Trials@uspto.gov
Tel: 571-272-7822

Paper 27
Entered: August 6, 2014

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.

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.

[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").

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:

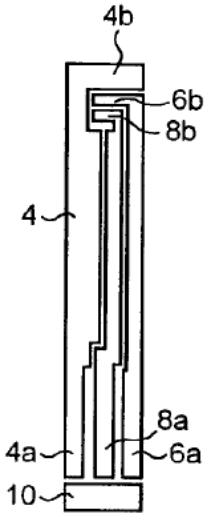


FIG. 2

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:

FIG. 12

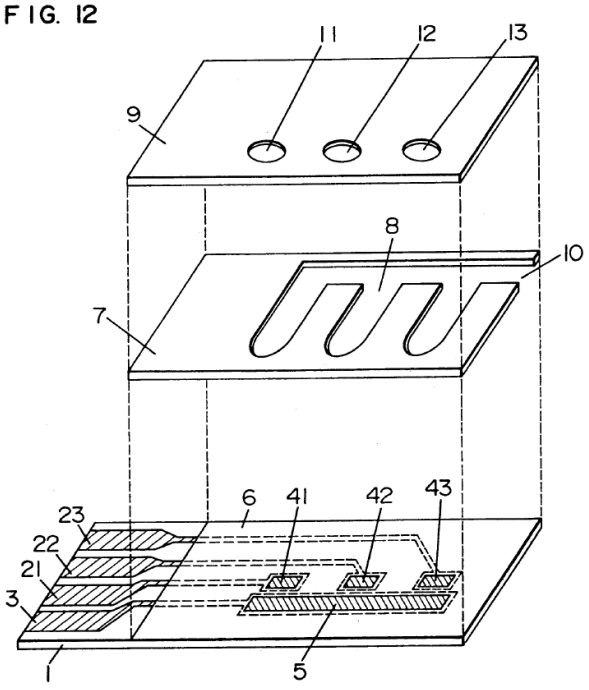


Figure 12 shows a glucose sensor having base plate 1 on which is formed lead 3 and corresponding counter electrode 5, and leads 21, 22, and 23, and corresponding measurement electrodes 41, 42, and 43. *Id.* at 8:5-10. Spacer 7 overlies the base plate, and space 8 cut out from the spacer provides a conduit 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[2] testimony (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

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

measurements, and signal an error if they diverge, transcend the particular sensor systems for which they are implemented. We agree with Pharmatech, 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.

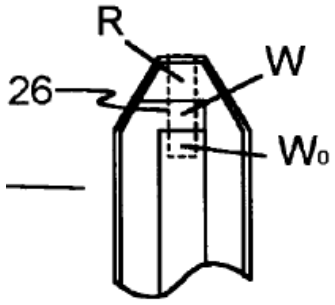
1. The level of skill in the art

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 ¶ 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.*

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.

FOR PETITIONER:

William A. Rudy
A. Justin Poplin
LATHROP & GAGE LLP

FOR PATENT OWNER:

Dianne B. Elderkin
Steven Maslowski
AKIN GUMP STRAUSS HAUER
& FELD LLP