



Supreme Court Holds That Confidential Licensing Agreements Can Trigger The America Invents Act's "On-Sale" Bar

Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA Inc., No. 17-1229

Decided January 22, 2019

Today, the Supreme Court held that confidential licensing agreements can trigger the Leahy-Smith America Invents Act's "on-sale" bar, which prohibits awarding patents to claimed inventions that have already been "in public use, on sale, or otherwise available to the public."

Background:

In order to finance the development of a new pharmaceutical drug, Helsinn entered into a licensing agreement with another pharmaceutical company, MGI Pharma. Under the agreement, MGI Pharma received the right to purchase and eventually distribute the drug if it obtained the appropriate governmental approval. Although the existence of the licensing agreement was itself made public, MGI Pharma was required to keep confidential all proprietary information related to the drug. More than a year after entering into the licensing agreement with MGI Pharma, Helsinn applied to patent its new drug. The Leahy-Smith America Invents Act's "on-sale" bar prohibits awarding patents for claimed inventions that were "in public use, on sale, or otherwise available to the public" for more than one year before a patent application is filed.

Issue:

Whether entering into a confidential licensing agreement can place the underlying invention "on sale" such that it triggers the Leahy-Smith America Invents Act's "on-sale" bar.

"In light of this settled pre-[America Invents Act ("AIA")] precedent on the meaning of 'on sale,' we presume that when Congress reenacted the same language in the AIA, it adopted the earlier judicial construction of that phrase."

Justice Thomas,
writing for the unanimous Court

Gibson Dunn Named
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Court's Holding:

Yes. A commercial sale to a third party who is required to keep the invention confidential may place the invention "on sale" under the Leahy-Smith America Invents Act.

What It Means:

- The Court's holding means that inventors have a reduced incentive to enter into "secret" sales of their invention, since both public and private sales can trigger the Leahy-Smith America Invents Act's one-year time limit.
- The opinion highlights the interaction between new legislation and prior judicial precedent. Noting that "[e]very patent statute since 1836 has included an on-sale bar" which had not been interpreted to apply to public sales alone, the Court concluded that Congress did not signal an intent to alter the historical understanding of the term "on sale" when Congress added the catchall phrase "or otherwise available to the public" to the Leahy-Smith America Invents Act's "on-sale" bar.
- The decision will particularly affect companies in the pharmaceutical industry, where inventors often need to raise capital early on in the research and development process. Pharmaceutical companies must now think even more strategically about when and how to best raise capital.

Gibson Dunn's lawyers are available to assist in addressing any questions you may have regarding developments at the Supreme Court. Please feel free to contact the following practice leaders:

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