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United States Court of Appeals for the Federal Circuit

04-1495, -1540

MALLINCKRODT, INC. and NELLCOR PURITAN BENNETT, INC.,

Plaintiffs-Cross Appellants,

٧.

MASIMO CORPORATION.

Defendant-Appellant.

DECIDED: September 7, 2005

Before MICHEL, <u>Chief Judge</u>, LOURIE and PROST, <u>Circuit Judges</u>.

MICHEL, <u>Chief Judge</u>.

Masimo Corporation ("Masimo") filed a patent infringement action against Mallinckrodt, Inc. and Nellcor Puritan Bennett, Inc. (collectively "Nellcor") in the United States District Court for the Central District of California, asserting that Nellcor willfully infringed Masimo's U.S. Patent Nos. 5,769,785; 6,206,830; 6,263,222; and 6,157,850 by manufacturing and selling its O4, O5, and O5CI models of pulse oximeters. Nellcor counterclaimed against Masimo, alleging that Masimo infringed U.S. Patent No. RE36,000 by manufacturing and selling its own line of pulse oximeters that employ Signal Extraction Technology (SET™). Nellcor also alleged that Masimo's asserted

patents were invalid on anticipation, obviousness, indefiniteness, lack of written description, and lack of enablement grounds under 35 U.S.C. §§ 102, 103, and 112, and unenforceable due to inequitable conduct.

Following a six-week trial, a jury found in favor of Masimo as to willful infringement and validity. The parties filed post-trial motions seeking to overturn the jury's verdict. In response to these motions, the district court reversed the jury's verdict that the '785 patent was infringed. Mallinckrodt v. Masimo, No. 00-6506, slip op. at 21 (C.D. Cal. July 14, 2004). It upheld the jury's verdict that the '222 and '850 patents were not invalid and infringed, id. at 15, 36, 40, but reversed the jury's finding of willfulness, id. at 27. The district court nevertheless declined to enter a permanent injunction prohibiting Nellcor's continued infringement of these two patents. Id. at 68. The district court also upheld the jury's verdict that the '830 patent was not invalid and infringed, id. at 40, but again reversed the jury's finding of willfulness, id. at 27.

The district court subsequently held a bench trial on the alleged indefiniteness of the '222 patent and on inequitable conduct. It held that the '222 patent was not invalid for indefiniteness. <u>Id.</u> at 48. It also held that Masimo procured the '830 patent by engaging in inequitable conduct, thus rendering that patent unenforceable. <u>Id.</u> at 58. The district court did not, however, find the '222 or the '850 patents unenforceable for inequitable conduct. <u>Id.</u> at 60-61.

Masimo appeals the district court's grant of judgment as a matter of law ("JMOL") of noninfringement of the '785 patent, JMOL reversing the jury's finding that Nellcor infringed the '222 and '850 patents willfully, and denial of a permanent injunction with respect to the '222 and '850 patents. Masimo also appeals the district court's judgment

of unenforceability of the '830 patent. Nellcor cross-appeals the district court's JMOL upholding the jury's verdict of infringement of the '222 patent and validity of the '222 and '850 patents. Nellcor further cross-appeals the district court's judgment of enforceability of the '222 and '850 patents.

The appeal was submitted for decision after oral argument on July 7, 2005. We hold that the district court correctly entered judgment in all respects, except for the reversal of the jury's verdict of infringement of the '785 patent and the denial of a permanent injunction to redress Nellcor's infringement of the '222 and '850 patents. Accordingly, the district court's judgment is <u>affirmed-in-part</u>, <u>reversed-in-part</u> and <u>remanded</u>.

I. BACKGROUND

A. The Technology and Asserted Patents

The patents involved in this case relate to pulse oximetry, a non-invasive diagnostic procedure for measuring the level of oxygen saturation in a patient's arterial blood. A pulse oximeter has two main components: (1) a sensor attached to a patient's finger to acquire signals; and (2) a monitor with electronics and software that processes the signals to calculate and display arterial blood oxygen saturation and pulse rate. If a patient moves while the sensor is attached to his finger, that movement may disrupt the signal by causing erratic "noise," which results in inaccurate readings. The development of "adaptive filters" permitted resolution of varying levels of "noise" to isolate the desired signal.

i. '785 Patent

The '785 patent is entitled "Signal Processing Apparatus and Method," but is commonly referred to as the "Linear Relationship" patent. Masimo asserted claims 29

and 30 of the '785 patent against Nellcor. These two claims are directed to a method of making physiological measurements by passing light of two different wavelengths through a physiological medium to generate two resulting signals. Each resulting signal contains the desired measurement and "noise." The wavelengths are, nevertheless, chosen so that there will be a linear relationship between the resulting "noise" components. That linear relationship is manipulated to remove the "noise" from the resulting signals, thereby yielding the desired physiological measurement. Claim 29 recites in pertinent part:

passing light energy of at least first and second wavelengths through a light-absorptive physiologic medium to a light-sensitive detector to generate, respectively, first and second signals . . . the first and second wavelengths selected based on light absorption characteristics of the physiologic medium such that a substantially linear relationship exists between the secondary portion of the first and second signals; and combining said first and second signals to generate a signal which is primarily correlated to the physiologic measurement portions, the step of combining comprising using the linear relationship to substantially remove the secondary portion of the signals.

'785 patent, col. 54, II. 1-16 (emphasis added). Claim 30 depends from claim 29. It narrows the physiologic measurement to "information indicative of arterial blood absorption." '785 patent, col. 54, II. 21-21. The '785 patent was asserted against only Nellcor's O5Cl pulse oximeter.

ii. '830 Patent

The '830 patent is entitled "Signal Processing Apparatus and Method," but is commonly referred to as the "Self-Optimizing Filter" patent. Masimo asserted claims 9, 14, 20, and 25 against Nellcor's O4, O5, and O5CI pulse oximeters. These claims include both apparatus and process claims for a self-optimizing filter that adjusts in

response to changes in the signals to optimize the output. Claim 9, a representative apparatus claim, recites in pertinent part:

a filter responsive to signals representing the first and second signals to filter the first and the second signals, wherein the filter adjusts its transfer function in response to changes in at least one of the first and the second signals and in response to an evaluation of an error to optimize at least one of a first and a second filtered output signals . . .

'830 patent, col. 44, Il. 24-30.

iii. '222 Patent

The '222 patent is entitled "Signal Processing Patent," but is commonly referred to as the "Kalman Filter" patent. Masimo asserted claims 1, 4, 16, 17, 18, 21, 22, and 23 against Nellcor's O4, O5, and O5CI pulse oximeters. The majority of the asserted claims are directed to the use of a Kalman filter. Claims 17 and 18 are referred to by the parties as the "motion" claims. They are directed to filtering the signals described in the other asserted Masimo patents to determine arterial oxygen saturation. Claim 17 recites:

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

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

'222 patent, col. 74, II. 57-67; col. 75, II. 1-8 (emphasis added). Claim 18 is dependent on claim 17 and narrows the motion-induced "noise" to that caused by venous blood. '222 patent, col. 75, II. 10-11.

iv. '850 Patent

The '850 patent is entitled "Signal Processing Apparatus," but is commonly referred to as the "Parallel Engine" patent. Masimo asserted independent claim 1 and dependent claims 10, 11, 12, 15, 17, and 22 against Nellcor's O4, O5, and O5CI pulse oximeters. The asserted claims describe an "alternative calculation" method wherein two signals are processed in parallel and analyzed to determine which one of the two represents the more accurate arterial oxygen saturation level.

B. The Relationship Between Masimo and Nellcor

In the 1980s, Joe Kiani and Mohamed Diab collaborated to solve the "motion problem" encountered in the pulse oximetry field by using particular filtering algorithms. Beginning in 1991, they filed several patent applications, which resulted in numerous issued patents, including the four asserted in this appeal. In 1998, they founded a small private company in Mission Viejo, California called Masimo, an acronym for "Methods for Artifact Suppression In Motion."

In 1992, Kiani met with two Nellcor representatives, Drs. David Swedlow and Tom Yorkey, to discuss Masimo's motion-tolerant technology. Masimo originally planned to either sell or license its technology to an established medical device company like Nellcor. Kiani shared a "black box" demonstration of a motion-tolerant pulse oximeter prototype with Nellcor, but did not disclose its inner workings.

In 1993, the parties commenced business discussions. Nellcor provided Masimo with raw data to test in one of Masimo's motion-tolerant pulse oximeter prototypes. In exchange, Masimo provided Nellcor with test results. Masimo also gave Nellcor a copy of a PCT application, which correlated to one of its 1991 patent applications. In 1994, Nellcor broke off discussions with Masimo, explaining that it changed its strategy and decided to manufacture and market its motion-tolerant technology itself. In 1998, Masimo launched its SET™ technology in the United States.

In 1999, Nellcor introduced a new motion-tolerant technology called the O4 algorithm in its previously marketed N-395 pulse oximeter. Thereafter, Nellcor introduced later generations of the O4 algorithm, called the O5 and O5CI algorithms. As noted above, Nellcor's pulse oximeters incorporating the O4, O5, and O5CI algorithms are the accused products in this action.

C. Prior Litigation Between Masimo and Nellcor

In 2000, Masimo sued Nellcor for infringement of claims 16 and 28 of U.S. Patent No. 6,036,642, asserting that Nellcor's N-395 and MP-404 pulse oximeters met all of the asserted claim limitations. In July of 2000, Masimo filed a motion for a preliminary injunction to prevent Nellcor from continuing to sell the two accused products. In August of 2000, Nellcor filed a motion for summary judgment of noninfringement or, in the alternative, of invalidity.

In September of 2000, the district court conducted a hearing on the parties' motions. The parties specifically addressed the claim constructions for the terms "adaptive filter" and "adaptive signal processor" as used in claims 16 and 28. In October of 2000, the district court construed the terms "adaptive filter" and "adaptive

signal processor" without explanation as requiring a specific type of adaptive filter known as an "adaptive noise canceler." Masimo Corp. v. Mallinckrodt Inc., No. 99-1245, slip op. 1 (C.D. Cal. Oct. 4, 2000) ("Masimo I"). The district court then granted summary judgment in favor of Nellcor, because it found that Nellcor's accused products do not use an adaptive noise canceler. Id. at 2. The district court also denied Masimo's motion for a preliminary injunction. Id. Masimo appealed, and this court affirmed. Masimo Corp. v. Mallinckrodt Inc., 18 Fed. Appx. 852 (Fed. Cir. Aug. 8, 2001) ("Masimo II").

D. Relationship Between Masimo I and the '830 Patent

In <u>Masimo I</u>, Steven Jensen appeared before the district court as counsel for Masimo. At the claim construction hearing in September of 2000, he argued that the terms "adaptive filter" and "adaptive signal processor" should be broadly construed and not limited to requiring an "adaptive noise canceler."

Three days after the hearing, Jensen amended the application leading to the '830 patent, adding separate independent claims to an "adaptive filter" and an "adaptive signal processor." For each independent claim, Jensen also added dependent claims "wherein the adaptive filter [or adaptive signal processor] is an adaptive noise canceler."

On October 4, 2000, the district court construed the terms "adaptive filter" and "adaptive signal processor" narrowly, as noted above. Masimo did not, however, notify the PTO during the prosecution of the '830 patent of either the Masimo I litigation or the claim construction issued by Masimo I court, even though the same terms were implicated in both proceedings. In October of 2000, the PTO issued a notice of

allowance for the application leading to the '830 patent, and the patent issued in March of 2001.

II. DISCUSSION

A. JMOL Motions on Jury Verdicts

We review the grant or denial of a party's motion for JMOL <u>de novo</u>, reapplying the district court's JMOL standard. <u>Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co.</u>, 308 F.3d 1167, 1185 (Fed. Cir. 2002). In doing so, this court must consider all the evidence that was placed before the jury and draw all reasonable inferences in favor of the party who prevailed on that issue. <u>Richardson-Vicks Inc. v.</u> Upjohn Co., 122 F.3d 1476, 1479 (Fed. Cir. 1997).

i. Whether the district court erred by granting JMOL of noninfringement of the '785 patent

At the outset, the district court noted that Masimo offered the software specification for the O4 algorithm used in Nellcor's O4 pulse oximeters, not the one in Nellcor's O5CI product. Having made this observation, the district court nevertheless addressed the merits of Nellcor's challenge to the jury's verdict. The district court agreed with Nellcor that it was not apparent from the O4 software specification that the combination of the two signals in Nellcor's O5CI pulse oximeter, called an "€mix signal," is "primarily correlated to the physiologic measurement portion of the first and second signal" and has "noise" substantially removed, as required by the asserted claims of the '785 patent. Mallinckrodt, slip op. at 20. The district court likewise noted that Masimo did not offer expert testimony to show that the €mix signal was substantially "noise" free.

<u>Id.</u> Thus, the district court concluded that substantial evidence did not support the jury's verdict that claims 29 and 30 were literally infringed. <u>Id.</u> at 21.

Masimo argues that the district court erred in reversing the jury's verdict. It contends that the district court overlooked the parties' stipulation that the O4 software specification represents that of the O5CI product and other evidence supporting the jury's verdict. Masimo points out that the O4 software specification makes clear that the O5CI product uses a linear combination of red and infrared signals to cancel "noise" and to allow oxygen saturation levels to be measured during periods of motion, thus meeting the limitations of claims 29 and 30. Masimo also asserts that its expert, Dr. Jack Goldberg, testified based upon his review of the O4 software specification that Nellcor's O5CI pulse oximeter infringes the '785 patent.

Alternatively, Masimo claims that it is entitled to a new trial on the issue of infringement under the doctrine of equivalents because the district court refused to instruct the jury to consider that theory of liability. By overturning the jury verdict of literal infringement, without ordering a trial on the issue of equivalent infringement, Masimo argues that the district court wrongly left the question of infringement by equivalents unanswered.

Nellcor argues that the district court did not misunderstand that the O4 software specification did not apply to the O5CI product. Rather, Nellcor claims that the district court analyzed the O4 software specification with the understanding that it applied to the O5CI product. The O4 software specification, Nellcor claims, simply does not establish that the combined signal present in the O5CI product has "noise" removed. Additionally, Nellcor points out that its expert, Dr. Benjamin Friedlander, testified in

detail that the O5CI product does not operate in the same manner as set forth in claims 29 and 30 of the '785 patent. In fact, Nellcor points out that Friedlander explained that the O5CI product operates in the reverse manner, to wit, preserving "noise" in the combined signal.

With respect to Masimo's alternative argument regarding infringement under the doctrine of equivalents, Nellcor claims that Masimo must offer particularized evidence regarding the insubstantiality of the differences between each claim limitation and the accused device in order to show equivalents. Nellcor claims that Masimo did not introduce such evidence, thus justifying the district court's refusal to instruct the jury to consider infringement under the doctrine of equivalents.

We agree with Masimo that the combination of the O4 software specification and Golberg's testimony adequately supports the jury's verdict of literal infringement. At the outset, Masimo is correct that the parties stipulated that the O4 software specification, which was in evidence, is representative of the O5CI software specification, which was not in evidence. Indeed, the pretrial conference order specifically identifies the source code contained in the O4 software specification as representative of the source code in Nellcor's O5CI product. The district court's oversight was, however, harmless because the district court substantively analyzed the O4 software specification as though it constituted the software specification for Nellcor's O5CI product.

Our review of the O4 software specification reveals that a reasonable jury could have concluded that the O5CI product infringes claims 29 and 30 of the '785 patent. While the O4 software specification does not explicitly state that the resulting signal is free of "noise," it offers an equation used to calculate that signal:

The O4 software specification states that the letter "w" in the equation represents a chosen mixing weight. When the mixing weight of 0.55 is selected, the specification states it "is intended to cancel the influence of deoxyhemoglobin in €mix and [gamma] mix. Deoxyhemoglobin is more abundant in non-arterial blood, which influences the plethysmograph primarily due to motion and respiratory artifacts." The explanatory language accompanying the equation suggests that any "noise" caused by motion is accounted for and removed by incorporating an appropriate mixing weight into the resulting signal calculation. The numeric value for the resulting signal thus represents only arterial oxygen saturation, exactly as set forth in claims 29 and 30 of the '785 patent.

Additionally, a reasonable jury could have found infringement based upon Goldberg's testimony alone, without resort to the O4 software specification, and certainly with the two combined. Goldberg expressly testified that the O5CI product infringes independent claim 29 of the '785 patent:

- Q: It looks like you did some more looking at Nellcor documents. Let's take a look at Exhibit 5073, and tell me what you've done in this exhibit.
- A: Okay. This is the same quote that we discussed earlier. This is a further description of that linear combination step. That's apparent in the O5Cl adaptive comb filter. And the W is the multiplier. It was the W that was present in that multiplier box. And the W has a range, and when W equals [0].55, the intention is to cancel the influence of deoxyhemoglobin at the output of that combiner. That is to cancel the influence of venous blood in the output of the combiner. As it says, deoxyhemoglobin is more abundant in nonarterial blood. This quote we've looked at before.

THE COURT: Yes, we have.

Q: Nonarterial means venous?

A: Yes.

THE COURT: We've been over that.

- Q: All right. So your conclusion with regard to this third or final step of claim 29?
- A: My opinion is that claim 29 of Masimo's '785 patent is infringed by Nellcor's O5CI products.

That Nellcor's expert, Friedlander, offered contradictory testimony does not automatically negate the impact of Goldberg's testimony or render it less than substantial. He testified:

- Q: There is some sort of multiplication going on somewhere; correct?
- A: The epsilon red is multiplied by some number and subtracted from epsilon IR.
- Q: And the resulting signal and we'll see in a minute whether this is in fact the resulting signal the resulting signal is what?
- A: Well, the resulting signal is also "noise."
- Q: So in the O5CI, we start with "noise." We do some calculations, and we end with "noise;" is that correct?
- A: That is correct.

. .

- Q: And now, having in mind what signals are combined and what the result is, can you compare that, please, to claim 29.
- A: Yes. Let me just read in the claim it says combine said first and second signals. What they are talking about is combining the red and the infrared signals. That little box which by the way, the little box doesn't appear in the Nellcor document. It's something that Mr. Goldberg or whoever prepared the slide added. The inputs to that box where the epsilon R and epsilon IR, which are not the red and infrared signals. But they are some "noise" signals derived from it. And then there is the question of outputs. It says to generate a signal which is primarily correlated to the physiologic measurement portion. But that box shown by Mr. Goldberg generates a signal which is "noise." And it's not correlated to the physiologic portion, the physiologic measurement portion. So neither the inputs nor the outputs of what was pointed out in that slide correspond to what's in the claim.

His testimony summarily discounts the significance of the multiplier without addressing why it does not function to remove "noise," unlike Goldberg's testimony. Lacking this critical explanation, we are hard pressed to conclude that Friedlander's testimony in any way either overcomes or calls into question the substantiality of Goldberg's testimony,

especially when considered together with the O4 software specification. Moreover, a jury is entitled, based upon its assessment of Goldberg's and Friedlander's credibility, to discount in whole or in part either witness's testimony for neither has been rebutted conclusively by some authoritative document or shown to be inherently implausible. It is apparent here that the jury chose to credit Goldberg's testimony over Friedlander's in finding that the O5CI product literally infringes the '785 patent. For these reasons, we conclude that the supporting evidence was substantial and that the district court erred in overturning the jury's verdict of literal infringement.

ii. Whether the district court abused its discretion by failing to give collateral estoppel effect to the construction of the "filter" terms in Masimo I warranting a new trial on the issue of infringement and validity of the '222 patent

Nellcor argues that the district court erred in not construing the terms "Kalman filter," "filtering," "processor," "signal processor," "adaptive signal processor," and "adaptive filter" (collectively, "filter" terms) as used in claims 1, 4, 16, 17, 18, 21, 22, and 23 of the '222 patent. Nellcor contends that the district court should have accorded the "filter" terms the same meaning that the district court gave to the term "adaptive filter" in Masimo I, which this court affirmed on appeal in Masimo II. By declining to do so, Nellcor contends that it was prejudiced and is entitled to retry all issues related to the '222 patent.

Masimo responds that the claim construction of the "filter" terms is not relevant to any judgment on appeal because Nellcor did not challenge the jury's verdict of literal infringement of the '222 patent post-trial. Even if Nellcor had, Masimo argues that Masimo II are narrow holdings, intended only to resolve Nellcor's motion for summary judgment of noninfringement of the '642 patent. As such, Masimo

maintains that the district court correctly rejected the claim construction from <u>Masimo I</u> on grounds that the present case involves different patents with different claims, specifications, and prosecution histories.

At the outset, we note that the law of the regional circuit applies to the issue of collateral estoppel. See Bayer AG v. Biovail Corp., 279 F.3d 1340, 1345 (Fed. Cir. 2002). Under Ninth Circuit law, a district court's decision to apply collateral estoppel is reviewed for abuse of discretion. See Plaine v. McCabe, 797 F.2d 713, 718 (9th Cir. 1986). A party seeking to invoke collateral estoppel bears the burden to prove three elements: (1) the issue at stake must be identical to the one alleged in the prior action; (2) the issue must have been actually litigated; and (3) the determination of the issue in the prior litigation must have been a necessary part of the judgment in the prior action. Trevino v. Gates, 99 F.3d 911, 923 (9th Cir. 1996).

Here, the first element is plainly not met. Nellcor asks the district court to apply the definition of "adaptive filter" from the '642 patent to the "filter" terms in the '222 patent. Nellcor does not, however, cite any evidence showing that the use of the "filter" terms in the '222 patent is identical to the use of the term "adaptive filter" in the '642 patent. While both the '642 and '222 patents ultimately trace priority to U.S. Application No. 07/666,060, filed on March 7, 1991, the specifications of the '642 and '222 patents are not identical. Claim terms in the two patents, therefore, may or may not carry the same meaning, depending on the use of the terms in the written description. This is particularly true in light of the advancements made in the field of pulse oximetry between the filing date of the '642 patent in June of 1998 and the filing date of the '222 patent in October of 1997.

With regard to the "adaptive filter" term in particular, which appears only in dependent claim 22 of the '222 patent, we recognize that the same terms in related patents are presumed to carry the same meaning. See Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1334 (Fed. Cir. 2003) ("[W]e presume, unless otherwise compelled, that the same claim term in the same patent or related patents carries the same construed meaning."). Nellcor, nonetheless, does not raise this argument, and we are not persuaded that the presumption should apply. Although both patents trace priority to the '060 application, the '222 patent is not descendent from the '642 patent. Additionally, the '222 patent is primarily directed to the use of a certain kind of filter, namely a Kalman filter, to remove motion-induced "noise." The '642 patent, by contrast, does not so limit the type of filter used to remove "noise." Consequently, the district court was not in any way bound by collateral estoppel to give effect to the Masimo I claim construction of the term "adaptive filter" in this case. We thus conclude that Nellcor is not entitled to retry all issues related to the '222 patent.

iii. Whether the district court erred in overturning the jury's verdict of willful infringement with respect to the '222, '850, and '830 patents

The district court found that Masimo failed to present clear and convincing evidence from which a jury could either conclude or infer that Nellcor was aware of the '222, '850, and '830 patents and proceeded with its infringing activities without a good faith belief that the asserted patents were invalid and/or not infringed. With respect to Nellcor's awareness, the district court noted that the three patents issued only a short time before Masimo asserted them against Nellcor, making it highly unlikely that Nellcor knew of their existence. Mallinckrodt, slip op. at 24. Also, the district court found that the jury could not have inferred that Nellcor was aware of the asserted patents based on

Masimo's evidence, including a summary of Masimo's patents prepared by Yorkey, Nellcor's announcement that Masimo had five patents, or Kiani's discussions with Nellcor, because those documents were generated more than two years after the three asserted patents issued. <u>Id.</u> at 25.

The district court also found that Masimo presented no evidence upon which a jury could infer that Nellcor acted in bad faith. The district court observed that Nellcor did not become aware of the asserted patents until Masimo filed suit, at which time, it sought the advice of counsel to prepare a defense. <u>Id.</u> at 26. The district court observed that Nellcor, after consultation with counsel, sought to defend itself from Masimo's infringement allegations by asserting that the '222, '850, and '830 patents were invalid and/or not infringed. <u>Id.</u> The district court concluded that these defenses were reasonable in light of Nellcor's prior success using them in the <u>Masimo I</u> litigation. <u>Id.</u>

Lastly, the district court addressed Masimo's argument that Nellcor copied its patented technology, finding that there was no evidence from which a reasonable jury could have concluded there was copying. <u>Id.</u> at 27. The district court noted that Masimo's copying argument rested on the testimony of Kiani, who stated that he engaged in numerous meetings with Nellcor regarding Masimo's technology. <u>Id.</u> The district court found, however, that Kiani did not testify that he told Nellcor about the patented features. Thus, the district court reasoned that a jury would have had to speculate there was copying based solely on the fact Kiani met with Nellcor, but concluded that such speculation does not rise to the level of clear and convincing

evidence. <u>Id.</u> Accordingly, the district court held that Masimo failed to meet its burden of proving willfulness.

Masimo argues that the district court erred in reversing the jury's finding that Nellcor's infringement of the '222, '850, and '830 patents was willful for several reasons. First, Masimo claims that Nellcor regularly monitored the patent literature and was aware of Masimo's patents. For example, Masimo points out that Dr. Ross Flewelling, Nellcor's former Director of Technology Development, maintained an intelligence file on Masimo, which identified Masimo's published and issued patents. Second, Masimo asserts that Nellcor had access and motivation to copy Masimo's inventions. Indeed, Masimo points out that Kiani met with Nellcor personnel, Swedlow and Yorkey, and discussed the idea of using adaptive filters in pulse oximetry to solve the motion problem. Masimo also points out that Kiani even showed Nellcor a prototype as early as 1992 and allowed Swedlow to test it. Thereafter, in 1993, Masimo further states that it provided Nellcor with a copy of a PCT application, which disclosed the inventions claimed in the '222, '850, and '830 patents. Third, Masimo contends that Nellcor's post-suit conduct does not evidence good faith. Although Nellcor's former president testified that she believed that the present litigation would be favorable to Nellcor like the Masimo I litigation, Masimo emphasizes, she admitted that she did not understand how the decision in Masimo I related to the '222, '830, and '850 patents. Finally, Masimo stresses that Nellcor, after being sued by Masimo for patent infringement, did not obtain a legal opinion concerning whether its products were infringing or whether the asserted patents were valid. This failure, Masimo claims, was particularly egregious in light of Nellcor's long-standing policy of ensuring its "products did not infringe any other company's patents." It thus avers that the jury could have found that Nellcor did not present a good faith defense to its alleged infringement of the '222, '830, and '850 patents.

Nellcor argues that Masimo merely speculates that Nellcor was aware of the asserted patents without presenting any concrete evidence showing that Nellcor actually possessed copies of those patents. Nellcor also asserts its reliance on defenses that it raised in Masimo I does not show lack of good faith. Additionally, Masimo contends that the absence of an opinion of counsel does not permit an adverse inference of willfulness pursuant to Knorr-Bremse Systeme Fuer Natzfahrzeuge GMBH v. Dana Corp., 383 F.3d 1337 (Fed. Cir. 2004) (en banc). Nellcor thus maintains that the district court properly drew inferences favorable to Nellcor in overturning the jury's finding of willfulness as to the '222, '830, and '850 patents.

We agree with Nellcor that Masimo did not present sufficient evidence to support the jury's verdict of willfulness. Willfulness is a question of fact that must be determined from the totality of the circumstances and proven by clear and convincing evidence. Knorr-Bremse, 383 F.3d at 1342-43. As Nellcor argues, Masimo does not identify any specific evidence upon which a reasonable jury could have found that Nellcor was, for certain, aware of the '222, '830, and '850 patents. Masimo instead offered evidence upon which a jury could only surmise awareness. Just because Nellcor regularly monitored the patent literature, for example, does not mean that Nellcor automatically knew about the asserted patents. Indeed, as noted by the district court, it seems highly unlikely that Nellcor could have known of the '222 patent because it issued only one day before Masimo filed its infringement suit against Nellcor.

Masimo likewise did not present any evidence upon which a reasonable jury could have found that Nellcor copied Masimo's inventions. Masimo's evidence of copying involved only inferential leaps. Masimo asked the jury to infer that Nellcor copied Masimo's inventions simply because (1) Kiani engaged in meetings with Nellcor's personnel; (2) Nellcor sought to maintain its position as the technology leader in the pulse oximetry market; and (3) Nellcor knew that Masimo had developed state-of-the-art technology. Nellcor's desire to remain at the top of the pulse oximetry market, nevertheless, does not prove copying; it merely evidences the competitive nature of business. All top market players want to retain their lead over the competition. That goal does not mean that all such players copy the inventions of competitors to retain their lead. Even if Nellcor was motivated to do so, it did not have the opportunity. Kiani's meetings with Nellcor in no way exposed the patented technology. Although Kiani showed Nellcor a prototype, Nellcor was not permitted to disassemble it or to inspect its inner workings. Nor was Nellcor able to review engineering diagrams or software code employed in creating the prototype.

Lastly, Masimo failed to offer any evidence showing that Nellcor intentionally or recklessly disregarded the asserted patents after being sued by Masimo. Contrary to Masimo's contention, the lack of an opinion cannot be held against Nellcor. In <u>Knorr Bremse</u>, 383 F.3d at 1345, this court specifically addressed the question of whether it is appropriate to draw an adverse inference with respect to willfulness when an accused infringer had not obtained legal advice. We answered that question in the negative. <u>Id.</u> Hence, the district court correctly concluded that no reasonable jury could have found that Masimo willfully infringed the '222, '830, or '850 patent.

iv. Whether the district court erred in declining to grant JMOL that Nellcor's N-200 pulse oximeter anticipates the '222 patent under 35 U.S.C. § 102(b)

The district court concluded that Masimo presented evidence that Nellcor's N-200 pulse oximeter did not tolerate motion as the term "motion" was defined by the court's claim construction. Mallinckrodt, slip op. at 38. The district court noted that Kiani and others testified that Nellcor's N-200 pulse oximeter gave readings during "motion" that did not "accurately reflect the arterial oxygen saturation." Id. In light of this evidence, the district court determined that a reasonable jury could have concluded that Nellcor failed to prove that its N-200 product anticipates claims 17 and 18 of the '222 patent. Id.

Nellcor argues that the district court erred in denying its motion for JMOL that Nellcor's N-200 pulse oximeter anticipates the '222 patent under § 102(b). Nellcor claims that its N-200 product was able to calculate arterial oxygen saturation levels in the presence of "motion" before the filing date of the '222 patent on October 6, 1997. Nellcor points out that Masimo's expert, Dr. Steve Barker, even published an article in the January 1997 issue of Anesthesiology containing test results showing that Nellcor's N-200 product performed accurately much of the time ("Barker Study"). In that study, Barker compared the accuracy and dropout rates of Nellcor's N-200, Nellcor's N-3000, and a prototype of Masimo's SET pulse oximeters during standardized motion in healthy

The district court construed the term "motion" as used in the '222 patent to mean "movement of body tissue which causes erratic noise that, in the absence of a filter, will cause the ratio of red to infrared signals to not accurately reflect the arterial oxygen saturation." Mallinckrodt, slip op. at 46.

volunteers. Barker's data showed that Nellcor's N-200 product displayed a SpO₂ value² within seven percent of control 76 percent of the time when the oximeter was functioning before motion began and 68 percent of the time when the oximeter was connected after motion began. Accordingly, Nellcor claims that the availability of its N-200 pulse oximeter on the market at the time Masimo filed the application which issued as the '222 patent anticipates claims 17 and 18 of that patent.

Masimo rebuts Nellcor's contention by arguing that it presented overwhelming evidence showing that Nellcor's N-200 product is incapable of giving accurate readings with "noise," thereby not anticipating the invention claimed in claims 17 and 18. Specifically, Masimo contends that several witnesses testified that Nellcor's N-200 pulse oximeter did not perform reliably during motion. These witnesses included Barker, Kiani, and James Welch, a former Nellcor employee. Masimo points out that Barker, the very author upon whose study Nellcor heavily relies, plainly stated that Nellcor's N-200 pulse oximeter "does not perform reliably during motion."

We agree with Masimo that it presented substantial evidence upon which a reasonable jury could have found that the '222 patent was not anticipated by Nellcor's N-200 pulse oximeter. Multiple witnesses testified about the problems encountered when using Nellcor's N-200 product during "motion." Notably, Barker carefully explained the bases for his testimony that Nellcor's N-200 product does not perform reliably during motion, which included both his own experimentation as well as his review of the relevant literature:

A SpO₂ value refers to the oxygen saturation level in a patient's blood. See Steven J. Barker & Nitin K. Shah, The Effects of Motion on the Performance of Pulse Oximeters in Volunteers (Revised publication), <u>Anesthesiology</u>, Vol. 86, No.1, 101-108 (1997).

- Q: Have you done tests to evaluate how well Nellcor's N-200 without C-Lock performs during motion?
- A: Yes, I have.
- Q: And have you reached an opinion as to how well Nellcor's N-200 without C-Lock performed during motion?
- A: Yes.
- Q: And what is your opinion?
- A: It does not perform reliably during motion.
- Q: And what is the basis for that opinion?
- A: My own experiments, as well as the review of the literature.
- Q: Can you cite to any particular pieces of literature or volume of literature that supports that opinion?
- A: Certainly. There's actually an excellent paper by William Hay that was published in the Journal of Perinatology in 2002 in which they made comparisons. I will not discuss the comparisons, but among other instruments, they looked at the N-200 without C-Lock and found that it had a very high late rate of false alarms during motion. Another study by Bohnhorst and Poets in the Journal of Critical Care Medicine, year 2000, found the same thing. This was a clinical study in a neonatal intensive care unit. So these were newborn babies. Again, the false alarm rate was very high with the N-200.

A reasonable jury was entitled to accept Barker's testimony alone or in combination with the testimony from Kiani and Welch, who each testified that Nellcor's N-200 pulse oximeter did not read through "motion," over Barker's single comparative study. Doing so, a reasonable jury readily could have found that it was not possible for Nellcor's N-200 pulse oximeter to give an arterial oxygen saturation level as required by the asserted claims of the '222 patent. See, e.g., '222, col. 74, ll. 11 (Claim 17 recites: "A physiological monitor that computes arterial oxygen saturation . . . comprising . . . a signal processor responsive to the first and second intensity signals to calculate arterial oxygen saturation without significant interference in the calculation from the motion induced noise portion of the first and second intensity signals.") (emphasis added). Thus, a reasonable jury could have concluded that Nellcor's N-200 pulse oximeter did not anticipate the invention claimed in claims 17 and 18 of the '222 patent.

Even if the jury ignored all testimony from Barker, Kiani, and Welch concerning the problems associated with using Nellcor's N-200 product during motion, the jury may have found no anticipation based solely upon testimony from Masimo's expert, Goldberg, who focused on the structural features of Nellcor's N-200 pulse oximeter and why those features were not capable of overcoming "noise." He plainly testified that Nellcor's N-200 product did not anticipate claims 17 and 18 of the '222 patent because the features employed in that pulse oximeter, such as the boxcar filter, were capable of filtering out only certain frequencies of "noise," but not all frequencies. For example, Goldberg testified:

[T]he boxcar filter is a low pass filter, gets rid of high frequency noise. It doesn't get rid of erratic noise that's – well, I don't want to get too technical, but the erratic noise that has the same sort of spectrum as the pulse rate itself. The really ugly noise the boxcar can't get rid of.

. . .

As such, the jury may have concluded that Nellcor's N-200 pulse oximeter could not completely filter "noise" to produce an arterial oxygen saturation level during motion as set forth in the asserted claims of the '222 patent. Indeed, Goldberg testified to this effect:

- Q: Without significant interference means the calculated oxygen saturation is accurate enough for the purposes of which the calculation is being employed. And in the context of the claim, it's the calculation in the presence of motion-induced noise. So could the N-100 or N-200 contain a signal processor to calculate arterial oxygen saturation without significant interference as set forth in the claim?
- A: No, it couldn't. Inasmuch as it doesn't handle the motion-induced noise. It can't meet the limitations of claim 17.
- Q: And the basis of your opinion?
- A: The basis of my opinion is study of the Nellcor documentation that describes those products, how they work software specifications, the Court's claim construction.

Accordingly, because substantial evidence supports the jury's verdict, the district court correctly denied Nellcor's motion for JMOL of anticipation of the '222 patent under § 102(b).

v. Whether the district court erred in declining to grant JMOL that Nellcor's O4 pulse oximeter anticipates the '850 patent under 35 U.S.C. § 102(g)

The district court found that Nellcor's O4 algorithm does not anticipate claims 10, 11, 12, 15, 17, and 22 of the '850 patent. The district court concluded that "[t]he jury was free to reject Nellcor's evidence that arbitration was introduced into Nellcor's O4 algorithm in 1993." Mallinckrodt, slip op. at 33. In addition, the district court noted that Masimo introduced evidence that Diab conceived of the "alternative calculation" method by the fall of 1991. Id. In light of that evidence, the district court concluded that a reasonable jury could have found that "Nellcor failed to meet its burden to prove that Nellcor's O4 algorithm is prior art to the alternative calculation claims in the '850 patent."

The district court also observed that Nellcor alternatively attempted to establish prior invention by its use of "alternative calculations" in its PCSat software in 1991. <u>Id.</u> at 34. The district court noted that Nellcor's software engineer, Mr. Clark Baker, nevertheless testified that the PCSat software was not used outside of Nellcor. <u>Id.</u> On that basis, the district court decided that a reasonable jury could have concluded that the PCSat research project was "abandoned, suppressed, or concealed" and thus was not invalidating under § 102(g). <u>Id.</u>

Nellcor argues that the district court erred in denying its motion for JMOL that Nellcor's O4 algorithm anticipates the asserted claims of the '850 patent under § 102(g). Nellcor contends that it invented the "alternative calculation" method claimed in the

asserted claims of the '850 patent before Masimo filed U.S. Application No. 08/320,154, the parent application of the '850 patent, on October 7, 1994.³ Specifically, Nellcor asserts that Baker testified about calculating saturation in multiple ways when working on the PCSat program in 1991. Nellcor points out that Baker also testified that he began writing software to implement his "alternative calculation" method in May of 1991 and was able to use that method by June of 1991. Nellcor further contends that Baker and Yorkey testified that they implemented Baker's "alternative calculation" method in Nellcor's O4 algorithm in the summer of 1993. Considering Baker's activity in the early 1990s, allegedly well before Masimo had even conceived of using "alternative calculations" to remove "noise" caused by motion, Nellcor maintains that a reasonable jury could not have found the '850 patent valid under § 102(g).

Masimo responds that Nellcor failed to present evidence showing that its O4 algorithm used in the 1993 time frame contained each and every limitation of the asserted claims. Alternatively, Masimo argues that it presented substantial evidence showing that it conceived of the "alternative calculation" method claimed in the '850 patent in 1991. Masimo points out that the district court, in fact, cited various evidence in denying Nellcor's JMOL of invalidity, including testimony from Diab, one of the named inventors on the '850 patent, lab notebook entries, daytimer entries, software code, and Nellcor's response to an interrogatory that the court read into the record at trial, stating that the inventors conceived of the invention set forth in the majority of the asserted claims as early as the fall of 1991. Hence, Masimo argues that the district court correctly denied Nellcor's motion for JMOL that the '850 patent is invalid under § 102(g).

The '850 patent is a continuation-in-part of the '154 application. The application which issued as the '850 patent was filed on May 16, 1997.

We agree with Masimo that Nellcor failed to show that the alleged "alternative calculation" method that Baker conceived of in 1991 embodied each and every limitation of the asserted claims of the '850 patent. Baker's testimony did not in any way correlate the invention he allegedly made in May of 1991 with even a single limitation of the asserted claims of the '850 patent. Baker merely testified that as of May 17, 1991, he had "a saturation calculation being made that corresponded to the same signal processing paths as both of the two pulse rate calculations that were derived from the oximetry signal." He likewise explained that as of June 17, 1991, one month later, he revised the PCSat software to employ "a reasonable set of criterion [sic] to start trying out by means of which the software would automatically select which of the multiple available pulse rate or oxygen saturation estimates it would use to make up to update its final oxygen saturation and pulse rate calculation." While this testimony seems to suggest the use of a sorting process to isolate pulse rate and/or oxygen saturation values from several possibilities, it does not explain, contrary to the limitations of independent claim 1, that the input signals contained both a desired portion and an undesired portion or that Nellcor's PCSat software used at least two possible estimates to determine a final result which "likely most closely correlates to the physiological parameter." '850 patent, col. 109, Il. 12-13. Absent evidence demonstrating that Nellcor's O4 algorithm satisfied each and every limitation of claims 10, 11, 12, 15, 17, and 22 of the '850 patent, we have no choice but to conclude that a reasonable jury could not have found prior invention. Hence, we hold that the district court correctly

denied Nellcor's motion for JMOL of invalidity of the '850 patent under § 102(g).4

vi. Whether the district court abused its discretion in denying a permanent injunction to redress Nellcor's adjudicated infringement of the '222 and '850 patents

The district court observed that this case is not a "typical" patent infringement action such that the customary rules concerning injunctions apply. Mallinckrodt, slip op. at 68. Rather, the district court noted that even Masimo emphasized that the pulse oximetry market is unique because hospitals strongly prefer to standardize oximetry products. Having made this observation, the district court concluded that "[t]his unusual aspect of the pulse oximetry industry leads to the conclusion that an injunction in this case (in the form that Masimo suggested) would be against the public interest." Id. More specifically, the district court elaborated:

Masimo's proposed injunction would force hospitals currently using Nellcor's infringing technologies to make a choice between two undesirable options: either work with an amalgam of oximeters of different brands, or make the substantial investment it would take to convert the entire hospital to a non-infringing brand. Forcing this choice would likely compromise patient safety by forcing health professionals to switch back and forth between types of oximeters, or by driving up the hospitals' costs and making care less accessible. . . . The Court [also] recognizes that at least some physicians will prefer Nellcor's oximeters to Masimo's products. . . . The Court is concerned that forcing physicians who have been trained on one product and who prefer it in their practice to use a different product would compromise the safety of their patients.

<u>Id.</u> at 69. The district court further inferred that an injunction would enable Masimo to control the pulse oximetry market for the duration of its patents and beyond because, it

Because Nellcor failed to establish that it invented the "alternative calculation" method in 1991, we need not decide Masimo's alternative argument regarding whether it presented substantial evidence showing that it conceived of the "alternative calculation" method before 1991.

said, hospitals who want to standardize equipment will convert to Masimo's products. <a href="https://doi.org/10.1007/jde.no.1

Finally, the district court reasoned that an injunction would allow Masimo to make some sales for which it has already been compensated since it was awarded damages for future Nellcor sensor sales and for lost hospital conversions. <u>Id.</u> To that end, the district court explained:

Masimo's damages model included compensation for lost hospital conversions. If an injunction is granted in this case, because of the importance of standardization, Masimo will likely be able to convert those hospitals that wish to use the patented technology. Should those hospitals for which lost conversion damages were awarded wish to pursue additional oximeters, they will have to convert to Masimo's products to be able to standardize. Thus Masimo will receive the benefit of the actual conversion in addition to the theoretical one for which the jury awarded damages.

<u>Id.</u> at 72. Because the district court concluded, on balance, that Masimo would not suffer irreparable harm, the district court denied a permanent injunction to stop Nellcor's infringement of Masimo's '222 and '850 patents. <u>Id.</u> at 73.

Masimo argues that the district court abused its discretion in not granting a permanent injunction to enforce Masimo's right to exclude, given Nellcor's adjudicated infringement of the '222 and '850 patents. Masimo contends that a court should decline a request for a permanent injunction only in cases involving a critical public interest, which it advocates is not the situation here. Masimo asserts there is no evidence at all that an injunction would adversely affect patient care or increase hospital costs, despite the district court's contrary findings. Even if there were such evidence, Masimo claims, it would not be enough to deny a permanent injunction against a proven patent infringer where, as here, non-infringing products are available. Additionally, Masimo argues that

its market share after its asserted patents expire is irrelevant to whether a permanent injunction should issue. Any post-expiration increase in market share, it claims, is a natural consequence of the injunction, one that a district court should not hold against a patentee in deciding whether to issue a permanent injunction. Lastly, it refutes the district court's finding that a permanent injunction might allow Masimo to make sales for which it has already been compensated by the damage award. Masimo points out that the injunction it sought would neither require Nellcor to recall previously sold infringing products nor prohibit Nellcor from selling replacement sensors to maintain those products. Masimo explains that it only seeks to prevent Nellcor from making future pulse oximeter sales.

Nellcor replies that the district court correctly found that Masimo would not suffer the irreparable harm needed to justify a permanent injunction. Nellcor contends that hospitals and doctors would bear a substantial financial burden if a permanent injunction issued, as noted by the district court. It also points out that the district court considered testimony that some doctors have safety concerns about Masimo's products. Lastly, Nellcor claims that a permanent injunction would enjoin sales for which Masimo has already recovered money damages because Masimo's damage model accounted for five years of future sensor sales.

We agree with Masimo that on the present record the district court abused its discretion in refusing to grant a permanent injunction against Nellcor for infringing Masimo's '222 and '850 patents. "An abuse of discretion may be established by showing that the district court either made a clear error of judgment in weighing relevant factors, or exercised its discretion based on an error of law or on findings which were

clearly erroneous." <u>Joy Techs., Inc. v. Flakt, Inc.</u>, 6 F.3d 770, 772 (Fed. Cir. 1993). "Because the 'right to exclude recognized in a patent is but the essence of the concept of property," the general rule is that a permanent injunction will issue once infringement and validity have been adjudged." <u>Mercexchange, L.L.C. v. eBay, Inc.</u>, 401 F.3d 1323, 1338 (Fed. Cir. 2005) (quoting Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1246-47 (Fed. Cir. 1989)). Nevertheless, "courts . . . in rare instances [have] exercised their discretion to deny injunctive relief in order to protect the public interest." <u>Rite-Hite Corp. v. Kelley, Inc.</u>, 56 F.3d 1538, 1547 (Fed. Cir. 1995) (<u>en banc</u>).

While the district court conducted a post-trial hearing in June of 2004 solely on the issue of whether to issue such relief, allowing the parties the opportunity to prove or disprove the need for such relief, the district court's reasons for denying a permanent injunction were neither supported by the evidence of record nor persuasive enough to lead us to agree that this case is exceptional. The district court appeared specifically concerned with: (1) patient safety; (2) rising health care costs; (3) standardization in the use of pulse oximeters; and (4) doctors' preferences. Based upon our careful review of the record, however, Masimo is correct that there is insufficient evidence to substantiate the district court's concerns.

Nellcor offered testimony from only two doctors, Drs. Timothy Deakers and Leonard Kim, regarding their personal preferences and the need for standardization. Such testimony cannot be interpreted and cited as though it represents that of the majority of doctors in the United States. Moreover, Deakers practices only at two hospitals, Children's Hospital in Los Angeles, California and Huntington Memorial Hospital in Pasadena, California; Kim practices only at Huntington Memorial Hospital in

Pasadena, California. Their opinions, therefore, can hardly be said to represent that of a broad spectrum of hospitals in the United States.

What is more, Kim testified about just two instances where Masimo's Radical pulse oximeter performed poorly, although he mentioned without elaborating about other instances and stated that the anesthesiology group at his hospital eventually returned to using a Hewlett Packard pulse oximeter in operating rooms after testing the Masimo Radical. Virtually every product, however, malfunctions at some point in time. We thus are not persuaded that the two cited examples are sufficient to prove that Masimo's pulse oximeters pose a safety risk to patients. Indeed, Deakers even testified that if his child were placed in the neo-natal intensive care unit, he thought either Nellcor's N-200 pulse oximeter or Masimo's SET pulse oximeter would be adequate to use on his child. Moreover, Kim admitted during his testimony that the neo-natal intensive care unit of Huntington Memorial Hospital continued to use Masimo's pulse oximeter, despite the fact that operating rooms in other areas of the hospital returned to using Hewlett Packard's product.

Further, neither Deakers nor Kim testified that patient safety would be compromised if they were no longer able to use Nellcor's products. Both doctors mentioned other acceptable brands of pulse oximeters, including ones made by Ohmeda, In Vivo, Draeger Best, Space Labs, General Electric, and Hewlett Packard. They remain available on the market in addition to Masimo's and Nellcor's products. If an injunction were to issue, doctors and hospitals would have the option of switching to any of those brands instead of Masimo's products. The issuance of a permanent injunction certainly will not create the situation where doctors and hospitals, against

their will, would be forced to choose between using Masimo's products or Nellcor's infringing products, risking the possibility of being sued by Masimo for infringement. Moreover, that hospitals may switch to Masimo's products and continue to use them after the expiration of the '222 and '850 patents does not bear upon whether an injunction should issue. As this court has repeatedly held, it is contrary to the laws of property to deny a patentee the right to exclude others from the use of his property, except in rare and unusual circumstances such as where "a patentee's failure to practice a patented invention frustrates an important public need for the invention." See Richardson, 868 F.2d at 1246-47 (quoting Rite-Hite Corp. v. Kelley, Inc., 56 F.3d 1538, 1547 (Fed. Cir. 1995)). That certainly is not the situation here since several other companies in the market offer pulse oximeters for sale.

Finally, we agree with Masimo that the district court's conclusion that an injunction may allow Masimo to make sales for which it has already been compensated by the damage award is not well supported by the record. As Masimo points out, the injunction it seeks here would only prevent Nellcor from making future sales of its infringing pulse oximeters. It would not require Nellcor to recall previously sold infringing products or require doctors or hospitals to discontinue using those products. It likewise would not prevent Nellcor from selling replacement sensors for previously sold infringing products. Indeed, Masimo's proposed permanent injunction states:

- 2. [Nellcor], their officers, servants, agents, employees, subsidiaries, affiliates and those persons in active concert with the foregoing parties . . . are hereby enjoined from making, using, selling, offering to sell or importing any product that includes the O4, O5, or O5Cl algorithms or any product employing an algorithm that is no more than colorably different from the O4, O5, or O5Cl algorithms ("Enjoined Algorithms").
- 3. Nellcor is further enjoined from supplying any software embodying the Enjoined Algorithms to others.

This language is no different from the routine language employed in a permanent injunction normally issued in cases where patent infringement has been proven. Additionally, we do not follow the district court's conclusion regarding lost hospital conversions. There is no evidence of record showing that hospitals which decide to standardize will automatically select Masimo's products; those hospitals may, as previously noted, just as likely resort to using Hewlett Packard products. On this basis, it is entirely unclear how or why the district court concluded that an injunction would be duplicative of the jury's damage award and allow for double recovery. The district court's concern about double recovery thus appears purely speculative. Accordingly, we reverse the district court's denial of a permanent injunction and remand the case to the district court with instructions to enter a permanent injunction.

B. Bench Rulings

i. Whether the district court erred in holding that claims 17 and 18 of the '222 patent were not invalid for indefiniteness under 35 U.S.C. § 112, second paragraph

The district court explained that Nellcor challenged the definiteness of the terms "motion" and "without significant interference" as used in claims 17 and 18 of the '222 patent. Mallinckrodt, slip op. at 44. The district court noted that it construed the term "motion," as noted above, as "movement of body tissue which causes erratic noise that, in the absence of a filter, would cause the ratio of red to infrared signals not to accurately reflect the arterial oxygen saturation," and the phrase "without significant interference" as requiring that "the calculated oxygen saturation is accurate enough for the purposes for which the calculation is being employed." Id. at 46. Acknowledging

that these constructions were qualitative, instead of quantitative, it nevertheless reasoned that this distinction did not alone render the terms indefinite. <u>Id.</u> at 45.

The district court also noted that indefiniteness is determined from the perspective of one of skill in the art and that both parties presented evidence that those skilled in the relevant field understood what was meant by the term "motion." In fact, the district court particularly recognized: "Even Mr. [James] Corenman from Nellcor admitted that the Court's construction of 'motion' was 'completely understandable.'" Id. at 47. Accordingly, the district court found that "the claims of 'motion' and 'without significant interference,' as defined by this Court, are sufficiently definite to give those of skill in the art notice as to what is claimed by the '222 patent." Id. at 48.

Nellcor argues that the district court erred in holding that claims 17 and 18 of the '222 patent were not invalid for indefiniteness under § 112, second paragraph. Nellcor asserts that the language "without significant interference in the calculation from the motion induced noise" in claims 17 and 18 is indefinite because it is not possible for a person of skill in the art to know from reading the '222 patent either how much or what kind of "motion" a pulse oximeter must be able to handle to avoid infringement. Additionally, Nellcor contends that the district court's construction of the phrase "without significant interference" makes it even more difficult for a skilled artisan to understand the scope of claims 17 and 18.

Masimo responds that Nellcor fails to cite any evidence showing that a person of skill in the art is unable to understand the scope of claims 17 and 18. In this regard, Masimo points out that Corenman admitted that the language "without significant interference," as construed by the district court, was "completely understandable."

Consequently, Masimo argues that the district court correctly held that claims 17 and 18 of the '222 patent were not invalid for indefiniteness.

We review the district court's determination as to indefiniteness <u>de novo</u>, since "[a] determination of claim indefiniteness is a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims." <u>Personalized Media Communications</u>, <u>LLC v. Int'l Trade Comm'n</u>, 161 F.3d 696, 705 (Fed. Cir. 1998)). "A claim is indefinite if its legal scope is not clear enough that a person of ordinary skill in the art could determine whether a particular [product or method] infringes or not." <u>Howmedica Osteonics Corp. v. Tranquil Prospects</u>, <u>Ltd.</u>, 401 F.3d 1367, 1371 (Fed. Cir. 2005) (quoting <u>Geneva Pharms.</u>, <u>Inc. v. GlaxoSmithKline PLC</u>, 349 F.3d 1373, 1384 (Fed. Cir. 2003) (alternation in original)).

Applying that standard here, we conclude that Nellcor bases its indefiniteness challenge entirely on attorney argument. Nellcor did not adduce any evidence to substantiate its claim of indefiniteness. Additionally, as Masimo points out, Corenman's testimony, which Nellcor does not attempt to qualify or distinguish in any way, makes clear that a person of ordinary skill in the art would not encounter difficulty in ascertaining the type of motion, the removal of which would result in infringement of claims 17 and 18, after reviewing the court's claim construction:

- Q: Now, the Court's claim construction with regard to the word motion, do you find the Court's claim construction to be indefinite or ambiguous?
- A: The Court's words are completely understandable. The Court said that motion was movement, erratic movement, which would cause an instrument with no filters to not be able to compute accurately. And that to me includes a wide range of possible motions. My little wiggle would be motion that meets the Court's definition of motion, and a baby thrashing in a bassinet would also meet the Court's construction for what constitutes motion.

Accordingly, we conclude that the district court correctly held claims 17 and 18 of the '222 patent are not invalid for indefiniteness under § 112, second paragraph.

ii. Whether the district court abused its discretion in holding the '830 patent unenforceable due to inequitable conduct

To begin, the district court set forth the framework for an inequitable conduct analysis. Mallinckrodt, slip op. at 48. It observed that it must determine as the first step whether Nellcor demonstrated by clear and convincing evidence that Masimo withheld information material to the patentability of the '830 patent and did so with deceptive intent. If so, the district court then noted that it must evaluate whether, on balance, Masimo's conduct rose to the level of inequitable conduct.

Focusing on materiality, the district court observed that the '830 patent shares the same specification as the '642 patent and that the same limitations in dispute in the Masimo I litigation were in dispute before the PTO during the prosecution of the '830 patent. The district court stated: "The Masimo I dispute was highly relevant to the '830 patent because the '830 and '642 patents share a specification, and Masimo was pursuing an amendment before the PTO that would add to the '830 patent exactly those terms being disputed in the '642 litigation." Mallinckrodt, slip op. at 53. The district court then observed that Masimo argued before the PTO that the term "adaptive filter" should be broadly construed. It also noted that the Masimo I court required the "adaptive filter" term to be limited to an "adaptive noise canceler." The district court thus reasoned: "By not disclosing the existence of the [Masimo I] litigation, or the Court's ruling on the 'adaptive filter' issue, Masimo withheld material information from the PTO."

Turning to intent, the district court concluded that Masimo had every reason to know that the <u>Masimo I</u> litigation was material to the prosecution of the '830 patent given that (1) the same patent counsel represented Masimo in both the <u>Masimo I</u> litigation and the prosecution of the application which issued as the '830 patent; and (2) the same terms were in dispute in both proceedings. Indeed, it stated:

That Masimo knew that the '642 examiner was concerned that the specification supported only "adaptive noise canceler" and not "adaptive filter" claims gave Masimo reason to know that the <u>Masimo I</u> Court's decision essentially affirming the '642 examiner's concerns would be material to whether those same terms were patentable in the '830 patent, which contains the same specification.

<u>Id.</u> at 55. That there was a protective order governing the <u>Masimo I</u> litigation, the district court reasoned, could not save Masimo. <u>Id.</u> at 57. The district court observed that Masimo could have requested the court to remove confidential information from the scope of the order to allow it to disclose remaining information to the PTO. <u>Id.</u> But, it noted that Masimo neither did so nor alerted the PTO of the existence of the litigation or the court's claim construction rendered in that litigation. <u>Id.</u> Based upon this evidence, the district court inferred that Masimo intended to deceive the PTO. Id. at 58.

Finding that Nellcor established both materiality and intent by clear and convincing evidence, the district court thus concluded that Masimo committed inequitable conduct, thereby rendering the '830 patent unenforceable. <u>Id.</u> In the words of the district court: "Based upon the clear materiality of the '642 decision, the PTO's expressed interest in the exact question being considered by the '642 litigation, the fact that '642 litigation and the '830 prosecution were happening at the same time, the fact that the same lawyer controlled both the litigation and the prosecution, as well as Masimo's failure to demonstrate good faith, this Court finds that Masimo committed

inequitable conduct by neglecting to bring the '642 litigation to the attention of the PTO." Mallinckrodt, slip op. at 58.

Masimo argues that the district court erred in holding the '830 patent unenforceable for inequitable conduct based upon its failure to disclose the Masimo I litigation to the PTO during the prosecution of the '830 patent. Masimo first asserts that the district court applied an incorrect materiality standard. Pursuant to 37 C.F.R. § 1.56, the undisclosed information must, Masimo contends, "compel[] a conclusion that a claim is unpatentable" to establish a prima facie case of materiality. According to Masimo, the district court nevertheless applied a lesser standard, stating "Masimo I Court's determination that the term[s] 'adaptive filter' [and] 'adaptive noise canceler' [were] clearly important to the prosecution of the '830 patent." Under the correct legal standard, Masimo asserts that Masimo I is not material because it did not concern patentability, but instead only involved claim construction and noninfringement.

Second, Masimo asserts that the district court applied the wrong legal standard in inferring intent to deceive. The district court erroneously inferred intent, Masimo claims, based solely upon its patent attorney's awareness of the Masimo I litigation. However, Masimo claims that its attorney, Jensen, did not think that the Masimo I litigation had any effect on the claim scope supported by the specification of the application which issued as the '830 patent when he amended the claims. After all, Masimo points out that Jensen testified that the district court did not state in its claim construction ruling that the specification of the '642 patent did not support "anything other than an adaptive noise canceler." Moreover, that Jensen represented Masimo in

the <u>Masimo I</u> litigation and prosecuted the '830 patent, Masimo argues, does not by itself support a finding of deceptive intent.

Finally, Masimo asserts that its conduct after issuance of the '830 patent shows that it routinely acted in good faith when dealing with the PTO. Specifically, Masimo claims that when Nellcor first deposed Jensen, Nellcor implied that certain undisclosed information was material to the patentability of the invention claimed in '830 patent. Following his deposition, Masimo explains that Jensen timely submitted that information to the PTO in all relevant pending continuation applications. Masimo also points out that it disclosed the Masimo I litigation to the PTO during the reissue proceeding involving the '642 patent. Accordingly, Masimo contends that its pattern of good faith before the PTO shows that it did not prosecute the '830 patent in bad faith.

Nellcor refutes Masimo's attack on the legal standards applied by the district court with respect to both materiality and intent to deceive. Nellcor contends that the district court applied the correct materiality standard under § 1.56. Nellcor argues that Masimo had a duty to disclose both the existence and the substance of the Masimo I litigation during the prosecution of the application leading to the '830 patent, especially after the district court issued its narrow claim construction for the very terms for which Masimo sought broad coverage. Nellcor also points out that Masimo's duty of disclosure did not end with the notice of allowance, but instead continued until the PTO actually issued the '830 patent. Thus, even though Masimo received a notice of allowance prior to the district court's claim construction decision, Nellcor contends that Masimo was still obligated to alert the district court of the claim construction ruling because the '830 patent had not yet issued.

Additionally, Nellcor asserts that Masimo's intent to deceive the PTO can readily be inferred because Jensen represented Masimo during both the Masimo I litigation and the prosecution of the '830 patent, knowing full well that the meaning of the terms "adaptive filter" and "adaptive signal processor" were at issue in both proceedings. What is more, Nellcor points out that Jensen specifically knew that the examining attorney for the '642 patent, who happened to be the same examining attorney for the '830 patent, questioned whether the specification for the '642 patent could support Masimo's "adaptive filter" claims and sought to rewrite those claims to include only an "adaptive noise canceler." Accordingly, Nellcor maintains that the district court correctly held the '830 patent unenforceable for inequitable conduct.

"This court reviews a determination of inequitable conduct for abuse of discretion and reviews the underlying factual issues of materiality and intent for clear error." Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., 326 F.3d 1226, 1234 (Fed. Cir. 2003). To establish that Masimo secured the '830 patent by inequitable conduct, Nellcor must prove by clear and convincing evidence that (1) the omitted or false information was material to the patentability of the invention; (2) Masimo had knowledge of the existence and materiality of the information; and (3) Masimo intended to deceive the PTO. See Molins PLC v. Textron, 48 F.3d 1172, 1178 (Fed. Cir. 1995). Here, we agree with Nellcor that the district court did not abuse its discretion in finding all three elements satisfied.

Masimo mischaracterizes the district court's opinion with respect to the materiality and intent standards. The district court did not apply the wrong materiality standard under §1.56. Paragraph (b) of that regulation provides in pertinent part:

Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and . . .

- (2) It refutes, or is inconsistent with, a position the applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

37 C.F.R. § 1.56(b) (2000) (emphases added). The district court correctly recognized that the Masimo I litigation directly affected the patentability of the invention claimed in the '830 patent because the same terms were at issue in both proceedings. As the district court stated: "The Masimo I dispute was highly relevant to the '830 patent because the '830 and '642 patents share a specification, and Masimo was pursuing an amendment before the PTO that would add to the '830 patent exactly those terms being disputed in the '642 litigation." Mallinckrodt, slip op. at 53. Any decision from the district court regarding the scope of the terms "adaptive filter" and "adaptive signal processor" thus would likely address whether the specification of the '830 patent supported independent claims to an "adaptive filter" and an "adaptive signal processor" or whether such claims should be rejected under 35 U.S.C. § 112 for lack of written description or lack of enablement. Hence, under the standard set forth in § 1.56(b), applied by the district court, we conclude that the existence of the Masimo I litigation and the specific issues presented therein were highly material to the patentability of the application which issued as the '830 patent.

The Manual of Patent Examining Procedure ("MPEP") confirms our conclusion that the Masimo I litigation was material and should have been disclosed to the PTO. Section 2001.06 of the MPEP states: "Where the subject matter for which a patent is being sought is or has been involved in litigation, the existence of such litigation and any other material information arising therefrom must be brought to the attention of the [PTO]." Manual of Patent Examining Procedure § 2001.06(c) (Rev. 2, May 2004). Pursuant to § 2001.06, the fact that the terms "adaptive filter" and "adaptive signal processor" were involved in the '642 litigation, let alone were the sole focus of the claim construction ruling, and the particular subject of the amendment made during the prosecution of the '830 patent imposed a duty on Masimo to inform the PTO of the Masimo I litigation.

Additionally, contrary to Masimo's argument, the district court did not apply the wrong legal standard in inferring that Masimo intended to deceive the PTO by withholding the existence of the Masimo I litigation from the PTO during the prosecution of the '830 patent. "Intent may be inferred where a patent applicant knew, or should have known, that withheld information would be material to the PTO's consideration of the patent application." Critikon, Inc. v. Becton Dickinson Vascular Access, 120 F.3d 1253, 1256 (Fed. Cir. 1997) (citing Driscoll v. Cebalo, 731 F.2d 878, 885 (Fed. Cir. 1984)). Moreover,

[n]o single factor or combination of factors can be said always to <u>require</u> an inference of intent to mislead; yet a patentee facing a high level of materiality and clear proof that it knew or should have known of that materiality, can expect to find it difficult to establish "subjective good faith" sufficient to prevent the drawing of an inference of intent to mislead.

FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1416 (Fed. Cir. 1987) (emphasis in original).

The district court did not infer intent based simply upon Masimo's knowledge of the materiality of the Masimo I litigation. Rather, the district court inferred intent from the actions of Jensen, Masimo's attorney. Any competent attorney registered to practice before the PTO should have known that the Masimo I litigation was material to the patentability of the invention claimed in the '830 patent. After all, a registered attorney is required to be familiar with the laws, regulations, and ethical standards implicated in practicing before the PTO. Hence, that Jensen did not disclose the Masimo I litigation to the PTO, when he for certain knew about it since he was the lead attorney representing Masimo in that litigation, strongly suggests that he intended to deceive the PTO.

Lastly, Masimo's argument regarding its subjective good faith based upon its conduct outside of the prosecution of the '830 patent is unavailing. Masimo's attempt to show a pattern of good faith after the prosecution of the '830 patent is irrelevant to its conduct during the prosecution of the '830 patent. Jensen's subsequent disclosure in other pending applications does not mitigate his failure to disclose the Masimo I litigation or claim construction ruling therein to the PTO during the pendency of the application which issued as the '830 patent. Because Jensen failed to take even the most minimal steps toward any form of disclosure, all the while knowing that the Masimo I litigation had to be material to the patentability of the '830 patent, we can only conclude that the district court did not abuse its discretion in holding the '830 patent unenforceable for inequitable conduct.

iii. Whether the district court abused its discretion in declining to hold the '222 and '850 patents unenforceable due to inequitable conduct

The district court rejected Nellcor's argument, premised upon a declaration by Yorkey, that it invented both Kalman filters, as claimed in the '222 patent, and an "alternative calculation" method, as claimed in the '850 patent, before Masimo. In his declaration, Yorkey stated that by "early 1993" he had "coded software to implement a Kalman filter for computing blood oxygen saturation" and by "mid-1993" he had focused an algorithm "almost exclusively on the use of Kalman filters." Yorkey attached a document entitled "O4 Algorithm Performance Summary," dated August 5, 1994, to his declaration. That document described Nellcor's development of algorithms using alternative calculations, specifically stating that "[s]ince O4 calculates two saturations (with and without C-Lock), O4 arbitrates between them based on an ad hoc rule set to determine the best saturation."

The district court found, however, that Nellcor failed to demonstrate that anything in the Yorkey declaration was material to the patentability of the '222 or '850 patent because Nellcor did not establish that Masimo's priority date was subsequent to the inventions Nellcor alleged were discussed in the Yorkey declaration. In other words, the district court reasoned: "Nellcor has not demonstrated that Masimo could not prove earlier conception, with either reduction to practice prior to Nellcor's claimed invention date or diligent work until its reduction to practice." Mallinckrodt, slip op. at 61. The district court, therefore, concluded that Nellcor failed to offer clear and convincing evidence showing that the Yorkey declaration was material to the patentability of the either the '222 patent or the '850 patent. Accordingly, because the materiality element

of inequitable conduct was not satisfied, the district court declined to consider the intent element and held that the '222 and '850 patents were not unenforceable.

With respect to Nellcor's alternative contention that Masimo intentionally misrepresented to the PTO in the specification of the '222 patent the ability of Nellcor's N-200 pulse oximeter to function with "noise," the district court found that Nellcor misquoted the specification. In particular, the district court found that Nellcor took the statement that all prior art oximeters, which included Nellcor's N-200 product, were "totally inoperative" during movement out of context to mislead the court. After considering the complete passage in the specification, the district court determined that Masimo's statements regarding the prior art were qualified. See '830 patent, col. 2, II. 37-45. For this reason, the district court held that Nellcor failed to demonstrate by clear and convincing evidence that the Barker Study, which Nellcor claimed that Masimo should have disclosed to the PTO during the prosecution of the '222 patent, was material. It thus concluded that Masimo did not commit inequitable conduct by not disclosing those experiments.

Nellcor argues that the district court erred in declining to hold the '222 and '850 patents unenforceable based upon Masimo's awareness of, but failure to disclose, Nellcor's prior invention of both Kalman filters and an "alternative calculation" method.⁵ More specifically, Nellcor contends that Masimo was aware of both Yorkey's declaration and the attachment thereto during the prosecution of the '222 and '850 patents because Nellcor submitted those documents in response to Masimo's motion for a preliminary

Notably, Nellcor challenged the district court's JMOL that Nellcor's O4 algorithm does not anticipate the '850 patent under § 102(g) on prior invention grounds.

injunction in Masimo I. Despite this awareness, Nellcor points out that Masimo did not submit either document to the PTO and, therefore, committed inequitable conduct.

Nellcor further argues that the district court made an error of law in finding Masimo's nondisclosure to be immaterial. Nellcor claims that the district court erroneously required Nellcor to show that Masimo could not trace priority for Kalman filters and "alternative calculations" to the '060 application filed in 1991. Such requirement, Nellcor asserts, is beyond the materiality standard set forth in § 1.56(b). Under that standard, Nellcor claims that Masimo should have been required to submit the Yorkey declaration and attachment to the PTO and then been allowed to refute the implication of prior invention with evidence concerning priority to the '060 application.

Finally, Nellcor renews its alternative theory for why the '222 patent is unenforceable, separate from prior invention, charging that the Masimo made intentional misstatements about the prior art during the prosecution of the '222 patent and failed to disclose material information about Nellcor's N-200 product.

Masimo responds that the Yorkey declaration and attachment are not prior art under § 102(g) because Nellcor's activity described therein did not precede Masimo's date of invention for either Kalman filters or "alternative calculations." In characterizing the two documents as prior art, Masimo contends that Nellcor erroneously focused on Masimo's filing date for U.S. Application No. 08/132,812, which is the parent application of the '222 patent, and the '154 application, which is the parent of the '850 patent, instead of Masimo's actual dates of invention, which Masimo charges precede the Yorkey declaration and attachment. As a result, Masimo claims that it did not have a duty to submit either document to the PTO.

With respect to Masimo's alternative argument, Masimo asserts that the district court correctly noted that Nellcor quoted the discussion of prior art pulse oximeters from the specification of the '222 patent out of context. When correctly quoted, Masimo asserts that the specification of the '222 patent merely discusses the motion problem often encountered with traditional filtering techniques. The specification of the '222 patent did not, Masimo claims, single out any brands or problems associated with those brands. Consequently, Masimo avers that the district court correctly found that the allegedly withheld experiments involving Nellcor's N-200 product were not material to the patentability of the '222 patent.

We agree with Masimo that the district court did not abuse its discretion in declining to find either the '222 patent or the '850 patent unenforceable. First, Masimo is correct that Nellcor erroneously focuses its argument on the filing dates for the '812 and the '154 applications, instead of the invention dates for Kalman filters and "alternative calculations." The district court correctly observed Masimo's dates of invention are not synonymous with the filing dates of the '812 and the '154 applications. Second, Nellcor failed to show that the activities described in the Yorkey declaration and attachment thereto demonstrate that Nellcor invented both Kalman filters and an "alternative calculation" method prior to Masimo. The events described in Yorkey's declaration occurred in the late 1993 to 1994 time frame. Masimo, however, offered evidence showing that it invented the "alternative calculation" method in 1991. Notably, we rejected Nellcor's challenge that the district court erred in denying its motion for JMOL that the '850 patent is invalid under § 102(g) based upon Nellcor's prior invention of the "alternative calculation" method. See infra Section II, A, v. Because the activities

described in the Yorkey declaration and attachment cannot pre-date Masimo's invention of Kalman filters and the "alternative calculation" method, Masimo was not obligated to submit those documents to the PTO during the prosecution of either the '222 patent or the '850 patent. Hence, we conclude that the district court correctly found that the Yorkey declaration and attachment thereto were not material to patentability and thus the district court was not bound to consider whether Masimo intended to deceive the PTO in not disclosing those documents.

Second, like the district court, we are not persuaded by Nellcor's argument that Masimo made intentional misstatements about the state of the prior art in the '222 specification, all the while knowing about the Barker Study. The district court correctly noted that Nellcor, in quoting the specification of the '222 patent, selectively omitted certain words and sentences that Masimo used to qualify the state of the prior art. Indeed, the specification of the '222 patent provides in pertinent part:

Traditional signal filtering techniques are <u>frequently</u> totally ineffective and grossly deficient in removing these motion induced effects from a signal. The erratic or unpredictable nature of motion induced signal components is the major obstacle in removing or deriving them. Thus, presently available physiological monitors <u>generally</u> become totally inoperative during time periods when the measurement site is perturbed.

'222 patent, col. 2, II. 53-60 (emphases added). Viewing this complete passage in context, Masimo did not misinform the PTO about the state of the prior art. Masimo used the words "frequently" and "generally" to generalize its discussion of the prior art. More importantly, as Masimo points out, the specification of the '222 patent did not even mention Nellcor's N-200 pulse oximeter. Thus, there was no need, much less any prompt, triggering Masimo to disclose the Barker Study to the PTO. Because Masimo did not make any misstatements to the PTO about Nellcor's N-200 product, let alone

deceptively intentional ones, we conclude that the district court correctly found that the '222 patent is not unenforceable for inequitable conduct.

III. CONCLUSION

We conclude that the district court, in a thorough and well-reasoned opinion, correctly reversed the jury's finding that Nellcor's infringement of the '222 and '850 patents was willful, correctly upheld the jury's finding of no anticipation under § 102(g) with respect to the '850 patent and under § 102(b) with respect to the '222 patent, did not abuse its discretion in holding that the '830 patent was unenforceable due to inequitable conduct or in declining to hold the '222 and '850 patents unenforceable on inequitable conduct grounds, correctly declined to grant a new trial on the issue of infringement and validity of the '222 patent based on collateral estoppel, and correctly held that claims 17 and 18 of the '222 patent were not invalid for indefiniteness under § 112, second paragraph. Thus, we affirm-in-part. Nevertheless, because the district court erred in overturning the jury's verdict of literal infringement as to the '785 patent and in declining to grant a permanent injunction to redress Nellcor's proven infringement of the '222 and '850 patents, we reverse-in-part. We consequently remand the case to the district court with instructions to enter a permanent injunction in favor of Masimo with respect to the '222 and '850 patents and to re-adjust damages, if necessary, under the re-instated jury verdict of infringement of the '785 patent.