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Please find below and/or attached an Office communication concerning this application or proceeding.

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

ABBOTT DIABETES CARE, INC.
Requester and Appellant

v.

Patent of DEXCOM, INC.
Patent Owner and Respondent

Appeal 2011-003298
Reexamination Control 95/001,039
Patent 6,931,327 B2
Technology Center 3900

Before SALLY GARDNER LANE, MICHAEL P. TIERNEY, and JEFFREY B. ROBERTSON, *Administrative Patent Judges*.

ROBERTSON, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

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[1] The one-month time period for filing a request for rehearing as recited in 37 C.F.R. § 41.79, and the two-month period for filing an appeal, as recited in 37 C.F.R. § 1.304 (see 37 C.F.R. § 1.983(b)(1)), both begin to run from the "MAIL DATE" shown on the PTOL-90A cover letter attached to this decision.

Patent Owner appeals from the Examiner's decision to reject claims 1-41, 43-45, and 47 under 35 U.S.C. §§102(e) and 103(a).[2] Third-Party Requester (hereinafter "Requester") cross appeals from the Examiner's final decision not to adopt various rejections and confirming the patentability of claims 42 and 46.[3] In response to each appeal, both the Requester and the Patent Owner agree with the Examiner's decision and dispute each other's contentions.[4] We have jurisdiction under 35 U.S.C. §§ 134 and 315.

For reasons discussed below, we do not have jurisdiction to decide an appeal on the non-appealable issue of whether a substantial new question of patentability exists. We AFFIRM the Examiner's refusal to reject certain claims and REVERSE the Examiner's decision to reject certain claims.

STATEMENT OF THE CASE

Both parties have identified *Abbott Diabetes Care, Inc. v. DexCom, Inc.*, Civil Action 1:05cv590 (D. Del.) as concurrent civil litigation related to the current reexamination proceeding (TPR App. Br. 2; PO App. Br. 4.) The parties have further informed us that the litigation has been stayed pending reexamination (*id.*).

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[2] *See* the Patent Owner's Appeal Brief filed April 2, 2010, hereinafter "PO App. Br.," at 4; Patent Owner's Rebuttal Brief filed November 5, 2010, hereinafter "PO Reb. Br."

[3] *See* the Requester's Appeal Brief filed April 5, 2010, hereinafter "TPR App. Br.," at 3; Requester's Rebuttal Brief filed November 8, 2010, hereinafter "TPR Reb. Br."; Right of Appeal Notice mailed December 24, 2009; Examiner's Answer mailed October 5, 2010, hereinafter "Ans."

[4] *See* the Patent Owner's Respondent Brief filed April 16, 2010, hereinafter "PO Resp. Br."

We heard oral arguments from both parties on March 16, 2011, a written transcript of which will be entered into the electronic record in due course.

The patent under reexamination (hereinafter the '327 Patent) relates to systems and methods for processing analyte sensor data, and in particular, a method for calibrating glucose sensors including evaluating received reference and sensor data, and evaluating the calibration for the analyte sensor. (Col. 1, ll. 6-11.) The method includes evaluating the clinical acceptability of reference data and/or time corresponding sensor data. (Col. 23, ll. 21-34, col. 37, ll. 23-40.)

Claim 1 of the '327 Patent reads as follows (underlining indicates additions relative to the originally issued claims):

> 1. A method for evaluating clinical acceptability of at least one of reference and sensor analyte data, the method comprising:
>
> receiving a data stream from an analyte sensor, including one or more sensor data points;
>
> receiving reference data from a reference analyte monitor, including one or more reference data points; and
>
> evaluating the clinical acceptability <u>of</u> at least one of said reference and sensor analyte data using substantially time corresponding reference or sensor data, wherein said at least one of said reference and sensor analyte data is evaluated for deviation from its substantially time corresponding reference or sensor data and clinical risk associated with that deviation based on the glucose value indicated by at least one of said sensor and reference data, further comprising a step of matching reference data to substantially time corresponding sensor data to form a matched pair after the clinical acceptability evaluation step.

(Claims App'x, PO App. Br. at 23.)

The Examiner relied upon the following prior art references as evidence of unpatentability (Ans. 6):

Say	6,175,752 B1	Jan. 16, 2001
Berner	6,233,471 B1	May 15, 2001
Mastrototaro	6,424,847 B1	July 23, 2002[5]
Bartkowiak	US 2003/0235817 A1	Dec. 25, 2003
Shin	6,895,263 B2	May 17, 2005

The Examiner adopted Requester's rejections of the claims as follows (Ans. 6-7):

I. Claims 1, 3-9, 11-17, 19-28, 30-33, 35-38, 40, 41, 43-45, and 47 under 35 U.S.C. § 102(e) as being anticipated by Shin or Mastrototaro;

II. Claims 2, 10, and 18 under 35 U.S.C. § 103(a) as being unpatentable over Shin or Mastrototaro, in view of Berner; and

III. Claims 29, 34, and 39 under 35 U.S.C. § 103(a) as being unpatentable over Shin or Mastrototaro, in view of Bartkowiak.

The Examiner refused to adopt or maintain the Requester's proposed rejections as follows (Ans. 7):

[5] Ex Parte Reexamination Certificate issued on October 16, 2007.

IV. Claims 1-28, 30-33, 35-38, 40, 41, 43-45, and 47 under 35 U.S.C. § 102(b) as being anticipated by Berner;

V. Claims 29, 34, and 39 under 35 U.S.C. § 103(a) as unpatentable over Berner in view of Bartkowiak;

VI. Claims 1-28, 30-33, 35-38, 40, 41, 43-45, and 47 under 35 U.S.C. § 102(b) as anticipated by Say;

VII. Claims 2, 10, and 18 under 35 U.S.C. § 102(e) as being anticipated by Shin; and

VIII. Claims 42 and 46 under 35 U.S.C. § 102(e) as being anticipated by or under 35 U.S.C. § 103(a) as unpatentable over Shin or Mastrototaro.

ISSUES

Matters Regarding Substantial New Question of Patentability (SNQ)

Rejection VI: Say

The Examiner determined that Say did not raise a SNQ because "there does not appear to be any evidence that the Say reference is considered in a different light over the manner in which it was considered by the Examiner [during prosecution]." (Right of Appeal Notice mailed December 24, 2009, hereinafter "RAN" at 3-4.)

The Patent Owner contends that an appeal is not a proper venue to challenge determinations that a reference fails to raise a SNQ because, a determination by the Director that a substantial question of patentability does not exist is final and non-appealable. (PO Resp. Br. 22, quoting 35 U.S.C. § 312(c)).

The Requester asserts that "once any SNQ is found and the *inter partes* reexamination is granted, there is no longer any reason to limit the patentability analysis to the SNQ issue. Instead, the focus shifts to the proposed rejections and whether they should be adopted or not. To limit patentability analysis solely as to whether an SNQ issue exists or not and therefore simply ignore a prior art reference that directly bears on patentability would contravene a very reason behind reexamination which is patent validity." (TPR App. Br. 27.)

A dispositive issue is:

(1) Do we have jurisdiction to review the Examiner's decision that proposed Rejection VI does not raise a substantial new question of patentability?

Rejections I-III

The Patent Owner, the Examiner, and the Requester limit their discussion of Rejections I-III to Shin due to the overlapping disclosures of Shin and Mastrototaro. (PO App. Br. 10, FN 2; TPR Rep. Br. 10, FN 1; RAN 10.) We do the same throughout this opinion, with the understanding that our comments apply equally to Mastrototaro except where expressly indicated.

Patent Owner contends that Shin does not disclose evaluating clinical acceptability of at least one of reference and sensor analyte data by evaluating the deviation of at least one of substantially time corresponding sensor analyte data or reference data from the other and the clinical risk associated with the deviation between reference data and sensor data. (PO App. Br. 11-17.)

The Examiner agreed with Requester's position that the calibration performed in Shin compares a sensor reading to one or more previous readings, or "reference points," to evaluate system accuracy and calibrate it. (Ans. 11.) The Examiner further agrees with Requester's position that there is a clinical risk associated with the consequences of a false reading, such that the matter in which Shin corrects calibration enhances the clinical acceptability of readings. (Ans. 11.)

Thus, a dispositive issue on appeal is:

(2) Does Shin disclose evaluating the clinical acceptability of at least one of substantially time corresponding reference or sensor data?

Non-Adopted Proposed Rejections:

Rejections IV & V-Rejections based on Berner

Requester contends that Berner's calibration factor check evaluates clinical acceptability by assessing the deviation between reference data (BGcal) and time corresponding sensor data (Ecal). (TPR App. Br. 14.) Requester additionally argues that Berner's sensor consistency check verifies consistency between two sensors. (TPR App. Br. 15.) Requester contends that Berner discloses forming matched pairs after the calibration factor check and the sensor consistency check. (TPR App. Br. 19-21.) Requester further argues that Berner discloses a multi-point calibration process, which corresponds to evaluating matched pairs for clinical acceptability as recited in the claims on appeal. (TPR App. Br. 16-19.)

Patent Owner contends that Berner's calibration factor is a conversion factor, and does not measure the deviation between the reference data and its

substantially time corresponding sensor data. (PO Resp. Br. 12-13.) In addition, Patent Owner argues that Berner's calibration factor check does not involve evaluating the clinical risk associated with the deviation based on the glucose value. (PO Resp. Br. 14-15.) Patent Owner contends that Berner's sensor consistency check does not include evaluating time corresponding reference or sensor data for deviation or clinical risk. (PO Resp. Br. 15-18.) Patent Owner argues that Berner does not disclose matching reference data and sensor data in the manner claimed. (PO Resp. Br. 18.) The Examiner agreed with Patent Owner's positions. (RAN 6-7.)

A dispositive issue on appeal is:

(3) Did the Examiner err in finding that the recited evaluating steps in the claims do not read on Berner's calibration check or sensor consistency check?

FINDINGS OF FACT ("FF")

Issue (1): Matters Regarding SNQ

1. The Requester did not identify any petition to invoke the supervisory review authority of the Director as to the Examiner's determination that Rejection VI does not raise a substantial new question of patentability under 35 U.S.C. § 312.

Shin

2. Shin discloses a method for calibrating a glucose monitor where a calibration factor, called a sensitivity ratio, is calculated by dividing a valid memory storage value corresponding to a continuous electrical current signal generated by a glucose sensor at regular intervals (Valid ISIG value) by a temporally

correlated reference reading from a blood glucose measuring device. (Col. 8, ll. 46-67, col. 11, l. 41 – col. 12, l. 13.)

3. Shin discloses that all interval values are compared to an out-of-range limit of 200 Nano-Amps, such that if three consecutive values are equal to or exceed the limit, an alarm is activated to notify the user that re-calibration is required. (Col. 10, ll. 39-44.)

4. Shin discloses that an instantaneous calibration check is performed, where for every meter blood glucose entry, a Calibration Factor current (CFc) ratio of a blood glucose reference reading immediately entered into a glucose monitor expressed in mg/dl or mmol/l, and the current ISIG value is calculated to determine if the calibration factor is between an expected range, e.g., 1.5 to 12. (Col. 11, ll. 44-46 and col. 16, ll. 25-36.) If the calibration is outside this value, a calibration error alarm is triggered. (Col. 16, ll. 36-40.)

5. Shin discloses "once calibration is complete, Valid ISIG values are converted to blood glucose readings based on a particular version of the sensitivity ratio, and the resulting blood glucose readings are compared to an out-of range limit. If the resulting calculated blood glucose level is greater than a maximum out-of-range limit of 200 mg/dl (or equivalently 3600 mmol/l), the out-of-range alarm is activated." (Col. 21, ll. 41-48.)

Berner

6. Berner discloses a method for continually or continuously monitoring an analyte present in a biological system, such as blood glucose concentration. (Col. 1, ll. 14-20.)
7. Berner's method entails obtaining a raw signal from a sensing device, which is related to a target analyte, optionally subjecting the raw signal to a data screening method, and converting the raw signal into an analyte-specific value through a calibration step. (Col. 11, l. 41 – col. 12, l. 38.)
8. Berner discloses a "Calibration Factor Check" that "provides control over unreasonable finger prick measurements or incorrect entries and provides additional assurance that a reasonable calibration slope has been generated." (Col. 32, ll. 27-32.)
9. Berner discloses performing a "Calibration Factor Check" by calculating a CAL RATIO according to the following formula:

$$CALRATIO = \left[\frac{BG_{cal}}{E_{cal} + OS}\right]$$

where BG_{cal} is the true blood glucose at the calibration point (in mg/dL), E_{cal} is the analyte signal at calibration (in nanocoulombs (nC)) and OS is a constant offset term. (Col. 24, l. 1, col. 30, ll. 1-14, col. 32, ll. 27-50.)
10. Berner discloses that if the CAL RATIO is greater than or equal to a predetermined threshold value, then a calibration error indicates that calibration must be performed again. (Col. 32, ll. 35-40.)

11. Berner also discloses performing a "sensor consistency check" which evaluates "whether the signals from [two active] reservoirs are changing in concert with one another." (Col. 32, ll. 17-20.)

PRINCIPLES OF LAW

"During reexamination, as with original examination, the PTO must give claims their broadest reasonable construction consistent with the specification." *In re ICON Health and Fitness, Inc.*, 496 F.3d 1374, 1379 (Fed. Cir. 2007). Nevertheless, our reviewing court has also "instructed that any such construction [must] be '*consistent with the specification* . . . and that claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art.'" *In re Suitco Surface, Inc.*, 603 F.3d 1255, 1260 (Fed. Cir. 2010).

ANALYSIS

Issue (1): Matters Relating to SNQ of Patentability

The Examiner, under authority delegated from the Director, found that the Requester's proposed Rejection VI does not raise a substantial new question of patentability. Under 35 U.S.C. § 312(c), the Director's determination in an *inter partes* reexamination as to the existence of a substantial new question of patentability is "final and non-appealable." *See also* Clarification on the Procedure for Seeking Review of a Finding of a Substantial New Question of Patentability in *Ex Parte* Reexamination Proceedings, 75 Fed. Reg. 36,357, 36,358 (Dep't of Commerce, June 25, 2010) ("A determination by the USPTO in an *inter partes* reexamination

either that no SNQ has been raised or that a reference raises a SNQ is final and non-appealable.").

In *Belkin International, Inc. et al v. Optimumpath, LLC*, an expanded panel recently considered whether the Board has jurisdiction to decide SNQ matters in the context of *inter partes* reexamination.[6] In *Belkin*, the Examiner had found an SNQ over a proposed rejection in light of a Peirce reference, but did not find SNQs for proposed rejections with respect to three other references, the Transistor Article, the Howto Guide, and the Redlich reference. (Slip op. at 4-5.) The expanded panel held that the Board did not have jurisdiction to decide an appeal on the non-appealable issue of whether a substantial new question of patentability exists. (Slip op. at 11.) Thus, although the Examiner determined that the proposed Peirce rejection raised a substantial new question of patentability, the expanded panel concluded that the Board did not have jurisdiction to review the Examiner's determination that substantial questions of patentability did not exist with respect to the other proposed rejections. In essence, *Belkin* held that an SNQ attaches to a particular rejection. Accordingly, the determination that an SNQ exists with respect to a particular rejection does not necessarily permit a third party requestor to pursue proposed rejections not found to raise an SNQ outside of the attached rejection, regardless of whether or not the additional rejections are directed to the same claims.

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[6] Appeal 2011-003697 (BPAI March 29, 2011) (Reexamination Control 95/001,089, Inter Partes Reexamination of U.S. Patent 7,035,281 B1, Panel expanded for consideration of substantial new question of patentability jurisdictional issue) available at http://des.uspto.gov/Foia/ReterivePdf?system=BPAI&flNm=fd2011003697-03-29-2011-1.

In light of the above discussion, we agree with Patent Owner, that Appeal is not a proper venue for challenging the Examiner's determination that a particular reference does not raise a SNQ. Requester's view that a finding of a SNQ with respect to the claims shifts the focus to the proposed rejections regardless of whether the proposed rejections were found to raise a SNQ is inconsistent with § 312(c) and our decision in *Belkin*.

Therefore, the Requester should have sought relief by filing a timely petition rather than an appeal. Requester has failed to identify whether such a petition has been filed. (FF 1). Thus, we lack jurisdiction to review the Examiner's finding that Rejection VI does not raise any substantial new question of patentability, which is a petitionable matter.

Issue (2)-Shin-Rejection I

We agree with Patent Owner that Shin does not disclose evaluating "time corresponding reference or sensor data" for deviation and clinical risk associated with that deviation as required in the claims. The Examiner relies on Shin's disclosure of out-of-range limits for blood glucose levels as a measure of clinical acceptability. (RAN 11; FF 5.) However, Shin discloses that Valid ISIG readings are converted to blood glucose readings based on a particular version of a sensitivity ratio and compared to an out-of-range limit "once calibration is complete." (FF 5.) Thus, the sensor data in the form of the Valid ISIG is compared to previously obtained reference and sensor data used to calibrate the glucose monitor and generate the sensitivity ratio. (FF 2-3.) Therefore, Shin does not disclose that the Valid ISIG is evaluated for

deviation *from substantially time corresponding* reference data and the clinical risk associated with that deviation, as required in the claims.

Shin's Instantaneous Calibration Check

Requester advances an alternative theory of rejection that Shin's instantaneous calibration check anticipates the instant claims.[7] (TPR Res. Br. 14.) However, we agree with Patent Owner that Shin's calibration check is a conversion factor and does not evaluate clinical risk associated with a deviation based on the glucose value. (PO Reb. Br. 11.) Shin discloses thatin performing the instantaneous calibration factor check, a Calibration Factor current (CFc) ratio of a blood glucose reference reading immediately entered into a glucose monitor and the current ISIG value is calculated and compared to a criteria range, for example 1.5 to 12. (FF 4.)

The CFc ratio is not a measure of the deviation between the reference and sensor analyte data glucose values. Although the magnitude of the CFc ratio depends on the difference between the blood glucose reference reading and the ISIG value, the CFc ratio does not result in a meaningful deviation, because the ISIG values are expressed in Nano-Amps and the reference blood glucose values are expressed in mg/dl or mmol/l. (FF 4.) Thus, while the ISIG value is directly dependent on the glucose level at the glucose sensor, the ISIG value cannot directly be used to evaluate the deviation between the reference data and sensor data as required in the claims. Thus,

[7] As pointed out by Requester and Patent Owner, Mastrototaro does not disclose an instantaneous calibration check. (TPR Res. Br. 14, FN 3; PO Rebut. Br. 11.)

Shin's instantaneous calibration check does not anticipate the claims on appeal.

Rejections II and III

We reverse the Examiner's rejections of claims 2, 10, 18, 29, 34, and 39 as obvious over Shin or Mastrototaro in view of Berner or Bartkowiak for the same reasons as discussed for rejection I. Berner or Bartkowiak fail to remedy the deficiencies of Shin discussed above.

Non-Adopted Rejections

Issue (3)-Berner-Rejection IV

Regarding Berner, both the Requester and Patent Owner provide similar arguments as discussed above with respect to Shin's instantaneous calibration check. (TPR App. Br. 12-14; PO Resp. Br. 12-15.) Similar to Shin, Berner also discloses a Calibration Factor check, where a ratio of true blood glucose (BG_{Cal}) at the calibration point to analyte signal (E_{Cal}) (plus a constant) at calibration, where if the calculated ratio is greater than or equal to a threshold value an error is indicated. (FF 8-10.) Like the instantaneous calibration check provided in Shin, Berner's Calibration Factor check fails to result in a deviation as recited in the claims.

Additionally, we are unpersuaded by Requester's contention that Berner's Sensor Consistency Check anticipates the claims on appeal. (TPR App. Br. 15.) In Berner's Sensor Consistency Check, signals from two sensors changing in concert with one another are evaluated. (FF 11.) Thus, Berner's Sensor Consistency Check evaluates sensor data for deviation from

other sensor data, not the deviation between substantially time corresponding reference and sensor analyte data as required in the present claims. (PO Res. Br. 15-16.)

Moreover, we are not persuaded by Requester's arguments that Berner's multi-point calibration process meets the limitations of the claims, because Requester's arguments also rely on Berner's Calibration Factor Check or Sensor Consistency Check for the recited evaluation of clinical acceptability. (TPR App. Br. 16-17.) Thus, we agree with Patent Owner, that the Examiner did not err in failing to adopt the grounds of rejection based on Berner.

Rejection V

Regarding the proposed rejection of claims 29, 34, and 39, the Examiner did not err in refusing to adopt the proposed rejection under 35 U.S.C. §103 for the reasons discussed for Rejection IV. Bartkowiak fails to remedy the discussed deficiencies of Berner.

Rejections VII and VIII (Claims 2, 10, & 18) Shin, (Claims 42 & 46) Shin or Mastrototaro

Claims 2, 10, and 18 depend from claims 1, 9, and 17. Shin does not disclose the limitations of claims 2, 10, and 18 as discussed above, with respect to Rejection 1. Accordingly, the Examiner did not err in refusing to adopt the Rejection VII.

Claims 42 and 46 also contain the limitations discussed above with respect to Rejection I. Accordingly, the Examiner did not err in refusing to adopt the Rejection VIII.

CONCLUSION

(1) We do not have jurisdiction to review the Examiner's decision that proposed Rejection VI does not to raise a substantial new question of patentability.

(2) Shin does not disclose evaluating the clinical acceptability of at least one of substantially time corresponding reference or sensor data.

(3) The Examiner did not err in finding that the recited evaluating steps in the claims do not read on Berner's calibration check or sensor consistency check.

ORDER

The Examiner's rejections of the claims under 35 U.S.C. §§ 102(e) and 103 (a) are reversed.

The Examiner's decision not to adopt the proposed grounds of rejection of the claims under 35 U.S.C. §§ 102(e) and 103 (a) is affirmed.

Requests for extensions of time in these *inter partes* reexaminations proceedings are governed by 37 C.F.R. § 1.956. *See* 37 C.F.R. § 41.79.

AFFIRMED-IN-PART

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cc:

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