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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte HUAN-PING WU[1]

Appeal 2017-007857
Application 12/329,698
Technology Center 1600

Before DEBORAH KATZ, JOHN G. NEW, and TIMOTHY G. MAJORS, *Administrative Patent Judges*.

NEW, *Administrative Patent Judge*.

DECISION ON APPEAL

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[1] Appellant identifies Ascensia Diabetes Care Holdings AG as the real party-in-interest. App. Br. 1.

SUMMARY

Appellant files this appeal under 35 U.S.C. § 134(a) from the Examiner's Final Rejection of claims 1–5, 7[2]–13, 16, 18–27, 83, and 84 as unpatentable under 35 U.S.C. § 101 as being directed to nonstatutory subject matter.

Claims 1–5, 7–13, 16, 18–27, 83, and 84 also stand rejected as unpatentable under 35 U.S.C. § 112, second paragraph, as being indefinite.

Claims 1, 4, and 5 stand rejected as unpatentable under the nonstatutory doctrine of obviousness-type double patenting over claims 1, 4, 5, 6, 18, and 24 of Huang et al. (US 9,164,076 B2, October 20, 2015) (the "'076 patent").

We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM-IN-PART.

NATURE OF THE CLAIMED INVENTION

Appellant's invention is directed to a biosensor system that adjusts a relation for determining analyte concentrations in a biological sample from output signals with one or more index functions responsive to one or more errors that could bias the determined analyte concentrations. Spec. ¶ 20.

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[2] Independent claim 7 is not listed as a claim on appeal in the Examiner's Final rejection, or otherwise addressed by the Examiner. *See* Final Act. 1. However, claims 8–12, which depend from claim 7, were included in the Examiner's rejections under 35 U.S.C. §§ 101 and 112, second paragraph. *Id.* We therefore include independent claim 7 in our analyses with respect to these rejections.

REPRESENTATIVE CLAIM

Claim 1 is representative of the claims on appeal and recites:

1. A method for determining an analyte concentration in a fluid sample via a biosensor system comprising:

providing an analyte measurement device and a sensor strip, the analyte measurement device including a storage device, a sensor interface, and a processor, the processor coupled to storage device and the sensor interface, the sensor interface for receiving the sensor strip, the sensor strip including an electrode that contacts the sensor interface of the measurement device when the sensor strip is placed in the sensor interface;

applying an electrical input signal to the sample via the electrode of the sensor strip when the sensor strip is placed in the sensor interface of the analyte measurement device and a fluid sample is applied to the sensor strip;

generating at least one output signal value from an analysis of the fluid sample via the sensor interface of the analyte measurement device, the at least one output signal value responsive to the analyte concentration in the sample;

determining at least one ΔS value from at least one error parameter via the processor of the analyte measurement device, where the at least one ΔS value is a value of slope deviation or a value of normalized slope deviation in relation to at least one previously determined reference correlation relating previously determined reference output signal values to reference sample analyte concentration values, the previously determined reference sample analyte concentration values obtained from a reference instrument, the previously determined reference correlation stored in the storage device of the analyte measurement device, and where the at least one error parameter causes one or more errors in the at least one output signal value; and

> determining the analyte concentration in the sample from the at least one output signal value, the at least one ΔS value, and the at least one previously determined reference correlation relating the at least one output signal value to one of the reference sample analyte concentration values via the processor of the analyte measurement device,
>
> where the determining the analyte concentration in the sample comprises adjusting the at least one previously determined reference correlation with the at least one ΔS value, and
>
> where the determining the at least one ΔS value from at least one error parameter and the determining the analyte concentration in the sample from the at least one output signal value are performed by the processor of the analyte measurement device using computer readable software code.

App. Br. 27–28.

ISSUES AND ANALYSIS

We decline to adopt the Examiner's findings, reasoning, and conclusion that Appellant's claims 1–5, 7–13, 16, 18–27, 83, and 84 are directed to nonstatutory subject matter or indefinite. However, we adopt the Examiner's conclusion that claims 1, 4, and 5 are obvious under the nonstatutory doctrine of obviousness-type double patenting. We address the arguments raised by Appellant below.

A. Rejection of claims 1–5, 8–13, 16, 18–27, 83, and 84 under 35 U.S.C. § 101

Issue

Appellant argues that the Examiner erred in finding that the claims recite no more than an abstract concept and are therefore directed to nonstatutory subject matter. App. Br. 9.

Analysis

In performing an analysis of patentability under Section 101, we follow the framework set forth by the Supreme Court in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012). We are also mindful of, and guided by, the USPTO's *2019 Revised Patent Subject Matter Eligibility Guidance*, 84(4) Fed. Reg. 50–57 (January 7, 2019) (the "2019 Guidance").

Appellant's claim 1 recites: "A method for determining an analyte concentration in a fluid sample via a biosensor system comprising…." Following the first step of the *Mayo* analysis, we agree with the Examiner that the claims are directed to a method or "process" and therefore fall into one of the broad statutory categories of patent-eligible subject matter under 35 U.S.C. § 101. Final Act. 2.

In the next step of the *Mayo* analysis, we determine whether the claims at issue are directed to a nonstatutory, patent-ineligible concept, i.e., a law of nature, a phenomenon of nature, or an abstract idea. *Mayo*, 566 U.S. at 70–71. If the claims are so directed, we next consider the elements of each claim both individually and "as an ordered combination" to determine whether additional elements "transform the nature of the claim" into a

patent-eligible application. *Id.* at 78–79; *see also Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1375 (Fed. Cir. 2015). Specifically, the Supreme Court considered this second step as determining whether the claims recite an element or combination of elements that is "sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself." *Mayo*, 566 U.S. at 72–73.

More specifically, in this second step of the *Mayo* analysis, we look to whether the claim recites one of the judicially-created exceptions to Section 101, i.e., an abstract idea, a law of nature, or a natural phenomenon. *See* 2019 Guidance 54 (step 2A, prong 1). In the case of claims reciting an abstract idea, these exceptions comprise mathematical concepts, certain methods of organizing human activity, and mental processes. *Id.* If we determine that the claim is directed to a judicial exception, we then determine whether the limitations of the claim reciting the judicial exception are integrated into a practical application. *Id.* (step 2A, prong 2).

Finally, if we determine that the claim is directed to a judicially-created exception to Section 101, we evaluate assess the claims under step two of the Mayo analysis, considering the elements of each claim both individually and "as an ordered combination" to determine whether additional elements "transform the nature of the claim" into a patent-eligible application. *Mayo*, 566 U.S. at 78–79; 2019 Guidance at 56 (Step 2B).

Claim 1 recites, in relevant part:

> [D]etermining at least one ΔS value from at least one error parameter via the processor of the analyte measurement device, where the at least one ΔS value is a value of slope deviation or a value of normalized slope deviation in relation to at least one previously determined reference correlation relating previously determined reference output signal values to reference sample

> analyte concentration values, the previously determined reference sample analyte concentration values obtained from a reference instrument, the previously determined reference correlation stored in the storage device of the analyte measurement device, and where the at least one error parameter causes one or more errors in the at least one output signal value; and
>
> determining the analyte concentration in the sample from the at least one output signal value, the at least one ΔS value, and the at least one previously determined reference correlation relating the at least one output signal value to one of the reference sample analyte concentration values via the processor of the analyte measurement device,
>
> where the determining the analyte concentration in the sample comprises adjusting the at least one previously determined reference correlation with the at least one ΔS value, and
>
> where the determining the at least one ΔS value from at least one error parameter and the determining the analyte concentration in the sample from the at least one output signal value are performed by the processor of the analyte measurement device using computer readable software code.

The Examiner finds that these "determining" limitations recited in claim 1 are directed to an ineligible mathematical concept. Final Act. 2. Specifically, the Examiner finds the limitations recite determining the slope differential (ΔS) between a measured analyte concentration function and a reference function, and then using the ΔS to determine the actual analyte concentration by removing possible sources of error, such as temperature, hematocrit levels, etc. Final Act. 2–3; *see also, e.g.*, Spec. Fig. 5; ¶¶ 88–94.

We agree with the Examiner's conclusion at this step of the analysis. Claim 1 recites: "generating at least one output signal value." The "determining" steps of the analysis relate to a comparison of the measured output signal value (i.e., the slope function derived from measurements of the actual test analyte) and comparing the derived slope values to a set of reference values stored previously to arrive at a slope deviation, ΔS. This ΔS value is then used to correct for possible error parameters that can cause differences between the measured slope function and the stored reference slope function, and to arrive at a corrected and accurate analyte concentration value. Although the claims do not expressly recite mathematical formulae for determining ΔS, the Specification discloses algorithms for the determination of ΔS, and for using ΔS in correcting the measured analyte slope function to obtain an accurate analyte concentration value, which are fairly characterized as mathematical relationships. *See* Spec. ¶¶ 84, 92, 104, 107, 111.

Furthermore, claim 1 also recites a "processor" upon which these quantitative values may be determined and a "storage device" from which the reference values may be retrieved for comparison with the measured values. Claim 1 additionally recites that: "the at least one output signal value [is] performed by the processor of the analyte measurement device using computer readable software code." Claim 1 thus relates to the manipulation of mathematical data (comparing derived values to stored values to correct for measurement error) by a processor using computer-readable software code. We therefore conclude that the claims recite a mathematical relationship, which is a category of an "abstract idea" and an exception to Section 101. *See* Mayo 566 U.S. at 89.

Our analysis, however, does not end there. We next look to evaluate whether the claim recites additional elements that integrate the exception into a practical application. 2019 Guidance 54. We perform this evaluation by: (1) identifying whether there are any additional elements recited in the claim beyond the judicial exception(s); and (2) evaluating those additional elements individually and in combination to determine whether they integrate the exception into a practical application. *Id.* at 54–55.

Claim 1 also recites:

> [A]n analyte measurement device and a sensor strip, the analyte measurement device including a storage device, a sensor interface, and a processor, the processor coupled to storage device and the sensor interface, the sensor interface for receiving the sensor strip, the sensor strip including an electrode that contacts the sensor interface of the measurement device when the sensor strip is placed in the sensor interface.

This device is then employed by:

> [A]pplying an electrical input signal to the sample via the electrode of the sensor strip when the sensor strip is placed in the sensor interface of the analyte measurement device and a fluid sample is applied to the sensor strip

The end result of the ensuing "determining" steps recited in the claim is the determination of: "the analyte concentration in the sample."

Claim 1 is thus directed to a specific analyte measurement device, comprising: (1) a storage device; (2) a sensor interface; (3) a processor coupled to the storage device; and (4) a sensor interface for receiving a sensor strip including an electrode. This device is used in a specific application or method as recited in claim 1, i.e., the accurate measurement of

an analyte (i.e., blood glucose concentration; *see*, *e.g.*, Spec. ¶ 14). The recited mathematical concept described *supra* is employed within the device to ensure an accurate reading of the analyte by correcting for possible errors.

The mathematical processes recited in the claims are thus incorporated into a specific device that is recited in the claim and used in a specific application: *viz.*, the accurate, corrected measurement of an analyte. We therefore conclude that the claims recite additional elements that implement the judicial exception with, and uses a judicial exception in conjunction with, a particular machine or manufacture that is integral to the claim. *See, e.g.*, *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 64–65 (1923).

We note that the claims on appeal differ from those at issue in *Diamond v. Diehr*, 450 U.S. 175 (1981), in that they are not directed to a transformation or reduction of a particular article to a different state or thing. *Diehr*, 450 U.S. at 184. Nevertheless, we conclude that the claims are directed to a sufficiently specific and non-abstract application, i.e., determining the concentration of an analyte. Furthermore, we note that the measurement of a defined substance or property is the very essence of a measurement device.

We therefore conclude that, although the claims may recite a mathematical concept, the claim also recites additional elements that integrate the exception into a practical application. As such, the claims are not directed solely to a judicial exception to Section 101, and our eligibility analysis concludes there. *See* 2019 Guidance 54. We consequently reverse the Examiner's rejection of the claims upon this ground.

B. Rejection of claims 1–5, 8–13, 16, 18–27, 83, and 84 under 35 U.S.C. §112, second paragraph as being indefinite

Issue 1: "reference correlation"

Appellant argues that the Examiner erred in finding that the claim term "one previously determined reference correlation" is indefinite. App. Br. 20.

Analysis

The Examiner finds that claim 1 does not set forth any previous steps whereby a "reference correlation" is previously determined or provided. Final Act. 6. The Examiner also finds that the claim does not set forth any previous steps by which "reference sample analyte concentration values" are determined or provided. *Id.* The Examiner therefore contends that the claim is incomplete because it omits essential steps. *Id.*

The Examiner further finds with respect to the claim language reciting "relating … output signal values to reference sample analyte concentration values," it is unclear what positive process limitation(s) is/are intended. Final Act. 6. The Examiner finds that this feature does not impart any active method steps (i.e. relating two things), but merely describes the nature of the reference correlation (i.e., the nature of the data). *Id.*

Appellant responds that the reference correlation is a predetermined (e.g., calculated in advance) set of values and is stored in the measurement device for use in the measurement process. App. Br. 20. Appellant argues that a person of ordinary skill in the art would have understood "reference correlation" to mean a standard or reference relationship between output

current and analyte concentration. *Id.* Appellant contends, by way of example, that a 100 nA analytic output signal may correspond to a 50 mg/dL analyte concentration in the reference correlation. *Id.* Therefore, argues Appellant, when a 100 nA analytic output signal is received, the sensor would output an analyte concentration of 50mg/dL, based on the reference correlation. *Id.* Appellant asserts that the term "reference correlation obtained from a reference instrument" is explained in paragraph [0086] of Appellant's Specification, and refers to previous test data of analyte concentrations and corresponding output currents that are used to assemble the correlation. *Id.*

According to Appellant, a person of ordinary skill in the contemporary art would not have found this term indefinite, as explained in the Declaration of the inventor, Dr. Huan-Ping Wu (the "Wu Declaration"). App. Br. 20 (citing Wu Decl. ¶ 7). Furthermore, contends Appellant, a person of ordinary skill in the art would have understood that the previous steps recited in claim 1 involved obtaining reference sample analyte concentration values from a reference instrument and assembling a reference correlation table for storage and use in the method in claim 1. *Id.*

We agree with Appellant. Paragraph [0086] of Appellant's Specification discloses, in relevant part:

> Thus, the output signal preferably has a linear relationship with the analyte concentration in the sample and may originate from a redox reaction, light-identifiable species, or other process. The reference correlation equation describes a function relating the output signals from a biosensor system to analyte concentration values determined from a reference instrument. For example, the output signal from a biosensor system for a specific sample may be related to the analyte concentration values determined from a YSI reference instrument for the same sample.

With respect to the last sentence quoted *supra*, paragraph [0012] of Appellant's Specification further discloses that: "Accepted reference values may be obtained with a reference instrument, such as the YSI 2300 STAT PLUS™ available from YSI Inc., Yellow Springs, Ohio." We agree with the Appellant that a person of ordinary skill, having read the language of the claims in light of the Specification, would have understood that the claim term "reference correlation" refers to a set of previously or concurrently determined reference values obtained by a standard reference measurement instrument, e.g., a YSI 2300 STAT PLUS™.

Furthermore, Dr. Wu opines that:

> It is known in the art that a reference correlation can be determined by a reference instrument such as a glucose analyzer manufactured by YSI. To obtain the reference correlation, different samples of varying analyte concentrations are measured and the corresponding output currents are recorded. After sufficient testing samples are taken, a reference correlation may be obtained that correlates different current values with corresponding analyte concentrations. This reference correlation is stored and used by a processor in the actual instrument to output the analyte concentration corresponding to a generated output current.

Wu Decl. ¶ 7. We are persuaded by Appellant that the storage of previously collected reference data from a standard instrument, for the purposes of comparison with test measurements, is an ordinary practice in the art of analyte sensing that would have been reasonably understood by a skilled artisan. We therefore reject the Examiner's findings and conclusion.

Issue 2: "error parameter"

Appellant argues that the Examiner erred in finding that the claim language reciting: "where the at least one error parameter causes one or more errors in the output signal," is indefinite with respect to how error parameters cause one or more errors in the output signal. App. Br. 20.

Analysis

The Examiner finds that the claim term "causes" appears to be nothing more than an intended use recitation of the error parameter, and it is unclear to the Examiner in what way an error parameter "causes" errors in the output signal. Final Act. 6. Consequently, the Examiner finds, it is unclear as to what the limiting effect of the claimed error parameter is intended by this phrase such that one of ordinary skill in the art would know how to avoid infringement. *Id.* The Examiner further finds that a review of Appellant's Specification does not provide any limiting definition or clarifying examples. *Id.*

Appellant responds that claim 1 is directed to a method for compensating for an actual error by adjusting the reference correlation. App. Br. 21. Appellant asserts that a person of ordinary skill in the art would understand that errors are present in measuring an analyte, due to factors such as temperature or hematocrit content, that will distort the reading as explained in paragraph [0013] of the Specification. *Id.* (also citing Wu Decl. ¶ 8). According to Appellant, compensating for such errors to produce a more accurate analyte concentration reading is the inventive feature of Appellant's claims. *Id.*

Appellant argues further that the term "error parameter" is also explained in paragraph [0094] of the Specification as being any value

responsive to one or more errors in the output signal. App. Br. 21. Appellant explains that these errors are not measured or determined from the signal separately. *Id.* For example, Appellant contends, temperature or hematocrit content can result in error in the output signal, but the output signal does not have a separate component that is measured for this error. *Id.* Appellant contends that, because such errors are known to be in the output signal value, and because these error parameters cause such errors, the claimed process corrects such errors by employing the correction function based on slope deviation for such conditions. *Id.* Appellant argues that a person of ordinary skill in the art would have understood that the claimed method corrects the error caused by the error parameters. *Id.*

We are persuaded by Appellant's argument. Appellant's Specification discloses:

> Biosensor systems may provide an output signal during the analysis of the biological fluid that includes one or multiple errors. These errors may be reflected in an abnormal output signal, such as when one or more portions or the entire output signal is non-responsive or improperly responsive to the analyte concentration of the sample. These errors may be from one or more contributors, such as the physical characteristics of the sample, the environmental aspects of the sample, the operating conditions of the system, interfering substances, and the like. Physical characteristics of the sample include hematocrit (red blood cell) concentration and the like. Environmental aspects of the sample include temperature and the like. Operating conditions of the system include underfill conditions when the sample size is not large enough, slow-filling of the sample, intermittent electrical contact between the sample and one or more electrodes in the sensor strip, degradation of the reagents that interact with the analyte, and the like. Interfering substances include ascorbic acid, uric acid, acetaminophen, and the like.

> There may be other contributors or a combination of contributors that cause errors.

Spec. ¶ 13. The Specification further discloses that such errors are well known in the art and that various techniques have been employed as a means of correcting those errors so as to provide accurate analyte measurement. Spec. ¶¶ 14–17.

Dr. Wu further attests that factors causing errors in analyte measurement are well known to those of skill in the art:

> A problem with using a reference correlation is that the concentration values may be subject to errors based on external factors such as temperature or hematocrit content that differ from those when the testing was conducted to determine the reference correlation. For example, if the reference correlation was taken at a hematocrit content of 42% and an analytic output signal is taken from a sample with a hematocrit content of 60%, the biosensor will inaccurately report a different analyte concentration value at the higher hematocrit content of 60% using the reference correlation. One skilled in the art would understand that such an error will occur as it is well understood that such external factors distort the readings.

Wu Decl. ¶ 8.

Appellant's Specification further discloses that:

> An index function may be responsive to an error parameter, such as temperature, which is measurable by another means. An index function may be a calculated number that correlates with an error parameter such as hematocrit and represents the influence of this error parameter on the slope deviation ΔS. Thus, error parameters may be any value responsive to one or more errors in the output signal and may be measured, calculated, or determined through other means. Index functions may be experimentally determined as a regression equation of the plot between ΔS_{cal} and an error parameter.

> Other methods may be correlated with error parameters, such as the %-hematocrit level of whole blood samples. For example, US Patent No. 7,338,639 describes using AC phase angle measurements to determine the hematocrit level and temperature errors associated with whole blood samples. EP 1,742,045 A1 describes the determination of the hematocrit by an independent electrode and the correlation of the hematocrit level with output currents.

Spec. ¶¶ 94–95 (paragraph numbers omitted).

The combined evidence thus teaches that it was well known in the art that a number of factors can cause quantitative errors in analyte measurement and that it is of concern of those in the art to devise methods of correcting for such error parameters. We therefore agree with Appellant that a person of ordinary skill in the art, upon reading the claims in light of the Specification, would have understood what is meant by the language of claim 1 reciting "at least one error parameter causes one or more errors in the at least one output signal."

Issue 3: "reference sample analyte concentration"

Appellant argues that the Examiner erred in finding the language of claim 1 reciting: "reference sample analyte concentration" is indefinite and "appears from out of nowhere." App. Br. 21 (quoting Final Act. 6).

Analysis

The Examiner finds that claim 1 recites: "determining the analyte concentration … where the determining the analyte concentration in the sample comprises adjusting the at least one previously determined reference

correlation with the at least one ΔS value." Final Act. 6. The Examiner finds that it is unclear what positive process limitations are intended by the above phrase. *Id.* On one hand, the Examiner finds, the claim requires "determining" the analyte concentration, apparently by comparison to a reference sample analyte concentration. *Id.* On the other hand, the Examiner finds, the claim recites a "where" phrase that appears to require adjusting a reference correlation. *Id.* The Examiner states that, if Appellant's invention is a method of correcting the output signal using a correlation equation, this is not clear. *Id.*

Appellant repeats the argument presented *supra*, that the determined reference correlation is described in claim 1 as "relating the at least one output signal value to reference sample analyte concentration values." App. Br. 21. Appellant contends that the sample analyte concentration values are determined by adjusting the previously determined reference correlation with the ΔS value that represents the slope deviation due to error. Appellant contends that a person of ordinary skill in the art would have understood that this element of claim 1 is a description of the process of eliminating error in the measured analyte concentration by determining the ΔS value (slope deviation due to error) and applying that value to correct the error to produce a corrected output. *Id.* at 20–21.

We agree with Appellant. As we have explained *supra*, Appellant's Specification discloses that the reference sample analyte concentration is determined by a reference set of concentration values compared to a reference set of sensor outputs that are derived from a standardized source and are stored in memory for comparison to the sensor output from a test source. These concentration values reflect the concentration in the reference

standard in the absence of error-causing factors. Specifically, Appellant's Specification discloses that:

> Accuracy may be expressed in terms of bias of the sensor system's analyte reading in comparison to a reference analyte reading, with larger bias values representing less accuracy…. Accepted reference values may be obtained with a reference instrument, such as the YSI 2300 STAT PLUS™ available from YSI Inc., Yellow Springs, Ohio.

Spec. ¶ 12. We consequently agree with Appellant that a person of ordinary skill would have understood from the disclosures of the Specification that a "reference sample analyte concentration," as recited in claim 1 is the basis for the stored "a reference analyte reading," disclosed in the Specification.

Issue 4: "index function"

Appellant argues that the Examiner erred in finding that the claim term "index function" recited in claims 7, 18, and 19 is indefinite. App. Br. 22.

Analysis

The Examiner notes that the claims recite: "where … the predetermined index function being determined by a regression equation…." Final Act. 7. The Examiner points to MPEP § 2111.04, noting that the following are examples of language that may raise a question as to the limiting effect of the language in a claim: (1) statements of intended use or field of use; (2) "adapted to" or "adapted for" clauses; (3) "wherein" clauses; or (4) "whereby" clauses. *Id.* The Examiner finds that, in the claims at issue, the quoted limitation merely describes the environment in which the

data was obtained, i.e., a product-by-process type limitation, and does not impose any additional positive process limitations of the method as claimed and is therefore indefinite. *Id.*

The Examiner further finds that it is unclear as to the metes and bounds of the term "index function" such that a skilled artisan would have understood what mathematical function is intended. Final Act. 7. The Examiner again notes that the phrase has been described in terms of how it is obtained, i.e., a product-by-process type limitation, but not what actually comprises this function. *Id.* The Examiner finds that paragraphs [0061] and [0071] suggest that index functions could be represented as the %-bias, but finds that these disclosures do not amount to a limiting definition for index functions. *Id.*

Appellant responds that the claim term "index function" is recited to further define the step of determining at least one ΔS value from a predetermined index function that is part of the error parameter. App. Br. 22 (citing Wu Decl. ¶¶ 10–12). Appellant asserts that index functions may be used for any error parameter and, therefore, claim 7 is a general process for any error parameter. *Id.* at 23.

Appellant argues that, based upon the disclosures of the Specification, a person of ordinary skill in the art would have understood that an index function is a function relating intermediate values of an output signal to the error in determined analyte concentrations to provide a value of slope deviation from a reference correlation as explained in paragraphs [0056] and [0057] of the Specification. App. Br. 23 (also citing Wu Decl. ¶ 12). According to Appellant, a skilled artisan would have understood the

mathematical functions that fall within the metes and bounds of the "index function" term recited in these claims. *Id.*

Appellant argues that claim 7 recites that the "predetermined index function" is "determined by a regression equation of a plot between the deviation in a slope of the reference correlation in response to the at least one error parameter." App. Br. 23 (citing Spec. ¶¶ 91, 94). Appellant argues that regression analysis is a well understood statistical method to determine variables for inclusion in mathematical functions. *Id.*

We are not persuaded by the Examiner's reasoning. Appellant's Specification discloses that:

> The present invention provides a biosensor system that adjusts a relation for determining analyte concentrations in a biological sample from output signals with one or more index functions responsive to one or more errors that could bias the determined analyte concentrations. The bias may be represented by slope deviations, ΔS values, and normalized slope deviations obtained from one or more error parameters. The ΔS values represent slope deviations determined with one or more index functions from the error parameters. The index functions are extracted from the output signals.

Spec. ¶ 20. The Specification further discloses:

> In a method for determining index functions from error parameters, at least one error parameter responsive to the percent bias in a determined analyte concentration in a sample is determined. The at least one error parameter is related to at least one ΔS value with at least one index function, the at least one ΔS value representing the difference in slope between the slope from a reference correlation and a hypothetical slope of a line for the output signal value that would provide an analyte concentration in the sample without bias.

Id. at ¶ 22. In other words, the Specification discloses that an index function is a mathematical function derived from the effect of an error parameter on a measured analyte sample and relating that error parameter to a ΔS value (the slope deviation between test and reference measurements (*see* Spec. Fig. 5)).

Appellant's Specification further discloses:

> *Index functions compensate the measured analyte concentration for one or more errors in the analyte concentration analysis*. One or more index functions may be used. An index function that correlates with the total slope deviation ΔS would provide an ultimate total error compensation of the analyte concentration since this index function could be used to compensate for the total error in the analysis without having to know the exact cause of the slope deviation ΔS and thus the bias of the measured analyte concentration. An index function may be responsive to an error parameter, such as temperature, which is measurable by another means. *An index function may be a calculated number that correlates with an error parameter such as hematocrit and represents the influence of this error parameter on the slope deviation ΔS*. Thus, error parameters may be any value responsive to one or more errors in the output signal and may be measured, calculated, or determined through other means. *Index functions may be experimentally determined as a regression equation of the plot between ΔS_{cal} and an error parameter.*

Spec. ¶ 94 (emphases added). Dr. Wu explains that:

> One skilled in the art would clearly understand, based on reading [Appellant's Specification], the process of determining an index function based on test data and application of statistical methods. The published application describes throwing out potential error parameters to select those with the most influence on error. The selected error parameters are then incorporated into the determined index function. The determined index function is stored in the medical device for use to predict error (slope deviation value ΔS) in the measurement environment. It is my opinion that one skilled in the art therefore would not find the term "index function" indefinite as used in claims 7, 18 and 19.

> One skilled in the art would also understand that the ΔS value (compensation for error) would be influenced by the error parameter and would be expressed by the index function based on the claimed language.

Wu Decl. ¶12.

> Appellant's Specification further discloses that:
>
> *Index functions correspond to the %-bias in the correlation between the analyte concentrations and the output signals due to one or more errors in the analysis. The %-bias in the correlation may be represented by one or more ΔS values obtained from one or more error parameters.* The ΔS values represent slope deviations of the correlation between analyte concentrations and output signals determined from one or more error parameters. Index functions corresponding to the slope or change in slope may be normalized to reduce the statistical effect of changes in the output signals, improve the differentiation in variations of the output signals, standardize the measurements of the output signals, a combination thereof, or the like.

Spec. ¶ 57 (emphasis added). Paragraphs [0060]–[0070] of the Specification provide a mathematical example of determining the relationship between the %-bias and an index function.

We agree with Appellant that a person of ordinary skill in the art would have understood, from both the disclosures of the Specification and the knowledge of those skilled in the art, that an index function serves to relate the slope deviation (i.e., the ΔS) between test and reference samples to reflect the effect of the error parameter upon the actual analyte measurement.

Issue 5: "perfect correlation"

Appellant argues that the Examiner erred in finding that the limitation of claim 11 reciting: "the ΔS_{cal} value representing the difference between the reference correlation and a hypothetical perfect correlation having an R^2 value of at least 0.3" is indefinite. App. Br. 23.

Analysis

The Examiner finds that Appellant's Specification does not provide any limiting definition or clarifying examples for the term "having an R^2 value of at least 0.3 correlation." Final Act. 8. The Examiner also finds that it is unclear as to what way this claim further limits the subject matter of parent claims 1 and 7, as these claims do not set forth any previous steps by which a "ΔS_{cal}" having R^2 values are determined or even explicitly calculated for a reference correlation. *Id.*

Appellant first points to paragraphs [0082], [0088], and Figure 5 of the Specification as explaining the concept of a hypothetical perfect correlation between an analyte concentration and the output signal obtained from applying an electrical signal to the biological sample. App. Br. 23. Appellant argues that the use of such a perfect correlation would result in a completely accurate determination of the analyte concentration from the output signal. *Id.*

Appellant further asserts that a person of ordinary skill in the art would have understood that R^2 is a coefficient of determination that is well known in the art of statistical measurement, and used to describe how close the data is to the fitted regression line correlation, as explained in paragraph [0060] of Appellant's Specification. According to Appellant, a person of ordinary skill in the art would have therefore understood how the R^2 value is

determined to describe how closely the ΔS_{cal} term should be as applied to the method in claim 1.

We agree with Appellant. R^2 is known in the art as a statistical measurement as measuring the "fit" of a regression to the data. *See* "Coefficient of Determination" *available at*: https://stattrek.com/statistics/dictionary.aspx (last visited March 21, 2019). Claim 11 expressly recites that a "perfect correlation" is one "having an R^2 value of at least 0.3." This is not the traditional understanding of a perfect correlation (where R^2 approaches 1.0) but Appellant may define claim terms to suit his own purpose, as long as they are clearly defined. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1319 (Fed. Cir. 2005) (holding that Appellants may act as their own lexicographer as long as they have clearly set forth an explicit definition of the term). We agree with Appellant that a person of ordinary skill in the art would understand Appellant's use of the term to mean that a perfect correlation is one having an R^2 of at least 0.3. We consequently reverse the Examiner's rejection of the claims upon this ground.

C. Rejection of claims 1, 4, and 5 under the nonstatutory doctrine of obviousness-type double patenting.

Issue

Appellant argues that the Examiner erred because the claims are not obvious over claims 1, 4, 5, 6, 18, and 24 the '076 patent. App. Br. 24.

Analysis

The Examiner finds that claims 1 and 18 of the '076 patent both teach all aspects of instant claim 1 except determining a ΔS values from an error

parameter and compensating the output signal based ΔS values. Final Act. 8. However, the Examiner finds, claim 6 of the '076 patent teaches compensating analyte concentration with a slope compensation equation, which is effectually teaching ΔS values, and claims 13 and 24 of the '076 patent both teach index functions equivalent to slope deviations, which also reads on ΔS values, since they represent deviation of test and reference slopes. *Id.* The Examiner therefore concludes that the claims are obvious over the cited claims of the '076 patent, because it would have been obvious to a person of ordinary skill in the art, and because it would have been obvious to combine the limitations taught in the cited claims of the '076 patent. *Id.*

Appellant responds that claims 1 and 18 of the '076 patent recite an index function that relies on error parameters based on a first secondary measurement and a second secondary measurement to assist in correction. App. Br. 24. According to Appellant, these secondary measurements are taken from external means other than the analyte concentration and assist in error correction. *Id.* In contrast, argues Appellant, the claims on appeal are directed toward the general process of determining a single error parameter from a slope deviation from the reference correlation to perform the corrective process. *Id.* Appellant therefore argues that the claims on appeal are patentably distinct from those of the '076 patent since they do not include the extra step of obtaining a secondary output and determining an index function from the secondary output. *Id.*

We are not persuaded by the Appellant's arguments. Claim 1 of the '076 patent, which is representative, recites:

1. A method for determining an analyte concentration in a biological sample using a biosensor system comprising a sample interface having a working electrode and a counter electrode, a processor, and a signal generator connected to the processor, comprising:

generating by the processor, a command to direct the signal generator to provide an electrical input signal;

applying the electrical input signal provided by the signal generator to the biological sample through the working electrode and the counter electrode of the sample interface;

generating from the electrical input signal at least one output signal in response to a redox reaction of an analyte from the biological sample;

generating using the processor a second command to direct the signal generator to provide a second electrical input signal;

applying the second electrical input signal to the biological sample through an electrochemical or optical sensor system;

in response to the second command, generating multiple secondary output signals using the electrochemical or optical sensor system from the biological sample independently from the at least one output signal and redox reaction of the analyte from the biological sample;

determining by the processor at least one index function responsive to at least one error parameter from the at least one output signal and at least two error parameters from the multiple secondary output signals; and

determining by the processor, the analyte concentration in the biological sample from the at least one output signal and a slope compensation equation responsive to the at least one index

> function, where the slope compensation equation includes at least one reference correlation and at least one slope deviation,
>
> where the at least one index function represents the influence of the error parameters on the slope deviation, and
>
> where the at least one index function is responsive to at least one of a slope deviation of the error parameters and an intercept deviation of error parameters.

Claim 1 of the '076 patent thus requires, as Appellant argues, generating a command for, and applying, a second electrical input signal, to the biological sample through an electrochemical or optical sensor system. However, claim 1 of the claims on appeal recites: "A method for determining an analyte concentration in a biological sample … *comprising*…." (emphasis added). As such, the claims can include other, unrecited elements, including the generation of a second command to apply a second electrical signal. *See Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l, Inc.*, 246 F.3d 1336, 1348 (Fed. Cir. 2001) (holding that: "In the parlance of patent law, the transition 'comprising' creates a presumption that the recited elements are only a part of the device, that the claim does not exclude additional, unrecited elements"). The fact that claim 1 of the '076 patent recites additional elements, i.e., the second electrical input signal to generate additional error parameters does not preclude claim 1 of Appellant's claims from comprising that additional element.

Furthermore, we note that claim 1 of the '076 patent further recites:

> [D]etermining by the processor at least one index function responsive to at least one error parameter from the at least one output signal . . . and

> determining by the processor, the analyte concentration in the biological sample from the at least one output signal and a slope compensation equation responsive to the at least one index function, where the slope compensation equation includes at least one reference correlation and at least one slope deviation [i.e., ΔS],
>
> where the at least one index function represents the influence of the error parameters on the slope deviation, and
>
> where the at least one index function is responsive to at least one of a slope deviation of the error parameters and an intercept deviation of error parameters.

Claim 1 of the '076 patent thus recites the same processing steps involving generating: "at least one index function responsive to at least one error parameter from the at least one output signal" and then, using the at least one index function as a measurement of the slope deviation and intercept deviation, comparing it to a reference correlation.

Claim 1 of Appellant's claims recites these same steps:

> determining at least one ΔS value from at least one error parameter via the processor of the analyte measurement device, where the at least one ΔS value is a value of slope deviation or a value of normalized slope deviation in relation to at least one previously determined reference correlation…
>
> and
>
> determining the analyte concentration in the sample from the at least one output signal value, the at least one ΔS value.

In other words, the multiple error parameters derived from the second electrical input signal in claim 1 of the '076 patent is not essential to the "determining" steps recited in that claim, which requires only determining:

"at least one index function" derived from "at least one error parameter from the at least one output signal." Therefore, the second electrical signal, and the error parameters generated from it, are not essential to the "determining" steps required in claim 1 of the '076 patent.

Because claim 1 of the '076 patent recites additional steps that are not essential to the "determining" steps of either the '076 patent or the claims on appeal, and because the inclusion of a second electric input signal is within the scope of the "comprising" language of Appellant's claims, we affirm the Examiner's rejection upon this ground.

DECISION

The Examiner's rejection of claims 1–5, 7–13, 16, 18–27, 83, and 84 as unpatentable under 35 U.S.C. § 101 is reversed.

The Examiner's rejection of claims 1–5, 7–13, 16, 18–27, 83, and 84 as unpatentable under 35 U.S.C. § 112, second paragraph, is reversed.

The Examiner's rejection of claims 1, 4, and 5 as unpatentable under the nonstatutory doctrine of obviousness-type double patenting is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED-IN-PART