Prehearing Schedule ("Schedule") prepared by the parties. Among other things, the Schedule provided the following deadlines:

June 21, 2002: Exchange Positions on party's own patents (and submit expert declarations in support

thereof).

July 19, 2002: Reply to other party's patents (and expert declarations in support); expert discovery opens.

Nellcor argues that the Schedule required both parties to submit their detailed expert declarations, at the latest, by July 19, 2002. Rather than adhere to the Schedule, Nellcor asserts, Masimo chose to create its own. The sum of the declarations initially submitted by Masimo was a two-page rubber stamp by Jack Goldberg:

[I]t is my opinion that all of the claim terms should be readily understood by people in the biomedical instrumentation field having educational or practical experience in the biomedical signal processing. I have reviewed Masimo's Initial Claim Construction On Its Asserted Patents and believe that the definitions therein are consistent with the ordinary and accustomed meaning of those terms in the above-identified technical field in the context of the patent claims and the corresponding specifications and file histories.

(Chan Exh. 4 at 2.) It was not until September 16, 2002 that Masimo-concurrent with the filing of its Opening Claim Construction Brief-submitted a 33 page "rebuttal" Goldberg Declaration along with the declaration of Jon Gurka, attached to which were (by conservative estimate) over 800 pages of supporting evidence (collectively, the "New Declarations").

Nellcor asserts that in so doing, Masimo disregarded the Schedule and prejudiced Nellcor. It thus requests that the Court strike the New Declarations.

A. Legal Standard

[45] The focus of Rule 16 is "on the use of the pretrial conference as a means to familiarize the litigants and the court with the issues actually involved in a lawsuit so that the parties can accurately appraise their cases and substantially reduce the danger of surprise at trial." Charles A. Wright, Arthur R. Miller & Mary Kay Kane, Federal Practice and Procedure: Civil 2d s. 1522 (1990). The 1983 Amendments added a new subdivision (f), which explicitly authorizes the courts to impose sanctions for failure to comply with Rule 16. Rule 16(f) thus "reenforces the rule's intention to encourage forceful judicial management." Fed.R.Civ.P. 16(f), Advisory Comm. Note to 1983 Amendment. Rule 16(f) leaves the Court with great discretion in fashioning a remedy by allowing it to make such orders "as are just." Moreover, the remedies listed in Rule 16(f) are neither mandatory nor exhaustive.

Rule 26(f) was also implemented to facilitate the pretrial process and is related to Rule 16(f). It requires the parties to confer at least 21 days before a scheduling conference is held or a scheduling order is due under Rule 16(b). *See* Fed.R.Civ.P. 26(f). Among other things, Rule 26(f) requires that the parties confer on "orders that should be entered by the court ... under Rule 16(b) and (c)." Fed.R.Civ.P. 26(f)(4). To give bite to Rule 26(f), Rule 37(b)(2) authorizes, inter alia, this Court to impose such orders "as are just" when a party "fails to obey an order entered under Rule 26(f)." Fed.R.Civ.P. 37(b)(2).

Since the Schedule is silent as to whether it was entered pursuant to Rule 26(f) or Rule 16, it is unclear whether an order granting Nellcor's request should be made pursuant to Rule 16(f) or Rule 37(b)(2). From a practical point of view, the distinction is an academic one, as both sections authorizing enforcement action by the Court are discretionary and do not impose any kind of mandatory relief.

B. Analysis

[46] Masimo makes two arguments against the motion to strike. First, it argues that the New Declarations were merely rebuttals to Nellcor's declarations, and hence do not violate either the spirit or the letter of the Schedule. It argues that "[o]nly after Nellcor submitted Dr. Stone's lengthy expert declaration arguing that the words of the claims should be ignored, did Masimo provide rebuttal declarations from its expert and inventor." (Masimo Mem. of P. & A. in Opp'n to Mot. to Strike at 4.) Second, Masimo asserts that even if its actions violated the Schedule, such violation has not caused actual prejudice to Nellcor. As evidence of the lack of prejudice, Masimo points out that had Nellcor honestly expected detailed declarations, it would have "attempted to mitigate or alleviate the prejudice" shortly after July 19, 2002 rather than waiting until October 2002 to file its motion. (Masimo Mem. of P. & A. in Opp'n to Mot. to Strike at 4.)

Preliminarily, Masimo's characterization of its declarations as merely "rebuttals" is not well-founded. Masimo knew from an early time that Nellcor would dispute the interpretation of many of the asserted claims. Additionally, knowing that there is a "heavy presumption" that a claim term carries its ordinary and customary meaning (Masimo Open. Mem. on Cl. Const. at 2), Masimo should have also expected that both parties would differ on the claim terms' "ordinary meaning." Particularly since the patents-in-suit all involve pulse oximetry, a specialized scientific field, such "ordinary meanings" are not expected to be within the common knowledge of this Court. Thus, the task for the parties that the Schedule endeavored to govern was how best to educate the Court on these "ordinary meanings." This task, Masimo could not have expected to accomplish merely by attaching an expert's declaration that stated, in essence, "I concur."

To say then, that the New Declarations, which support Masimo's asserted "ordinary meanings" by making repeated references to the specification (Goldberg Decl. para. 13), the file history (Goldberg Decl. para. 18), and extrinsic evidence (Goldberg Decl. para. 19), was offered only in response to Nellcor's declarations, would be to ignore the purpose of the claim construction hearing, the purpose of the Schedule, and the parties' understanding of the claim construction process. While the New Declarations do assert that Nellcor's constructions are wrong, they do so by simultaneously asserting that Masimo's constructions are right. And this latter category of argument should have been asserted by June 21, 2002 pursuant to the Schedule.

Masimo also argues that whatever violation might have occurred, it did not prejudiceNellcor. Initially, Masimo argues that because certain parts of the new evidence, including dictionary definitions, technical treatises, and prosecution history are always used by a court during claim construction, the submission of those documents cannot prejudice Nellcor. This argument ignores the distinction between evidence that the Court, *sua sponte,* examines, and evidence that the Court examines at the request of a party. Regardless of what research this Court might independently conduct, each party wished to direct this Court's attention to particular evidence favorable to it. The Schedule governed the assertion of these types of evidence specifically so that both the parties and this Court would have adequate time to analyze and possibly refute such evidence. Hence, the fact that the Court might have independently reviewed a *type* of evidence does not excuse Masimo's late production of a *particular* piece of evidence, whether of that type or another.

Masimo's argument that the actual time with which Nellcor had to analyze and prepare to argue against the untimely declarations minimized the prejudice has more merit. Pursuant to the Schedule, Nellcor had one month after the New Declarations were filed before its reply claim construction papers were due. Additionally, at Nellcor's request, the claim construction hearing was delayed for an additional month from November 12, 2002 to December 16, 2002. Moreover, just as Masimo could not have realistically expected Nellcor to not advance its own interpretation of the claim terms, so too, Nellcor could not have been completely caught off guard by the New Declarations. In short, both parties as well as the Court ultimately had ample time to consider all the filed declarations.

Ample time, of course, does not necessarily imply that no prejudice occurred or that Masimo's behavior should be condoned or even tolerated. With enough effort by opposing counsel and this Court, even a 300 page declaration filed the night before a claim construction hearing could be fully considered. In many perhaps imperceptible and immeasurable ways, such a filing would still result in undue prejudice and stress. And it is exactly these kinds of surprise and unfair behavior that Rule 26 and Rule 16 seek to avoid.

Thus, the Court GRANTS the Motion to Strike. It does so, however, while expressly noting that in this particular instance, the granting or denying of the motion would have had no effect on either the party's ability to advocate their client's position; nor would the outcome of the motion to strike affect any of the Court's claim construction rulings. The Court extends to Masimo the benefit of the doubt and assumes that whatever mis-communication and misinterpretation might have occurred happened in good faith. As the parties were made aware at oral argument however, any further mishaps by either party will be looked upon with skepticism and the parties are admonished to proceed with the remainder of the case in a fairer and more efficient manner.

VI. Conclusion

Having considered the papers filed in support of each party's claim construction, the evidence presented by the parties, the other pleadings and papers on file, and the oral argument at the *Markman* hearing, the Court gives each of the disputed terms the meanings stated in Section IV.

The Motion to Strike is GRANTED.

IT IS SO ORDERED.