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COUNSEL COMMENTARY

IP: Patent exhaustion clarification from the Federal Circuit

PATENT EXHAUSTION DOCTRINE APPLIES TO PRODUCTS GIVEN AWAY TO DRIVE FUTURE SALES SIMILARLY TO PRODUCTS THAT HAVE BEEN SOLD

Although the doctrine of patent exhaustion is well-recognized, various wrinkles in applying the doctrine remain undecided. A recent decision by the Federal Circuit provided further guidance regarding the application of patent exhaustion to patent method claims, specifically answering two questions: 1. If a product is given away and the patent owner did not receive any compensation, did the distribution of that product exhaust the patent claim? 2. In a patent claim covering a method of using a combination of items, does the authorized distribution of one of those items exhaust the method claim?

The doctrine of patent exhaustion has often been described as holding that the sale of a patented device exhausts the patent owner's right to exclude and infringement cannot be found based on the subsequent sale or use of the device. It is well-settled that the doctrine applies to method claims where the product sold substantially embodies the patented invention.

On Nov. 4, 2013, the Federal Circuit determined, as a matter of first impression, in *LifeScan Scotland, Ltd. V. Shasta Technologies, et al.*, that the patent exhaustion doctrine applies to products given away to drive future sales of accessories in the same manner that the doctrine applies to products that have been sold. The court also addressed the application of patent exhaustion to authorized distribution of only one item in a patented combination, where that item embodies the inventive concept of the patent claim. The Federal Circuit reversed the grant of preliminary injunction and remanded the case to the district court.

The plaintiff in the case, LifeScan, owns U.S. Patent No. 7,250, 105 covering a method for monitoring blood glucose levels. The patented method includes an electromechanical meter and disposable test strips. To use the meter, a user draws a small drop of blood, places it on the test strip and inserts the test strip into the meter. The meter then measures the electric current that corresponds to the concentration of glucose in the blood sample. LifeScan's marketing strategy was to sell 40 percent of its meters at below cost prices and distribute the remaining 60 percent through health care providers to give to diabetic individuals for free. LifeScan expects that customers will use these meters with the test strips that LifeScan sells separately and will have then derived its profits from test strip sales. These test strips are not separately patented. The defendants in the case sell test strips designed for use in LifeScan meters.

A general design for blood glucose meters and disposable test stripes first became available in the 1980s. The '105 patent claims an improvement on those systems by allowing a user to determine if there is an error with a sample such as inadequate sample volume or manufacturing defects through a comparison of the readings of two working electrodes and a reference electrode and determining if the variance between readings is too great.

The district court granted LifeScan's motion for preliminary injunction, rejecting defendants' arguments that patent exhaustion should apply to the 60 percent of products that LifeScan gave away for free, because the court concluded that patent exhaustion is only applicable to a sale where the patentee has received consideration in exchange for the patented product. The district court's opinion also reasoned that the '105 patent is a method patent that requires both a meter and a test strip to be practiced, so the meters distributed by LifeScan do not "substantially embody" the invention as is required for a finding of patent exhaustion.

In addressing LifeScan's argument that distribution of the meter did not exhaust the method claims requiring both a meter and test strip to be used, the Federal Circuit first determined what actually constituted the inventive concept of the '105 patent. The court considered the undisputed facts in the case, the specification of the patent, and the prosecution history. The abstract of the patent described the invention as "a measuring device [that] compares the current generated by two working sensor parts and gives an error indication if they are too dissimilar." The specification additional emphasized error detection. LifeScan argued to the district court that the "idea of comparing the currents from two working sensors and seeing if they are in substantial agreement or not…is the crux of the invention." During prosecution, LifeScan attempted but failed to obtain apparatus claims directed to the design of the disposable test strips. The Federal Circuit then held that the authorized distribution of the item embodying the inventive concept of a patented combination exhausts the method claim in that patented combination where the second item in the combination is either unpatented or the patent on that item is invalid. So, in this instance, sale of the meter embodying the inventive concept exhausted the method claims such that sale of the unpatented item, the test strips, could not be found to infringe. The court expressed concern that it would be akin to an improper tying arrangement to allow LifeScan to eliminate competition in the sale of the unpatentable test strips.

The court then addressed LifeScan's argument that it received no compensation for distribution of the meters so patent exhaustion should not apply. The court determined that prior precedent referring to sales and purchases should be read to encompass all instances in which transfer of legal title to the patented product is authorized by the patent owner. The court drew an extensive analogy to the copyright first sale doctrine in confirming its decision, potentially implying that the Supreme Court's recent copyright ruling in *Kirtsaeng v. John Wiley & Sons, Inc.* will provide important guidance to answer some of the remaining patent exhaustion questions.

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