

**Keywords:** patent exhaustion, method claim

**General:** A method patent is exhausted upon the sale of a product that substantially embodies the inventive elements of the patented method.

*LifeScan Scotland, Ltd. v. Shasta Techs., LLC*  
108 U.S.P.Q.2d 1757 (Fed. Cir. 2013).

## **I. Facts**

The patent at issue relates to a method of measuring blood glucose concentration using an electronic meter and a test strip. In particular, the patent includes a method claim that recites providing a measuring device/test strip having first and second working sensor parts and a reference sensor part; “applying the sample to said measuring device; measuring an electric current at each working sensor part proportional to the concentration of said substance in the sample liquid; comparing the electric current from each of the working sensor parts to establish a difference parameter; and giving an indication of an error if said difference parameter is greater than a predetermined threshold.”

LifeScan manufactures meters and test strips configured to perform the patented method. However, LifeScan sells 40 percent of the meters at or below costs, and provides 60 percent of the meters to health care providers for free. LifeScan’s profits are generated by selling the compatible test strips.

On September 9, 2011, LifeScan filed suit against Shasta, alleging that Shasta indirectly infringed the method claim by selling test strips to customers, who would in turn perform the patented method. The district court granted a preliminary injunction against Shasta. In particular, the district court found that meters distributed for free were not subject to patent exhaustion because they were not sold to customers. In addition, the court found that patent exhaustion did not apply to the remaining meters because the method “requires both a meter and a test strip for an individual to practice it.”

## **II. Issue**

- 1) Is the only reasonable and intended use of the LifeScan meters to practice the claimed method?
- 2) Do the LifeScan meters embody the essential features of the method claim?
- 3) Does patent exhaustion apply to a product that is distributed for free?

## **III. Holding**

- 1) Yes. There is no suggestion of a reasonable noninfringing use, and the only intended use involves using the LifeScan meter with the compatible strips.
- 2) Yes. The meter controls and carries out the inventive functions of the method claim by comparing the readings of two working electrodes.
- 3) Yes. Patent exhaustion applies to any product that has been conveyed by “authorized and unconditional transfer of title.”

## **IV. Discussion**

With regard to a method patent, the sale of a product triggers exhaustion when 1) its only reasonable and intended use is to practice the patent and 2) it substantially embodies the essential features of the patented invention.

1)  
Alternative uses are only relevant if they are “reasonable and intended” by the patentee. LifeScan admitted that it distributed its meters “in the expectation and intent that customers will use” the LifeScan meter with the LifeScan strips.

2)  
The court notes that the test strips could not embody the essential features of the patented invention because test strips having multiple working electrodes were known in the art, and are therefore not inventive. Instead, the novel and inventive features of the method include steps performed by the meter. “Because it is the meter alone that performs these key inventive steps of the claimed method, the meter substantially embodies the method claims of the ‘105 patent.”

A product substantially embodies the patent when the inventive elements of the method are embodied in the product, and additional elements necessary to practice the patent only involve “the application of common processes or the addition of standard parts.” LifeScan contended that the strips are not standard, and thus, the meter does not substantially embody the method claim. The court notes that standard parts are parts that could easily be adapted to work with the product substantially embodied by the patent. “The fact that the prior art strips might have required some reconfiguration to 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.”

3)  
The court began by examining the policy behind the exhaustion doctrine. The court noted that exhaustion is based on the principle that when a product passes from the patentee to a new owner, the product becomes the private property of the new owner and is no longer subject to the patent monopoly. Adopting LifeScan’s position that consideration is required for patent exhaustion to apply “would be inconsistent with the doctrine’s underlying rationale—to permit the owner of an item who received it in an authorized transfer to use it.”

The court also noted that receiving a “reward” is not required for patent exhaustion to apply. The patentee may give a device away for free and attempt to earn a profit by other strategies. “Where a patentee unconditionally parts with ownership of an article, it cannot later complain that the approach that it chose results in an inadequate reward and that therefore ordinary principles of patent exhaustion should not apply.”

In addition, the court looked to copyright law, and noted that the first sale doctrine does not require an actual sale. Finally, the court reasoned that giving a component away to avoid exhaustion “and tying the recipient’s ability to use that component to the subsequent purchase of another component” would render patent exhaustion “a dead letter and consumers’ reasonable expectations regard their private property would be significantly eroded.”

The court was also concerned about establishing an impermissible tying arrangement. “Here, barring the use of the meter with strips manufactured by the accused infringer would bar the use of the meters for their contemplated function and extend the patent monopoly improperly.”

## V. Dissent

The dissent contended that the test strips embody the essential elements of the method patent, and thus, providing meters to consumers does not exhaust the patent. The dissent reasoned that “the inventive contributions of the components to the method, as opposed to the inventiveness of the components themselves, determines their essentialness.” Because the test strips are essential to practicing the

inventive method, and the meter is not (the process could be performed manually with an ammeter and a test strip), patent exhaustion does not apply to providing the meters to the customers.

Moreover, the dissent noted that denying LifeScan the ability to collect a “reward” for its patented method undermines the principles of patent law. “The declared purpose of the patent law is to promote the progress of science and the useful arts by granting to the inventor a limited monopoly, the exercise of which will enable him to secure the financial reward for his invention.” Exhausting the method patent upon the sale of the meter establishes a mismatch between invention and reward.

## **VI. Conclusion**

A method patent is exhausted upon the sale of a product that substantially embodies the patent. A product substantially embodies the patent when the inventive elements of the method are embodied in the product and additional elements necessary to practice the patent only involve “the application of common processes or the addition of standard parts.”