United States Court of Appeals for the Federal Circuit

04-1247

NELLCOR PURITAN BENNETT, INC.
and MALLINCKRODT INC.,

Plaintiffs-Appellants,

v.

MASIMO CORPORATION,

Defendant-Appellee.

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Appealed from: United States District Court for the Central District of California

Senior Judge Mariana R. Pfaelzer

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DECIDED: April 8, 2005

Before NEWMAN, BRYSON, and DYK, Circuit Judges.

BRYSON, Circuit Judge.

Appellants Nellcor Puritan Bennett, Inc., and Mallinckrodt Inc. (collectively, "Nellcor") produce pulse oximeters, medical devices that measure the level of oxygen saturation in a patient's blood. Nellcor owns U.S. Patent No. 4,934,372 ("the '372 patent"), which covers a method and apparatus for using red light, infrared light, and signal processing techniques to measure oxygen saturation noninvasively. Appellee Masimo Corporation makes pulse oximeters that also use red light, infrared light, and signal processing techniques to calculate the patient's arterial blood oxygen level. Nellcor filed suit in the United States District Court for the Central District of California alleging that numerous Masimo products, including the Radical and Rad-9 pulse oximeters and MS circuit boards, infringe claims 1, 2, 20, and 21 of the '372 patent.

The district court granted summary judgment of noninfringement as to all the asserted claims. Nellcor Puritan Bennett, Inc. v. Masimo Corp., 300 F. Supp. 2d 923 (C.D. Cal. 2004). We conclude that the district court made errors in claim construction that affected the judgment. We therefore vacate the judgment and remand for further proceedings.

I

A commonly configured pulse oximeter contains a sensor that is attached to a portion of a patient's body where there is strong blood flow, such as a finger. The pulse oximeter includes one light emitting diode ("LED") that emits red light, another that emits infrared light, and a photodetector that detects the emitted light that passes through the patient's finger from both LEDs. The red light and the infrared light are absorbed in different amounts, respectively, by oxygenated and deoxygenated hemoglobin, so the degree of oxygen saturation of the blood can be calculated based on the differences between the amounts of light detected at the red and the infrared wavelengths.

In addition to differences in the levels of light detection attributable to the degree of oxygen saturation, the amount of light detected by the photodetector in both the red and infrared wavelengths changes in a periodic manner, because as blood pulses through the patient's finger with each heartbeat, more light is detected when there is less blood in the finger and less light is detected when there is more blood in the finger. The detected signals may also contain additional, aperiodic noise caused by the patient's movements or other artifacts unrelated to arterial blood flow. That aperiodic noise, if not suppressed, can interfere with the accuracy of the oximeter's measurements.

Nellcor's '372 patent covers a method and apparatus for digitizing the signals received by the photodetector, processing those signals, separating much of the aperiodic noise from the signal variations caused by the pulsing of the patient's blood, and calculating the oxygen saturation from the processed signal using a well-known formula. Claim 1 of the '372 patent claims the method as follows (emphasis added):

> 1. A method for calculating the amount of a blood constituent from the blood flow characteristics of a patient comprising:
>
> detecting an absorption signal corresponding to the absorption of light measured at two or more wavelengths in the patient's tissue including periodic changes in amplitude caused by periodic arterial pulses in the blood flow characteristics related to the patient's heartbeat and aperiodic changes in amplitude unrelated to the patient's heartbeat, and, for each of the measured wavelengths;
>
> obtaining a time-measure of the absorption signal including periodic information and aperiodic information;
>
> processing the time-measure collectively to determine a composite waveform having a relative maximum and minimum amplitude corresponding to a composite periodic waveform of the periodic information in the time-measure so that the aperiodic information present in the time-measure is attenuated and filtered from the composite; and thereafter
>
> calculating the amount of blood constituent from the relative maximum and minimum amplitude of the composite periodic waveforms of the detected wavelengths.

Claim 2 depends from claim 1; claim 20 is an apparatus claim corresponding to the method of claim 1; and claim 21 depends from claim 20.

The district court construed the phrase "attenuated and filtered" to mean "reduced and removed." The court also ruled that the minimum amplitude of the composite periodic waveform must be part of the composite and that it must be determined and used only after the composite waveform is generated. Based on its claim construction, the court granted summary judgment of noninfringement.

II

Nellcor first contends that the trial court improperly interpreted "attenuated and filtered" to mean "reduced and removed." We agree with Nellcor that the district court's interpretation is incorrect.

The '372 patent describes two embodiments of the invention in detail. The patent first describes a time domain method, which it characterizes as the preferred embodiment of the invention. The time domain method begins with a trigger that is related to the patient's heartbeat and thus indicates the beginning of an arterial pulse. The device then detects optical data from the photodetector for both the red and infrared sources throughout the duration of the pulse. That data is digitized and then moved to a buffer that collects data for the red and infrared signals over time. With each subsequent pulse, new data is gathered and stored in a "new data" buffer. In the preferred embodiment, the value of each data point in the new data buffer is divided by 6, and the values for each of those data points are added to 5/6 of the value of the corresponding data points in the data collection buffer. The sum of those two values is then stored in the data collection buffer, replacing the data previously stored in that buffer. '372 patent, col. 6, line 20, to col. 8, line 49.

Each set of new data contains information from the pulse of interest, together with aperiodic noise. Because the data in the data collection buffer is weighted five times as heavily as the new data that is introduced with each pulse, and because the aperiodic data does not share the same characteristics for each pulse (and thus does not accumulate over time), the effect of using this method of data accumulation is to reduce the effect of the aperiodic data in each pulse by 5/6. Additionally, the effect of

older aperiodic data on the cumulative data is reduced at each triggering event by 1/6. Thus, the aperiodic data is not eliminated altogether, but it is continuously reduced in magnitude in comparison to the desired, periodic data.

A second embodiment of the invention described in the ’372 patent is a frequency domain method that can be used with or without a separate pulse-identifying event. ’372 patent, col. 11, line 12, to col. 12, line 60. In that embodiment, the output of the photodetector for each of the red and infrared signals is digitized at a rate of 57 samples per second for about nine seconds. In the time domain, the amplitude of that data is represented as a function of the time at which the data was sampled. The resulting 512 data points for each wavelength are then averaged; the resulting value represents the average background intensity for each wavelength. That average value is then subtracted from each of the 512 data points for each wavelength. The resulting data is then transformed to the frequency domain using a mathematical operation known as a Fourier transform. The transformation of the data to the frequency domain produces a value for each of a number of frequencies above zero for both the red and infrared wavelengths. The average background intensity of the detected optical signals at the red wavelength and at the infrared wavelength is the amplitude at zero frequency for each of those wavelengths. When the data is transformed to the frequency domain, the amplitude of the pulse data for each wavelength can easily be detected because it is the value located at the pulse frequency.

Because the aperiodic noise has components at many frequencies, the aperiodic noise “appears spread across the frequency domain spectrum.” ’372 patent, col. 11, ll. 53-54. The frequency domain embodiment, however, uses data at only two of the 512

frequencies for each wavelength—the heartbeat frequency (which contains the most useful data for determining blood constituents) and zero frequency (which contains the background level of the optical signals). Accordingly, while some noise still remains at those two frequencies, the noise is not concentrated at those frequencies. The relative impact on the selected data is therefore considerably reduced.

Nellcor contends that the district court erred by construing the term "filtered" to require that the aperiodic signal data be removed rather than simply reduced in comparison to the desired periodic signals. Nellcor submits that the district court's interpretation is not supported by the ordinary meaning of the claim language to one of skill in the art, and that it is not supported by the specification or the prosecution history of the '372 patent.

A standard dictionary prepared by the Institute of Electrical and Electronics Engineers ("IEEE") provides eight different meanings for the noun "filter." Those definitions include a device "that separates data, signals, or material in accordance with specified criteria" and a circuit "that eliminates certain portions of a signal, by frequency, voltage, or some other parameter." IEEE, Authoritative Dictionary of IEEE Standard Terms 435 (7th ed. 2000). It is reasonable to characterize the disclosed processes as involving the separation of signals "in accordance with specified critieria," including their frequency, and it is fair to characterize the process of reducing the relative magnitude of aperiodic noise as the elimination of "certain portions of a signal, by frequency . . . or some other parameter." Thus, two of the definitions of the term "filter" given in the standard dictionary of electrical engineering and electronics are consistent with the

definition proposed by Nellcor; in any event, the IEEE definition certainly does not compel rejection of Nellcor's proposed construction of the term.

The meaning that the patentees intended to accord to the claim phrase "attenuated and filtered" is made clear from an examination of the specification of the '372 patent. In the Background of the Invention portion of the specification, the patent describes one of the objects of the invention as being to "provide enhanced periodic information from which the patient's blood constituent can be accurately determined" by "collecting successive portions of detected optical signals encompassing periodic information for more than one heartbeat and processing the collected portions to attenuate and filter therefrom aperiodic signal waveforms." '372 patent, col. 4, ll. 28-35. That passage summarizes the cumulation technique described in more detail later in the patent as resulting in the attenuation and filtering of aperiodic signals. As such, it indicates that the words attenuated and filtered are used to describe the relative reduction in the significance of aperiodic noise that results from the cumulation technique described in the patent.

The same is true of the more detailed description of the invention in the Summary of the Invention portion of the specification. There, the patent describes the relative reduction of the impact of aperiodic noise on the composite signal through non-synchronous (and thus canceling) addition and through the spreading of noise signals across the relative time frame of the composite signal. '372 patent, col. 7, ll. 3-9. The patent describes that effect, and in particular the small relative weight given to new information as compared to the prior composite, as resulting in new aperiodic information being "quickly and effectively attenuated, and thus filtered out of the

resultant additive portions." Id., col. 7, ll. 21-22. The patent then summarizes the process as follows: "The collective additive sum having synchronized periodic information waveforms thus presents enhanced periodic information that is a composite data set that corresponds to a composite optical pulse from which noise, spurious signals, and motion artifact, have been filtered out." Id., col. 7, ll. 33-38. Because the disclosed process does not actually remove data, but merely results in the suppression of aperiodic noise relative to the periodic signal, it is clear from those passages that the patent uses the terms "attenuated and filtered" to refer to the process of reducing the effect of the aperiodic noise as compared to the periodic signal. Thus, the specification confirms that the claim phrase "attenuated and filtered from the composite" is used to refer to what the patent at one point calls "effective removal" of data, id., col. 8, line 28, rather than the absolute removal of unwanted data, as held by the district court.

Apart from the manner in which the term "filtered" is used in the patent, construing the term "filtered" to require removal of the aperiodic noise would have the effect of excluding all the embodiments described in the specification. That is because none of the embodiments actually "remove" the aperiodic noise from the data used for calculations, as opposed to reducing its relative impact on that data. As this court has explained, a construction that excludes all of the embodiments of an invention is "rarely, if ever, correct." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1996). The fact that the construction adopted by the district court and advocated by Masimo would have the effect of placing all the embodiments of the invention outside the scope of the claims is powerful evidence that the court's construction is incorrect.

Masimo argues that the district court's construction would not mean that the claims would fail to read on all the embodiments set forth in the written description, but we disagree with that contention. The claim language in question provides for "obtaining a time-measure of the absorption signal including periodic information and aperiodic information," and processing that data "to determine a composite waveform" so that "the aperiodic information present in the time-measure is attenuated and filtered from the composite." The portions of the specification that describe that claimed process disclose the use of various means to reduce the impact of the aperiodic data on the resulting composite waveform. In each instance, the aperiodic data is reduced in impact but is not altogether removed from the composite. Thus, in the time domain embodiments of the invention the data is manipulated so that the periodic data cumulates, while the aperiodic data does not. As a result, the relative impact of the aperiodic data is constantly reduced in comparison with the impact of the periodic data. Similarly, in the frequency domain embodiment the selection of only the zero frequency and the heartbeat frequency as the frequencies from which data is obtained has the effect of substantially reducing the effect of aperiodic noise, which is spread across many frequencies, but it does not remove the noise altogether. From the context of the patent, it is clear that those processes are what the patent refers to as attenuation and filtering. See '372 patent, col. 11, ll. 43-58. While it may be that, in hindsight, the patentees would have been wise to choose a word other than "filtered," it is clear that they meant for that term to describe the "relative reduction" processes set forth in the specification. The use of the term in that fashion is not at odds with the understanding of the term "filtered" in the pertinent art, and in the absence of a clear contrary directive

in the patent, we decline to give that term a definition that would exclude the preferred embodiments from inclusion within the language of the claims.

In construing the phrase "attenuated and filtered from the composite," the district court relied heavily on the prosecution history of the '372 patent. The portion of the prosecution history on which the court relied was the applicant's discussion of a prior art patent to New (U.S. Patent No. 4,653,498), which the examiner had cited against the application in an office action. The New patent disclosed a pulse oximeter in which the instrument tested each pulse-like signal against certain parameters to determine whether the signal was related to a heartbeat and therefore should be used in making the blood constituent measurement. The applicants argued that the method used to identify the proper source of meaningful data in New was quite different from the method set forth in the application. In particular, the applicants noted that the New patent disclosed a method consisting of "detecting an absorption signal and determining a related maximum and minimum value in the absorption signal corresponding to a pulse." New's method then evaluated each maximum and minimum "using preselected confidence criteria to determine whether or not they correspond" to a periodic pulse or an aperiodic event unrelated to the patient's heartbeat. In New, the applicants explained, "[a] pulse history is formed based on accepted maximum and minimum signal values that are averaged to smooth out small deviations in pulse rate and oxygen saturation due to physiologic and artifactual noise variations."

The applicants argued to the examiner that the New patent described calculating blood constituents "in a manner that is fundamentally different from, and which does not teach or suggest applicants' claimed invention." In contrast to the New patent, the

applicants claimed that their invention "teaches that by collecting and collectively processing time-measures to obtain a composite waveform from which aperiodic information is removed, and which yields a composite relative maximum and minimum, one does not need to examine each pulse against confidence criteria or to determine whether that pulse is [a] periodic or aperiodic pulse before the blood constituent can be reliably and accurately determined."

The district court seized on the applicants' characterization of their invention as one in which "aperiodic information is removed" from the composite waveform, and concluded from that statement that the reference to aperiodic information being "attenuated and filtered" should be construed to mean that aperiodic information is removed altogether. In context, however, the prosecution history does not support that interpretation. The distinction that the applicants sought to draw between the method described in the New patent and the method used in their invention was between (1) testing each pulse-like event to determine whether it was related to the patient's heartbeat, and (2) using a cumulation technique to separate synchronous pulse events from aperiodic events unrelated to the patient's heartbeat. Their method, the applicants pointed out, reduced the relative amplitude of the aperiodic events through processing and thus effectively removed those events from consideration in the blood constituent measurements. The applicants' reference to the "removal" of aperiodic noise thus must be interpreted to refer to a reduction in the aperiodic noise relative to the desired signal, so that the aperiodic noise does not materially affect the composite waveform generated by the patented method. Accordingly, we do not regard the prosecution history as providing support for the district court's construction of the claim phrase "attenuated and

filtered from the composite waveform." For that reason, and because Nellcor's proposed construction of that phrase as meaning "reduced in comparison to the desired information" is consistent with the written description of each embodiment of the invention, we hold that the district court erred in its construction of that critical claim language and that "attenuated and filtered from the composite waveform" means "reduced in comparison to the desired information."

III

Nellcor next contends that the trial court erred when it ruled that "calculating . . . from the relative maximum and minimum" requires that any calculation using the relative minimum must be made only after formation of the composite signal. We agree with Nellcor that the district court's claim construction is incorrect. The composite signal in the frequency domain embodiment of the '372 patent consists of data for each of 512 frequencies starting at zero frequency. The Fourier transform at zero frequency is equal to the average value of the signal in the time domain and represents the average background intensity of that signal. '372 patent, col. 11, ll. 54-58 & Fig. 10.

In the frequency domain embodiment of the '372 patent, the zero frequency component of the composite signal is computed when the average value of the signal is determined, which is before the transformation for the other frequencies that make up the composite signal. That average value is then subtracted from each of the 512 data points before the Fourier transform is computed for the rest of the 511 frequencies that make up the composite signal.

The district court was correct when it stated that the relative minimum value must be part of the composite signal, but it was incorrect in concluding that the minimum

value may be determined only after the composite waveform is generated. Experience with oximeters has shown that infrared light has a different average detected background intensity than does red light. The detected background intensities for the red and infrared light are represented by the average value of the signal for each of those two wavelengths. Calculating the oxygen saturation of blood requires a determination of the ratio of the difference in absorbance level at those two wavelengths, with the detected average background intensities removed from each. Accordingly, in order to make that calculation, the infrared and red signals have to be normalized relative to one another. In the invention of the '372 patent, the relative maximum values of the infrared and red signals are divided by their respective relative minimum, or zero frequency, components to normalize each relative to the other. This division produces the same result regardless of whether it is performed before or after the transformation of the data to the frequency domain.

The district court found that the placement of the word "thereafter" in claim 1 supported its conclusion that the minimum value could be used only after the composite signal was generated. We disagree. "Thereafter" refers to the time when the amount of blood constituent is calculated, not to the time when the relative minimum is used. By requiring that the relative minimum value be used in any calculation of the oxygen saturation only after the composite signal has been formed, the district court added a limitation that is not present in the claim language and is not supported by the specification or prosecution history. We have stated that we "cannot construe the claim to add a limitation not present in the claim itself." Hewlett-Packard Co. v. Mustek Sys., 340 F.3d 1314, 1325 (Fed. Cir. 2003). In light of our analysis, we believe that

"calculating the amount of blood constituent from the relative maximum and minimum amplitude of the composite periodic waveforms of the detected wavelengths" means only that both the relative maximum and the relative minimum of the red and infrared waveforms must be mathematically used in the oxygen saturation calculation.

On remand, the district court should reassess Nellcor's claim of infringement against Masimo based on the claim construction that we have adopted with respect to the claim term "attenuated and filtered" and the reference to the "relative minimum" value in claim 1 of the '372 patent. While we express no opinion with respect to the ultimate issue of infringement, the changes in claim construction that we have ordered require that the district court reexamine the infringement question. Accordingly, we vacate the district court's summary judgment ruling of noninfringement, and we remand for further consideration based on our construction of the two critical claim terms discussed above.

VACATED and REMANDED.