Paper No. __

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PHARMATECH SOLUTIONS, INC.
Petitioner

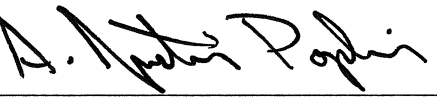
v.

LIFESCAN SCOTLAND LTD.
Patent Owner

Case IPR2013-00247
Patent 7,250,105

REPLY TO PATENT OWNER'S NOVEMBER 15, 2013 RESPONSE

Respectfully submitted,
LATHROP & GAGE LLP



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Through this paper, Petitioner Pharmatech Solutions, Inc. ("Pharmatech") respectfully replies to the November 15, 2013 Response of Patent Owner Lifescan Inc. ("Lifescan"). If any fee is necessary for this paper to be fully considered, Pharmatech respectfully requests that all such fees be charged to Deposit Account No. 12-600 with reference to attorney docket number 533625. Lifescan is being served a copy of this paper as shown by the attached Certificate of Service.

I. INTRODUCTION

Nearly two week before Lifescan filed its Response, the Federal Circuit issued its opinion entitled *Lifescan Scotland Ltd. v. Shasta Technologies LLC* , 734 F.3d 1361 (Fed. Cir. 2013) ("*Lifescan Decision*", Exh. 1029). In its *Lifescan Decision*, the Federal Circuit reversed the grant of a preliminary injunction against Pharmatech and others. 734 F.3d at 1377. The Federal Circuit "conclude[d] that Lifescan's OneTouch Ultra meters substantially embody the methods claim in [U.S. Patent No. 7,250,105 (Exh. 1002)] and their distribution therefore exhausts Lifescan's patent rights." *Id.* In reaching this conclusion, the Federal Circuit decided that "strips with two working electrodes were disclosed by the prior art." *Id.* at 1369. "The fact that the prior art strips might have required some reconfiguration to work use with Lifescan's meters is irrelevant. There is no suggestion that prior art strips with two working electrodes could not be easily configured to work with meters performing a comparing function." *Id.* 1373.

Lifescan's Response makes no mention of the *Lifescan Decision*. Instead, after differentiating between the "test strip elements" and the steps performed by a "measuring device," Lifescan argues extensively that the "test strip elements" are

not in the prior art. (Response, Paper 16 at 17-26) Collateral estoppel, however, prevents Lifescan from once again re-litigating this issue. And in any event, Lifescan also ignores both the '105 Patent, which says, "The two working sensor parts may be arranged as convenient," and Nankai's teaching that the shape and arrangement of the sensors may vary. (Exh. 1002 at 3:36-58; Exh. 1003 at 8:47-52; Exh. 1024 at ¶ 20) Lifescan cannot overcome those disclosures, its "criticality" argument (Response, Paper 16 at 50) rings hollow, and the USPTO should maintain its decision that the strips are obvious. (Paper 11 at 11-19)

What remains at issue are the steps performed by the "measuring device"—"comparing the electric current from each of the working sensor parts to establish a different parameters; and giving an indication of an error if said different parameter is greater than a predetermined threshold." (the '105 Patent, Exh. 1002 at 8:1-5). Specifically, the issue is whether these elements save claims 1-3 from being unpatentable as obvious.[1]

Responding to the Board Decision that Schulman (U.S. Pat. No. 5,791,344, Exh. 1007) discloses "a particular way in which multiple measurements from a single blood sample are compared and used to alter the user to an unreliable test," (Decision, Paper 11 at 13) Lifescan simply raises a series of strawmen to divert the issue at hand: what would have been obvious to do with prior art test strips capable

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[1] As the Board noted with respect to Lifescan's Preliminary Response, Lifescan's current arguments "are [again] directed to claim 1, and Lifescan does not address claims 2 and 3 with separate specific arguments. (Decision, Paper 11 at 18)

of obtaining multiple measurements? Shulman teaches and claims "means for comparing the sensor signals obtained from each of said plurality of sensors and generating a composite signal only if the respective sensor signals are within a first prescribed amount of each other." (*Id.* at 21:32-36) Schulman further teaches "means for generating an error message in the event that the respective signals are not with said first prescribed amount of each other." (*Id.* at 22:20-23)

Knowing, as Lifescan concedes, that "obtaining accurate glucose measurements . . . is critical," (Response, Paper 16 at 2) a person of ordinary skill in the art would only have a finite number of solutions to address the accuracy problem when presented with a prior art test strip with multiple working sensors capable of obtaining multiple measurements from a single blood sample. Schulman (Exh. 1007 at 21:34-35), Nankai (U.S. Pat. No. 5,120,420, Exh. 1003 at 9:1-5) and the '105 Patent (Exh. 1002 at 4:9-13) each disclose averaging multiple measurements to present more accurate results. And Schulman further taught presenting an error message if the difference between the multiple measurements is too disparate. (Exh. 1007 at 22:21-24). The decision in the '105 Patent to signal an error when the multiple measurements are too disparate is simply a "predictable variation" that "a person of ordinary skill can implement." It is thus obvious and unpatentable. *See KSR Int'l Co. v. Teleflex, Inc.* 550 U.S. 398, 417 (2007).

Finally, copying is the only objective indicia of non-obviousness (or "secondary considerations") cited by Lifescan. But Lifescan ignores that such identity is necessary for the Genstrip to work with Lifescan's OneTouch Ultra meters that purportedly practice the '105 Patent. Moreover, evidence of copying alone is insuf-

ficient. *See Cable Elec. Prods., Inc. v. Genmark Inc.*, 770 F.2d 1015, 1028 (Fed. Cir. 1985).

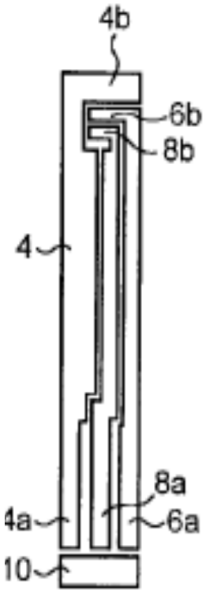
Consistent with the Board's Decision (Paper 11), Pharmatech has met its burden and proved the unpatentability of claims 1-3 of the '105 Patent by a preponderance of the evidence.

II. OVERVIEW

A. Diabetes/Blood Glucose Monitoring

"Glucose monitoring systems…are used by individuals with diabetes to assist them in maintaining healthy glucose levels. Such systems typically consist of an electrochemical meter and disposable test strips" *Lifescan Decision*, 734 F.3d at 1363. Pharmatech agrees with Lifescan that "[o]btaining accurate glucose measurements with these systems is critical because patients adjust one or both of their food intake and insulin doses based on the measurements. Inaccurate measurements can have dire results for patients." (Response, Paper 16 at 2 (citations omitted))

B. The '105 Patent



"The '105 Patent claims to improve upon earlier [glucose monitoring] systems. It claims a method of comparing the measurements taken by two separate working electrodes [6b 8d]. If the readings of the two working electrodes differ significantly, this indicates problems such as inadequate sample volume or manufacturing defects, and the readings are to be discarded. A reference electrode [4b] on the strip serves as a common reference for both

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