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"Secret Sale" of Drug Counts as Prior Art in Patent Battle

On January 22, 2019, the U.S. Supreme Court affirmed the U.S. Court of Appeals for the Federal Circuit's decision in *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*, No. 17-1229 (Jan. 22, 2019). In a unanimous decision authored by Justice Thomas, the Supreme Court considered whether the enactment of the Leahy-Smith America Invents Act (AIA) changed the meaning of "on sale" under the provision that defines prior art, which sets forth that a "person shall be entitled to a patent unless (1) 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." Specifically, the Supreme Court granted certiorari to determine whether a "sale of an invention to a third party who is obligated to keep the invention confidential" places the invention "on sale" under the AIA, concluding such a sale—sometimes called a "secret sale"—may qualify as prior art.

Helsinn Healthcare, a Swiss pharmaceutical company, makes a drug using specific doses of palonosetron for treating nausea and vomiting caused by chemotherapy, and it acquired patents covering this drug. Teva Pharmaceuticals USA sought FDA approval to market a generic version of the Helsinn drug, and Helsinn sued Teva for patent infringement. Teva alleged the asserted patent claims were invalid because of a prior sale.

About two years before the effective filing date of Helsinn's asserted patents, Helsinn entered agreements with a U.S.-based pharmaceutical company, MGI Pharma, in which Helsinn agreed to supply any palonosetron products approved by the FDA to MGI Pharma. In exchange, Helsinn received up-front royalty payments

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and exclusivity. MGI Pharma also agreed to maintain as confidential Helsinn's proprietary information. Because the formulation claimed in Helsinn's patents was not revealed to the public prior to patenting, the district court determined that the on-sale bar did not apply, but the Federal Circuit reversed.

The Supreme Court affirmed the Federal Circuit's judgment. In doing so, the Court noted that the Patent Act has included an on-sale bar since 1836 and pre-AIA precedent applying the "on-sale" bar did not require public disclosure. The Court looked to precedent to support the proposition that "on sale" had a "well-settled meaning" prior to the AIA's enactment. According to the Court, under that settled meaning, sales or offers for sale "need not make an invention available to the public" to qualify as prior art.

The Court further concluded the AIA did not change the meaning of "on sale." Helsinn relied on the catchall phrase "or otherwise available to the public" in the applicable section to suggest that Congress intended to alter the meaning of "on sale" to require public availability. The Supreme Court disagreed, saying this addition "was simply not enough of a change" to show Congressional intent to change the meaning of "on sale."

This is an important decision for companies applying for patents and litigating patent issues. Applicants and patentees need to be cognizant of agreements and activities with third parties that could trigger the "on sale" bar. Such activities, which might not bar a patent application in other jurisdictions, may qualify as prior art under U.S. law. In disputes involving post-AIA patents, this decision may open the door to additional prior art defenses for accused infringers, for which patentees need to be prepared.

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