Buyer Beware: Secret Sales May Result in Subsequent Patent Invalidity

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Recently on January 22, 2019, the Supreme Court affirmed the Federal Circuit's judgment in Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA Inc. The case centered around the "on sale" bar of the Leahy-Smith America Invents Act (AIA), effective as of March 16th, 2013. Under the AIA, 35 U.S.C. ? 102(a)(1) bars an inventor from a receiving a patent on an invention that was "in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention."
The case posed the question of whether an inventor's sale of an invention to a third party that is obligated to keep the invention confidential qualifies as prior art for the purpose of determining patentability?

The case first developed when Helsinn Healthcare S.A. (Helsinn) started making a treatment for chemotherapy induced nausea and vomiting using the chemical palonosetron. Palonosetron is a 5-HT3 antagonist, given either orally or intravenously prior to chemotherapy to prevent delayed nausea and vomiting. Palonosetron is a favorable product due to its long halflife (between 40-50 hours), enabling long periods of time between subsequent doses. While developing this product, in 2001, Helsinn entered into an agreement with another company granting that company the right to distribute, promote, market, and sell palonosetron in the 0.25mg dosage form. The agreement specified that the company would keep proprietary information secret.

Two years later in 2003, Helsinn filed a provisional patent application for the 0.25mg dosage form. Over the next ten years, Helsinn continued to file patent applications, including one filed in 2013, after enactment of the AIA. In 2011, Teva Pharmaceuticals USA Inc (Teva) sought approval to market a genetic 0.25mg palonosetron product. At this point, Helsinn sued Teva for patent infringement of its patents covering palonosetron. Teva then countered that Helsinn's patent filed in 2013 was invalid under the "on sale" provision of the AIA. Teva claimed that the 0.25mg dose was on sale more than one year before Helsinn filed its original provisional patent application in 2003.

The District Court held that the AIA's on sale bar did not apply because the agreement between Helsinn and the other company, even if considered a public disclosure, did not disclose the 0.25mg dose. The Federal Circuit reversed, holding that the sale was publicly disclosed, regardless of whether the details of the invention were publicly disclosed in the terms of the sale agreements. The Supreme Court then heard the case, and in a 9-0 ruling, affirmed the decision of the Federal Court. The Supreme Court ruled that a commercial sale to a third party who is required to keep the invention confidential may place the invention "on sale" under ?102(a). The Supreme Court reasoned that a sale or offer of sale need not make an invention available to the public to constitute invalidating prior art. The Supreme Court further reasoned that "secret sales" could indeed invalidate a patent.

This case is monumental, in that even though it did not eliminate secret prior art, it provides clarity as to the scope of the "on sale" bar, and allows inventors and lawyers alike to create custom patent strategies based on this new information. Going forward, this case offers several key takeaways. First, this decision will be particularly impactful on small companies looking to partner with larger corporations to bring their novelty to market. This is especially true of biotech and pharma startups, that often collaborate with bigger corporations to offset costs needed for drug discovery and research and development. Secondly, inventions must now be evaluated early on to determine whether they should maintain a trade secret or be protected via patents. Further, inventions deemed patentable should be considered for early provisional patent applications filings before any anticipated disclosures or offers for sale. Lastly, confidentiality agreements such as non-disclosure agreements (NDA) should not be relied upon to prevent loss of patent rights based on offers for sale of the invention.