U.S. Supreme Court Decision Emphasizes Need for Early Filing of Patent Applications

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A recent U.S. Supreme Court ruling may make an already difficult patent application consideration even more treacherous.

The Court last week ruled Helsinn Healthcare took too long to file a patent application for a drug that limits the side effects of chemotherapy, a case that sparked further debate concerning the 2013 updates of the Leahy-Smith America Invents Act. In the update, five words - "otherwise available to the public" - produced disparate views on whether the act altered the timeline for filing a patent application.

There are two primary mechanisms by which a patent applicant's own actions can prevent them from being able to obtain patent protection for their invention. A public disclosure of the invention or an offer of the invention for sale trigger a one-year clock in the U.S. Any potential patent rights in the invention are forfeited if the applicant fails to file a patent application on the invention by the end of this one-year period. Most foreign countries impose an even more rigorous standard, eschewing the one-year "grace period" of U.S. law and requiring the inventor to file a patent application before any public disclosure or offer for sale.

The public disclosure and offer for sale portions of the rule are contained in a section of the America Invents Act that was revised in 2013:

A person shall be entitled to a patent unless the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

Part of the 2013 revisions is the "otherwise available to the public" portion of the rule that left uncertainty over whether secret or confidential offers for sale would trigger the one-year timeframe.

Helsinn's chemotherapy drug tested these murky waters in *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.* where the company offered and agreed to a sale of the drug almost two years prior to filing a provisional patent application on the drug. At the time of the offer and sale, the buyer agreed to buy the drug contingent upon Food and Drug Administration approval and to maintain as confidential any proprietary information surrounding the sale. The subsequent FDA approval came after the filing of the provisional application.

After issuance of a series of patents claiming priority to the original provisional application on the drug, Helsinn sued a manufacturer of generic drugs, asserting infringement of one of Helsinn's patents. The generic manufacturer contended that Helsinn's patent was invalid because Helsinn had offered the invention for sale more than one year prior to the earliest patent application filing date. Helsinn countered that the sale was confidential and is required to be

"available to the public" under the Leahy-Smith America Invents Act.

The district court, agreeing with the stance of the U.S. Patent and Trademark Office, determined that the "available to the public" language of the act was intended to modify "on sale," and that Helsinn's patent remained valid because the sale was confidential. The federal circuit reversed the district court, concluding that details of an invention do not need to be publicly disclosed to trigger the one-year time clock if the existence of the sale is public. The existence of this sale was public because Helsinn issued a press release and submitted the agreement of sale to the Securities and Exchange Commission, although both of these public announcements omitted the details critical to patentability of the invention. The Supreme Court affirmed the federal circuit and found that Helsinn's patent was invalid. The Supreme Court decided that the act did not intend to alter the meaning of "on sale," and that "otherwise available to the public" was intended only as a catch-all for public disclosures that did not clearly fit into the previous language of the statute.

The divergence in rationale between the federal circuit and the Supreme Court highlights an important consideration. The federal circuit was willing to conclude that Helsinn's sale triggered the one-year time clock because at least a portion of the sale -its existence - was public. The Supreme Court more broadly concluded that the act did not change the previous meaning of "on sale" at all, that a completely confidential offer for sale still triggers the beginning of the grace period for filing in the U.S.

The decision emphasizes the importance of filing a patent application as early as possible once the inventor is sufficiently able to describe the details and functioning of the invention. The pitfalls of any commercial pursuits related to the invention, along with broadly construed "public" disclosures of the invention, are significant and can undermine valuable rights without proper care. Innovators and companies developing technology should have a structured internal system for prompt analysis and action on new developments to prevent patent rights on a potentially valuable invention from slipping through the cracks.

If you have any questions on this Supreme Court ruling and how it can affect your business, please reach out to me or any of the attorneys in the Barley Snyder Intellectual Property Practice Group.

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