United States Court of Appeals for the Federal Circuit

PHARMA TECH SOLUTIONS, INC., DECISION IT CORP.,
Plaintiffs-Appellants

v.

LIFESCAN, INC., LIFESCAN SCOTLAND, LTD., JOHNSON AND JOHNSON,
Defendants-Appellees

2019-1163

Appeal from the United States District Court for the District of Nevada in No. 2:16-cv-00564-RFB-PAL, Judge Richard F. Boulware, II.

Decided: November 22, 2019

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

EUGENE M. GELERNTER, Patterson Belknap Webb & Tyler LLP, New York, NY, argued for defendants-appellees. Also represented by GREGORY DISKANT; CHARLES DAVISON HOFFMANN, SEAN REEVES MARSHALL, Hoffmann Marshall Strong LLP, New York, NY.

Before MOORE, REYNA, and STOLL, *Circuit Judges*.

STOLL, *Circuit Judge*.

This is an appeal from the district court's summary judgment of noninfringement under the doctrine of equivalents. Because prosecution history estoppel bars the claims for infringement under the doctrine of equivalents, we affirm.

BACKGROUND

I

Pharma Tech Solutions, Inc. sued LifeScan, Inc. for infringement of its U.S. Patent Nos. 6,153,069 and 6,413,411, which concern blood glucose monitoring systems for home use by individuals with diabetes. To test blood glucose, an individual typically draws blood by pricking a finger, placing the blood on the end of a test strip, and placing the test strip into a meter. The test strip contains a pair of electrodes, including a working electrode and a second electrode. The working electrode is coated with an enzyme that oxidizes glucose in the blood sample. Following an incubation period, the meter (1) applies a known electric potential across the electrodes, creating a diffusion limiting electric current (referred to as the "Cottrell current") through the sample; and (2) measures Cottrell current. A proportional relationship exists between the measured current and blood glucose concentration. Based on this proportional relationship, a microprocessor in the meter converts the measured electric current to a blood glucose level and then reports the blood glucose level to the user.

The shared specification of Pharma Tech's '069 and '411 patents states that the claimed inventions improve on these prior art blood glucose monitoring systems by "eliminat[ing] several of the critical operator depend[e]nt variables that adversely affect the accuracy and reliability" of these systems. '069 patent col. 4 l. 66–col. 5 l. 3. The

specification explains that the invention accomplishes this objective by performing multiple Cottrell current measurements and comparing the results. "In a system that is operating correctly, the results should agree within reasonable limits." *Id.* at col. 4 ll. 51–52. Results outside of a prescribed percentage of each other, however, generally indicate a system error, and the system will alert the user of a potential measurement error.

With emphasis added to highlight the claim limitation at issue on appeal, illustrative claim 1 of the '069 patent recites:

> 1. An apparatus for measuring compounds in a sample fluid, comprising:
>
> a) a housing having an access opening therethrough;
>
> b) a sample cell receivable into said access opening of said housing, said sample cell being composed of;
>
> (i) a first electrode which acts as a working electrode;
>
> (ii) a second electrode which acts to fix the system potential and provide opposing current flow with respect to said first electrode, said second electrode being made of the same electrically conducting material as said first electrode, and being operatively associated with said first electrode, the ratio of the surface area of said second electrode to the surface area of said first electrode being 1:1 or less;
>
> (iii) at least one non-conducting layer member having an opening therethrough, said at least one non-conducting layer member being disposed in contact with at least one of said first and second electrodes and being sealed against at least one of said first and second electrodes to

> form a known electrode area within said opening such that said opening forms a well to receive the sample fluid and to allow a user of said apparatus to place the sample fluid in said known electrode area in contact with said first electrode and said second electrode;
>
> c) means for applying an electrical potential to both said first electrode and said second electrode;
>
> d) means for creating an electrical circuit between said first electrode and said second electrode through the sample fluid;
>
> e) means for measuring a first Cottrell current reading through the sample fluid at a first predetermined time after the electrical potential is applied and for obtaining at least one additional Cottrell current reading through the sample fluid, the at least one additional Cottrell current reading occurring at a second predetermined time following the first predetermined time;
>
> f) microprocessor means for *converting the first Cottrell current reading into a first analyte concentration measurement using a calibration slope and an intercept specific for the first Cottrell current measurement, for converting the at least one additional Cottrell current reading into an additional analyte concentration using a calibration slope and an intercept specific for the at least one additional Cottrell current measurement, and for comparing the first analyte concentration measurement with the at least one additional concentration measurement to confirm that they are within a prescribed percentage of each other*; and
>
> g) means for visually displaying the results of said analyte concentration measurements.

Id. at col. 13 ll. 10–61.

II

The product accused of infringing under the doctrine of equivalents is LifeScan's OneTouch® Ultra® system, a blood glucose meter for home use. When blood is detected on a test strip inserted into LifeScan's meter, the meter measures current from two working electrodes during a five-second countdown period. LifeScan's meter obtains final current measurements from the first and second working electrodes at "5 seconds + 40 milliseconds (±25ms) after the measurement period begins" and "5 seconds + 340 ms (±25ms) after the measurement period begins." J.A. 57.

LifeScan's meter then conducts a "Current Difference Test" to ensure that the difference between the recorded currents is within a defined limit. J.A. 57. "If the Current Difference Test passes, then the total final current (combining both working electrodes) is calculated." J.A. 58. "[A] single glucose result is calculated from the total final current using a strip slope and intercept based on the strip's calibration code." J.A. 58.

It is undisputed that LifeScan's meters neither convert multiple Cottrell current readings to analyte concentration measurements nor compare multiple analyte concentration measurements. Pharma Tech agrees that the accused products therefore do not literally infringe the claim. But Pharma Tech asserts that "an analyte measurement can be expressed as a current at a given time or as a concentration" and, thus, the accused device infringes under the doctrine of equivalents. Appellant's Br. 40.

III

Because this appeal involves prosecution history estoppel, a discussion of the relevant prosecution history is helpful. Pharma Tech agrees that any prosecution history estoppel determined to apply to the '069 patent extends to the related '411 patent, so we focus on the prosecution history of the '069 patent.

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