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18 **UNITED STATES DISTRICT COURT**
19 **NORTHERN DISTRICT OF CALIFORNIA**
SAN JOSE

20 LIFESCAN, INC. and
LIFESCAN SCOTLAND, LTD.,
21
22 Plaintiffs,

23 v.

24 SHASTA TECHNOLOGIES, LLC,
DECISION DIAGNOSTICS CORP.,
25 PHARMATECH SOLUTIONS, INC., and
CONDUCTIVE TECHNOLOGIES, INC.,
26 Defendants.

Case No. 11-04494-EJD (PSG)

**SUPPLEMENTAL DECLARATION
OF MARK E. MEYERHOFF IN
SUPPORT OF PLAINTIFFS'
MOTION FOR A PRELIMINARY
INJUNCTION**

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SUPP. DEC. OF MARK MEYERHOFF
IN SUPPORT OF PL MOTION

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Mark E. Meyerhoff, Ph.D., declares as follows:

1. I am the Philip J. Elving Professor of Chemistry at the University of Michigan. I have been retained by Plaintiffs LifeScan, Inc. and LifeScan Scotland, Ltd. as an expert on the technical issues concerning the infringement and validity of U.S. Patent No. 7,250,105 (the '105 patent).

2. I previously submitted a Declaration in this case, dated December 10, 2012, in support of LifeScan's motion for a preliminary injunction. *See* D.E. 176-2. My earlier Declaration discusses my qualifications (at ¶¶1-3). My curriculum vitae is attached to that Declaration as Exhibit A.

3. I submit this supplemental declaration to respond to assertions in the Declaration of Defendants' expert, Dr. Joseph Wang, concerning the validity of claim 3 of the '105 patent and concerning the infringement of that claim by the intended use of Defendants' GenStrip product with LifeScan's OneTouch® Ultra® meters. As discussed below, it is my opinion that:

- a) the method described in claim 3 of the '105 patent would not have been obvious at the time of the invention to persons of ordinary skill in the relevant art;
- b) the specification of the '105 enables one of ordinary skill in the art to practice the invention of claim 3 without undue experimentation, and the invention of claim 3 has utility; and
- c) the electric current measured at each working sensor of the GenStrip is "proportional to the concentration of [glucose] in the sample liquid," as that phrase is used in the '105 patent.

1 **I. SUMMARY OF OPINIONS**

2 **A. Claim 3 of the '105 Patent Would Not Have Been Obvious**

3 4. I have reviewed Dr. Wang's Declaration. At the highest level, Dr. Wang asserts that
4 it would have been obvious to combine one of two references (Winarta '229¹ or Nankai '420) with a
5 hodgepodge of other references in order to create the invention of the claims of the '105 patent.

6 5. Dr. Wang's analysis wholly fails to show that the invention of claim 3 of the '105
7 patent would have been obvious to a person of ordinary skill in the art. His Declaration ignores the
8 primary problems addressed by the '105 patent, ignores the level of ordinary skill in the relevant art,
9 relies completely on hindsight to puzzle together the cited references, ignores that the solutions
10 taught in the prior art to the problems addressed by the '105 patent differ significantly to the solution
11 claimed in the '105 patent, provides no reason why a person of ordinary skill in the art would have
12 combined the cited references, ignores that the PTO considered and rejected his arguments on
13 obviousness, and ignores "secondary considerations," which I understand to be crucial to the
14 analysis.

15 6. The claims of the '105 patent offer a simple, yet elegant solution to the existing
16 problems associated with reliability in glucose measurements using single-use disposable glucose
17 test strips at the time the patent was filed. Given the implications of inaccurate glucose readings
18 (*i.e.*, for diabetics taking insulin, when they should not and vice versa), assurance of the reliability of
19 measurements in disposable glucose test strips is of critical importance.

20 7. The '105 patent sought to achieve greater reliability in disposable glucose test strip
21 measurements by providing a way to (1) ensure that an adequate volume of blood was covering the
22 entirety of the working electrode of a test strip and (2) ensure the electrodes were not defective either
23 due to manufacturing irregularities or user error, while (3) not increasing the volume of blood
24 required for testing. *See* ¶¶39-50, *infra*

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26 ¹ Throughout this declaration, it is my convention to refer to a given patent by its first named author and the last 3 digits
of the patent number.

1 8. The '105 patent accomplished all three of these goals by providing a test strip where
2 the working electrode of the strip is divided into two working sensor parts. These parts are arranged
3 such that when blood is introduced to the test strip, the blood first traverses a reference electrode,
4 then traverses a first working sensor part and only then ultimately traverses a second working sensor
5 part. By utilizing this construction, there will not be a current generated on the second working
6 sensor part until after the blood has traversed the first working electrode. The patent then provides
7 for a method of comparing the current at the first sensor part with the current at the second sensor
8 part to see if those currents are substantially the same. If not, an indication of an error is given. *See*
9 *Ex. 1, ('105 Patent) at Claim 1.*

10 9. This solves the problem of ensuring that the working electrode is completely covered
11 because the only realistic way the current measured at the two working sensor parts would be the
12 same is if they are both completely covered. This is because the two electrodes have effectively the
13 same conductive areas. This also solves the problem of working electrode defects, because the only
14 realistic way the currents would be the same is if there was not something wrong with one or both of
15 the sensor parts. This is of utmost importance when relying on values of glucose concentration from
16 a single-use device, such as disposable glucose test strips, that cannot be checked by classical quality
17 control methods to ensure proper functionality prior to their use, as can be accomplished with
18 conventional, fully reversible, enzyme electrodes. And, finally, by splitting the working electrode
19 part into two, the amount of blood required for the measurement does not change. This simple
20 modification results in an innovative disposable test strip and measurement system that substantially
21 enhances the reliability of the system's measurements.

22 10. A strip that enabled such a comparison is not disclosed in any prior art reference
23 relied on by Dr. Wang or in any prior art reference that I have reviewed. *See ¶¶57-83, infra.* This is
24 fatal to Dr Wang's analysis because, in order to perform the method of the claims of the '105 patent,
25 one needs a test strip that has the design described in the claims of the '105 patent. Moreover, none
26

1 of the prior art references in the disposable test strip art that Dr. Wang relies on provides the method
2 of electrode comparison. Indeed, none of the prior art identifies the specific problems that the '105
3 patent describes and addresses via an innovative approach. This is especially true in the context of
4 single-use glucose test strips that cannot be factory tested, or tested for functionality immediately
5 prior to patient use of the device.

6 11. Dr. Wang's analysis does not consider whether a person of ordinary skill in the art²
7 would have appreciated the problem of reliability that the inventors of the '105 patent recognized and
8 does not consider whether a person of ordinary skill in the art would have come to the innovative
9 solution claimed by the '105 patent. Instead, Dr. Wang's analysis focuses on whether persons with
10 an unidentified level of skill in the art could have located references that separately have elements of
11 the claims of the '105 patent and then pieced them together to create the invention claimed by the
12 '105 patent, while having the claims of the '105 patent with them to guide them along their way. *See*
13 ¶¶84-95, *infra*. Dr. Wang's analysis considers whether one of skill in the art would have been
14 capable of creating the strip described in the methods of the '105 patent and performing the
15 comparison claimed by the '105 patent. This is, at core, a hindsight analysis and a different question
16 from whether it would have been obvious for a person of ordinary skill in the art to do so at the time
17 the '105 patent was filed.

18 12. Dr. Wang's analysis further fails to acknowledge that the solutions that the disposable
19 test strip art taught for improving reliability were different from the solution claimed by the '105
20 patent. There is nothing in the prior art that suggests that there are any problems with those earlier
21 solutions as to provide a motivation for a better solution. Rather, only the '105 patent's novel
22 approach of dealing with multiple problems provided the solution claimed in the '105 patent.
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25 ² As set forth below in ¶33, in my opinion, a person of ordinary skill in the art of the '105 patent would have a bachelors
26 degree in chemistry or electrical engineering, or an equivalent degree in the sciences/engineering fields (e.g., physics or
27 chemical engineering), and have experience working in the field of electrochemical glucose sensors for at least five
28 years.

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