

## **Doctrine of Equivalents: Prosecution History Estoppel Can Be Both Amendment and Argument-Based**

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In a case involving at-home glucose monitoring systems, the US Court of Appeals for the Federal Circuit found the patent owner was estopped from asserting a doctrine of equivalents theory of infringement based on subject matter surrendered during prosecution. [Pharma Tech Solutions, Inc. v. LifeScan, Inc.](#), Case No. 19-1163 (Fed. Cir. Nov. 22, 2019) (Stoll, J).

Pharma sued LifeScan for infringement of two patents concerning at-home blood glucose monitoring systems. Typical home blood glucose tests measure glucose by placing a drop of blood on a test strip that contains a pair of electrodes. An electrical potential is applied across the electrodes and the current is measured. This current measurement is used to determine the blood glucose level. Pharma's patents improved upon the reliability and accuracy of at-home tests through a monitor that performed multiple current measurements to account for variability that might indicate measurement or user error.

The claims of Pharma's patents require "converting" at least two current measurements into analyte concentrations using a calibration slope, and "comparing" the analyte concentrations to determine whether they are within a prescribed percentage of each other. The subject limitation was added by amendment in order to distinguish the claims from multiple prior art references cited by the examiner.

LifeScan's accused product—an at-home blood glucose monitor that also takes multiple current measurements—calculated variability slightly differently than the claimed method. Rather than converting each current measurement into an analyte concentration and comparing the differences in analyte concentrations as recited in the patent, the LifeScan monitor compared the current measurements to ensure the difference between recorded currents was within a defined limit, then calculated a single analyte measurement based on the current measurements.

Recognizing that the LifeScan monitor did not fall within the literal scope of the claims, Pharma alleged infringement under the doctrine of equivalents. LifeScan responded that Pharma was estopped from asserting the doctrine of equivalents based on claim amendments and argument made during prosecution. After the district court agreed with LifeScan and granted summary judgment of non-infringement, Pharma appealed.

The Federal Circuit explained the well-settled notion that prosecution history estoppel can occur in

two ways: by making a narrowing amendment to the claim (amendment-based estoppel), or by surrendering claim scope through argument to the patent examiner (argument-based estoppel). Here, the Court found that Pharma was estopped under both amendment-based estoppel and argument-based estoppel.

Under amendment-based estoppel, a patentee's decision to narrow claims through amendment may be presumed to be a general disclaimer of equivalents in the territory between the original claim and the amended claim. This presumption may be overcome if the rationale underlying the amendment may be no more than a tangential relation to the equivalent in question. Here, Pharma presumptively surrendered any bioelectrical blood glucose monitoring system that did not convert a plurality of current readings into analyte concentration measurements and compare the resulting analyte measurements. The Federal Circuit found that this amendment was not tangential to the equivalent in question, because the inventors unambiguously distinguished their invention over the prior art based on these converting and comparing limitations.

Under argument-based estoppel, the issue turned on whether the prosecution history evinced a clear and unmistakable surrender of systems that did not convert and compare analyte concentration measurements. On this legal theory, the Federal Circuit found that the inventors clearly and unambiguously distinguished their invention over the prior art based on these limitations.

Accordingly, the Federal Circuit upheld the district court's finding of both amendment-based and argument-based estoppel and affirmed summary judgment.

**Practice Note:** Fewer written arguments—and perhaps greater use of examiner interviews—during prosecution may help prevent estoppel issues.

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National Law Review, Volume IX, Number 358

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