

United States Court of Appeals for the Federal Circuit

2008-1577
(Interference No. 105, 471)

THOMAS J. YORKEY,

Appellant,

v.

MOHAMED K. DIAB, ESMAIEL KIANI-AZRBAY JANY,
IBRAHIM M. ELFADEL, REX J. MCCARTHY,
WALTER M. WEBER, and ROBERT A. SMITH,

Appellees.

Robert C. Morgan, Ropes & Gray LLP, of New York, New York, argued for appellant. With him on the brief was Marina Len.

Joseph R. Re, Knobbe, Martens, Olson & Bear, LLP, of Irvine, California, argued for appellees. With him on the brief were Brenton R. Babcock, Irfan A. Lateef and Jarom D. Kesler.

Appealed from: United States Patent and Trademark Office
Board of Patent Appeals and Interferences.

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Appeal from the United States Patent and Trademark Office, Board of Patent Appeals and Interferences.

DECIDED: April 7, 2010

Before MICHEL, Chief Judge, GAJARSA, Circuit Judge, and KENDALL, District Judge¹.

MICHEL, Chief Judge.

Appellant Thomas J. Yorkey (“Yorkey”) appeals from a decision of the Board of Patent Appeals and Interferences (the “Board”) denying his motion seeking invalidity of claims 16-18 and 21 of Appellees Mohamed K. Diab, Esmail Kiani-Azraby Jany, Ibrahim M. Elfadel, Rex J. McCarthy, Walter M. Weber, and Robert A. Smith’s (collectively “Diab”) U.S. Patent Application Ser. No. 09/110,542 (the “Diab application”)

¹ Hon. Virginia M. Kendall, U.S. District Court for the Northern District of Illinois, sitting by designation.

on the grounds that the claims fail to comply with the written description requirement of 35 U.S.C. § 112, ¶ 1. Yorkey also appeals from the Board's ruling that he failed to establish a prima facie case of actual reduction to practice and the Board's consequent award of priority to the Diab application over Yorkey's U.S. Patent No. 5,645,060 (the "Yorkey patent"). Because we find that that the asserted claims of the Diab application meet the written description requirement of § 112, we affirm the Board's denial of Yorkey's motion. However, we reverse the Board's finding that Yorkey failed to establish a prima facie case of actual reduction to practice and remand the case to the Board for further proceedings.

PROCEDURAL HISTORY

The patent and patent application at issue in this appeal claim inventions for measuring the concentration of oxygen in blood. Yorkey is named as the inventor of the Yorkey patent, which issued on July 8, 1997 and was based on U.S. Application Ser. No. 08/490,315, filed on June 14, 1995. The patent was subsequently assigned to Nellcor Puritan Bennet, Inc. ("Nellcor") which is the party in interest. Diab is the named inventor of the Diab application filed on July 6, 1998, which claims priority in turn from U.S. Application Ser. Nos. 08/859,837 (filed May 16, 1997) and 08/320,154 (filed October 7, 1994); the party in interest in the Diab application is Masimo Corporation ("Masimo"). An interference (No. 105,471) was declared by the Board on July 18, 2006, and Yorkey was declared the junior party.

Two counts were declared in the interference: Count 1 included claims 1, 2, 8, and 12-16 of the Yorkey patent and 15, 19, and 20 of the Diab application; Count 2

embraced claims 3-5, 7, 10, 11, and 17 of the Yorkey patent and claims 16-18 and 21 of the Diab application.

During the motions phase of the interference, Yorkey filed four motions, all of which were denied by the Board. At issue in the instant appeal is the Board's denial of Yorkey's motion seeking to have Diab's claims corresponding to Counts 1 and 2 denied for failure to comply with the written description requirement of 35 U.S.C. § 112, ¶ 1.

Yorkey also appeals the Board's holding that he failed to establish a prima facie case that he had reduced his invention to practice prior to Diab's benefit date of October 7, 1994.

BACKGROUND

The technology at issue in this case is medical instrumentation designed for the measurement of physiological signals. Specifically, the inventions claimed by the Yorkey patent and the Diab application are directed at the noninvasive measurement of the amount of oxygen in the blood of a patient ("pulse oximetry") which is an indicator of the healthful function of the pulmonary and cardiovascular systems responsible for the delivery of oxygen to the body's tissues.

A major problem in the detection of blood oxygen saturation is the presence of ambient interference ("noise") which can obscure the measurement of blood oxygen saturation by introducing extraneous signals into the recorded measurement. Improving the signal-to-noise ratio is a central concern in the design of biomedical instrumentation for detecting physiological signals, which are often weak when compared to background noise. Certain types of noise can be removed by the use of passive or active bandpass or notch filters (which filter out signals of frequencies that are outside the range of the

signals that the device is attempting to detect). However, if the signal and the noise are coincident within the same range of frequencies, simple frequency filtering is insufficient and a means of separating the signal from the noise in which it is embedded must be contrived.

Prior technologies for the suppression of noise have relied upon the direct subtraction of noise from the signal. However, the claims at issue in the interference are directed to a method of noise filtering that does not directly subtract motion-induced noise from the detected signal. This method relies upon two assumptions: (1) that the amount of actual motion is the same for each of the two separate intensity signals measured by the probe (typically one signal is measured from transmitted light in the red wavelengths of the visible light spectrum and one in the infrared wavelengths); and (2) the motion component portions of the detected signals are proportionate. The relevant portion of Count I is set forth below:

A method for measuring saturation of a blood constituent in a patient comprising the steps of:

irradiating said patient with electromagnetic radiation of two discrete, different wavelengths;

sensing an intensity of said radiation for each of said wavelengths after it passes through a portion of said patient to produce first and second intensity signals including motion components; and

determining said saturation by mathematically manipulating said first and second intensity signals without subtracting said motion components and with the assumptions that

i) an amount of motion is the same at the same time for each of said intensity signals, and

ii) the motion components of said intensity signals are proportional to one another.

Count 2 is similar to Count 1, but includes additional steps directed to determining oxygen saturation in the presence of motion-induced interference. Claim 16 of the Diab application is representative of the claims embraced by Count 2; the claim recites identical language to Count 1 recited above, and continues after the ellipsis:

A method for measuring saturation of a blood constituent in a patient comprising the steps of:

...

taking the logarithm of each representation of said first and second intensity signals;

removing signal portions outside a known band of interest to create first and second filtered signals;

equating the first filtered signal of the first intensity signal to $s + n$, where n is the portion of the signal due to motion and s is the portion of the signal not due to motion;

equating the second filtered signal of the second intensity signal to $r_{as} + r_{vn}$, where r_a is a ratio indicative of saturation;

expressing said representations as a matrix;

using said matrix to determine r_a , by assuming s and n are uncorrelated; and determining said saturation from r_a .²

The latter two limitations are at the heart of the first issue in this case.

DISCUSSION

I. Written Description

The written description requirement set forth by 35 U.S.C. § 112, ¶ 1 states that:

² r_a and r_v represent, respectively, ratios corresponding to arterial and venous oxygen saturation. According to the Diab application, r_a is the ratio indicating oxygen saturation, whereas the motion artifact is in large part due to circulatory movement of venous blood, therefore r_v is a ratio relating the motion component of the two intensity signals. The term s equals the actual signal (light attenuation as a function of arterial oxygen saturation) to be measured, and n equals the motion-induced noise.

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.

35 U.S.C. § 112, ¶ 1. Whether the written description requirement is met is a question of fact. Martek Biosciences Corp. v. Nutrinova, Inc., 579 F.3d 1363, 1369 (Fed. Cir. 2009) (citing Wang Labs., Inc. v. Toshiba Corp., 993 F.2d 858, 865 (Fed. Cir. 1993)). The test for sufficiency of support in a parent application is whether the disclosure of the parent application “reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.” In re Kaslow, 707 F.2d 1366, 1375 (Fed. Cir.1983). This Court will uphold the Board's finding that the Diab application's claims are adequately described so long as that finding is supported by substantial evidence in the record. See Shu-Hui Chen v. Bouchard, 347 F.3d 1299, 1304 (Fed. Cir. 2003).

Yorkey argues that the Board erred in finding that the Diab application's written description of the Count's limitations “assuming s and n are uncorrelated” and “expressing said representations as a matrix” are sufficient to convey to a person of skill in the art that the patentee had possession of the claimed invention at the time of the application. Specifically, Yorkey argues that two of the methods disclosed in the Diab application fail to convey to a person of ordinary skill in the art that Diab had possession of the two limitations when he filed his application.

A. Assuming that s and n are Uncorrelated

With respect to the first limitation, the claim language at issue is as follows:
“using said matrix to determine r_a , by assuming s and n are uncorrelated; and determining said saturation from r_a .”

In support of his argument, Yorkey relies upon the Declaration of his expert, Dr. Elvir Causevic (“Causevic”), who argued that:

[I]n determining r_a using a matrix, Diab makes reiterative calculations and then selects the calculation that minimizes the correlation between s and n . The action and signal processing steps of minimization of correlation are different from assuming the two values (s and n) are already uncorrelated before doing the signal processing.

Moreover, argues Causevic:

To obtain r_a and r_v , an exhaustive scan is executed for a good cross-section of possible values for r_a and r_v The minimum of the correlation function is then selected and the values of r_a and r_v which resulted in the minimum are chosen as r_a and r_v .

Causevic dilated considerably on the argument that the specification’s disclosure reveals a method of minimizing correlation, rather than assuming that s and n are simply uncorrelated, and concludes:

To a person of ordinary skill in the art, performing a scan of 20-50 values is entirely different from a priori assuming that s and n are uncorrelated. When assuming that s and n are uncorrelated, a person of ordinary skill in the art would recognize that no iterative calculation is involved. No effort to determine the minimum degree of correlation is involved. On the other hand, scanning for 20-50 values assumes that there is a correlation and uses the iterative process to find the minimum correlation. Accordingly, Diab’s iterative signal processing step of minimizing a correlation described in their approach is a different approach from assuming that two values (s and n) are uncorrelated, as set forth in claims 16-18 and 21.

(emphasis in original).

The Board was unconvinced. Citing the Declaration of Dr. Gail Baura, Diab’s expert witness, the court noted that the specification of the Diab application described

the limitation “at least four different times in at least four different ways in two embodiments ...” The Board found that, on its face, the Diab application repeatedly described embodiments in which it determined that s and n are uncorrelated. For example: the Diab application contains the description:

[W]here s_1 and n_1 are at least somewhat (preferably substantially) uncorrelated and s_2 and n_2 are at least somewhat (preferably substantially) uncorrelated.

(emphases in Board’s original). The Board found that the description quoted above would have described, by virtue of the phrase “at least ... (preferably substantially) uncorrelated” an embodiment in which s_1 and n_1 are completely uncorrelated. This, found the Board, was consistent with Baura’s testimony that: “It is clear that in assuming s and n to be [at least somewhat] ‘preferably substantially’ uncorrelated, the ideal constraint would be that s and n have no correlation.”

The Board relied heavily on Baura’s testimony, finding her to be a more credible witness than Causevic. The Board criticized Causevic’s testimony for averring that “a person of ordinary skill in the art would recognize that no iterative calculation was involved”, without producing any reason why this should be so.

We defer to the Board’s findings concerning the credibility of expert witnesses. See Velander v. Garner, 348 F.3d 1359, 1371 (Fed. Cir. 2003) (“It is within the discretion of the trier of fact to give each item of evidence such weight as it feels appropriate”). Thus the Board was well within its discretion to give more credibility to Baura’s testimony over Causevic’s unless no reasonable trier of fact could have done so.

At first glance, equating the term “substantially uncorrelated” with “uncorrelated” might be likened to equating the term “substantially not pregnant” with “not pregnant.” However, correlation, like any other mathematical term of art, is a statistical function wherein the significance of the relationship is, in effect, arbitrarily decided. For example, the standard confidence level of $p < 0.05$ indicates at least a 95% probability that a significant statistical relationship does not exist between two sets of values, and that 95% probability limit (not 94% or 96%) is generally (but arbitrarily) accepted as definitive of statistical significance. In the instant appeal, “substantially uncorrelated” could be synonymous with “statistically significantly uncorrelated”, which would in turn be, by definition, synonymous with “uncorrelated.” Although such a value is described by the Diab application as being obtained by a process of iterative calculation, finding the values of s and n that are substantially uncorrelated (and ideally “statistically significantly uncorrelated”) is a necessary preliminary step prior to the ensuing computation.

Furthermore, in addition to the language of the Diab application quoted above, the application similarly states, on pages 101-02, that:

In order to determine r_a and r_v in accordance with this implementation, the energy in the signal s_2 is maximized under the constraint that s_2 is uncorrelated to n_2 . Again, this implementation is based upon minimizing the correlation between s and n

Again, if minimizing the correlation between s and n forms the basis for the ensuing constraint of non-correlation between s_2 and n_2 , then the optimal results will be obtained when the correlation between s and n is at a minimum, below statistical significance, or “uncorrelated.”

Given the deference that we are required to show to the Board’s evaluation of the credibility of Baura over Causevic, and reviewing her declaration testimony, we find that the Board’s ruling that the Diab application possessed the limitation that s and n are assumed to be uncorrelated is supported by substantial evidence in the record and we therefore affirm the Board’s decision in this respect.

B. That the Signal be Expressed as a Matrix Solved for r_a .

The Board likewise found that Baura was more credible than Causevic with respect to the written description of the limitation “expressing said representations as a matrix.” Causevic acknowledges the use of a matrix in the embodiment described by Diab relating to $r_a s + r_v n$. This matrix is used to determine r_a by finding the minimum of the correlation, and appears as follows:

$$\begin{vmatrix} S_{red} \\ S_{IR} \end{vmatrix} = \begin{vmatrix} r_a & r_v \\ 1 & 1 \end{vmatrix} \begin{vmatrix} s_2 \\ n_2 \end{vmatrix}$$

However, Causevic contends that the second embodiment’s description of a “further implementation to obtain r_a and r_v ” does not explicitly refer to the matrix depicted above relating to $r_a s + r_v n$. The Board noted, however, that this observation was not accompanied by any meaningful discussion as to the actual text of Diab’s disclosure.

Page 101 of the Diab application states:

In a further implementation to obtain r_a and r_v , the same signal model set forth above is again used. In order to determine r_a and r_v in accordance with this implementation, the energy in the signal s_2 is maximized under the constraint that s_2 is uncorrelated with n_2 .

The pages of the Diab application immediately preceding the quoted text, beginning on page 98, are contained within a section entitled “Alternative Determination of Coefficients r_a and r_v .” This section begins with a series of equations defining the coefficients r_a and r_v (Eq. 89-91). The text then sets forth a method for the determination of r_a and r_v by determining the minimum (preferably none) correlation between s_k and n_k that can be determined (where $k = 2$) (Eq. 93). The text continues:

Minimizing this quantity often provides a unique pair of r_a and r_v if the noise component is uncorrelated to the desired signal component. Minimizing this quantity can be accomplished by solving Equations (90) and (92) for s_2 and n_2 , and finding the minimum of the correlation for possible values of r_a and r_v . Solving for s_2 and n_2 provides the following [matrix equation].

The text of the Diab application then recites the two-by-two matrix recited above. The text then describes further refinements of the model, inverting the matrix and solving for s_2 and n_2 , and suggesting the use of a Blackman Window as the preferred embodiment for minimizing the correlation of s_2 and n_2 .

The Board gave more credence to Baura’s testimony with respect to this point. Baura points out the explicit language describing “the same signal model” disclosed for the first embodiment (in which the matrix above is employed) as being the one for the “further implementation to obtain r_a and r_v .” Moreover, according to Baura:

It is my opinion that this is referring to the signal model of the first embodiment. It makes sense that the signal model referred to as “set forth above” would refer to the first embodiment model because it immediately precedes the above-quoted statement.

The Board found that Causevic’s failure to state what mathematical methodology, other than the matrix, Diab’s disclosure would have reasonably conveyed to a skilled artisan for the “further implementation” embodiment was fatal to Yorkey’s motion. Likewise Yorkey’s failure to point to any other factual or legal basis for contending that

the absence of an undefined alternative function also necessitated the Board's holding that he had failed to meet his burden.

Given that substantial evidence supports the Board's conclusions, we affirm the Board's finding that Yorkey failed to meet his burden of showing that the limitation "expressing said representations as a matrix" of claims 16-18 and 21 of the Diab application is not supported by a written description in violation of 35 U.S.C. § 112, ¶ 1.

II. Yorkey's Reduction to Practice

Yorkey next argues that the Board erred in holding that he failed to establish a prima facie case that he had reduced Count 1 to practice prior to Diab's benefit date of October 7, 1994. Whether an invention has been reduced to practice is a question of law based on underlying facts. Henkel Corp. v. Procter & Gamble Co., 560 F.3d 1286, 1288 (Fed. Cir. 2009). Accordingly, the Board's ultimate conclusion of reduction to practice is reviewed de novo, while its underlying factual findings are reviewed for substantial evidence. Henkel Corp. v. Procter & Gamble Co., 485 F.3d 1370, 1374 (Fed. Cir. 2007). Substantial evidence "is more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." Consol. Edison Co. v. NLRB, 305 U.S. 197, 229 (1938).

"In order to establish an actual reduction to practice, the inventor must prove that: (1) he constructed an embodiment or performed a process that met all the limitations of the interference count; and (2) he determined that the invention would work for its intended purpose." Cooper v. Goldfarb, 154 F.3d 1321, 1327 (Fed. Cir. 1998). The inventor must also "contemporaneously appreciate that the embodiment worked and

that it met all the limitations of the interference count.” Id. With the exception of very simple inventions (which pulse oximetry is manifestly not), demonstration that the invention works for its intended purpose requires testing. Mahurkar v. C.R. Bard, Inc., 79 F.3d 1572, 1578 (Fed. Cir. 1996). As the junior party to the interference, Yorkey had the burden of proof of establishing actual reduction to practice by a preponderance of the evidence. 37 C.F.R. § 41.121(b) & 41.207(a)(2); see also Bosies v. Benedict, 27 F.3d 539, 541 (Fed. Cir. 1994).³

Count 1, with respect to the Yorkey patent, consists of claim 1, which reads:

A method for measuring saturation of a blood constituent in a patient comprising the steps of:

irradiating said patient with electromagnetic radiation of two discrete, different wavelengths;

sensing an intensity of said radiation for each of said wavelengths after it passes through a portion of said patient to produce first and second intensity signals including motion components; and determining said saturation by mathematically manipulating said first and second intensity signals without subtracting said motion components and with the assumptions that

- i) an amount of motion is the same at the same time for each of said intensity signals, and
- ii) the motion components of said intensity signals are proportional to one another.

Yorkey’s principal evidence of reduction to practice is a computer program, two versions of which (v. 1.0 and 1.1) were archived on June 18 and 23, 1993, respectively. The two versions are identical insofar as the method of Count 1 is concerned. The

³ The Board did not consider, and Yorkey does not argue on appeal that he conceived of the claimed invention prior to Diab’s priority date and exercised reasonable diligence in reducing the invention to practice from conception to his date of constructive reduction to practice.

software has nothing to do with the first two steps of Count 1, i.e., irradiating a patient with electromagnetic radiation of two discrete, different wavelengths and sensing an intensity of the radiation for each of the wavelengths after it passes through a portion of the patient to produce first and second intensity signals including motion components. Rather, the program receives the patient data resulting from those two steps as input.

Two sources of data were used by the program; some data were collected from patients in hospitals and other data were collected from in-house clinical studies known as “breathe-down” tests.⁴ Yorkey argues that the Board erroneously discredited the evidence collected in hospitals because Yorkey did not submit evidence from anyone who was involved in the collection of the hospital data who could corroborate that the data was collected in accordance with the methods described in the Count. Specifically, the Board noted that it was “uncertain and speculative” whether the data charts referred to in Yorkey’s motion corresponded to the data collected by Yorkey’s research associate, Clark R. Baker (“Baker”) in the breathe-down tests, or whether it was gathered from the hospital patients. The Board found this purported ambiguity significant in that it could not assume that the data, if collected from the hospital patients, was generated via the first two steps recited in the Count and included a motion component.

Yorkey argues that, on the contrary, testimony by Baker demonstrated that the data collected both at hospitals and in the in-house breathe-down tests identified the

⁴ In the breathe-down tests, volunteer subjects breathed a gas mix, administered by an anesthesiologist, containing sub-atmospheric concentrations of oxygen to decrease their blood oxygen saturation levels.

model of oximeter used to collect the data, the Nellcor N-200 oximeter. In fact, Baker testified that:

I generated a series of charts, illustrating the oxygen saturation values computed by (a) the various saturation algorithms we had implemented and (b) the pulse oximeter that had been used to collect the data (e.g., the Nellcor N-200).

And indeed, the charts do show a line labeled N-200, which could reasonably be apprehended as corresponding to data from the Nellcor-200 oximeter. Moreover, the Yorkey patent illustrates oximetry data showing two separate wavelengths, although the model of the oximeter is not identified, nor did Yorkey provide any direct evidence that the Nellcor N-200 model oximeter uses two wavelengths

The Board clearly erred in finding that the issue of whether the data referred to in Baker's testimony was derived from hospital patient data or from the breathe-down tests creates a fatal ambiguity in Yorkey's claim of reduction to practice. Baker testified that "Nellcor's clinical engineers had collected patient data in hospitals. The patients had been moving during some aspect of the data collection." (emphasis added). Although Baker may have had no direct knowledge that the patients were actually moving during the tests conducted by Nellcor's engineers, such direct knowledge is not necessary. See, e.g., Cooper v. Goldfarb, 154 F.3d 1321, 1330 (Fed. Cir. 1998) ("In order to corroborate a reduction to practice, it is not necessary to produce an actual over-the-shoulder observer."). Furthermore, Baker averred that he had observed, via a manual examination of the regularity of the oximetry data, whether the changes in value were attributable to motion or physiological changes. By comparing the saturation from oximetry probes collecting data simultaneously at different sites on the body, Baker was able to determine whether a change in the blood saturation data was due to induced

motion or to other physiological causes. In short, Baker was able to determine whether the data included a motion component by inspection of the collected data, regardless of whether the data was derived from hospital patients by Nellcor engineers or from the breathe-down test volunteers.

Moreover, Baker testified that the data used was derived from pulse oximeters (i.e., the Nellcor N-200). The Yorkey patent describes oximeters as typically emitting two wavelengths of light. Yorkey patent at Col. 2, ll. 2-4 (“The oximeter relies on mathematical analysis of the reading at two different wavelengths”). Furthermore, the Yorkey software requires input from two discrete wavelengths, red and infrared, to complete its saturation analysis. We conclude therefore, that the issue of whether the data presented by Yorkey as evidence of his reduction to practice was derived from hospital patients or from breathe-down volunteers does not undermine Yorkey’s claim that he had successfully reduced to practice his invention prior to Diab’s benefit date of October 7, 1994.

The Board next found that the two versions of the computer program archived by Yorkey in 1993 were thirty-six and thirty-seven pages long respectively, and neither version was accompanied by an explanatory flow chart tracking the operational flow of the program. The Board found the program not to be self-explanatory, and objected to the notion that it should be required to undertake an independent determination of what each line of code means.

In his priority motion, Yorkey contended that the program was “based on” his “eta methodology”, troubling the Board with what precisely “based on” might mean. The Board found that Yorkey had explained what the eta methodology is with sufficient

clarity, but had failed to show that the computer program implements or executes it. In particular, the Board found that Yorkey had not specifically identified in the software: (1) the input interface; (2) the output interface; or (3) the sequence of computational steps and calculations which transforms the input patient data to the determined oxygen saturation output. In other words, the Board found that Yorkey had made an inadequate showing as to how the computer program implements the central equation of the eta methodology.

Specifically, the Board found that Yorkey's only argument supporting the implementation of the eta methodology equation in his motion comprised the following lines:

The software set forth code for two or more wavelengths, taking the logarithm of each representation of the first and second intensity signals, and using a high pass filter to provide the functionality of taking the derivative of the logarithm.

According to the Board, this conclusory statement that assumptions were made in writing the program was inadequate and unpersuasive.

Yorkey takes umbrage at the Board's finding, responding that it was both based on a faulty premise and irrelevant. According to Yorkey, his testimony, and that of Baker, establishes that Count 1's assumptions were taken into account when the software code was written. The lines of code, according to Yorkey, are the embodiment of the assumptions and corroborate Yorkey's and Baker's testimony.

Specifically, Yorkey maintains that he and Baker explained in detail how the software works to implement the eta methodology. He contends that the following lines of code indicate that red and infrared wavelengths were to be used by the software, with a placeholder for other possible wavelengths:

```

struct LED
long
    IR,
    Red,
    Other

```

The software subsequently log-converts these signals and then differentiates the infrared- and red-wavelength signals using a differential high pass filter — the implementation enabled by the mathematical equation of the intensity function and the assumptions concerning motion as described in the following lines:

```

"if (hardware Log == FALSE)
*newir = (float) log ((double) *newir);
*newred = (float) log ((double) *newred)"
**newir = hpf (*newir, 0);
*newred = hpf (*newred, 1)"

```

These lines of code, according to Yorkey, followed by saturation determination, embody Count 1's assumptions in the form of log conversion and differentiation calculations on both red- and infrared-wavelength signal intensities.

Yorkey further argues that he and Baker identified in the code the ratio-of-ratios ("ROR") saturation calculation. Yorkey argued to the Board that Baker's notation on the test results that: "the eta sat calculator used here was incapable of calculating sat[uration]s for which the ratio-of-ratios approached or exceed 1.0" indicated application of the eta methodology. According to Yorkey, this characteristic of the ROR method is referred to in the Yorkey patent. See Yorkey patent at Col. 7, ll. 34-37.

Yorkey then quoted a portion of the code demonstrating the use of the ROR:

```

if (RoR) < (float)RoRMax)
sat = (betas.betaRred - RoR * betas.betaRir) /
(betas.debetair * RoR - betas.dbetared);
else
sat = - 1;
return (sat);13

```

Importantly, Yorkey's explanations of the computer program are found in his declaration and are corroborated by Baker's declaration.

According to Yorkey, the Yorkey patent teaches that, following logarithmic conversion and differentiation, oxygen saturation can be calculated by mathematically manipulating the intensity signals, without subtracting an independently monitored motion signal, using matrix algebra. The Yorkey patent teaches:

For example, to account for motion and noise, we can modify equation (1) by multiplying by a time varying function $\eta(t)$ representing wavelength-independent motion or noise. This gives the following equation:

...

We can then solve for s using the same steps as used above.

First, we take the logarithm:

...

Next, we differentiate with respect to time:

...

Then, we determine the ratio of Red to IR:

...

Now if $d \log \eta/dt$ is large compare to the other terms the ratio of ratios will be driven towards unity, driving s towards a wavelength-dependant constant. So because in this model optical coupling due to motion appears identically in both wavelengths, its presence drives the saturation to this wavelength-dependant constant.

The present invention thus allows a calculation of blood oxygen saturation by mathematically recognizing the motion signal.

Yorkey patent at Col. 5 ll. 23-53 (equations omitted). The term $\eta(t)$ is the time-dependent motion signal Yorkey argues is the basis of the eta methodology, which determines the ROR without subtracting the motion signal. And, as explained by the Yorkey patent's teaching above, this forms the basis of a calculation of oxygen saturation. Yorkey argues that his testimony, and Baker's, thus established a prima

facie case that Count 1 had been successfully reduced to practice and that the Board's contrary finding is erroneous.⁵

We find that Yorkey met his burden of establishing a prima facie case of actual reduction to practice. The Board acknowledged that the first claim and its limitation were met by Baker's testimony and data with respect to the breathe-down tests. Moreover, the "two discrete wavelengths" limitation is met by the software code, which requires inputs from infrared ("IR") and red ("Red") wavelengths as well as possible other ("Other") wavelengths.

Finally, the limitation of:

[D]etermining said saturation by mathematically manipulating said first and second intensity signals without subtracting said motion components and with the assumptions that

- i) an amount of motion is the same at the same time for each of said intensity signals, and
- ii) the motion components of said intensity signals are proportional to one another.

is met by Yorkey's explanation of the code with respect to the determination of the ROR, which is in turn based upon the eta methodology, which implicitly meets limitations i and ii, i.e., because $\eta(t)$ is only a time-dependent factor, and is used to determine the ROR, it must be the same for each of the signals and proportionate to them. Therefore, Yorkey has met his burden of establishing a prima facie case showing that his invention met the limitations of Count 1 and worked successfully for its intended purpose.

⁵ Yorkey argues that the method was successful in measuring blood oxygen saturation, noting Baker's comment of "eta wins" accompanying the data resulting from the testing. The Board does not contest that fact.

For the foregoing reasons, we reverse the Board's rulings that Yorkey failed to establish a prima facie case of actual reduction to practice of Count 1 prior to the Diab application's benefit date of October 7, 1994. We consequently remand this case to the Board for further proceedings consonant with this order.

CONCLUSION

For the reasons set forth above, we affirm the Board's ruling that the asserted claims of the Diab application meet the written description requirement of § 112 and its denial of Yorkey's motion. However, we reverse the Board's finding that Yorkey failed to establish a prima facie case of actual reduction to practice of Count 1 prior to the Diab application's benefit date of October 7, 1994. We therefore remand this case to the Board for further proceedings consonant with this order.

AFFIRMED IN PART, REVERSED IN PART, AND REMANDED