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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte GEORGE A. MECKLENBERG[1]

Appeal 2017–001517
Application 10/592,218
Technology Center 1600

Before TONI R. SCHEINER, DEMETRA J. MILLS, and JOHN G. NEW, *Administrative Patent Judges.*

NEW, *Administrative Patent Judge.*

DECISION ON APPEAL

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[1] Appellant states that the real party-in-interest is Bayer HeathCare LLC. App. Br. 1.

SUMMARY

Appellant files this appeal under 35 U.S.C. § 134(a) from the Examiner's Final Rejection of claims 1–4, 8–11, 13–16, 18, 20–23 and 25–27 as unpatentable under 35 U.S.C. § 101 as being directed to nonstatutory subject matter.

Claims 1–2, 8–11, 14–16, 18, 20–23 25, and 26 also stand rejected as unpatentable under 35 U.S.C.§ 103(a) as being obvious over Berner et al. (US 2001/0016682 A1, August 23, 2001) ("Berner").

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

We AFFIRM.

NATURE OF THE CLAIMED INVENTION

Appellant's invention is directed to method and apparatus for implementing threshold-based correction functions for biosensors. Abstr.

REPRESENTATIVE CLAIM

Appellant argues all of the claims together. App. Br. 4. Claim 1 is representative of the claims on appeal and recites:

> 1. A method for determining an analyte value from a sample by implementing threshold based correction functions for a biosensor system including a biosensor, a processor, and a memory, the method comprising the acts of:
>
> applying the sample to the biosensor and obtaining a primary measurement of an analyte value from the biosensor responsive to a command from a processor;
>
> obtaining a secondary measurement of a secondary effect on the sample via a command from the processor;

> comparing said secondary measurement of the secondary effect with a threshold value;
>
> responsive to said compared values, the processor identifying a correction function from a plurality of potential correction functions stored in the memory based on said compared values wherein said identified correction function is a first correction function if the secondary measurement is less than the threshold value, and said identified correction function is a second different correction function if the secondary measurement is greater than the threshold value; and
>
> applying said identified correction function to said primary measurement via the processor to provide a corrected analyte value.

App. Br. 30.

ISSUES AND ANALYSES

We are persuaded by, and expressly adopt, the Examiner's findings and conclusions establishing that Appellant's claims are: (1) directed to nonstatutory subject matter; and (2) *prima facie* obvious over the cited prior art. We address the arguments raised by Appellant below.

A. Rejection of the claims under 35 U.S.C § 101

Issue 1

Appellant argues that the Examiner erred because, when viewed as a whole, the claims do not seek to tie up any judicial exception such that others cannot practice it. App. Br. 6.

Analysis

Appellant points to Part I.B.3 of the *2014 Interim Guidance on Patent Subject Matter Eligibility*, 79(241) Federal Register 74618 (2014) (the "Guidance," which states that:

> For purposes of efficiency in examination, a streamlined eligibility analysis can be used for a claim that may or may not recite a judicial exception but, when viewed as a whole, clearly does not seek to tie up any judicial exception such that others cannot practice it. Such claims do not need to proceed through the full analysis.

App. Br. 6 (quoting Guidance 74625). Appellant next points to *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S.Ct. 2347 (2014), which Appellant asserts: "describes the purpose of the exclusion of abstract ideas as addressing concerns of pre-emption and ensuring that patent law does not inhibit future discovery by improperly tying up the use of laws of nature and the like by granting patents on laws and principles that are "the basic tools of scientific and technological work." *Id.* (quoting *Alice*, 134 S.Ct. at 2354). Appellant argues that the claims on appeal are not "directed to" such abstract ideas and, when viewed as a whole, do not seek to preempt an abstract idea such that others cannot practice it. *Id.*

Appellant contends that the claims on appeal are directed to the functioning of biosensor systems, such as those used by persons who suffer from diabetes. App. Br. 7. According to Appellant, the claimed measurement process is not for abstract data, rather, it is directed toward measuring liquid samples (e.g., blood) for a specific substance, an analyte (e.g., glucose). *Id.* Appellant argues that measuring an analyte concentration in a liquid sample is not an abstract process, and that, as

explained by Appellant's Specification, the resulting testing data from the sample assists, for example, in monitoring physiological abnormalities such as diabetes, which requires accurate knowledge of blood glucose levels. *Id.* (citing App. Br., Ex. A ¶ 3).[2]

Appellant asserts that the claims at issue are a particular inventive embodiment of a biosensor measurement device having improved accuracy and, when viewed as a whole, are not of a scope to broadly pre-empt biosensors or measurements of analyte concentrations, in general. App. Br. 7. According to Appellant, when viewed as a whole, the claims are not directed to an abstract idea and are not similar to, or analogous to, any of the abstract ideas referenced in *Alice*. *Id.* Furthermore, argues Appellant, the claims at issue do not seek to grant a monopoly on all biosensors, let alone "basic tools of scientific and technological work." *Id.* (quoting *Alice*, 134 S.Ct. at 2354).

We do not find Appellant's argument persuasive. As an initial matter, we note that Appellant omits from their quotation of the Guidance the sentence immediately subsequent to the passage quoted above, *viz.*: "However, if there is doubt as to whether the applicant is effectively seeking coverage for a judicial exception itself, the full analysis should be conducted to determine whether the claim recites significantly more than the judicial exception." Guidance 74625. As we explain below, we are not persuaded by Appellant's contention that the claims recite so much substantially more than the judicially-created exceptions to Section 101 that the claims are self-

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[2] Appellant's Exhibit A is Mecklenburg (US 2008/0274447 A1, November 6, 2008), the published application of the claims on appeal.

evidently directed to patent-eligible matter. To be sure, all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas. *Mayo Collaborative Servcs. v. Prometheus Labs. Inc.*, 566 U.S. 66, 71 (2012). However, "to transform an unpatentable law of nature into a patent-eligible application of such a law, one must do more than simply state the law of nature while adding the words 'apply it.'" *Mayo*, 566 U.S. at 72 (citing, e.g., *Gottschalk v. Benson*, 409 U.S. 63, 71–72 (1972). The same holds true of the other judicial exceptions to Section 101, i.e., "natural phenomena, and abstract ideas." *Alice*, 134 S.Ct. at 2354.

Moreover, we note that neither *Alice* nor *Mayo* instructs us to consider in our analysis whether the claims attempt to preempt one of the judicial exceptions. Rather, such preemption is an outcome to be avoided in any such analysis, rather than an established step in the analytical framework itself. *See Mayo*, 566 U.S.at 72–73.

The Examiner concludes that the claims on appeal are directed to nonstatutory subject matter. Appellant contends that the claims on appeal do not seek to preempt the judicial exception that the Examiner concludes they fall within, i.e., an abstract idea. Taking Appellant's argument, *arguendo*, on its face, the Guidance instructs us to turn to the full *Mayo/Alice* analysis. We therefore so proceed.

Issue 2

Appellant argues that the Examiner erred in concluding that the claims on appeal are directed to a judicially-created exception to Section 101, i.e., to an abstract idea. App. Br. 9.

Analysis

We agree with Appellant that the claims are directed to a "process" and therefore fall into one of the broad statutory categories of patent-eligible subject matter under 35 U.S.C. § 101. *See* App. Br. 8–9. We consequently next turn to determining whether this process is patent eligible or comes under one of the nonstatutory exceptions to Section 101.

In performing such a patentability analysis under 35 U.S.C. § 101, we follow the framework set forth by the Supreme Court in *Mayo*. As a first step, we determine whether the claims at issue are directed to a 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.

Appellant argues that it is important to consider what the claims are actually directed toward, not merely what may be involved. App. Br. 10. Appellant contends that the proper interpretation is that the whole of the identified steps are part of an analyte measurement process, a process that is not abstract. *Id.* Appellant asserts that an abstract idea must be the type of concept that constitutes a fundamental practice, building block, or basic tool

of the relevant industry or society or a disembodied concept such as a motive or result that is dissociated from a manner of accomplishment. *Id.* at 11 (citing *Alice*, 134 S.Ct. at 2354 and *Internet Patents Corp. v. Active Network, Inc.*, 790 F.3d 1343, 1348 (Fed. Cir. 2015)).

Appellant disagrees with the Examiner's finding that the steps of the claim are drawn to an abstract process that only manipulates data or is directed toward a mathematical function. App. Br. 12 (citing Final Act. 3–6). Appellant asserts that the Examiner's conclusion improperly focuses on individual elements of the claim such as the correction function in asserting that the claim is directed to the abstract concept of manipulation of data. *Id.* Appellant contends that the claims as a whole are directed toward an analyte measurement process and are not directed toward mathematical algorithms themselves or data manipulation. *Id.* According to Appellant, the correction process is inherent to analyte measurement and cannot be separated from the overall analyte measurement process. *Id.* Viewed as a concept, argues Appellant, the claims relate to an analyte measurement method that provides accurate readings of an analyte value via selection of different error correction functions. *Id.*

Appellant argues further that the Examiner has cited a series of cases, referenced by the July 2015 Update of the Guidance, as supporting the principle that storing and comparing data constitute abstract ideas. App. Br. 12 (citing Final Act. 5–6). Appellant asserts that none of these cases is applicable to Appellant's claims, as all of them involved claims focused on the data itself and none of them relate to data in the context of measurement instruments that obtain and correct data to produce a measurement. *Id.* Appellant contends that the Examiner ignores the fact that subject-eligible

devices, such as measurement devices, whose function is to gather data are not rendered ineligible because their function relates to data gathering. *Id.* Appellant asserts that such devices including the correction of the gathered data in these devices have been traditionally found to be patent eligible by the Patent Office and have their own classification system. *Id.*

We are not persuaded by Appellant's arguments. Appellant's claims are expressly directed to a method, and thus are within the scope of patent-eligible subject matter under 35 U.S.C. § 101. We must therefore determine whether the claims fall, as the Examiner finds, within one of the judicially-created exceptions to Section 101, *viz.*, an abstract concept or idea, and if so, whether the elements of the claim, individually or "as an ordered combination" contain additional elements sufficient to "transform the nature of the claim" into a patent-eligible application.

The Supreme Court "has not established a definitive rule to determine what constitutes an 'abstract idea.'" *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1334 (Fed. Cir. 2016) (citing *Alice*, 134 S.Ct at 2357). Our reviewing court *has* held that information, as such, is intangible, and the collecting of information, including when limited to particular content (which does not change its character as information), is within the realm of abstract ideas. *Electric Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1353–54 (Fed. Cir. 2016) (collecting cases). The Federal Circuit has similarly treated the analyzing of information by steps that a person is capable of performing mentally, or *via* mathematical algorithms, without more, as essentially mental processes falling within the abstract idea category. *Id.* Furthermore, the court has held that the mere presentation of the results of abstract processes of collecting and analyzing information,

without more, is abstract, as an ancillary part of such collection and analysis. *Id.*

Appellant's claims are directed to obtaining a first measurement value, e.g., in the form of an electrical signal, from a biosensor and a second value from a measurement of a secondary effect, e.g., temperature. A processor compares the second value to a threshold value stored in the processor and, depending upon whether the second value exceeds the threshold a first correction factor is applied to the first value. If the second value does not exceed the stored threshold value, a different, second correction factor is applied to the first value.

We find that there is nothing in these processes that represents more than the routine collection of data from a generic biosensor and the routine manipulation of information according to an algorithm by a generic processor, i.e., comparing the second measurement value against a stored threshold value and performing an "if, then" decision process to select which correction factor to apply to the first measurement value. Moreover, we find that the comparison of a first measurement value against a stored threshold value and then deciding which correction factor to apply to the first measurement value is the sort of process that an individual could perform mentally, or with a pencil and paper. Because, with the exception of the step requiring acquisition of the signal from a biosensor, all of claim 1's method steps could be performed in the human mind, or by a human using pencil and paper, the claims are directed to an abstract idea without significantly more, and therefore, not patent eligible. *See, e.g., CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1372 (Fed. Cir. 2011).

Appellant contends that the claims are directed to significantly more than merely an abstract idea. Reply Br. 2. First, Appellant asserts that the claims at issue constitute improvements to another technology or technical field. *Id.* at 3. According to Appellant, correcting for errors is crucial to accurate measurement and as such is not a mere manipulation of data, rather it is an improvement in the technical field of biosensor measurement instruments. *Id.* Appellant contends that the Specification is evidence of the technical improvement as the subject of a patent is, by definition, an improvement in the art. *Id.* Specifically, Appellant argues that the Specification discloses a new and improved biosensor and further discloses that the invention improves the accuracy of diagnostic chemistry tests by correcting for secondary effects. *Id.* (citing Spec. ¶¶ 16, 27).

Second, Appellant argues that the allegedly abstract idea of the claims is applied to a particular machine. Reply Br. 4. Appellant contends that the correction functions of the claims (the alleged abstract idea) are applied for a specific analyte biosensor system that is a recognized type of particular machine. *Id.* Appellant argues that a biosensor is a particular type of machine that is not subject to the analysis for applications of a generic computer. *Id.* at 5. Furthermore, argues Appellant, there is no requirement that a particular claimed machine cannot be composed of known components in a field that are used in a routine manner and that, in this instance, the elements of the particular apparatus are the claim as a whole. *Id.*

Third, Appellant argues that the claims include a specific limitation other than what is well-understood, routine in the field, or add unconventional steps that confine the claim to a particular useful application.

Reply Br. 5. Appellant disputes the Examiner's finding that a generic biosensor, a processor and a memory were well-known, routine and conventional in the field. *Id.* (citing Ans. 21). Appellant contend, rather, that even if individual elements themselves are common, the combination may provide meaningful limitations: in the case of Appellant's claimed invention, the combination of claim elements (processor, biosensor, and memory) with the selection of correction functions via the processor to determine the correction of the measurement performed by the biosensor provide such specific limitations. *Id.*

Finally, Appellant points to *Diamond v. Diehr*, 450 U.S. 175, 188 (1981) as supporting the patent eligibility of their claimed invention. Reply Br. 6. According to Appellant, the Supreme Court held, in *Diehr*, that a claim for a particular machine (a rubber curing machine) combined with an abstract concept (the curing algorithm) was patent eligible. *Id.* Similarly, argues Appellant, in this case, the claims relate to a specific machine (a biosensor) in conjunction with an abstract concept (the corrective functions). *Id.*

Appellant argues that the Examiner errs in analyzing the claims by improperly separating out individual elements such as the processor, biosensor and memory, rather than employing the proper approach of viewing the claim as a whole, as in *Diehr*. Reply Br. 6 (citing Ans. 14). Appellant asserts that the Examiner errs further by conflating inventive concepts under 35 U.S.C. §§ 102 or 103 with eligibility under 35 U.S.C. § 101. *Id.* Appellant contends that there is no requirement that the individual elements that are significantly more than the abstract concept need be inventive. *Id.* Appellant notes that, in *Diehr*, the Court cautioned

against such an approach when evaluating 35 U.S.C. § 101 subject matter eligibility, because all inventions incorporate known elements, thus making it essential to consider the claim as a whole. *Id.* (citing *Diehr*, 450 U.S. at 188). Therefore, Appellant argues, focusing on individual elements of the claim erroneously avoids the requirement that the pending claims must be considered as a whole when conducting the analysis under 35 U.S.C. § 101. *Id.* at 7.

We do not find Appellant's arguments persuasive. With respect to Appellant's first point, that the claimed invention constitutes an improvement to another technology or technical field, we find that the application of a correction factor to a first measured value obtained from a generic biosensor by a generic processor, the correction factor being determined by a second measurement and a stored threshold value, could improve the function of the measuring device. But the application of a correction factor based on comparing an obtained measurement against a stored threshold is an abstract principle which, as we have explained *supra*, could be performed mentally, or with pencil and paper, by a person of ordinary skill in the art.

Here we rely on the distinction between, on one hand, computer-functionality improvements and, on the other, uses of existing computers as tools in aid of processes focused on abstract ideas. *Electric Power Grp.*, 830 F.3d at 1355 (citing *Enfish*, 822 F.3d at 1335–36; *see also Alice*, 134 S.Ct. at 2358–59). In this instance, the manipulations embodied in the abstract idea are performed on a generic processor in a manner that would be a matter of simple and routine programming, i.e., comparing a value against a stored

threshold and performing an "if, then" decision. We do not find this to be an inventive or patent eligible advance in the technology.

The same reasoning applies to Appellant's second and third points. Appellant's claims require a generic biosensor, an unspecified second measuring means, and a generic processor to perform a simple calculation. The generic biosensor and the second measuring means do no more than routine data-gathering, well known in the art, and supply the values to the processor used in performing the recited application of a correction factor based on a threshold comparison. As such, and coupled with the abstract idea (i.e., the "if, then" steps) by routine computer processing activity, the claims do not rise to significantly more than the abstract idea recited in the claims. *See OIP Techs., Inc. v. Amazon.com, Inc.*, 788 F.3d 1359, 1363 (Fed. Cir. 2015) (Holding that claims reciting no more than an abstract idea coupled with routine data-gathering steps and conventional computer activity are unpatentable); *see also Mayo*, 566 U.S. at 72.

We can thus distinguish the appeal before us from the facts of *Diehr*, which Appellant's fourth point argues is dispositive. In *Diehr*, the claims at issue were directed to the transformation of raw, uncured synthetic rubber, into a cured, molded product. *Diehr*, 450 U.S. at 184. The claims recited in detail a step-by-step method for accomplishing such, beginning with the loading of a mold with raw, uncured rubber and ending with the eventual opening of the press at the conclusion of the cure. *Id.* The claims also recited, in several of the steps, use of a mathematical equation and a programmed digital computer. *Id.* The Court noted that such transformative processes were of the type that were historically afforded the protection of patent law. *Id.*

The fact that several of these steps used an algorithm and a computer did not change the Court's conclusion. *Diehr*, 450 U.S. at 185. The Court noted that the respondents sought patent protection for a process of curing synthetic rubber and that, although that process employed a well-known mathematical equation, respondents sought only to foreclose from others the use of the equation in question only in conjunction with all of the other steps in their claimed process. *Id.* In concluding, the Court held that when a claim containing a mathematical formula implements or applies that formula in a structure or process which, when considered as a whole, is performing a function which the patent laws were designed to protect (e.g., transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of Section 101. *Id.* at 192.

Appellant's argument to the contrary notwithstanding, we find that the claims on appeal are distinguishable from those at issue in *Diehr*. The *Diehr* claims were directed to a process for accurately curing synthetic rubber and employed a computer driven algorithm to accurately direct the time required for curing. Appellant's claims are directed to no more than gathering information and then using a processor to determine which correction factor to apply to the measured value. In essence, Appellant's claims are directed to no more than the conversion of one measured value (i.e., a number; an abstract idea) into another, corrected value. As we have noted, our reviewing court's holding in *OIP Technologies* (citing *Mayo*) informs us that claims reciting no more than an abstract idea coupled with routine data-gathering steps and conventional computer activity are unpatentable is dispositive of Appellant's claims. *OIP Techs.,* 788 F.3d at 1363.

At oral argument on September 26, 2018, counsel pointed additionally to *Thales Visionix Inc. v. United States*, 850 F.3d 1343 (Fed. Cir. 2017), as further supporting the contention that Appellant's claims do not fall into an exception to Section 101.[3] Oral Hearing Transcript, September 26, 2018, ("Transcript") at 8. Counsel argued that the improvement in the technology, i.e., an improvement in the accuracy of measurement, is basically the same improvement that Appellants were attempting to achieve in the claims. *Id.* at 9. Counsel argued that, as in *Thales*, the elements from which the data is obtained, i.e., the biosensor and the surrounding components including the processor and the memory, as well as the output are all things that are not abstract. *Id.* at 10. Counsel asserted that the combination of those elements with the abstract idea removes the claim from the realm of an abstract idea. *Id.*

We do not find Appellant's argument with respect to *Thales* persuasive. In *Thales*, the court held that:

> [T]he '159 patent claims at issue in this appeal are not directed to an abstract idea. The claims specify a particular configuration of inertial sensors and a particular method of using the raw data from the sensors in order to more accurately calculate the position and orientation of an object on a moving platform. The mathematical equations are a consequence of the arrangement of the sensors and the unconventional choice of reference frame in order to calculate position and orientation. Far from claiming the equations themselves, the claims seek to protect only the application of physics to the unconventional configuration of sensors as disclosed. As such, these claims are

[3] *Thales* was decided by the Federal Circuit subsequent to the filing date of Appellant's Reply Brief (November 7, 2016).

> not directed to an abstract idea and thus the claims survive *Alice* step one.

Thales, 850 F.3d at 1349. We find the facts of *Thales* distinguishable from the claims on appeal because the claims in *Thales* were directed to "a particular [and novel] configuration of inertial sensors and a particular method of using the raw data from the sensors." *Id.* Furthermore, the algorithms employed were a function or consequence of the arrangement of the sensors and the unconventional choice of reference frame and the claims sought protection only for the unconventional configuration of the sensors. *Id.*

Appellant's claims, by contrast, recite no such inventive concept as an unconventional arrangement of inertial sensors, but merely recite the routine and well known gathering of data from a generic biosensor to a generic processor and the application of a correction factor based on a second external value. We conclude that there is nothing significantly more in Appellant's claims beyond the abstract idea of applying a correction factor, based on a threshold value, other than routine data gathering and generic computer activity. *OIP Techs.*, 788 F.3d at 1363. We consequently affirm the Examiner's rejection of the claims on this ground.

B. Rejection of claims 1–4, 8–11, 13–16, 18, 20–23 and 25–26 under 35 U.S.C § 103(a)

Issue

Appellant argues that the Examiner erred because Berner neither teaches nor suggests the limitation of claim 1 reciting: "identifying a

correction function from a plurality of potential correction functions stored in memory." App. Br. 21.

Analysis

Appellant argues that the teachings of Berner are directed only to single correction function during its operation. App. Br. 21–22 (citing Berner ¶ 131). According to Appellant, there is no teaching or suggestion in Berner that multiple correction functions are stored in memory that would be available to correct a measurement during operation of the device. *Id.* at 22. Rather, Appellant argues, Berner suggests that multiple corrective functions are available, but does not teach or suggest that the device may select between multiple corrective functions during the measurement operation. *Id.* Appellant asserts that the storage of different correction functions in the memory is directed to the use of different correction functions selected by the processor in the operation of the biosensor. *Id.* This feature, argues Appellant, allows the application of an appropriate correction function in view of a secondary measurement during the operation of the biosensor system, and is not obvious over the teachings of Berner. *Id.*

Appellant argues further that Berner teaches three different temperature correction functions: (1) an Arrhenius-type function (Berner ¶¶ 132–138); (2) a K2 temperature correction (*id.* ¶¶ 139–145); and (3) an anodal subtraction (*id.* ¶¶ 146–154), that may be selected by the device designer to take advantage of a sampling system that includes an active reservoir and a blank reservoir. App. Br. 22–23 (also citing Berner ¶¶ 109, 130–163). Appellant contends that none of the three temperature correction

methods taught by Berner is optimally selected based on a secondary measurement, rather they each have different characteristics based on the dual blank and active reservoirs. *Id.* at 23. Appellant argues further that none of the example correction methods is selected based on the comparison of a temperature measurement to a threshold value. *Id.* Rather, Appellant asserts, all of the described correction functions taught by Berner would be used over the entire range of temperatures and are therefore not selected on the basis of a secondary measurement as recited by the claims. *Id.* Appellant argues that a person of ordinary skill in the art, understanding the teachings of Berner, would have used a single correction function based on the designer's desire for the advantage offered by each of the correction functions. *Id.*

Appellant disputes the Examiner's finding that paragraphs [0110]–[0113] teaching comparing secondary measurements to threshold values and that such measurements may be used for correcting measurements. App. Br. 24 (citing Final Act. 12). According to Appellant, the threshold value in Berner is not used to determine a selection of a correction function to produce a corrected analyte value. *Id.* Rather, argues Appellant, the threshold value is used for another purpose: *viz.*, to invalidate temperature, perspiration or analyte measurements, as explained in paragraphs [0110]–[0112]. Appellant contends that paragraph [0113] of Berner teaches only that departure from expected values is indicative of an incorrect measurement requiring correcting measurements, and that Berner does not teach or suggest that the solution to an incorrect measurement is to select another correction function if the measurement is incorrect. *Id.*

Appellant argues that the Examiner relies on paragraphs [0016] and [0130] of Berner as teaching that temperature correction functions may be used to reduce temperature-related effects on the signal. App. Br. 24 (citing Final Act. 13–14). Appellant argues that nothing in paragraph [0130] teaches or suggests what criteria are used to select the temperature function to be used. *Id.* Appellant contends that the remainder of Berner subsequent to paragraph [0130] would have been understood by one of skill in the art to mean that the temperature correction functions refer to a number of different temperature correction functions that could be selected by a designer of the monitoring system, and that Berner does not disclose, teach or suggest tying the selection to the comparison of a secondary measurement with the threshold value as recited by the claims. *Id.*

Appellant argues that, contrary to the Examiner's findings, the calibration parameters cited in paragraphs [0106], [0017] and [0110] reinforce the Appellant's contention that Berner does not store the correction functions for selection. App. Br. 24. Appellant asserts that Berner teaches that these correction functions are selected based on calibration performed on the system during manufacture and not during operation. *Id.* Appellant also contends that paragraph [0110] also teaches the invalidation of a measurement based on temperature. *Id.*

Appellant also argues that paragraph [0147], upon which the Examiner also relies, teaches six related temperature correction functions, but does not describe any criteria by which any one should be selected. App. Br. 25. Appellant asserts that the only guidance provided by Berner is that the correction function may be used based on alternating anodal and cathodal phases during the measurement cycle to produce a smooth signal.

Id. According to Appellant, the functions taught by paragraph [0147] are selected not based upon comparison to a threshold value, but on the method of measurement used for the analyte sample. *Id.*

Finally, Appellant argues that the Examiner erroneously finds that use of generally recited measurement values implies routine optimization based on different conditions, and is a routine practice that would be obvious for one of ordinary skill to apply, and that that determining a correction function is routine optimization based on different conditions. App. Br. 26 (citing Final Act. 14, 20).

Appellant repeats the assertion that the correction functions in Berner are selected when the device is designed, and that the different conditions that the Final Office Action relies upon for the different correction functions are not derived from a secondary measurement, rather they are design functions, such as smoothing the signal. App. Br. 26. Appellant further asserts that the selection of different correction functions during the operation of the device would not be routine optimization as it produces the unexpected result of accurate measurements for different external conditions such as varying temperatures. *Id.* Appellant argues that Berner would only allow a biosensor designer to select one correction function from multiple correction functions for all external conditions. *Id.*

We are not persuaded by Appellant's arguments. The test for obviousness is not "that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425 (C.C.P.A. 1981).

Berner expressly teaches the use of a secondary measurement (e.g., temperature) measured against a threshold value as a means of determining whether a first measured value is acceptable or not:

> Accordingly, a temperature sensor is used to monitor changes in temperature over time. A maximum temperature change over time (d(temp)/d(time)) threshold value can then be used in a data screen to invalidate a measurement. Such a threshold value can, of course, be set at any objective level, which in turn can be empirically determined depending upon the particular extraction/sensing device used, how the temperature measurement is obtained, and the analyte being detected. Absolute temperature threshold criteria can also be employed, wherein detection of high and/or low temperature extremes can be used in a data screen to invalidate a measurement. Temperature monitoring can be carried out using a separate, associated temperature sensing device, or, preferably using a temperature sensor that is integral with the sensing device.

Berner ¶ 110; *see also* ¶¶ 111–113. Berner further teaches that:

> Raw signal thresholds can also be used in the data screening method of the present invention. For example, any sensor reading that is less than some minimum threshold can indicate that the sampling/sensing device is not operating correctly, for example, where the biosensor electrode is disconnected. In addition, any chemical sensor will have a maximum range in which the device can operate reliably. A reading greater than some maximal value, then, indicates that the measurement is off-scale, and thus possibly invalid. Accordingly, minimum and maximum signal thresholds are used herein as data screens to invalidate or correct measurements. Such minimum and maximum thresholds can likewise be applied to background measurements

Berner ¶ 114. Berner thus expressly teaches the limitations of claim 1 reciting: "obtaining a secondary measurement of a secondary effect on the

sample via a command from the processor" and "comparing said secondary measurement of the secondary effect with a threshold value."

Berner further teaches correction factors as a means of correcting the first measured value (e.g., blood glucose) for the secondary effects (e.g., temperature) caused by physical or chemical factors and measured as a second value (*see* Berner ¶¶ 110–114) *via* various correction functions. *See* Berner ¶¶ 130–138. Specifically, Berner teaches that:

> [T]he conversion step is used to correct for changing conditions in the biological system and/or the biosensor system (e.g., temperature fluctuations in the biological system, temperature fluctuations in the biosensor element, or combinations thereof). Temperature can affect the signal in a number of ways, such as by changing background, reaction constants, and/or diffusion coefficients. Accordingly, a number of optional temperature correction functions can be used in order to reduce these temperature-related effects on the signal.
> ….
> More particularly, to compensate for temperature fluctuations, temperature measurements can be taken at each measurement time point within the measurement cycle, and this information can be used to base a temperature correction algorithm which adjusts the background current at every time point depending on the difference in temperature between that time point and the temperature when the previous background current was measured.

Berner ¶¶ 130–131. Berner teaches that one such temperature correction algorithm is based on an Arrhenius relationship: between the background current and temperature:

$$i_{bkgnd,corrected} = i_{bkgnd,T_0} \exp\left[-Kf\left(\frac{1}{T_t} - \frac{1}{T_{T_0}}\right)\right]$$

Where ($i_{bkgnd,corrected}$) is the temperature corrected baseline current; ($i_{bkgnd,\tau 0}$) is the baseline current at some reference temperature $T_{\tau 0}$, for example, the baseline background measurement temperature; (K1) is the temperature correction constant; and (T_τ) is the temperature at time τ. *Id.* ¶¶ 131, 134, 135. Such an algorithm involves determining the temperature constant K1 by plotting the natural log of the background current versus the reciprocal of the temperature for a learning set of data, and then using a best fit analysis to fit this plot with a line having a slope (-K1). *Id.* at ¶ 135. Thus, measured first values can be applied to this function to correct for the effects of temperature, a second measured value. Berner also teaches other methods of employing correction functions using a second measured to correct the first measured value based on various physical and chemical effects. *See id.* at ¶¶ 137–154.

We agree with Appellant that Berner does not expressly teach comparing a second measured value against a stored threshold measurement to select a stored correction factor depending upon whether the second measured value is sub- or suprathreshold. Nevertheless, we agree with the Examiner that the combined teachings of Berner that we have cited *supra,* would lead a person of ordinary skill to recognize that the limitation of claim 1 reciting:

> responsive to said compared values, the processor identifying a correction function from a plurality of potential correction functions stored in the memory based on said compared values wherein said identified correction function is a first correction function if the secondary measurement is less than the threshold value, and said identified correction function is a second different correction function if the secondary measurement is greater than the threshold value; and

> applying said identified correction function to said primary measurement via the processor to provide a corrected analyte value

would have been obvious over the combined teachings of Berner.

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For example, a threshold, such as suggested in paragraphs [0110]–[0113] of Berner could be used to determine if the incoming signal is too high or too low to be applied to a function such as the Arrhenius relationship correction function described in paragraphs [0131]–[0134]. If the second measured value was, e.g., suprathreshold, the first measured value could be either rejected or another correction function could be applied, whereas if the second measured value was subthreshold, the Arrhenius relationship correction function could be applied.

Our analysis is not limited to this specific example, nevertheless, we conclude that a person of ordinary skill, understanding the combined teachings of Berner with respect to both thresholds based upon second measured values and the application of various correction functions to correct the first measured value for the effects reflected by the second measured value, would find Appellant's claims to be obvious over these teachings. We consequently affirm the Examiner's rejection upon this ground.

DECISION

The Examiner's rejection of claims 1–4, 8–11, 13–16, 18, 20–23 and 25–27 under 35 U.S.C. § 101 is affirmed.

The Examiner's rejection of claims 1–4, 8–11, 13–16, 18, 20–23 and 25–26 under 35 U.S.C. § 103(a) 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