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Supreme Court Addresses Impact of AIA on "On-Sale Bar"

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The U.S. Supreme Court has issued a unanimous decision in *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.* regarding the impact of new language in the America Invents Act (AIA), 35 U.S.C. § 102, on the "on-sale bar." Before the adoption of the AIA, a patent was held invalid if, before the critical date, the product was the subject of a commercial offer for sale in the United States and the invention was ready for patenting.

As amended by the AIA, Section 102 now provides that: "[a] person shall be entitled to a patent unless... the claimed invention was... in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention." It provides a one-year grace period for disclosures made directly or indirectly by the inventor. Notably, the AIA added the phrase "or otherwise available to the public" as a basis for the on-sale bar.

In *Helsinn*, while developing a medication to treat chemotherapy-induced nausea, Helsinn entered into two confidential agreements granting another company the right to distribute, promote, and sell that medication in the United States. Nearly two years later, Helsinn filed a provisional patent application covering the medication. Over the next ten years, Helsinn filed four patent applications that claimed priority to the provisional application filing date. In 2011, Helsinn sued Teva Pharmaceuticals for infringing four of its patents, including one filed after the enactment of the AIA. Teva countered that the post-AIA patent-in-suit was invalid under the on-sale bar because the medication was "on sale" more than one year before Helsinn filed the provisional patent application.

The district court held that the post-AIA patent was not invalid under the on-sale bar because the agreement between Helsinn and its distributor did not publicly disclose the dosage levels of the drug. On appeal, the Federal Circuit reversed the district court's decision and found the post-AIA patent to be invalid. The court held that "after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of the sale" for the sale to be invalidating under Section 102.

Helsinn sought – and was granted – Supreme Court review on a single issue: whether, under the America Invents Act, an inventor's sale of an invention to a third party that is obligated to keep the invention confidential qualifies as prior art for purposes of determining the patentability of the invention. Helsinn's argument focused on the construction of the new catch-all language in Section 102 ("or otherwise available to the public").

The Supreme Court affirmed the Federal Circuit in a 9-0 decision, holding that a sale or offer of sale need not make an invention available to the public to constitute an invalidating sale or offer to sell. The Court determined that the addition of the phrase "or otherwise available to the public" was not sufficient to indicate that Congress intended to alter the meaning of "on sale."

The *Helsinn* decision resolves a significant question regarding whether the enactment of the AIA impacted the scope of the on-sale bar. Just as before the enactment of the AIA, an inventor's sale of an invention to a third party who is obligated to keep the invention confidential can be invalidating under Section 102(a).

If you have any questions about the *Helsinn* decision or the American Invents Act, please contact Adam S. Baldridge, Nicole D. Berkowitz, or any member of Baker Donelson's Intellectual Property Group.