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Avoiding Or Living With Patent Exhaustion

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Law360, New York (June 22, 2009) -- This guest column addresses ideas on how to avoid or live with patent exhaustion, especially for the biotechnology sector.

Patent exhaustion (also known as the "first-sale doctrine") precludes a patent owner from collecting multiple times on its patent rights. After an authorized and unrestricted sale of a patented product, a patent owner's patent rights have been exhausted. Thus, after the first sale, the patent owner can generally no longer control the use or sale of the patented product. In the simplest case, the rule of patent exhaustion means that, after a patent owner sells a product, the patent owner cannot stop the buyer from reselling the product.

As with all law, complex fact patterns arise that require judicial scrutiny and analyses.

Combinations: Assume a patent owner has a first patent to a component and a second patent to a combination that incorporates the component. Can a patent owner authorize the sale of the component, yet still claim patent infringement by a purchaser for the combination?

Methods: Assume a patent owner has a first patent to a component and a method patent to a particular use of the component. Can a patent owner authorize the sale of the component, yet still claim patent infringement by a purchaser for the particular use?

Use restrictions: Can a patent owner place a restriction on a patented product to only licensed uses? In this same vein, can a patent owner restrict the use of a patented product "for research use only" or "for single use only"?

Self-replicating products: Can a patent owner restrict a purchaser from taking advantage of the self-replicating properties of a patented product?

The Answers to the Question Regarding Combinations and Methods

In the recent Supreme Court case, Quanta Computer Inc. v. LG Electronics Inc. (2008), Intel had a license from LGE to sell memory controllers. The license required Intel to inform its customers, including Quanta, that they were not allowed to combine the memory controllers with non-Intel parts. Despite the warning from Intel, Quanta purchased the memory controllers from Intel and combined them with non-Intel parts. LGE sued Quanta for patent infringement for the combination.

Quanta argued that LGE could not control its use of the memory controllers, due to the doctrine of patent exhaustion. The district court originally found all claims exhausted. However, on reconsideration, the district court concluded that patent exhaustion did not apply to method claims. Then, the CAFC reversed the district court's decision, holding that patent exhaustion did not apply at all.

The U.S. Supreme Court granted certiorari.

The Supreme Court applied the reasoning of United States v. Univis Lens Co., 316 U.S. 241 (1942). In Univis Lens, the patent owner had patent rights to lens blanks and patent rights to lens finishing processes. The patent owner granted a license to a manufacturer to sell the lens blanks. Then, the patent owner tried to obtain additional license fees from the finisher for using the finishing process. The Supreme Court in Univis Lens found that the sale of the lens blanks exhausted the patent owner's rights to control the finishing process, since the finishing process included only the application of standard practices to the lens blanks, which had no other purpose.

Applying Univis Lens, the Supreme Court in Quanta ruled that LGE could not control Quanta's use of the

Intel memory controllers since Intel was fully authorized to sell the memory controllers, the only reasonable and intended use of the memory controllers was to practice the combination, and the combination sufficiently embodied the essential features of the licensed claims. The Supreme Court stated that an incomplete article substantially embodies a patent if the only remaining step necessary to fully practice the patent is the application of common processes or the addition of standard parts.

Accordingly, the Supreme Court ruled that the authorized sale of the memory controller by Intel exhausted LGE's rights to control its combination and use with standard parts and processes.

The Answers Regarding Use Restrictions and Self-Replicating Products

In Quanta, BIO filed an amicus brief to explain why patent exhaustion fails to translate well to biotech situations. BIO noted that many of the important advances in medical and agricultural biotechnology, such as cell lines, DNA sequences, or transgenic seed, involve DNA, which self-replicates through the ordinary process of cell division, but is also routinely capable of artificial replication.

As a result, the manufacture and further transfer of self-replicating products are often prohibited and restricted to use in research. Absent such a restriction, the first sale — which is often for a reduced price to permit universities and small companies to participate in research — would effectively extinguish the patentee's rights, because the purchaser would obtain, in effect, a never-ending supply of the product that it could use, sell, and market in competition with the patent owner.

BIO raises the following four important points unique to the biotechnology industry:

First, patent exhaustion relating to use of a patented product does not and should not extend to the manufacturing of the patent product. A central concern of the biotechnology industry is not restricting use of the patented product, but prohibiting purchasers from making the patented product by, for example, exploiting an item's self-replicating character. Patent exhaustion has never extended to the manufacturing of a patented product.

Second, patent exhaustion has two prerequisites — the sale must be authorized and the purchaser must be authorized to buy. The biotechnology industry commonly restricts the authority of licensees to sell their products and may also require purchasers to be licensed. If either the sale or purchase was unauthorized, then the use or sale the patented product will constitute infringement of the patent.

Third, patent exhaustion should have no effect on the patentee's right to enforce non-licensed uses of the licensed product. Biotechnology patent licenses are often granted "for research use only" even though the claimed inventions have extensive diagnostic, clinical, or therapeutic applications. When restrictions are imposed on purchasers, such as a "for research use only" restriction or a restriction that constrains the use of second-generation products, the restriction is designed not to constrain the only reasonable use of the invention, but rather to proscribe alternative uses of the invention, such as commercial uses that the buyer did not license.

Fourth, patent exhaustion should not be used to negatively effect the value of a biotechnology product whose value increases with time. Because biotechnology products often require years of research and development, early licenses and sales often do not reflect the ultimate value of the invention, but instead are a cooperative nominal exchange designed to promote further research. Likewise, with self-replicating products, the sale price of the first item sold (e.g., a single vial of genetically modified cells or a single packet of seeds) cannot capture the patentee's fair reward for painstakingly developing the product.

The patent law's current level of protection for such inventions has made enormous innovation possible in the last two decades, and patent exhaustion should accommodate the unique demands of modern technological development.

Two cases, which address the issues raised by BIO in their Quanta amicus brief, are Mallinckrodt Inc. v. Medipart Inc., 976 F.2d 700 (Fed. Cir. 1992) and Monsanto v. Scruggs, 459 F.3d 1328 (Fed. Cir. 2006).

In Mallinckrodt, the patented device is an apparatus for delivery of radioactive or therapeutic material in aerosol mist to the lungs of a patient for diagnosis and treatment of pulmonary disease. The device is manufactured by Mallinckrodt, who sells it to hospitals as a unitary kit that consists of a "nebulizer," which generates a mist of the radioactive material or the prescribed drug, a "manifold" that directs the flow of oxygen or air and the active material, a filter tube, tubing, a mouthpiece, and a nose clip. The device is marked with the appropriate patent numbers and the inscription "Single Use Only." The package in-

sert provided with each unit states "For Single Patient Use Only" and instructs that the entire contaminated apparatus be disposed of after use as a biohazard material.

After the initial use of the devices, the hospital sent the devices to Medipart for servicing with gamma radiation that enabled the hospital to re-use the device. The reassembled devices still bore the inscription "Single Use Only." Mallinckrodt claimed that Medipart infringed the patent and induced infringement by the hospitals.

Medipart argued that the restriction was unenforceable due to patent exhaustion. The district court agreed and held that since the hospital purchased the device from the patent owner (a situation where patent law controls), the patent owner could not place a restriction on the use of the device. Under the district court's analysis, if the hospital had purchased the device from a manufacturing licensee, the controlling law of sales and licenses may have made the restriction permissible.

The Federal Circuit reversed and held that, if the sale of the device was validly conditioned under the law of sales and licenses and the restriction on reuse was within the scope of the patent grant, then violation of the restriction may be remedied by an action for patent infringement.

Because the restriction was found valid, Medipart's activities rose to the level of an infringing reconstruction of the device. If the single use only restriction was found unenforceable, then Medipart's activities may have been considered to be permissible non-infringing repair.

In Monsanto, Monsanto licensed seed companies to incorporate their Roundup Ready® genes into cotton and soybean plants and authorizes the seed companies sell the genetically engineered plants to growers.

The licensing agreement with the seed companies requires that the growers buying the seeds from the seed company must sign one of Monsanto's licensing agreements, which includes the following four restrictions on the growers: (1) Exclusivity Provision: Growers must use only seeds containing Monsanto's technology for a single crop; (2) No Replant Provision: Transfer or reuse of seeds containing the biotechnology for planting is prohibited; (3) No Research Policy: Using the seeds for research or experimentation is prohibited; (4) Technology Fee: Payment is required under the contract.

Scruggs purchased Roundup Ready® soybean & JDSUPRA cotton seeds from seed companies, but never signed a licensing agreement; it planted the purchased seeds and after harvesting, retained the new generation of seeds and planted subsequent crops with the retained seeds. Monsanto sued Scruggs for patent infringement.

One of Scruggs defenses was patent exhaustion. Relying on Mallinckrodt, Scruggs argued that Monsanto's patent rights were exhausted because the seeds were purchased in an unrestricted first sale by the patentee.

The CAFC held that the doctrine of patent exhaustion was inapplicable. There was no unrestricted sale because the use of the seeds by seed growers was conditioned on obtaining a license from Monsanto. Furthermore, the "first sale" doctrine of patent exhaustion was not implicated because the new seeds grown from the original batch had never been sold; without the actual sale of the second generation seed to Scruggs, there can be no patent exhaustion.

The CAFC states in Monsanto, "The fact that a patented technology can replicate itself does not give a purchaser the right to use replicated copies of the technology. Applying the first sale doctrine to subsequent generations of self-replicating technology would eviscerate the rights of the patent holder."

Advice to Avoid or Live With Patent Exhaustion

By applying the teachings of the above cases, we identify below several strategies that may be available to avoid or live with patent exhaustion. Of course, we highly recommend that you speak with licensing counsel to develop a specific strategy best fitted to your unique fact pattern.

Manufacturing Restrictions

Require customer compliance in manufacturing agreements: Restrict the license granted to the manufacturer to require customer compliance. For example, a license may require that the manufacturer's customers must not combine the patented component with parts of a non-authorized company. Indicate in the license that customer noncompliance will render the sale unauthorized and will constitute an infringement by both the manufacturer and the customer.

Prohibit manufacturing of self-replicating species: For licenses covering patented biological organisms, include a provision in the license that prohibits manufacturing of the patented products. For example, the

license may recite that manufacturing of a self-replicating species (such as cells, bacteria, or enzymes) is prohibited.

Sale and Use Restrictions

Sale/buyer restrictions: Include provisions in the license that require the sellers and buyers of the products to be authorized to enter into the agreement. With respect to authorized sellers, the license may specify that licensees may not sell the patent product without express authorization from the patentee. With respect to authorized buyers, the licensee may specify that buyers of the patented products must be, for example, state certified research or clinical laboratories.

Non-licensed use restrictions: The license may specify that non-licensed uses of the product will constitute infringement. For example, if the license expressly specifies that the patented product is "for research use only," then use of the patented product for a commercial use will be a non-licensed use that amounts to an infringement.

Similarly, if the license expressly specifies that the patent product is "for single use only," then subsequent use of the patent product will be a non-licensed use that amounts to an infringement.

In addition, the license may also specify that a particular kit is to be used solely for a particular purpose. For example, the license covering the use of a DNA amplification kit may specify that the contents of the kit are to be used solely to amplify target DNA sequences and that use of the kit for purposes other than DNA amplification is a non-licensed use that is subject to infringement.

Repair restrictions: The license may specify that repair and reconstruction of the patent product is prohibited. With respect to the prohibition on repair, the license may specify that kits requiring repair must be returned to the patentee and/or the manufacturer for repair. With respect to reconstruction, the license may specify that reconstruction of the patented product is an automatic infringement.

Exclusivity restrictions: The license may indicate exclusivity restrictions for a combination. For example, within the context of a DNA amplification kit, the license may indicate that use of the individual components of the DNA amplification kit in a non-licensed manner will constitute an infringement.

In this example, non-licensed uses of the components of the kit may include using the contents of the kit to conduct experiments that are not related to the purpose of the kit and/or using the contents of the kit to supplement the contents of competing kit.

Additional Royalty Provisions

Vertical market royalties: Bring all players in the vertical market into a single negotiation. Then, establish fair royalties to be paid by each player.

Post-manufacturing royalties: Charge the manufacturer for downstream combinations or uses.

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