Court identifies commercial activities allowed under on-sale bar doctrine

ALERT | JUL 12, 2016

Are you considering releasing a product for public sale? If you plan to do so before filing a patent application, you may want to look at your commercial options before finalizing a business strategy.

Here's why.

The on-sale bar doctrine under 35 U.S.C. 102(b) holds that an invention cannot be patented if it has been on sale for a year prior to the patent filing. But yesterday, the U.S. Court of Appeals for the Federal Circuit held that a contract manufacturer's sale of its services to an inventor does not constitute an invalidating sale if neither title to the invention embodiments nor the right to market the embodiments passes to the third party.

This decision helps clarify what types of commercial activities may be allowed without risking loss of patent rights. It also clarifies that the focus of on-sale bar analysis should rely on what constitutes commercial marketing of a product, as opposed to merely obtaining commercial benefit from a transaction.

BACKGROUND ON THE MEDICINES CO. V. HOSPIRA, INC.

The Medicines Co. (MedCo) owns Angiomax, which is the brand name for a drug used to treat blood clots. MedCo has two U.S. patents for the drug, and alleged that Hospira's planned generic version infringes on those patents.

MedCo did not file for its patent applications until over a year after several transactions with third parties. Ben Venue Labs was hired by Medco to manufacture batches of its Angiomax product in October 2006. The product was then delivered to MedCo's exclusive distributor for quarantine and testing to ensure it met U.S. FDA requirements. MedCo then released batches of its invention embodiments from quarantine and made them available to the public after filing its patents on July 27, 2008.

The court found that MedCo's arrangement with Ben Venue Labs was not enough to trigger the on-sale bar, as the transactions must be one in which "the product is 'on sale' in the sense that it is commercially marketed." The mere sale of manufacturing services by a contract manufacturer to an inventor to create embodiments of a patented product for the inventor does not constitute a 'commercial sale' of the invention.

Notably, the court defined the term sale by relying on Section 2-106 of the Uniform Commercial Code which defines a sale as "the passing of title from the seller to the buyer for a price." This decision holds that a transaction for only manufacturing services wherein the inventor maintains control of the invention does not trigger the on-sale bar. The court further identified that, product stockpiling, either in-house or with a third party, does not trigger the on-sale bar.

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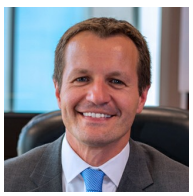

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