No. 16-

In The
Supreme Court of the United States

LIFESCAN SCOTLAND, LTD.,

Petitioner,

v.

PHARMATECH SOLUTIONS, INC. AND MICHELLE K. LEE, DIRECTOR, U.S. PATENT AND TRADEMARK OFFICE.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

The Leahy-Smith America Invents Act, following established principles of administrative law, sets up a scheme in its newly established inter partes patent challenge proceedings that requires separate decisions to be made for institution and adjudication by two different decisionmakers: The Act provides that "[t]he Director" of the U.S. Patent and Trademark Office "shall determine whether to institute an inter partes review under this chapter," 35 U.S.C. § 314(b), and that "[t]he Patent Trial and Appeal Board shall *** conduct each inter partes review instituted under this chapter," *id.* § 316(c).

The Director subsequently promulgated a regulation providing that "[t]he Board institutes the trial on behalf of the Director." 37 C.F.R. § 42.4(a). As a result, the separate statutory functions in sections 314 and 316(c) are now combined before a single panel of the Board, which first decides whether to institute inter partes review and then rules on the merits.

The question presented is:

Whether the Leahy-Smith America Invents Act permits the Patent Trial and Appeal Board instead of the Director to make inter partes review institution decisions.

PARTIES TO THE PROCEEDINGS

Petitioner LifeScan Scotland, Ltd., was the patent owner before the Patent Trial and Appeal Board and the appellant in the court of appeals.

Pharmatech Solutions, Inc., was the petitioner before the Patent Trial and Appeal Board and the appellee in the court of appeals.

Michelle K. Lee, Director, U.S. Patent and Trademark Office, intervened in the court of appeals.

RULE 29.6 DISCLOSURE

LifeScan Scotland, Ltd. is a subsidiary of Diabetes Diagnostics, Inc., which is a subsidiary of LifeScan, Inc., which is a subsidiary of Johnson & Johnson. No publicly held company directly owns 10% or more of LifeScan Scotland, Ltd. stock.

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No. 16-

LIFESCAN SCOTLAND, LTD.,
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OPINIONS BELOW

The per curiam judgment of the court of appeals affirming without opinion (App., *infra*, 1a-2a) is reported at 633 F. App'x 789. The order respecting the court of appeals' denial of rehearing (App., *infra*, 3a-4a) is unreported.

JURISDICTION

The court of appeals entered its judgment on January 20, 2016. LifeScan Scotland, Ltd., timely filed a petition for rehearing, which was denied on May 10, 2016. On August 2, 2016, the Chief Justice extended the time for filing a petition for a writ of

certiorari to and including September 20, 2016. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

RELEVANT STATUTORY AND REGULATORY PROVISIONS

The relevant statutory and regulatory provisions are reproduced at App., *infra*, 68a-80a.

STATEMENT OF THE CASE

A. Statutory and Regulatory Framework

1. The Leahy-Smith American Invents Act (AIA) creates a process called "inter partes review," which "allows a third party to ask the U.S. Patent and Trademark Office to reexamine the claims in an already-issued patent and to cancel any claim that the agency finds to be unpatentable in light of prior art." *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2136 (2016) (citation omitted). Congress separated inter partes review into two distinct phases with two distinct decisionmakers.

First, "[t]he Director" of the U.S. Patent and Trademark Office (PTO) "shall determine whether to institute an inter partes review." 35 U.S.C. § 314(b). Such review "may," in the Director's discretion, be "authorize[d]" and "instituted" only when "the Director determines *** that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." *Id.* § 314(a). If the Director finds institution appropriate, "the Director's determination under [section 314(a)]" is communicated to the petitioner and patent owner in writing. *Id.* § 314(c). No appeal may be taken from "[t]he determination by

the Director whether to institute an inter partes review." *Id.* § 314(d).

Second, following institution, "[t]he Patent Trial and Appeal Board shall, in accordance with section 6 [of title 35], conduct each inter partes review instituted under this chapter." 35 U.S.C. § 316(c). Section 6 specifies that the "Board shall *** conduct inter partes reviews" by at least "3-member panels" comprised of "administrative patent judges *** appointed by the Secretary [of Commerce]." *Id.* § 6(a)-(c). Other sections provide for further development of the record, including discovery, briefing, and an oral hearing, *id.* § 316(a)—culminating in the Board's issuance of a "final written decision with respect to the patentability" of the claims at issue, *id.* §§ 316(e), 318(a). The Board's final written decision is appealable to the Federal Circuit. 28 U.S.C. § 1295(a)(4)(A).

2. The Director is required to prescribe regulations governing inter partes review, taking into account "the effect of any such regulation on the economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete proceedings instituted under this chapter." 35 U.S.C. § 316(a)-(b). In 2012, the Director promulgated regulations providing (as relevant here) that "[t]he Board institutes the trial on behalf of the Director." 37 C.F.R. § 42.4(a); *see also id.* § 42.2 (defining "trial" to include inter partes review). The Director explained that "[s]ection 42.4(a) specifically delegates the determination to institute a trial to the Board." 77 Fed. Reg. 48612, 48616 (Aug. 14, 2012).

B. Factual and Procedural History

1. Respondent Pharmatech Solutions, Inc., petitioned the PTO to institute inter partes review of Petitioner LifeScan Scotland, Ltd.'s U.S. Patent No. 7,250,105 ("the '105 patent"). Consistent with 37 C.F.R. § 42.4(a), a three-judge Board instituted inter partes review of all '105 patent claims after finding a "reasonable likelihood" the claims were invalid. App., *infra*, 42a-67a. Following trial, two of the same three judges issued a final written decision invalidating the '105 patent claims for the same reasons articulated in the decision to institute inter partes review. *Id.* at 5a-41a.

On appeal to the Federal Circuit, LifeScan challenged whether 37 C.F.R. § 42.4(a) violates the AIA by allowing the Board—rather than "the Director," 35 U.S.C. § 314(a)—to institute inter partes review. The Director intervened. On January 20, 2016, the Federal Circuit issued a per curiam judgment of affirmance without opinion pursuant to Federal Circuit Rule 36. App., *infra*, 2a. On May 10, 2016, the Federal Circuit denied LifeScan's rehearing petition without opinion. *Id.* at 4a.

2. During the pendency of LifeScan's appeal, the Federal Circuit considered the same legal issue—*i.e.*, whether 37 C.F.R. § 42.4(a) violates the AIA—in *Ethicon Endo-Surgery, Inc. v. Covidien LP*, 812 F.3d 1023 (Fed. Cir. 2016). The Federal Circuit issued its split decision in *Ethicon* on January 13, 2016—one week before it affirmed the Board's decision in *LifeScan*.

In *Ethicon*, the majority held that nothing in the AIA precludes the Board from making both an

institution decision and a final determination of invalidity on the merits. According to the majority, the Director's delegation of the institution decision to the same entity that would ultimately decide the merits neither contravened the text or history of the AIA, nor raised separation-of-functions concerns. The majority therefore upheld the institution regulation. 812 F.3d at 1026-1033.

Judge Newman dissented. Because "the legislation divided the functions of institution and trial into separate bodies within the PTO," the "transfer to the Board of the Director's statutory assignment violates the text, structure, and purpose of the America Invents Act." 812 F.3d at 1035, 1038 (Newman, J., dissenting).

The Federal Circuit—over a further dissent from Judge Newman—denied Ethicon's petition for rehearing en banc. 826 F.3d 1366 (Fed. Cir. 2016).

ARGUMENT

The Federal Circuit's resolution of the question presented, by per curiam judgment of affirmance without opinion pursuant to Federal Circuit Rule 36, was controlled by its decision in *Ethicon Endo-Surgery, Inc. v. Covidien LP*, 812 F.3d 1023 (Fed. Cir.), *reh'g en banc denied*, 826 F.3d 1366 (Fed. Cir. 2016). In *Ethicon*, the Federal Circuit rejected a challenge to 37 C.F.R. § 42.4(a) as inconsistent with the AIA.

Contemporaneously with the filing of this petition, counsel for LifeScan—who also represents Ethicon Endo-Surgery, Inc.—is filing a petition for a writ of certiorari in this Court seeking review of the Federal Circuit's decision in *Ethicon*. Accordingly,

the Court should hold this petition pending its final disposition of *Ethicon* and then resolve the petition as appropriate in light of that disposition.

CONCLUSION

The petition for a writ of certiorari should be held pending this Court's final disposition of the petition for a writ of certiorari seeking review of the Federal Circuit's decision in *Ethicon Endo-Surgery, Inc. v. Covidien LP*, 812 F.3d 1023 (Fed. Cir.), *reh'g en banc denied*, 826 F.3d 1366 (Fed. Cir. 2016), and then resolved as appropriate in light of that disposition.

Respectfully submitted.

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September 20, 2016

APPENDIX TO THE PETITION FOR A WRIT OF CERTIORARI

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Note: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

LIFESCAN SCOTLAND, LTD.,
Appellant

v.

PHARMATECH SOLUTIONS, INC.,
Appellee

2015-1149

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2013- 00247.

JUDGMENT

DIANNE B. ELDERKIN, Akin, Gump, Strauss, Hauer & Feld, LLP, Philadelphia, PA, argued for appellant. Also represented by STEVEN D. MASLOWSKI, JASON WEIL.

JOHN J. SHAEFFER, Fox Rothschild, LLP, Los Angeles, CA, argued for appellee. Also represented by JEFFREY H. GRANT; WILLIAM A. RUDY, Denver, CO.

SCOTT WEIDENFELLER, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, argued for intervenor Michelle K. Lee. Also represented by NATHAN K. KELLEY, STACY BETH MARGOLIES.

THIS CAUSE having been heard and considered, it is

ORDERED AND ADJUDGED:

PER CURIAM (DYK, O'MALLEY, and STOLL, *Circuit Judges).*

AFFIRMED, ***See*** **Fed. Cir. R. 36**.

ENTERED BY ORDER OF THE COURT

January 20, 2016
Date

/s/ Daniel E. O'Toole
Daniel E. O'Toole
Clerk of Court

Note: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

LIFESCAN SCOTLAND, LTD.,
Appellant

v.

PHARMATECH SOLUTIONS, INC.,
Appellee

2015-1149

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2013-00247.

ON PETITION FOR REHEARING EN BANC

Before PROST, *Chief Judge,* NEWMAN, LOURIE, DYK, MOORE, O'MALLEY, REYNA, WALLACH, TARANTO, CHEN, HUGHES, AND STOLL, *Circuit Judges.*

O R D E R

Appellant Lifescan Scotland, Ltd., filed a petition for rehearing en banc. The petition was first referred as a petition for rehearing to the panel that heard the appeal, and thereafter the petition for rehearing en banc was referred to the circuit judges who are in regular active service.

Upon consideration thereof,

IT IS ORDERED THAT:

The petition for panel rehearing is denied.

The petition for rehearing en banc is denied.

The mandate of the court will issue May 17, 2016.

FOR THE COURT

May 10, 2016
Date

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PHARMATECH SOLUTIONS, INC.,
Petitioner,

v.

LIFESCAN SCOTLAND LTD.,
Patent Owner.

Case IPR2013-00247
Patent 7,250,105 B1

Before SALLY C. MEDLEY, SCOTT E. KAMHOLZ, and SHERIDAN K. SNEDDEN, *Administrative Patent Judges*.

KAMHOLZ, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73(b)

I. INTRODUCTION

A. Background

Pharmatech Solutions, Inc. ("Pharmatech") filed a Petition (Paper 1, "Pet.") to institute an *inter partes* review of claims 1-3 (the "challenged claims") of U.S. Patent No. 7,250,105 B1 (Ex. 1002, "the '105 patent"). We instituted trial for the challenged claims on the following grounds of unpatentability asserted by Pharmatech:

References[1]	**Basis**	**Claims challenged**
Nankai and Schulman	§ 103	1-3
Winarta and Schulman	§ 103	1-3

Decision to Institute 19 (Paper 11, "Dec.").

After institution of trial, LifeScan Scotland Ltd. ("LifeScan") filed a Patent Owner Response (Paper 16, "Resp."). Pharmatech filed a Reply (Paper 17, "Reply"). LifeScan did not file a motion to amend claims.

Pharmatech relies upon a declaration of Joseph Wang, D.Sc. (Ex. 1024) in support of its Petition. LifeScan relies upon a declaration of John L. Smith, Ph.D. (Ex. 2008) in support of its Response.

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[1] The references are: U.S. Patent No. 5,120,420 (Ex. 1003, "Nankai"), U.S. Patent No. 5,791,344 (Ex. 1007, "Schulman"), and U.S. Patent No. 6,258,229 (Ex. 1005, "Winarta").

Oral argument was conducted on May 14, 2014. A transcript is entered as Paper 26 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6(c). This final written decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

Pharmatech has proved that claims 1-3 are unpatentable.

B. The '105 Patent

The '105 patent relates to monitoring the level of a substance in a liquid, particularly the level of glucose in blood. Ex. 1002, 1:7-10. A glucose assay is performed by inserting a test strip into a meter and then applying a drop of blood to the test strip. *Id.* at 5:14-25. The test strip is made from layers of various materials, built up on a plastic base and capped with a cover. *Id.* at 4:35-5:14. Figure 2 is reproduced below:

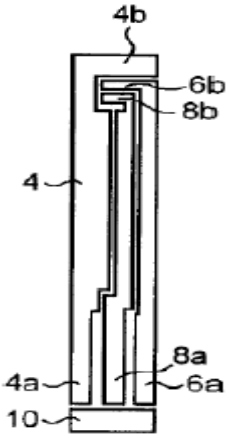

FIG. 2

Figure 2 illustrates one layer of the test strip, in which a pattern of carbon ink is screen-printed onto the test strip base. *Id.* at 4:23-24. The carbon ink forms three tracks 4, 6 (not labeled), and 8 (not labeled), along the strip, as well as a connecting bridge 10. *Id.* at 4:44-51. Each track has a connecting terminal 4*a*, 6*a*, 8*a* at one end of the strip and an electrode 4*b,* 6*b,* 8*b* at the other, distal, end. *Id.* A layer of glucose oxidase ("GOx") is printed on the electrodes. *Id.* at 4:65-66. Various other layers are deposited to define the rest of the structure, such as the precise sizes of the electrodes and a flow path for the blood. *Id.* at 4:54-5:14.

A user begins a glucose measurement by inserting the terminal end of the test strip into a meter device; the connecting bridge completes a circuit upon insertion to turn on the device. *Id.* at 5:16-18. The device applies a voltage between the

reference terminal 4*a* and terminal 6*a,* and also between the reference terminal 4*a* and terminal 8*a*. *Id.* at 5:19-22. A drop of blood is deposited at the distal end of the strip, and the blood is drawn by capillary action over electrode 4*b* for the reference sensor part and electrodes 6*b* and 8*b* for the working sensor parts. *Id.* at 5:23-26. The blood thereby comes into contact with the GOx printed on the electrodes, and the GOx reacts with glucose in the blood to release electrons.

The resulting electric currents through carbon tracks 4 and 6 are proportional to both the surface area of the electrode covered by GOx and the amount of glucose in the blood sample. *Id.* at 1:27-38. Because the GOx surface area is known, the electric current is indicative directly of the amount of glucose in the blood. *Id.* The currents are measured by the meter device after a predetermined time. *Id.* at 5:26-27. The current measurements are compared to one another, and if they differ by more than 10%, an error message is displayed so that the user will know to repeat the test. *Id.* at 5:27-30. If they are within 10% of each other, the measured currents are summed and converted into a glucose level, which is then displayed. *Id.* at 5:30-33. Regarding arrangement of the sensor parts, the '105 patent discloses that it is "preferred that both working sensor parts are downstream of the reference sensor part." *Id.* at 3:56-58.

The challenged claims are reproduced below:

1. A method of measuring the concentration of a substance in a sample liquid comprising the steps of:

providing a measuring device said device comprising:

a first working sensor part for generating charge carriers in proportion to the concentration of said substance in the sample liquid;

a second working sensor part downstream from said first working sensor part also for generating charge carriers in proportion to the concentration of said substance in the sample liquid wherein said first and second working sensor parts are arranged such that, in the absence of an error condition, the quantity of said charge carriers generated by said first working sensors part are substantially identical to the quantity of said charge carriers generated by said second working sensor part; and

a reference sensor part upstream from said first and second working sensor parts which reference sensor part is a common reference for both the first and second working sensor parts, said reference sensor part and said first and second working sensor parts being arranged such that the sample liquid is constrained to flow substantially unidirectionally across said reference

sensor part and said first and second working sensor parts; wherein said first and second working sensor parts and said reference sensor part are provided on a disposable test strip;

applying the sample liquid to said measuring device;

measuring an electric current at each working sensor part proportional to the concentration of said substance in the sample liquid;

comparing the electric current from each of the working sensor parts to establish a difference parameter; and

giving an indication of an error if said difference parameter is greater than a predetermined threshold.

2. The method as claimed in claim 1 comprising measuring the current at each working sensor part after a predetermined time following application of the sample.

3. The method as claimed in claim 1 wherein the substance to be measured is glucose, and each of the working sensor parts generates charge carriers in proportion to the concentration of glucose in the sample liquid.

II. DISCUSSION

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their

broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Office Patent Trial Practice Guide*, 77 Fed. Reg. 48756, 48766 (Aug. 14, 2012). Also, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.,* 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

We construed several claim terms as follows:

1. "Proportion" and "proportional to" as "correlated to" (Dec. 8);

2. "Downstream" as "further along a stream from its source" *(id.* at 8-9); and

3. "Substantially unidirectionally" as "along, or nearly along, one direction" *(id.* at 9).

The parties do not contest these constructions (Tr. 4:9-12, 16:1-21), and we maintain them.

B. Obviousness over Nankai and Schulman

Pharmatech argues that claims 1-3 are unpatentable under 35 U.S.C. § 103(a) over Nankai in combination with Schulman. Pet. 16-21. LifeScan responds, both arguing that Pharmatech has not demonstrated the obviousness of the claims

(Resp. 17-21, 26-43), and presenting objective evidence of nonobviousness. Resp. 45-49.

We undertake the four factual inquiries of an obviousness analysis: determining the scope and content of the prior art; ascertaining the differences between the prior art and the claims at issue; resolving the level of ordinary skill in the pertinent art; and assessing objective evidence of nonobviousness. *Graham* v. *John Deere Co.,* 383 U.S. 1, 17-18 (1966).

1. The level of skill in the pertinent art

"The person of ordinary skill in the art is a hypothetical person who is presumed to know the relevant prior art." *In re GPAC Inc.,* 57 F.3d 1573, 1579 (Fed. Cir. 1995). This person is of ordinary creativity, not merely an automaton, and is capable of combining teachings of the prior art. *KSR Int'l Co. v. Teleflex Inc.,* 550 U.S. 398, 420-21 (2007).

LifeScan argues that one of ordinary skill in the relevant art is a person having a Bachelor's degree in chemistry or electrical engineering, or an equivalent degree in a related field, such as physics or chemical engineering, and also having five years of experience working in the field of electrochemical glucose sensors. Resp. 13-14 (citing Ex. 2008 ¶ 13). Pharmatech does not dispute this proposed definition. The definition is reasonable, and we adopt it for purposes of this decision.

2. Scope and content of the prior art

a. Overview of Nankai

Nankai describes disposable biosensors for measuring, e.g., glucose concentration in blood. Ex. 1003, 3:65-68. Figure 12 of Nankai is reproduced below:

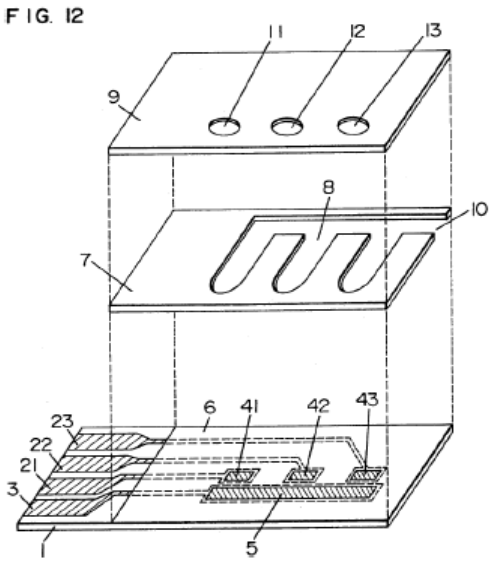

Figure 12 shows a glucose sensor having base plate 1 on which is formed lead 3 and corresponding counter electrode 5, and leads 21, 22, and 23, and corresponding measurement electrodes 41, 42, and 43. *Id.* at 8:5-10. Spacer 7 overlies the base plate, and space 8 cut out from the spacer provides a conduit for a blood sample to flow from introducing port 10 to the measurement and counter electrodes. *Id.* at Abstr., 8:15-18. Cover 9 provides discharge

ports 11, 12, and 13, through which air leaves space 8 as it is displaced by the flowing blood. The measurement electrodes are coated with GOx. *Id.* at 5:1, 8:11-14. During use, blood enters through the introducing port and flows along the main conduit of space 8, with portions of the sample entering successive branches along the main conduit. *Id.* at 8:25-27. A current measurement is made at each sensor, and the measurements are averaged to give a final result. *Id.* at 8:42-46. The shape or arrangement of sensors may vary. *Id.* at 8:50-52.

b. Overview of Schulman

Schulman describes an implantable sensor used to monitor blood glucose continuously by GOx-mediated current measurements. Ex. 1007, 3:17-28, 4:20-30, 7:35-37. Two or more sensors may be used to confirm the correctness of the measurement. *Id.* at 4:46-50. The readings from two sensors are compared, and if they are not within 10% of one another, the system requests sensor recalibration *(id.* at 11:16-22, 20:50-54), and issues an error message advising the user to check the sensors. *Id.* at 21:9-13.

3. Differences between the claimed subject matter and the prior art

a. Petitioner's Case-in-Chief

Pharmatech argues that Nankai discloses all limitations of claim 1 except *(a)* the position of the reference sensor part "upstream" of the first and second working sensor parts; *(b)* the step of

comparing the electric current from each of the working sensor parts to establish a difference parameter; and *(c)* the step of giving an indication of an error if the difference parameter is greater than a predetermined threshold. Pet. 16-21.

With regard to limitation *(a)*, Pharmatech points to Nankai's teaching that the arrangement of the sensors may vary. *Id.* at 16 (citing Ex. 1003, 8:47-52). Pharmatech argues that the '105 patent discloses that the sensors may be arranged "as convenient" and does not identify any benefit or unexpected result from the claimed arrangement. *Id.* (citing Ex. 1002, 3:36-58). Pharmatech cites evidence, from the testimony of Dr. Wang, that a person of ordinary skill in the art would have known that there was a finite number of ways to arrange a reference sensor part in relation to a working sensor part and that repositioning the reference sensor part upstream from the working sensor parts, as opposed to downstream from the working sensor parts, would have been obvious to try. *Id.* at 16, 19 (citing Ex. 1024 ¶ 25).

With regard to limitation *(b)*, Pharmatech argues that Schulman discloses taking multiple measurements in order to identify errors and that modifying Nankai to include this step would have been nothing more than the application of a known technique to improve a similar device with predictable results. *Id.* at 16-17, 21; Ex. 1024 27-28. With regard to limitation (c), Pharmatech argues that Schulman discloses giving an error indication if the difference parameter exceeds a predetermined

threshold. Pet. 17 (citing Ex. 1007, 3:17-28; Ex. 1024 ¶¶ 27-28); *see also* Reply 3 (citing Ex. 1007, 21:32-36 (disclosing generating a signal only if sensor signals are within a prescribed amount of one another); *id.* at 22:20-23 (disclosing generating an error message if they are not within the prescribed amount)).

b. Patent Owner's Response

LifeScan presents several arguments in response to Pharmatech's challenge. We address them in turn.

(1) Position of Nankai's reference sensor part relative to working sensor parts

LifeScan argues that Nankai's test strip provides a reference sensor part downstream of the working sensor parts, rather than upstream as claimed. Resp. 17. This is not in dispute. *See* Pet. 11:2-3; *see also* section II.B.2.a, *supra* (Nankai Fig. 12 showing that reference electrode 5 is downstream of working electrodes 41, 42, 43).

(2) Criticality of positioning reference sensor part upstream

LifeScan argues that it would not have been obvious to reposition Nankai's reference sensor part to be upstream of the working sensor parts, because there is criticality in positioning the reference sensor

part upstream. Resp. 17-18 (citing Ex. 2008 ¶ 43); Resp. 37 (citing Ex. 2008 ¶ 77). LifeScan argues that positioning the reference sensor part downstream of the working sensor parts, as Nankai does, would result in the reference sensor part being covered incompletely in the event an insufficient blood sample is applied. *Id.* If the reference sensor part is covered incompletely, it will give an unreliable baseline potential, which would then cause measurements relative to the working sensor parts to be erroneous. *Id.* at 18. Nankai then would average those erroneous readings and not detect the error. *Id.* In contrast, if an inadequate sample is applied to a device in which the reference electrode is upstream, it will be instead one of the working electrodes that is covered incompletely. Ex. 2008 ¶ 38. That electrode will give a reading that differs significantly from the other working electrode. *Id.* If that difference exceeds the threshold, the error will be detected and an inaccurate measurement avoided. *Id.* LifeScan argues that Pharmatech's expert, Dr. Wang, does not address this criticality in his testimony. *Id.* at 50.

The criticality of a claimed feature may be demonstrated by showing that the specific feature claimed achieves unexpected results compared to the generic prior art. *In re Woodruff,* 919 F.2d 1575, 1578 (Fed. Cir. 1990) (addressing criticality of a claimed range within a broader prior-art range). Without such a showing, the advantage is no more than a new benefit of an old method, and cannot, by itself, render the method again patentable. *Id.*

LifeScan's argument is unpersuasive, because it does not explain how the advantage it identifies is an unexpected consequence of how the reference sensor part and the working sensor parts are positioned relative to one another. Whichever sensor part is furthest downstream is the one most likely to be covered incompletely when a sample of inadequate volume is applied. *See* Ex. 2008 ¶¶ 38, 43. LifeScan does not offer any credible evidence to suggest that it is unexpected that a downstream working sensor part, covered incompletely by the dregs of an inadequate sample, will report a current measurement with a detectible discrepancy from the other, fully covered working sensor part.

(3) Disclosure in Nankai of multiple measurements

LifeScan argues that Nankai simply averages its multiple measurements, instead of comparing them to a difference parameter. Resp. 18-19 (citing Ex. 2008 ¶ 44); Resp. 37. LifeScan argues that Nankai's blind averaging would give inaccurate results if one of more of Nankai's working sensor parts were not completely filled with sample. *Id.* at 19.

This argument is unpersuasive, because Pharmatech relies on Schulman, not Nankai, for disclosing the comparison of multiple measurements to a difference parameter. *See* Pet. 16-17, 21. Pharmatech argues that it would have been obvious to apply this comparison technique to measurements

made using Nankai's test strip. *Id.* How Nankai itself performs the comparison is irrelevant.

(4) Adequate sample size

LifeScan argues that Nankai fails to address the detection of an inadequately sized sample. Resp. 20-21 (citing Ex. 2008 ¶¶ 46-48). LifeScan argues that the '105 patent is directed to avoiding the incomplete coverage problem by minimizing sample size. *Id.* at 21 (citing Ex. 1002, 2:51-55). According to LifeScan, Nankai gives no consideration to this problem because it uses sample sizes so much larger than those disclosed in the '105 patent (five microliters or more, compared to two microliters or less), that samples were guaranteed to cover all the electrodes fully. *Id.* at 20-21. LifeScan acknowledges that the challenged claims do not place any limitations on the sample size, but argues that Nankai's failure to appreciate the problem of inadequate sample size is evidence that one of ordinary skill in the art, attempting to solve the problem the '105 patent's inventors confronted, would not have considered Nankai. *Id.* at 21 (citing Ex. 2008 ¶ 48).

This argument is unpersuasive because, as LifeScan acknowledges, the claims do not limit the sample size, and LifeScan does not identify any other limitation in the claims to which the sample-size argument relates. Consequently, the claims encompass subject matter that this argument does not reach. *See In re Lintner*, 458 F.2d 1013, 1015 (CCPA 1972) ("Claims which are broad enough to

read on obvious subject matter are unpatentable even though they also read on nonobvious subject matter."); *In re Muchmore*, 433 F.2d 824, 826 (CCPA 1970) (affirming obviousness rejection where claim "reads on both obvious and unobvious subject matter.").

This argument also is not persuasive because, when considering the rationale for combining references, "the problem examined is not the specific problem solved by the invention but the general problem that confronted the inventor before the invention was made." *In re Kahn,* 441 F.3d 977, 988 (Fed. Cir. 2006). The rationale for combining references may be different from the inventor's specific reasons or goals for making the invention. *Id.* In the present case, the general problem confronting the inventors of the '105 patent was one of improving accuracy of the test strips. Ex. 1002, 1:15-18 ("the accuracy . . . is very important since an inaccurate reading could lead to the wrong level of insulin being administered which could be very harmful"). Pharmatech's rationale for combining Nankai and Schulman—that one of ordinary skill in the art would have recognized that Schulman's multisensor comparison method could improve the accuracy of Nankai's multisensor test strip (Pet. 17)—addresses the same general problem.

(5) Whether Schulman discloses a disposable test strip

LifeScan argues that Schulman does not disclose a test strip having the claimed structure. Resp. 30. Specifically, LifeScan argues that Schulman does not disclose a test strip which has two working sensor parts and a common reference sensor part. *Id.* LifeScan also argues that Schulman does not disclose applying sample liquid to the test strip. *Id.* Specifically, LifeScan argues that Schulman's device is implanted in the body and is, therefore, in continuous contact with sample. *Id.* LifeScan describes Schulman's arrangement as "not related" to test strips that are used for intermittent measurements. *Id.* LifeScan also argues that Schulman uses the term "sensor" differently from how the term is used in the '105 patent. Resp. 28-29. According to LifeScan, the term "sensor," or more specifically, "sensor part," is used in the '105 patent to refer to a single electrode on a test strip, whereas a "sensor" in Schulman is an entire assembly of several electrodes and other structure. *Id.* at 29 (citing Ex. 1002, claims 1-3; Ex. 1007, 7:28-30; Ex. 2008 ¶ 59).

These arguments are unpersuasive, because Pharmatech does not rely on Schulman for any of these disclosures. Pharmatech relies on Schulman simply for the limited disclosure that multiple measurements of a sample can be made, compared to establish a difference parameter, and rejected if the difference exceeds a threshold. Pet. 16-17, 21; Reply

3; *see id.* at 6 ("the proposed [challenges] do not rely upon the specific sensor of Schulman"). That Schulman happens to disclose this technique in the context of continuous monitoring by an implanted electrode, instead of intermittent monitoring by a disposable electrode, is of no moment.

LifeScan's arguments that (a) Schulman's measurement of oxygen depletion is not "in proportion" to the glucose concentration (Resp. 31-32, 37); (b) Schulman does not disclose a second sensor making an independent measurement *(id.* at 32-33); (c) Schulman does not compare the currents from its two sensors with one another directly because they measure different things *(id.* at 34, 37-38); and (d) Schulman does not disclose a single measuring device with multiple sensor parts *(id.* at 34-36, 38) each are unpersuasive for the same reason.

(6) "Fundamental technique" of measuring glucose.

LifeScan disputes our initial determination that Nankai, Schulman, and the '105 patent use the same "fundamental technique" for measuring glucose oxidase ("GOx")-mediated electrical current. Resp. 30-31 (citing Dec. 13). LifeScan argues that Schulman measures current resulting from oxygen reduction, not from a GOx-mediated oxidation of glucose followed by oxidation of a mediator. Resp. 31 (citing Ex. 2008 ¶ 68).

This argument is unpersuasive because LifeScan does not explain its relevance to the combinability of Nankai and Schulman. We also disagree with LifeScan's assertion. Schulman measures a GOx-mediated electrical current in the sense that the oxygen reduction it measures results from consumption of the oxygen by GOx to oxidize glucose in the blood. Ex. 1007, 3:35-62. We pointed out this similarity—the use of GOx and current measurements by each of Nankai, Schulman, and the '105 patent—to explain why we were not persuaded by LifeScan's Preliminary Response argument that Schulman is non-analogous to single-use test strip technologies. Dec. 12-13 (citing Paper 10, 28).

(7) Combination of Nankai and Schulman

LifeScan argues that there is no evidence supporting a rationale to combine Nankai and Schulman and that, instead, the evidence shows that one of ordinary skill would have been led away from the combination. Resp. 38-43.

LifeScan argues that Schulman's glucose calculation method, which involves subtracting an oxygen depletion signal from a background oxygen signal to obtain a glucose result, is less accurate than the claimed method of comparing two glucose results. *Id.* at 40-41 (citing Ex. 2008 ¶ 83).

This argument is unpersuasive for the reason discussed above in subsection (5): Pharmatech relies

on Schulman not for disclosure of the particular glucose measurement method, but rather only for disclosure of making multiple measurements and signaling an error if a difference parameter between the measurements exceeds a threshold. LifeScan does not credibly explain why it would not have been reasonable for one of ordinary skill in the art to have taken away from Schulman only this limited teaching. *See EWP Corp. v. Reliance Universal Inc.,* 755 F.2d 898, 907 (Fed. Cir. 1985) ("A reference must be considered for everything it *teaches* by way of technology and is not limited to the particular *invention* it is describing and attempting to protect.").

LifeScan identifies other purported disadvantages of Schulman's glucose measurement method, including errors that would be introduced by the local generation of hydrogen peroxide and local deficit of oxygen. Resp. 41-42 (citing Ex. 2008 ¶¶ 84-85). These arguments are unpersuasive for the same reason, because they depend on the incorporation of disclosure from Schulman beyond that which Pharmatech argues.

LifeScan argues that Schulman was less concerned with accuracy of individual measurements, because the continuous operation of the sensor would, instead, permit error detection by comparison of results over time. *Id.* at 42 (citing Ex. 2008 ¶ 88). Again, this argument is unpersuasive because it is not responsive to the challenge as Pharmatech has framed it.

LifeScan argues that Schulman's device has not been commercialized, and also that Dr. Smith never had any reason to consider implantable monitors in the course of decades of work seeking to improve disposable test strips. *Id.* at 43 (citing Ex. 2008 ¶¶ 86, 88-90). These arguments are unpersuasive, because they do not address why one of ordinary skill in the art would have been dissuaded from adapting the disclosure from Schulman that Pharmatech cites.

4. Objective evidence of nonobviousness

LifeScan argues that Pharmatech's copying of LifeScan's test strips demonstrates nonobviousness of claims 1-3. Resp. 45-49 (citing Ex. 2008 ¶¶ 92-95). LifeScan argues that Pharmatech's "GenStrip" test strip is similar to LifeScan's commercial strip. *Id.* at 46-48. LifeScan argues, and Pharmatech does not dispute in its Reply, that use of either a LifeScan test strip or a Pharmatech test strip with LifeScan's "One Touch Ultra" meter, to measure blood glucose, falls within the scope of claims 1-3. *Id.* at 47-48 (citing Ex. 2008 ¶¶ 92, 95). Pharmatech argues that its copying is not probative of obviousness because at least some level of copying was necessary to make its test strips operable with LifeScan's meter device, and because evidence of copying, without more, is not persuasive of *nonobviousness.* Reply 14 *(citing Cable Elec. Products, Inc. v. Genmark, Inc.*, 770 F.2d 1015, 1028 (Fed. Cir. 1985), *overruled on other grounds by Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356, 1359 (Fed. Cir. 1999)).

5. Analysis

Nankai discloses a test strip having the structure recited in claim 1, expect for the position of the reference sensor part being upstream from the two working sensor parts. *Supra* at section II.B.2.a. Nankai's disclosure that the arrangement of its sensors may vary (Ex. 1003, 8:50-52) provides adequate reason for one of ordinary skill in the art to have repositioned the reference sensor part, in view of Dr. Wang's unrebutted testimony[2] (Ex. 1024 ¶ 25) that positioning the reference sensor part upstream of the working sensor parts was one of a finite number of possibilities and would have been obvious to try. *See KSR,* 550 U.S. at 417 (arrangement of prior-art elements that yields no more than expected results is obvious); *In re Kuhle,* 526 F.2d 553, 555 (CCPA 1975) (particular placement of electrical contact an obvious matter of design choice absent showing of an unexpected result). As discussed above in section II.B.3.b(2), we are unpersuaded that there is criticality in the positioning of the reference sensor, because LifeScan has not explained how any benefits flowing from the claimed position are unexpected.

The combination of Nankai with Schulman similarly is reasonable. Schulman's teachings about the need to compare independent concentration measurements, and signal an error if they diverge, transcend the particular sensor systems for which they are implemented. We agree with Pharmatech,

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[2] Dr. Smith acknowledges Dr. Wang's testimony but does not respond to it directly. *See* Ex. 2008 ¶ 42.

and credit Dr. Wang's testimony, that one of ordinary skill in the art, seeking to improve the accuracy of a multisensor test strip such as Nankai's, would have had reason to use Schulman's comparison and error techniques. *See* Pet. 17; Ex. 1024 ¶ 27.

LifeScan's arguments to the contrary, discussed above in sections II.B.3.b(5)-(7), dwell on technical details of Schulman's sensor assemblies, not on the more general discussion of the need to detect divergence between redundant measurements in order to signal error. *See, e.g.,* Ex. 1007, 3:21-24 (calling for a "prescribed degree of correlation . . . to validate the correctness" of the measurement). LifeScan does not explain credibly why one of ordinary skill would have been deterred from using the general disclosure of Schulman by differences between Nankai's and Schulman's sensor structure or intended use.

Set against Pharmatech's evidence is LifeScan's evidence of copying by Pharmatech. LifeScan argues, and Pharmatech does not dispute, that measuring blood glucose with either company's test strip and LifeScan's meter falls within the scope of the claims. Resp. 47-48.

It is not sufficient, however, that a product or its use merely be within the scope of a claim in order for objective evidence of nonobviousness tied to that product or use to be given substantial weight. There must also be a causal relationship, termed a "nexus," between the evidence and the claimed subject matter. *Merck & Co., Inc.* v. *Teva Pharm. USA, Inc.,* 395 F.3d

1364, 1376 (Fed. Cir. 2005). A nexus is required in order to establish that the evidence relied upon traces its basis to the claimed subject matter, not to another source. *Institut Pasteur & Universite Pierre Et Marie Curie* v. *Focarino,* 738 F.3d 1337, 1347 (Fed. Cir. 2013). The stronger the showing of nexus, the greater the weight accorded the objective evidence of nonobviousness. *See Ashland Oil, Inc.* v. *Delta Resins & Refractories, Inc.,* 776 F.2d 281, 306 (Fed. Cir. 1985), *cert. denied*, 475 U.S. 1017 (1986). Like other types of objective evidence, evidence of copying must be shown to have nexus. *Wm. Wrigley Jr. Co.* v. *Cadbury Adams USA LLC,* 683 F.3d 1356, 1364 (Fed. Cir. 2012). A showing of nexus is required in order to demonstrate that the claimed subject matter drove the copying. *See Institut Pasteur,* 738 F.3d at 1338; *see also Cable Elec. Products,* 770 F.2d. at 1028 (copying could result from lack of concern about patent property, contempt for the patent, or accepted practices in the industry, among others).

LifeScan does not direct any argument or credible evidence to the issue of nexus. Instead, LifeScan argues, and Pharmatech does not dispute, that the copying was motivated by a desire to make Pharmatech's test strips compatible with LifeScan's "One Touch Ultra" meter system. Resp. 47 (citing Ex. 2008 ¶ 43); Reply 14 (acknowledging that "some level of copying was necessary to get the GenStrip to work with Lifescan OneTouch Ultra meters"). LifeScan does not show or explain credibly how this reason for copying relates to the claimed subject matter, as opposed to unclaimed features, or to considerations unrelated to the invention.

Pharmatech makes a rational argument for obviousness of claims 1-3 over Nankai and Schulman. As discussed above, we agree with Pharmatech that the evidence of record establishes that it would have been a matter of design choice to reposition Nankai's reference sensor to be upstream of the working sensor parts, and that one of ordinary skill would have had reason to adapt Schulman's comparison and error-signaling methods to Nankai's system.

LifeScan's objective evidence of copying is not sufficient to overcome Pharmatech's obviousness argument. As noted above, evidence of copying requires a nexus with the claimed subject matter. But LifeScan's evidence has not been tied credibly to the claims under review. As a result, the causal relationship between the claimed subject matter and the objective evidence is tenuous.

Because LifeScan has not shown nexus convincingly, the objective evidence does not persuade us that the apparent copying of its test strips can be traced to the claimed subject matter. When we balance Pharmatech's evidence of obviousness against the objective evidence of nonobviousness, we determine that a preponderance of the evidence supports Pharmatech's argument that it would have been obvious to combine Nankai and Schulman to reach the subject matter of claims 1-3.

Accordingly, we conclude that Pharmatech has demonstrated the unpatentability of claims 1-3 for obviousness over Nankai and Schulman, by a preponderance of the evidence.

C. Obviousness over Winarta and Schulman

Pharmatech argues that claims 1-3 are unpatentable under 35 U.S.C. § 103(a) over Winarta in combination with Schulman. Pet. 42-46. LifeScan responds, both arguing that Pharmatech has not demonstrated the obviousness of the claims (Resp. 21-43), and presenting objective evidence of nonobviousness. Resp. 45-49.

Again, we undertake the four factual inquiries of an obviousness analysis.

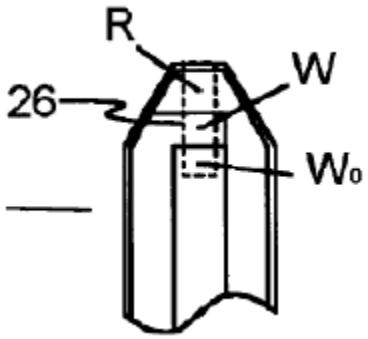
1. The level of skill in the art

The discussion presented above in section II.B.1 is equally applicable here.

2. Scope and content of the prior art

a. Overview of Winarta

Winarta describes a disposable GOx-coated electrode test strip used to calculate glucose in a blood sample by measuring current. Ex. 1005, 7:11-42. Detail from Figure 2 of Winarta is reproduced below:



The detail from Figure 2 shows the tip of a test strip. Reference electrode R, working electrode W, and pseudo-working electrode W_0 are positioned in electrode area 26. *Id.* at 8:63-67. All three electrodes are coated with a reagent mix that includes GOx. *Id.* at 7:25-26, 28, 41-42. A fluid channel runs over the electrodes, and the electrodes are arranged in the order R-W-W_0 from the open end, so that fluid entering the strip flows first over R, then W, and then W_0. *Id.* at 5:59-62. Flow onto W_0 causes a current that triggers a meter to begin a measurement. *Id.* at 5:64-65. W_0 also may be used as a counter electrode, and measurements may be taken between R and W_0. *Id.* at 6:1-10.

b. Schulman

The overview of Schulman presented above in section II.B.2.b is equally applicable here.

3. Differences between the claimed subject matter and the prior art

a. Petitioner's Case-in-Chief

Pharmatech argues that Winarta discloses all limitations of claim 1 except (*a*) measuring an electric current at a *second* working sensor part; (*b*) comparing the electric current from each of the working sensor parts to establish a difference parameter; and (*c*) giving an indication of an error if the difference parameter is greater than a predetermined threshold. Pet. 42-46. Pharmatech argues that Schulman discloses all three missing limitations. *Id.* at 43, 45-46. With particular reference to the claim requirement that the first and second working sensor generate "substantially identical" quantities of charge carriers in the absence of an error condition, Pharmatech argues that Winarta Figure 2 shows that W and W_0 are the same size, but that, even if they are not, it would have been obvious to make them the same size in order to take advantage of Schulman's comparisons based on multiple measurements. *Id.* at 44-45 (citing Ex. 1024 161).

With regard to limitation (*a*), Pharmatech argues that, because Winarta describes W_0 as capable of being used to take measurements, it would have been obvious to modify Winarta to do so in view of Schulman's disclosure to use two or more sensors to confirm reliability of a measurement. *Id.* at 43, 45 (citing Wang Decl. ¶ 63). With regard to limitations (*b*) and (*c*), Pharmatech argues, as it did in the

Nankai/Schulman challenge, that modifying Winarta to include these steps would have been nothing more than the application of a known technique to improve a similar device with predictable results. *Id.*

b. Patent Owner's Response

LifeScan presents several arguments in response to Pharmatech's challenge. We address them in turn.

(1) Uses of W_0

LifeScan argues that electrode W_0 is not disclosed by Winarta as being a working sensor part. Resp. 21-22. LifeScan argues W_0 is incapable of making a glucose measurement, because none of the roles for W_0 disclosed in Winarta—as counter electrode, resistance sensor, or trigger— can be used to make such a measurement. *Id.* at 22-25 (citing Ex. 2008 ¶ 18, 53-55).

This argument is unpersuasive, because Pharmatech's challenge is not premised on operating W_0 in the role of a counter electrode, resistance sensor, or trigger in order to obtain a glucose measurement. LifeScan presents numerous technical explanations as to why, for example, an electrode serving as a counter electrode could not be used to measure glucose, but none of those explanations is germane to the challenge that Pharmatech has presented. Pharmatech argues that the structural features of W_0 (such as its reagent coating), and its arrangement with the other parts of Winarta's test

strip, make it capable of being operated in an additional manner: as a working electrode. Pet. 42-44. In this mode, W_0 could be used to make a second glucose measurement, in addition to the measurement made at W.

Pharmatech has presented a reasonable explanation, supported by expert testimony, that W_0 is capable of being used as a working electrode. In particular, Pharmatech has shown that W_0 is formed as an electrode and is coated with the same reagents as W. *See* Pet. 42-44; Ex. 1024 ¶ 49. We are persuaded that W_0 is capable of being operated as a working electrode. LifeScan has not explained what essential structural feature W_0 lacks, or what extraneous structural feature it possesses, that would render W_0 incapable of functioning as a working electrode. LifeScan has not credibly explained why Pharmatech's argument on this point is in error.

(2) External circuit arrangement in Winarta

LifeScan argues that Winarta does not disclose any external circuit arrangement or calculation method in a device to allow glucose measurement at W_0. Resp. 25 (citing Ex. 2008 ¶ 55).

This argument is unpersuasive, because Winarta does have circuitry for making measurements involving W_0. *See* Ex. 1005, 6:5-7 (W_0 can be used with R to measure sample resistance). Upon consideration of the record, we are persuaded

that the modifications required to the existing external circuitry would have been within the ability of one of ordinary skill in the art.

(3) Modification of W_0 to make glucose measurements

LifeScan argues that, because Winarta already discloses three uses for W_0, there would have been no reason for one of ordinary skill to employ it for the undisclosed use of making a glucose measurement. Resp. 25 (citing Ex. 2008 ¶ 55). This argument is not persuasive, because LifeScan does not explain why three disclosed uses would have prevented or dissuaded one of ordinary skill from considering a fourth use.

(4) Size of W_0

LifeScan argues that, even if there were reason to use W_0 as a second working electrode, it would need to be of equal size to W, in order to meet the claim limitation that the two working sensor parts generate substantially identical quantities of charge carriers. Resp. 25-26. LifeScan argues that Winarta is silent as to whether W_0 is the same size as W. *Id.* at 26 (citing Ex. 2008 ¶ 54). As noted above, Pharmatech argues that Figure 2 of Winarta shows that W and W_0 have the same size and that, even if they were not uniform in size, it would have been obvious to make them so, in order to employ Schulman's methods for comparing multiple measurements. Pet. 44-45 (citing Ex. 1024 ¶ 61).

We agree with LifeScan that Winarta is silent as to whether W and W_0 are of the same size. Pharmatech relies on a patent drawing, and on an expert's interpretation of that patent drawing. *See* Pet. 44; Ex. 1024 ¶ 61. But unless a patent drawing is indicated as being to scale, it generally is not to be relied upon for precise proportions. *In re Wright,* 569 F.2d 1124, 1127 (CCPA 1977). There are, then, three possibilities for the size of W_0 relative to W: smaller, equal, or larger. We credit Dr. Wang's testimony that it would have been obvious to make them the same size in the course of adapting Schulman's comparison method to Winarta's test strip. *See* Ex. 1024 ¶ 61.

(5) Whether the combination of Winarta and Schulman meets all limitations

LifeScan argues that the combination of Winarta and Schulman fails to meet all limitations of the challenged claims. Resp. 44-45. LifeScan points out that Winarta does not disclose a test strip with two working sensor parts, and that Schulman does not remedy this deficiency. *Id.* at 44 (citing Ex. 2008 ¶¶ 50-55). LifeScan also argues that, because of this deficiency, neither Winarta nor Schulman discloses comparing the electric current from two working sensor parts. *Id.* at 44-45 (citing Ex. 2008 ¶ 81).

These arguments are unpersuasive, because they address the references individually. The relevant inquiry is what the combination of the

references would have conveyed to one of ordinary skill in the art. Pharmatech argues that Schulman's comparison method would have led one of ordinary skill to make Winarta's W_0 electrode the same size as W and to use it as a second working sensor part. Pet. 44-45. Under Pharmatech's argument, the notion of a test strip with two working sensor parts would have emerged from the combination of Winarta and Schulman, not from either reference by itself. *See EWP,* 755 F.2d at 907 ("On the issue of obviousness, the combined teachings of the prior art as a whole must be considered.").

(6) Whether one of ordinary skill would have been led to combine Winarta and Schulman

LifeScan asserts that the arguments it gave concerning the combination of Nankai and Schulman, discussed above in section II.B.3.b(7), are applicable to the combination of Winarta and Schulman. Resp. 45. These arguments are not persuasive, for the reasons given in that section.

4. Objective evidence of nonobviousness

The discussion presented above in section II.B.4 is equally applicable here.

5. Analysis

Winarta discloses a test strip having the structure recited in claim 1, except for specifying that one of the electrodes, W_0, is a working sensor part and would generate a number of charge carriers substantially identical to the number of charge carriers generated by the other working sensor part. As discussed above in section II.C.3.b(1), we agree with Pharmatech that W_0 has the structural features necessary to function as a working sensor part.

The combination of Winarta with Schulman is reasonable, for the reasons discussed above. We credit Dr. Wang's testimony that one of ordinary skill in the art would have had reason to implement Schulman's multiple measurement and comparison method in Winarta's device and would have thought to adapt W_0 as a second working electrode during that implementation. *See* Ex. 1024 ¶¶ 63-64. LifeScan's technical critique of Schulman's sensor assemblies does not persuade us that one of ordinary skill in the art would not have adapted other disclosure from Schulman for use in Winarta. LifeScan's evidence of copying is entitled to little weight, because LifeScan has not shown a nexus between that evidence and the claims, as discussed above in section II.B.5. When we balance Pharmatech's evidence of obviousness against the objective evidence of nonobviousness, we determine that a preponderance of the evidence supports Pharmatech's argument that it would have been obvious to combine Winarta and Schulman to reach the subject matter of claims 1-3.

Accordingly, we conclude that Pharmatech has demonstrated the unpatentability of claims 1-3 for obviousness over Winarta and Schulman, by a preponderance of the evidence.

III. CONCLUSION

Pharmatech has proved, by a preponderance of the evidence, that the subject matter of claims 1-3 would have been obvious over the combined teachings of Nankai and Schulman, as well as over the combined teachings of Winarta and Schulman.

IV. ORDER

For the reasons given, it is

ORDERED that claims 1-3 of U.S. Patent No. 7,250,105 B1 are determined to be UNPATENTABLE; and

FURTHER ORDERED that because this is a final decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PHARMATECH SOLUTIONS, INC.,
Petitioner,

v.

LIFESCAN SCOTLAND LTD.,
Patent Owner.

Case IPR2013-00247
Patent 7,250,105

Before SALLY C. MEDLEY, SCOTT R. BOALICK, and SCOTT E. KAMHOLZ, *Administrative Patent Judges*.

KAMHOLZ, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

A. Background

Pharmatech Solutions, Inc. ("Pharmatech") filed a petition (Paper 1, "Pet.") requesting an *inter partes* review of claims 1-3 (the "challenged claims") of U.S. Patent 7,250,105 (Ex. 1001, "the '105 patent"). Patent Owner LifeScan Scotland Ltd. ("LifeScan") filed a preliminary response (Paper 10, "Prelim. Resp."). The standard for instituting an *inter partes* review is set forth in 35 U.S.C. § 314(a), which provides as follows:

> THRESHOLD.—The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

Upon consideration of the petition and patent owner preliminary response, we conclude that Pharmatech has established a reasonable likelihood that it would prevail with respect to claims 1-3 of the '105 patent. Accordingly, we grant the petition and institute an *inter partes* review of claims 1-3 of the '105 patent.

B. Related Proceedings

Pharmatech indicates that the '105 patent is involved in a civil action captioned *LifeScan, Inc. v. Shasta Techs., LLC,* No. 5:11-CV-04494-EJD (N.D.Cal). Pet. 2. Pharmatech is a co-defendant in that action. *Id.* LifeScan indicates that a preliminary injunction, issued in that action, has been stayed pending Pharmatech's appeal to the U.S. Court of Appeals for the Federal Circuit, where the case is now under consideration. Prelim. Resp. 10-11.

C. The '105 Patent

The '105 patent relates to monitoring the level of a substance in a liquid, particularly the level of glucose in blood. Ex. 1002, 1:7-10. A glucose assay is performed by inserting a test strip into a meter and then applying a drop of blood to the test strip. *Id.* 5:14-25. The test strip is made from layers of various materials, built up on a plastic base and capped with a cover. *Id.* 4:35-5:14. Figure 2 is reproduced below:

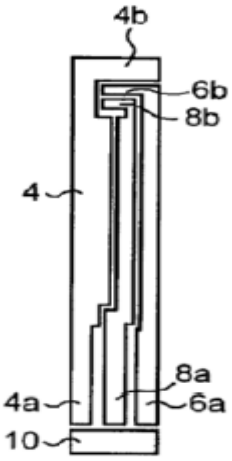


FIG. 2

Figure 2 illustrates one layer of the test strip, in which a pattern of carbon ink is screen-printed onto the test strip base. *Id.* 4:23-24. The carbon ink forms three tracks 4, 6 (not labeled), and 8 (not labeled), along the strip, as well as a connecting bridge 10. *Id.* 4:44-51. Each track has a connecting terminal 4*a*, 6*a*, 8*a* at one end of the strip and an electrode 4*b*, 6*b*, 8*b* at the other end. *Id.* A layer of glucose oxidase ("GOx") is printed on the electrodes. *Id.* 4:65-66. Various other layers are deposited to define the rest of the structure, such as the precise sizes of the electrodes and a flow path for the blood. *Id.* 4:54-5:14.

A user begins a glucose measurement by inserting the terminal end of the test strip into a meter device; the connecting bridge completes a circuit upon insertion to turn on the device. *Id.* 5:16-18. The device applies a voltage between the

reference terminal 4*a* and terminal 6*a,* and also between the reference terminal 4*a* and terminal 8*a*. *Id.* 5:19-22. A drop of blood is deposited at the distal end of the strip, and the blood is drawn over electrodes 4*b,* 6*b,* and 8*b* by capillary action. *Id.* 5:23-26. The blood thereby comes into contact with the GOx printed on the electrodes, and the GOx reacts with glucose in the blood to release electrons. The resulting electric currents through carbon tracks 4 and 6 are proportional to both the surface area of the electrode covered by GOx and the amount of glucose in the blood sample. *Id.* 1:27-38. Because the GOx surface area is known, the electric current is indicative directly of the amount of glucose in the blood. *Id.* The currents are measured by the meter device after a predetermined time. *Id.* 5:26-27. The current measurements are compared to one another, and if they differ by more than 10%, an error message is displayed so that the user will know to repeat the test. *Id.* 5:27-30. If they are within 10% of each other, the measured currents are summed and converted into a glucose level, which is then displayed. *Id.* 5:30-33.

The challenged claims are reproduced below:

> 1. A method of measuring the concentration of a substance in a sample liquid comprising the steps of: providing a measuring device said device comprising:
>
> a first working sensor part for generating charge carriers in proportion to the concentration of said substance in the sample liquid;

a second working sensor part downstream from said first working sensor part also for generating charge carriers in proportion to the concentration of said substance in the sample liquid wherein said first and second working sensor parts are arranged such that, in the absence of an error condition, the quantity of said charge carriers generated by said first working sensors part are substantially identical to the quantity of said charge carriers generated by said second working sensor part; and

a reference sensor part upstream from said first and second working sensor parts which reference sensor part is a common reference for both the first and second working sensor parts, said reference sensor part and said first and second working sensor parts being arranged such that the sample liquid is constrained to flow substantially unidirectionally across said reference sensor part and said first and second working sensor parts; wherein said first and second working sensor parts and said reference sensor part are provided on a disposable test strip;

applying the sample liquid to said measuring device; measuring an electric current at each working sensor part

proportional to the concentration of said substance in the sample liquid;

comparing the electric current from each of the working sensor parts to establish a difference parameter; and

giving an indication of an error if said difference parameter is greater than a predetermined threshold.

2. The method as claimed in claim 1 comprising measuring the current at each working sensor part after a predetermined time following application of the sample.

3. The method as claimed in claim 1 wherein the substance to be measured is glucose, and each of the working sensor parts generates charge carriers in proportion to the concentration of glucose in the sample liquid.

D. Prior Art Relied Upon in the Petition

Pharmatech relies upon the following references, as well as the declaration of Professor Joseph Wang, D.Sc. (Ex. 1024):

Horii	US 5,004,998	Apr. 2, 1991	Ex. 1011
Nankai	US 5,120,420	Jun. 9, 1992	Ex. 1003
Yee	US 5,672,256	Sep. 30, 1997	Ex. 1006
Schulman	US 5,791,344	Aug. 11, 1998	Ex. 1007

Say	US 6,175,752	Jan. 16, 2001	Ex. 1004
Winarta	US 6,258,229	Jul. 10, 2001	Ex. 1005
Stewart	US 6,540,891	Apr. 1, 2003	Ex. 1010
Khazanie	*Statistics in a World of Applications*	1997	Ex. 1008
Lichten	*Data and Error Analysis in the Introductory Physics Laboratory*	1996	Ex. 1009

E. The Asserted Grounds of Unpatentability

Pharmatech asserts that the challenged claims are unpatentable based on the following grounds (Pet. 4-5):

1. Claim 1 is unpatentable under 35 U.S.C. § 103(a) over Nankai and Say; or over Nankai, Say, and Winarta; or over Nankai, Say, and Yee; or over Nankai, Say, Winarta, and Yee;

2. Claim 1 is unpatentable under 35 U.S.C. § 103(a) over Nankai and Schulman; or over Nankai, Schulman, and Winarta; or over Nankai, Schulman, and Yee; or over Nankai, Schulman, Winarta, and Yee;

3. Claim 1 is unpatentable under 35 U.S.C. § 103(a) over Nankai and Khazanie; or over Nankai, Khazanie, and Winarta; or over

Nankai, Khazanie, and Yee; or over Nankai, Khazanie, Winarta, and Yee;

4. Claim 1 is unpatentable under 35 U.S.C. § 103(a) over Nankai and Lichten; or over Nankai, Lichten, and Winarta; or over Nankai, Lichten, and Yee; or over Nankai, Lichten, Winarta, and Yee;

5. Claim 1 is unpatentable under 35 U.S.C. § 103(a) over any of the combinations listed in 1-4 above, in further combination with Stewart;

6. Claim 1 is unpatentable over any of the combinations listed in 1-4 above, in further combination with Horii;

7. Claim 1 is unpatentable under 35 U.S.C. § 103(a) over Winarta and Say;

8. Claim 1 is unpatentable under 35 U.S.C. § 103(a) over Winarta and Horii;

9. Claim 1 is unpatentable under 35 U.S.C. § 103(a) over Winarta and Schulman;

10. Claim 1 is unpatentable under 35 U.S.C. § 103(a) over Winarta, Yee, and Khazanie;

11. Claim 1 is unpatentable under 35 U.S.C. § 103(a) over Winarta and Lichten;

12. Claim 2 is unpatentable under 35 U.S.C. § 103(a) over any combination listed in 1-11 above; and

13. Claim 3 is unpatentable under 35 U.S.C. § 103(a) over any combination listed in 1-11 above.

II. DISCUSSION

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Office Patent Trial Practice Guide,* 77 *Fed. Reg.* 48756, 48766 (Aug. 14, 2012). Also, claim terms are given their ordinary and customary meaning as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.,* 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen,* 30 F.3d 1475, 1480 (Fed. Cir. 1994).

1. "Proportion " and "proportional to"

Pharmatech and LifeScan agree that the terms "proportion" and "proportional to" in the claims should be construed as "correlated to." Pet. 5-6; Prelim. Resp. 11-14. Upon consideration of the

record, the agreed-upon construction of the terms "proportion" and "proportional to" to mean "correlated to" is consistent with the plain and ordinary meaning in the context of the specification. We adopt the agreed upon construction.

2. "Downstream"

According to LifeScan, a first working sensor part is not "downstream" of a second working sensor part unless the first part is covered completely before the second part begins to be covered, thereby avoiding any possibility that insufficient sample is applied to cover both working sensor parts. Prelim. Resp. 17-18 (citing Ex. 1002, 3:43-50).

We do not agree. The cited passage of the '105 patent describes certain properties and benefits that result from the *particular* downstream arrangement the patent discloses. The term "downstream" itself indicates that the position of one item is further along a stream from the source of the stream than is another item. Accordingly, for purposes of this decision, we construe "downstream" to mean "further along a stream from its source."

3. "Substantially unidirectionally"

LifeScan contends that "substantially unidirectionally" in the context of the flow of a liquid means substantially unidirectionally *along a single path,* not along multiple, parallel paths. Prelim. Resp. 17-18 (citing Ex. 1002, 3:43-50).

Again, we do not agree. Nothing in the passage LifeScan cites indicates that a unidirectional flow must be along a single path. Accordingly, for purposes of this decision, we construe "substantially unidirectionally" to mean "along, or nearly along, one direction."

B. Obviousness over Nankai and Schulman

Pharmatech argues that claims 1-3 are unpatentable under 35 U.S.C. § 103(a) over Nankai in various combinations with other references. *See* section I.D, *supra.* Upon consideration of the parties' arguments and evidence, we are persuaded that Pharmatech has demonstrated a reasonable likelihood that claims 1-3 are unpatentable as obvious over Nankai and Schulman. We deny as redundant all other challenges based on Nankai.

1. Overview of Nankai

Nankai describes disposable biosensors for measuring, e.g., glucose concentration in blood. Ex. 1003, 3:65-68. Figure 12 of Nankai is reproduced below:

FIG. 12

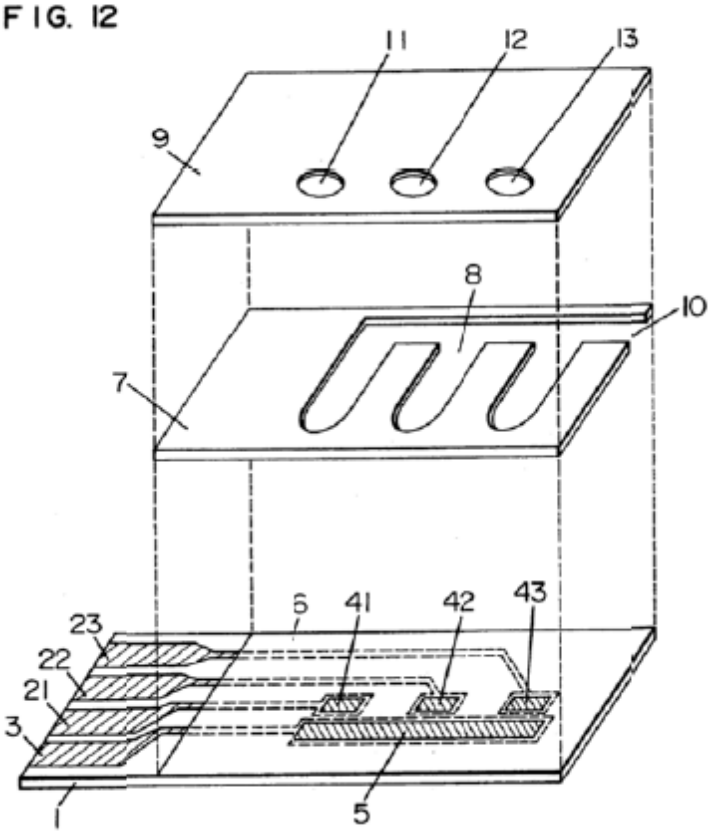


Figure 12 shows a glucose sensor having base plate 1 on which is formed lead 3 and corresponding counter electrode 5, and leads 21, 22, and 23, and corresponding measurement electrodes 41, 42, and 43. *Id.* 8:5-10. Spacer 7 overlies the base plate, and space 8 cut out from the spacer provides a conduit for a blood sample to flow from introducing port 10 to the measurement and counter electrodes. *Id.* Abstr., 8:15-18. Cover 9 provides discharge ports 11, 12, and

13, through which air leaves space 8 as it is displaced by the flowing blood. The measurement electrodes are coated with GOx. *Id.* 5:1, 8:11-14. During use, blood enters through the introducing port and flows along the main conduit of space 8, with portions of the sample entering successive branches along the main conduit. *Id.* 8:25-27. A current measurement is made at each sensor, and the measurements are averaged to give a final result. *Id.* 8:42-46.

2. Overview of Schulman

Schulman describes an implantable sensor used to monitor blood glucose continuously by GOx-mediated current measurements. Ex. 1007, 3:17-28, 4:20-30, 7:35-37. Two or more sensors may be used to confirm the correctness of the measurement. *Id.* 4:46-50. The readings from two sensors are compared, and if they are not within 10% of one another, the system requests sensor recalibration *(id.* 11:16-22, 20:50-54), and issues an error message advising the user to check the sensors. *Id.* 21:9-13.

3. Analysis

Pharmatech argues that Nankai discloses all limitations of claim 1 except (*a*) the position of the reference sensor part "upstream" of the first and second working sensor parts, (*b*) the step of comparing the electric current from each of the working sensor parts to establish a difference parameter; and (*c*) the step of giving an indication of an error if the difference parameter is greater than a predetermined threshold. Pet. 16-21.

With regard to limitation (*a*), Pharmatech argues that while Nankai positions the reference sensor part (i.e., counter electrode 5) downstream of the working sensor parts 43, 42, a person of ordinary skill in the art would have known that there was a finite number of ways to arrange a reference sensor part in relation to a working sensor part and that repositioning the reference sensor part upstream from the working sensor parts, as opposed to downstream from the working sensor parts, would have been obvious to try. *Id.* at 16, 19 (citing Ex. 1024 (Wang Decl.) ¶ 25). Pharmatech also argues that there is no criticality in arranging the reference electrode upstream and points to disclosure in the '105 patent indicating that the working sensors may be "arranged as convenient." *Id.* (citing Ex. 1024 ¶ 25 and Ex. 1002, 3:36-58).

Pharmatech's rationale that it would have been obvious to reposition the reference sensor part to be upstream of the working sensor parts is reasonable and supported by record evidence. LifeScan has not demonstrated otherwise.

With regard to limitations (*b*) and (*c*), Pharmatech argues that Schulman discloses them and that modifying Nankai to include these steps would have been nothing more than the application of a known technique to improve a similar device with predictable results. *Id.* at 16-17, 21; Ex. 1024 ¶ 27-28.

LifeScan argues that Schulman is concerned with "continuous measurement" of glucose, not

periodic measurements made with disposable strips, and that Pharmatech has not explained why one of ordinary skill would have looked to such a reference when considering modifications to Nankai. *Id.* at 23-24, 27-29. According to LifeScan, "continuous measurement" art, such as Schulman, is non-analogous to the single-use, disposable subject matter claimed in the '105 patent, because each faces problems the other does not. Prelim. Resp. 28; Ex. 2001 ¶¶ 116-117.[1] LifeScan argues that the combination of Nankai and Schulman is based, therefore, on hindsight reasoning. *Id.* LifeScan also argues that Dr. Wang's statements regarding obviousness of the combination are conclusory assertions that should be given no weight, while those of Dr. Meyerhoff are not conclusory and should be given weight. Prelim. Resp. 28-29.

We are unpersuaded by LifeScan's arguments. Dr. Wang's opinion testimony is unnecessary to support Pharmatech's argument that one of ordinary skill would have considered Schulman. Schulman, Nankai, and the '105 patent each are concerned with measuring blood glucose, and each uses the same fundamental technique of measuring GOx-mediated electrical current. LifeScan's arguments and expert testimony ignore this fundamental common theme among the '105 patent and the cited art and instead place undue emphasis on differences between the

[1] Exhibit 2001 is a declaration by Dr. Mark E. Meyerhoff, a professor of chemistry at the University of Michigan. Ex. 2001 ¶ 1. It was submitted in evidence by LifeScan in the civil action identified in section I.B, *supra*.

"continuous" and "single-use" settings in which this common technology is used. Schulman's descriptions of how to interpret current signals from its blood glucose sensors are relevant to other blood glucose sensor systems that generate like signals, regardless of the particular setting in which the sensors are used. Schulman is thus not non-analogous to the '105 patent or to disposable single-use test strips more generally.

Pharmatech relies on Schulman for disclosure of a particular way in which multiple measurements from a single blood sample are compared and used to alert the user to an unreliable test; that Schulman happens to disclose this method in the context of continuous monitoring by an implanted electrode instead of intermittent monitoring by a disposable electrode is of no moment.

LifeScan argues further that Nankai's second working sensor part is positioned *parallel* to the first working sensor part, not (*d*) *downstream* of the first working sensor part. Prelim. Resp. 17 (citing Ex. 2001 ¶¶ 72-74). LifeScan also argues that Nankai's sensor parts are not (*e*) arranged such that the sample liquid is constrained to flow substantially unidirectionally across them. *Id.* at 17-18 (citing Ex. 2001 1 74).

LifeScan's arguments concerning limitations (*d*) and (*e*) do not persuade us that Pharmatech's reliance on Nankai is misplaced. As to limitation (*d*), sensor 42 is "downstream" of sensor 43 in the sense that it is further along space 8 from introducing port

10 than is sensor 43. *See* section II.A.2, *supra.* The branch for sensor 42 takes off from the main conduit of space 8 at a point further along the direction of flow than does the branch for sensor 43. We discern no limitation that excludes Nankai's parallel branch structure from the scope of claim 1.

As to limitation (*e*), LifeScan argues that the flow is not substantially unidirectional because it is divided into multiple, parallel flow paths with only one working sensor part per path. Prelim. Resp. 17-18 (citing Ex. 2001 ¶ 74). But claim 1 does not require that the sample liquid be constrained to flow substantially unidirectionally across all three sensor parts *in a single path*. *See* section II.A.3, *supra.* Within each branch, the sample liquid flows along, or nearly along, one direction over one working electrode and then over the common counter electrode. *Id.* Moreover, the direction of flow in each branch is the same: toward the front edge of the strip, as shown in Figure 12. Thus, the sample liquid flows substantially unidirectionally across each electrode.

We agree as well with Pharmatech that Nankai discloses the limitations of claims 2 and 3, and that those claims would have been obvious over Nankai and Schulman for reasons similar to those given above. LifeScan's arguments are directed to claim 1, and LifeScan does not address claims 2 and 3 with separate specific arguments. *See, e.g.,* Prelim. Resp. 17-18.

For these reasons, Pharmatech has demonstrated a reasonable likelihood of prevailing on

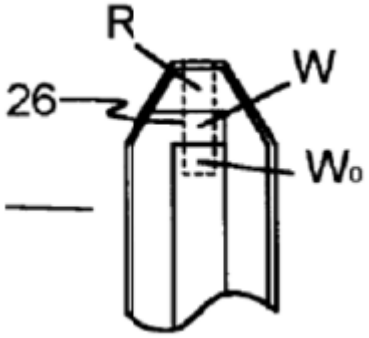
the ground of unpatentability of claims 1-3 as obvious over Nankai and Schulman.

C. Obviousness over Winarta

Pharmatech argues that claims 1-3 are unpatentable under 35 U.S.C. § 103(a) over Winarta in various combinations with other references. *See* section I.D, *supra*. Upon consideration of the parties' arguments and evidence, we determine that Pharmatech has demonstrated a reasonable likelihood that claims 1-3 are unpatentable as obvious over Winarta and Schulman. We deny as redundant all other challenges based on Winarta.

1. Overview of Winarta

Winarta describes a disposable GOx-coated electrode test strip used to calculate glucose in a blood sample by measuring current. Ex. 1005, 7:11-42. Detail from Figure 2 of Winarta is reproduced below:



The detail from Figure 2 shows the tip of a test strip. Reference electrode R, working electrode W, and pseudo-working electrode W_0 are positioned in electrode area 26. *Id.* 8:63-67. All three electrodes are coated with a reagent mix that includes GOx. *Id.* 7:25-26, 28, 41-42. A fluid channel runs over the electrodes, and the electrodes are arranged in the order R-W-W_0 from the open end, so that fluid entering the strip flows first over R, then W, and then W_0. *Id.* 5:59-62. Flow onto W_0 causes a current that triggers a meter to begin a measurement. *Id.* 5:64-65. W_0 also may be used as a counter electrode, and measurements may be taken between R and W_0. *Id.* 6:1-10.

2. Analysis

Pharmatech argues that Winarta discloses all limitations of claim 1 except (*a*) measuring an electric current at a *second* working sensor part, (*b*) comparing the electric current from each of the working sensor parts to establish a difference parameter; and (*c*) giving an indication of an error if the difference parameter is greater than a predetermined threshold. Pet. 42-46. Pharmatech argues that Schulman discloses all three missing limitations. *Id.* at 43, 45-46. With particular reference to the claim requirement that the first and second working sensor generate "substantially identical" quantities of charge carriers in the absence of an error condition, Pharmatech argues that Winarta Figure 2 shows that W and W_0 are the same size, but that, even if they are not, it would have been obvious to make them the same size in order to take

advantage of Schulman's comparisons based on multiple measurements. *Id.* at 44-45 (citing Ex. 1024 ¶ 61).

With regard to limitation (*a*), Pharmatech argues that, because Winarta describes W_0 as capable of being used to take measurements, it would have been obvious to modify Winarta to do so in view of Schulman's disclosure to use two or more sensors to confirm reliability of a measurement. *Id.* at 43, 45 (citing Wang Decl. ¶ 63). With regard to limitations (*b*) and (*c*), Pharmatech argues, as it did in the Nankai/Schulman challenge, that modifying Winarta to include these steps would have been nothing more than the application of a known technique to improve a similar device with predictable results. *Id.*

LifeScan argues that Winarta uses W_0 as nothing more than a trigger and in no way suggests using W_0 to make a glucose measurement. Prelim. Resp. 20-22. LifeScan's litigation expert states that a current measured from W_0 at the trigger time point would not be proportional to glucose due to an "initial charging current" that occurs when the circuit through W_0 is closed by the encroaching sample. Ex. 2001 ¶ 62.

LifeScan also disputes Pharmatech's argument that W and W_0 are the same size. Prelim. Resp. 22 (citing Ex. 2001 ¶ 61, 64). LifeScan submits an annotated version of Winarta's Figure 3, which is reproduced below:

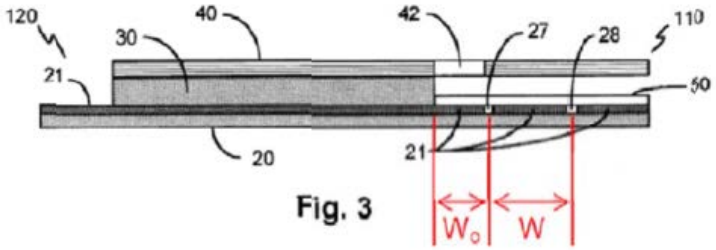


Fig. 3

LifeScan's annotated version of Winarta's Figure 3 purports to indicate that W extends between scribe lines 27 and 28, W_0 extends between scribe line 27 and the right end of middle layer 30, and that W_0 is smaller than W. *Id.* LifeScan argues that, because W_0 is smaller than W, the two sensors would not generate quantities of charge carriers "substantially identical" in the absence of an error condition, as required by the claim. *Id.* LifeScan also argues that one of ordinary skill in the art would not have considered Schulman because it is an implanted, continuous monitor. *Id.* at 23, 27-29.

Regarding limitation (a), we agree with Pharmatech that W_0 is capable of being used to make a glucose measurement, and that Winarta is suggestive of this use in stating that W_0 can serve as a counter electrode and can be used in measurements relative to reference electrode R. *See* Ex. 1005, 6:1-10. We agree further with Pharmatech that, given that Winarta has two sensors capable of making glucose measurements, it would have been obvious to make them the same size and to use them in the manner Schulman discloses in order to confirm

reliability of a measurement. We are unpersuaded by LifeScan's arguments that a combination of Winarta and Schulman would be based on hindsight reasoning, for the reasons explained above with reference to the combination of Nankai and Schulman. Dr. Meyerhoffs statement that a current measurement from W_0 at trigger time would not be proportional to glucose is irrelevant; Winarta discloses taking measurements after a twenty-second delay, not immediately upon the trigger. *See* Ex. 1005, 3:67-4:4.

We are not persuaded by LifeScan's argument and its annotated Winarta Figure 3 that W and W_0 are different sizes. Patent drawings generally are not to be relied upon for precise proportions of elements unless indicated as being to scale. *In re Wright*, 569 F.2d 1124, 1127 (CCPA 1977). Winarta's Figure 3 is not indicated as being to scale, so it neither supports nor contradicts size equality.

We agree as well with Pharmatech that Winarta discloses the limitations of claims 2 and 3, and that those claims would have been obvious over Winarta and Schulman for reasons similar to those given above. LifeScan's arguments are directed to claim 1, and LifeScan does not address claims 2 and 3 with separate specific arguments. *See, e.g.* Prelim. Resp. 23, 27-29.

For these reasons, Pharmatech has demonstrated a reasonable likelihood of prevailing on the ground of unpatentability of claims 1-3 as obvious over Winarta and Schulman.

D. Remaining Grounds of Unpatentability

Pharmatech alleges multiple alternative grounds of unpatentability in addition to those discussed above in detail. *See* list, *supra* at 6. Upon review of those alternative grounds, we conclude that they are redundant in light of the grounds on the basis of which we institute review.

III. CONCLUSION

For the foregoing reasons, we determine that Pharmatech has demonstrated that there is a reasonable likelihood of its proving unpatentability of claims 1-3 of the '105 patent by a preponderance of the evidence.

IV. ORDER

For the reasons given, it is

ORDERED that the Petition is *granted* as to claims 1-3 with respect to the following grounds:

1. Unpatentability of claims 1-3 under 35 U.S.C. § 103(a) for obviousness over Nankai and Schulman; and

2. Unpatentability of claims 1-3 under 35 U.S.C. § 103(a) for obviousness over Winarta and Schulman;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the '105 patent is hereby instituted commencing on the entry date of

this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial;

FURTHER ORDERED that all other grounds presented in Pharmatech's petition are *denied,* and no ground other than those specifically granted above is authorized for the *inter partes* review as to claims 1-3; and

FURTHER ORDERED that an initial conference call with the Board is scheduled for 1 PM Eastern Time on September 12, 2013. The parties are directed to the Office Trial Practice Guide, 77 Fed. Reg. 48756, 48765-66 (Aug. 14, 2012) for guidance in preparing for the initial conference call, and should come prepared to discuss any proposed changes to the Scheduling Order entered herewith and any motions the parties anticipate filing during the trial.

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United States Code Annotated

Title 35. Patents

Part I. United States Patent and Trademark Office

Chapter 1. Establishment, Officers and Employees, Functions

§ 6. Patent Trial and Appeal Board

(a) In general.--There shall be in the Office a Patent Trial and Appeal Board. The Director, the Deputy Director, the Commissioner for Patents, the Commissioner for Trademarks, and the administrative patent judges shall constitute the Patent Trial and Appeal Board. The administrative patent judges shall be persons of competent legal knowledge and scientific ability who are appointed by the Secretary, in consultation with the Director. Any reference in any Federal law, Executive order, rule, regulation, or delegation of authority, or any document of or pertaining to the Board of Patent Appeals and Interferences is deemed to refer to the Patent Trial and Appeal Board.

(b) Duties.--The Patent Trial and Appeal Board shall--

(1) on written appeal of an applicant, review adverse decisions of examiners upon applications for patents pursuant to section 134(a);

(2) review appeals of reexaminations pursuant to section 134(b);

(3) conduct derivation proceedings pursuant to section 135; and

(4) conduct inter partes reviews and post-grant reviews pursuant to chapters 31 and 32.

(c) 3-member panels.--Each appeal, derivation proceeding, post-grant review, and inter partes review shall be heard by at least 3 members of the Patent Trial and Appeal Board, who shall be designated by the Director. Only the Patent Trial and Appeal Board may grant rehearings.

(d) Treatment of prior appointments.--The Secretary of Commerce may, in the Secretary's discretion, deem the appointment of an administrative patent judge who, before the date of the enactment of this subsection, held office pursuant to an appointment by the Director to take effect on the date on which the Director initially appointed the administrative patent judge. It shall be a defense to a challenge to the appointment of an administrative patent judge on the basis of the judge's having been originally appointed by the Director that the administrative patent judge so appointed was acting as a de facto officer.

United States Code Annotated

Title 35. Patents

Part III. Patents and Protection of Patent Rights

Chapter 31. Inter Partes Review

§ 314. Institution of inter partes review

(a) Threshold.--The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

(b) Timing.--The Director shall determine whether to institute an inter partes review under this chapter pursuant to a petition filed under section 311 within 3 months after--

(1) receiving a preliminary response to the petition under section 313; or

(2) if no such preliminary response is filed, the last date on which such response may be filed.

(c) Notice.--The Director shall notify the petitioner and patent owner, in writing, of the

Director's determination under subsection (a), and shall make such notice available to the public as soon as is practicable. Such notice shall include the date on which the review shall commence.

(d) No appeal.--The determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable.

United States Code Annotated

Title 35. Patents

Part III. Patents and Protection of Patent Rights

Chapter 31. Inter Partes Review

§ 316. Conduct of inter partes review

(a) Regulations.--The Director shall prescribe regulations--

(1) providing that the file of any proceeding under this chapter shall be made available to the public, except that any petition or document filed with the intent that it be sealed shall, if accompanied by a motion to seal, be treated as sealed pending the outcome of the ruling on the motion;

(2) setting forth the standards for the showing of sufficient grounds to institute a review under section 314(a);

(3) establishing procedures for the submission of supplemental information after the petition is filed;

(4) establishing and governing inter partes review under this chapter and the relationship of such review to other proceedings under this title;

(5) setting forth standards and procedures for discovery of relevant evidence, including that such discovery shall be limited to--

(A) the deposition of witnesses submitting affidavits or declarations; and

(B) what is otherwise necessary in the interest of justice;

(6) prescribing sanctions for abuse of discovery, abuse of process, or any other improper use of the proceeding, such as to harass or to cause unnecessary delay or an unnecessary increase in the cost of the proceeding;

(7) providing for protective orders governing the exchange and submission of confidential information;

(8) providing for the filing by the patent owner of a response to the petition under section 313 after an inter partes review has been instituted, and requiring that the patent owner file with such response, through affidavits or declarations, any additional factual evidence and expert opinions on which the patent owner relies in support of the response;

(9) setting forth standards and procedures for allowing the patent owner to move to amend the patent under subsection (d) to cancel a challenged

claim or propose a reasonable number of substitute claims, and ensuring that any information submitted by the patent owner in support of any amendment entered under subsection (d) is made available to the public as part of the prosecution history of the patent;

(10) providing either party with the right to an oral hearing as part of the proceeding;

(11) requiring that the final determination in an inter partes review be issued not later than 1 year after the date on which the Director notices the institution of a review under this chapter, except that the Director may, for good cause shown, extend the 1-year period by not more than 6 months, and may adjust the time periods in this paragraph in the case of joinder under section 315(c);

(12) setting a time period for requesting joinder under section 315(c); and

(13) providing the petitioner with at least 1 opportunity to file written comments within a time period established by the Director.

(b) Considerations.--In prescribing regulations under this section, the Director shall consider the effect of any such regulation on the economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the

Office to timely complete proceedings instituted under this chapter.

(c) Patent Trial and Appeal Board.--The Patent Trial and Appeal Board shall, in accordance with section 6, conduct each inter partes review instituted under this chapter.

(d) Amendment of the patent.–

(1) In general.--During an inter partes review instituted under this chapter, the patent owner may file 1 motion to amend the patent in 1 or more of the following ways:

(A) Cancel any challenged patent claim.

(B) For each challenged claim, propose a reasonable number of substitute claims.

(2) Additional motions.--Additional motions to amend may be permitted upon the joint request of the petitioner and the patent owner to materially advance the settlement of a proceeding under section 317, or as permitted by regulations prescribed by the Director.

(3) Scope of claims.--An amendment under this subsection may not enlarge the scope of the claims of the patent or introduce new matter.

(e) Evidentiary standards.--In an inter partes review instituted under this chapter, the petitioner

shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence.

United States Code Annotated

Title 35. Patents

Part III. Patents and Protection of Patent Rights

Chapter 31. Inter Partes Review

§ 318. Decision of the Board

(a) Final written decision.--If an inter partes review is instituted and not dismissed under this chapter, the Patent Trial and Appeal Board shall issue a final written decision with respect to the patentability of any patent claim challenged by the petitioner and any new claim added under section 316(d).

(b) Certificate.--If the Patent Trial and Appeal Board issues a final written decision under subsection (a) and the time for appeal has expired or any appeal has terminated, the Director shall issue and publish a certificate canceling any claim of the patent finally determined to be unpatentable, confirming any claim of the patent determined to be patentable, and incorporating in the patent by operation of the certificate any new or amended claim determined to be patentable.

(c) Intervening rights.--Any proposed amended or new claim determined to be patentable and incorporated into a patent following an inter partes

review under this chapter shall have the same effect as that specified in section 252 for reissued patents on the right of any person who made, purchased, or used within the United States, or imported into the United States, anything patented by such proposed amended or new claim, or who made substantial preparation therefor, before the issuance of a certificate under subsection (b).

(d) Data on length of review.--The Office shall make available to the public data describing the length of time between the institution of, and the issuance of a final written decision under subsection (a) for, each inter partes review.

Code of Federal Regulations

Title 37. Patents, Trademarks, and Copyrights

Chapter I. United States Patent and Trademark Office, Department of Commerce

Subchapter A. General

Practice Before the Patent and Trademark Office

Part 42. Trial Practice Before the Patent Trial and Appeal Board

Subpart A. Trial Practice and Procedure

General

§ 42.4 Notice of trial.

(a) Institution of trial. The Board institutes the trial on behalf of the Director.

(b) Notice of a trial will be sent to every party to the proceeding. The entry of the notice institutes the trial.

(c) The Board may authorize additional modes of notice, including:

(1) Sending notice to another address associated with the party, or

(2) Publishing the notice in the Official Gazette of the United States Patent and Trademark Office or the Federal Register.