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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

A Post-Lexmark Plan For Multiple Inventive Methods Of Use

By **Jorge Goldstein and Neil Shull**
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Jorge Goldstein

Neil Shull

We propose here that, when a patentee holds multiple patented method-of-use claims that are inventive over one another, the first sale of a product for use in one method does not exhaust patent rights in the other methods. The patent holder (or an exclusive licensee with the right to enforce) may still use a suit for patent infringement of any of the other patented methods of use if the original buyer, with a post-sale restriction not to use for any of the other patented uses, violates the restriction.

Following the U.S. Supreme Court's 2017 decision in Impression Products v. Lexmark, companies — particularly pharmaceutical companies — should look to obtain multiple distinct patents with method-of-use claims in order to insulate at least part of their patent portfolios from the defense of patent exhaustion.

Patent Exhaustion of Product and Method Claims

The Supreme Court's recent decision in Impression Products v. Lexmark,[1] held that "a patentee's decision to sell a product exhausts all of its patent rights in that item regardless of any restrictions the patentee purports to impose or the location of the sale."[2]

After Lexmark, patent holders are left wondering if there is any legal avenue available that would allow them to impose and enforce post-sale restrictions after a first authorized sale of a patented product. It has been explained that a patent holder may still have a remedy for breach of contract if the buyer violates a post sale restriction.[3] However, a holder may ask if it is still possible to enforce, as patent infringement, restrictions on the use of a patented product after its first authorized sale. We believe that such avenues are still available. Let us explain.

Lexmark follows a line of Supreme Court case law that includes key holdings in United States v Univis Lens Co.,[4] and Quanta Computer Inc. v. LG Electronics Inc.[5]

Univis established the modern line of Supreme Court case law on exhaustion. Univis licensed an intermediate company to manufacture lens blanks that were then sold to licensees, who ground and polished the blanks to manufacture the finished, patented, lens. The court held that Univis could not use

its patent rights to control the price at which the licensee sold the finished lens. The court found Univis' patent rights to be exhausted even though the lens blanks were not functional as a lens until ground and polished by the licensees. To determine whether a patent is subject to exhaustion, the court looked to whether the sold product — the unpatented lens blanks — "embodies essential features of [the] patented invention [i.e., the finished lens or the method of finishing them]."[6]

More than six decades later, the court in Quanta expanded on this holding. In Quanta, the court looked at whether claims to methods of managing data traffic on a computer were exhausted by the sale of computer components. The court held that, just as is the case with product claims, method claims were also subject to exhaustion. The court then looked to whether the computer components sold "substantially embody" the patents in suit and found that the components did substantially embody the enforced method claims. After this finding, the court held that sale of the components exhausted the method claim patents.[7]

The next logical question then is: When does a sold product “substantially embody” a method of using it?

The Sale of a Product “Substantially Embodies” a Method Claim if it Embodies the Inventive Feature of the Method

To determine whether sale of a product substantially embodies a method claim, the court in Quanta looked to whether the sold products embodied the "essential, or inventive, feature of" the patents.[8] The court concluded that, in the case before it, "[e]verything inventive about each patent is embodied in the sold products."[9]

Thus, the Quanta test for whether a method claim is exhausted by the sale of a product is whether the inventive feature of the method claim is embodied in the sold product. The Federal Circuit has subsequently applied this test, most notably in Keurig Inc. v. Sturm Foods,Inc.,[10] and Lifescan Scot. Ltd. v. Shasta Techs. LLC.[11]

In Keurig, the Federal Circuit held that Keurig's patent claims to a method of brewing a beverage from a medium in a disposable cartridge were exhausted by the sales of its patented brewing machine (the claims for which were present in the same patent). Exhaustion was at issue because Sturm — who was accused of inducing to infringe the method claims — sold unpatented disposable cartridges that fit Keurig's machine; the cartridges were useful in carrying out the method of brewing claims. The court in Keurig stated that the patent with both product and method claims was exhausted if the sold item "(1) has no reasonable non-infringing use and (2) includes all inventive aspects of the claimed method."[12] The Federal Circuit found that the brewing machine had no other reasonable uses and included all of the inventive aspects of the method claims. Thus, the method claims were held to have been exhausted by sales of the machine.

In an important comment, the Keurig court also explained that exhaustion is not adjudicated on a claim-by-claim basis. The determination of exhaustion of patent rights is based on “the patents at issue, in their entirety, rather than the exhaustion of the claims at issue on an individual basis.”[13]

In Lifescan, the Federal Circuit further developed the "inventive aspects" part of the substantial embodiment test. The Federal Circuit in Lifescan looked at whether the sale of no longer patented blood glucose diagnostic meters exhausted patents with claims to methods of determining the concentration of a substance in a sample liquid. Exhaustion was at issue because Shasta sold test strips that fit

Lifescan's meters, and was accused of inducing infringement of the patented method. The Federal Circuit first found that the meters had no intended alternative use, stating that "alternative uses are relevant to the exhaustion inquiry under Quanta only if they are both 'reasonable and intended' by the patentee or its authorized licensee."[14]

Turning to the inventive part of the substantial embodiment test, the Federal Circuit found that "[w]hat is 'inventive' about patent claims in the patent exhaustion context is what distinguishes them from the prior art."[15] As such, the Federal Circuit in Lifescan looked to whether the features of the claims that were argued in prosecution to distinguish over the prior art were embodied in Lifescan's meters. Finding that they were, the Federal CIrcuit found Lifescan's method patents to be exhausted.

Thus, a two-step test may be derived from Quanta, Keurig and Lifescan:

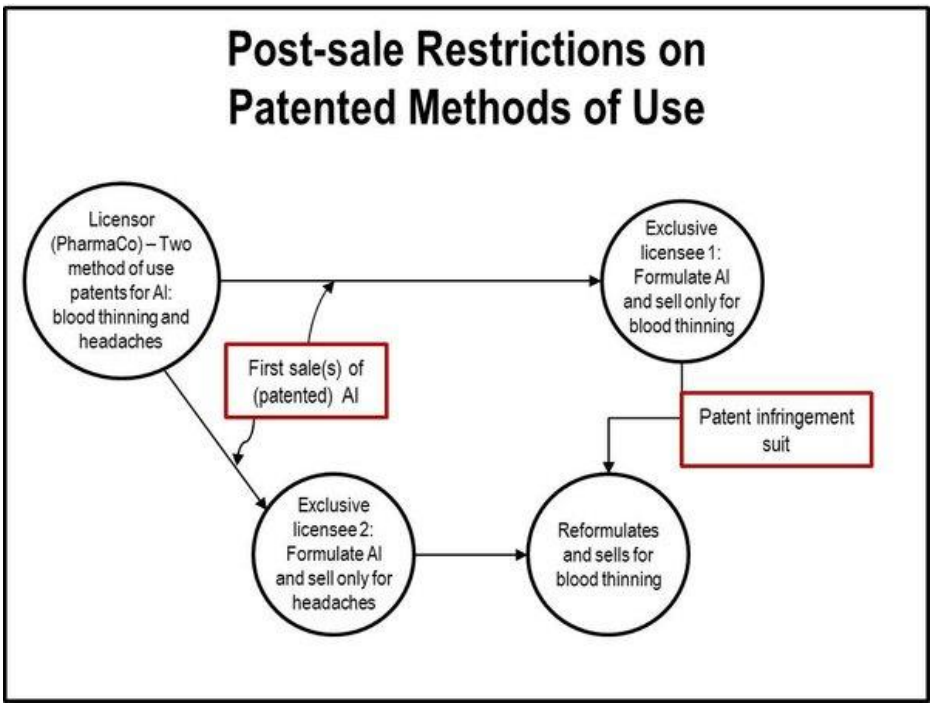
- First, if a method-of-use claim is inventive over the prior art and the product sold — whether patented (Keurig) or not (Lifescan) — substantially embodies the inventive features of the method claim (i.e., the features that distinguished the claim over the prior art), then the sale of the product substantially embodies that claim; and

- Second, if the sold product — again, whether patented or not — is not capable of a reasonable and intended noninfringing or alternate use, then the sale of the product embodies the method-of-use claim.

Conversely, if neither of these two steps applies, then the sale of a product does not substantially embody a method-of-use claim. This two-step test of “substantially embodies” leads directly to our proposal.

Proposal: Multiple Mutually Inventive Method-of-Use Claims for a Single Pharmaceutical Product

The figure below summarizes the central argument of our article:



A pharmaceutical patent holder (PharmaCo) makes and sells an (patented or unpatented) active Ingredient (e.g., aspirin) to two different buyers. Buyer 1 receives an exclusive license (with the right to enforce) to formulate aspirin for patented use 1 only (e.g. blood thinning), and Buyer 2 receives an exclusive license (with the right to enforce) to formulate aspirin for patented use 2 only (e.g., headaches). The patent holder holds both patents, one for method-of-use 1 and the other for method-of-use 2.

We propose that if (1) the use of aspirin as a blood thinner is inventive, i.e., nonobvious, over the use of aspirin as an analgesic, and vice versa, and (2) both uses are reasonable and intended by the authorized patent holder, then sale of aspirin for formulation into a blood thinner does not substantially embody the patented use of aspirin as an analgesic, and vice versa. Buyer 1/Licensee 1 will then be able to enforce, on a basis of inducement to infringe, the patent claim on a method of blood thinning against Buyer 2, if Buyer 2 — in violation of a post-sale restriction — attempts to reformulate the aspirin for blood thinning.

Conclusions and Generalizations

After Lexmark, restrictions on post-first sale activities are no longer enforceable as patent infringement unless the activities are patented in alternate and inventive method-of-use claims. Thus, restrictions on sale of a product "for research use only," or "not for commercial use," or "for single use only," or with resale price restrictions, are a priori not inventive, and continue being unenforceable after Lexmark. Plus, if a patented pharmaceutical product has only one patented use at the time of litigation, then, under Keurig, sale of the product exhausts the patented method.

In contrast, violation of restrictions based on multiple mutually inventive method-of-use claims should be actionable as patent infringement. These include, for example:

- A pharmaceutical product that may or not be patented and has two distinct method-of-use patents (e.g., a patented or unpatented antibody with a first patent having a claim to a method of treating cancer, and, in a second patent, a method of treating arthritis); or

- A pharmaceutical product and a first method that are no longer patented (e.g., an antibody with a first use in cancer) and a more recent patented method that is distinct from the first method (e.g., use of the antibody in arthritis).

Whenever possible, a pharmaceutical company should obtain different patents for mutually inventive, alternate and intended, uses of its products. If more than one use is invented at the time of invention of the product, the company should obtain multiple patents for the different uses. Certainly, as new uses are invented, new patents should be obtained.

Whether this model of enforceable post-first authorized sale restrictions is applicable to the nonpharmaceutical world is not as clear. An instrument or machine is normally designed to perform one specific method and no other. A post sale restriction on the first sale of the machine would — as in Keurig or LifeScan — exhaust the one and only contemplated use. If a machine can be designed with more than one inventive and intended method of use, then the exhaustion theory we propose here would work equally well in such context.

Aware of the possibilities of enforcing separate method-of-use patents, applicants should present distinct use claims in separate patent applications so that they end up in separate patents. If applicants start with distinct method-of-use claims in one application they should prosecute them without negating the proposition that each claimed method is inventive over every other claimed method. For example, an applicant should not traverse restriction requirements that posit that the claimed inventions are distinct.

License agreements should be carefully drafted with the above case law in mind. It should be made clear that a license is granted to a patented product to one and no other of multiple alternate and separately patented methods of use. License restrictions can be included on post sale use for any of the other alternate patented methods.

In sum, under the right set of circumstances, infringement remedies for post-first sale restrictions on the sale of a product are still available after Lexmark.

Jorge A. Goldstein, Ph.D., is a senior director at Sterne Kessler Goldstein & Fox PLLC in Washington, D.C. He chairs the firm's intellectual property and human rights pro bono practice, and is a founder and previous managing partner of the firm. His recent book "U.S. Biotechnology Patent Law," Thomson Reuters, 2017-2018 Second Edition, summarizes his lifelong work in the IP of biotechnology.

Neil P. Shull, Ph.D., is an associate in the firm's biotechnology/chemical group in Washington.

[1] Impression Products v. Lexmark, 137 S. Ct. 1523 (2017).

[2] Id. at 1526.

[3] The Supreme Court Redefines Patent Exhaustion, Michael Q. Lee, Paul A. Ainsworth, and Krishan Thakker, June 12, 2017, www.iipla.org.

[4] United States v Univis Lens Co., 316 U.S. 241 (1942).

[5] Quanta Computer, Inc. v. LG Electronics, Inc., 553 U.S. 617 (2008).

[6] Univis, 316 U.S. at 251.

[7] Quanta, 553 U.S. at 637.

[8] Quanta, 553 U.S. at 632.

[9] Id. at 633.

[10] Keurig, Inc. v. Sturm Foods, Inc., 732 F.3d 1370 (Fed. Cir. 2013).

[11] Lifescan Scot., Ltd. v. Shasta Techs., LLC, 734 F.3d 1361 (Fed. Cir. 2013).

[12] Keurig, 732 F.3d at 1373.

[13] Id. at 1374.

[14] Lifescan, 734 F.3d at 1369.

[15] Id.