

## Supreme Court Holds that Confidential Sales Still Qualify as Patent Prior Art

Written by DeAnn F. Smith, Janine S. Ladislaw, Ph.D.

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Earlier this week, the Supreme Court issued a unanimous opinion in *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, clarifying that a commercial sale of an invention more than one year before a patent application is filed is invalidating prior art under the Leahy-Smith America Invents Act (AIA) of 2011. This provision of the patent statute is known as the “on-sale bar” (35 U.S.C. §102(a)). The on-sale bar applies whether or not the details of the invention were publicly disclosed during the sale. The Supreme Court decision is significant because it had been argued that the America Invents Act had narrowed the on-sale bar so that only a “public sale” could qualify as prior art.

In the early 2000s, Helsinn, a small pharmaceutical company, entered into a license and a supply and purchase agreement with MGI Pharma to develop a drug to treat nausea and vomiting in patients undergoing chemotherapy. Under the agreements, details of the invention, such as important dosing considerations, were confidential. Several years later, Helsinn filed patent applications claiming its inventions; one of these applications was filed in 2013, and thus became subject to the revised provisions of §102(a) after the AIA came into effect.

In the patent infringement case brought by Helsinn, Teva, which sought to market a generic equivalent of the Helsinn drug, contended that the Helsinn patent is invalid in view of the agreements, which placed the claimed invention “on sale” to MGI. In order to decide the question of the patent’s validity, the court had to interpret the revised statutory definition of §102(a) “prior art” under the AIA, which states, in relevant part: “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.” 35 U.S.C. §102(a)(1), emphasis added.

During oral arguments, the Supreme Court grappled with the differences in statutory language between pre-AIA §102 and the language Congress included in the AIA. In particular, the justices questioned whether the catch-all phrase “otherwise available to the public” was intended to modify the preceding listed items. In other words, does the inclusion of this catch-all phrase mean that each of “patented,” “described in a printed publication,” “in public use,” and “on sale” be “available to the public”? If so, then “secret” sales would be excluded from the on-sale bar under the AIA.

The Court chose to separate its interpretation of the phrase “on sale” from the other phrases in the statute, including the catch-all phrase. Prior Supreme Court and Federal Circuit precedents interpreting the pre-AIA §102 had held that a sale or offer for sale does not need to make an invention available to the public to qualify as “on sale.” Because the phrase “on sale” appears in both the pre-AIA and AIA versions of §102, the Court presumed that Congress reenacted the same language in the AIA intentionally, to adopt the judicial construction of the phrase. Under this construction, the Helsinn/MGI agreements triggered the on-sale bar. As a result, the Helsinn patent is invalid because the claimed invention was “on sale” more than one year before the effective filing date of the patent.

The Supreme Court decision adopts the historic rationale for including an on-sale bar in the patent statute – inventors and applicants should not be permitted to benefit from or exploit their inventions for years before filing a patent application and still be entitled to the benefit of the limited monopoly associated with a valid patent.

### Takeaways

1. The decision conclusively held that the AIA did not narrow the on-sale bar. Indeed, the Supreme Court’s interpretation of the catch-all phrase “or otherwise available to the public” as not modifying the other categories of prior art in §102(a) suggests that the

AIA expanded the scope of prior art to include another category, an invention that is “otherwise available to the public.” We can expect future disputes about the meaning of this phrase.

2. The decision is consistent with other provisions of the AIA, such as the first-inventor-to-file provisions. In general, patent applicants should be diligent in filing patent applications, filing as early as possible.
3. Smaller companies with fewer resources must often outsource manufacturing of products, prototypes, or other materials related to product development and testing. In line with the *Helsinn* holding, these companies should consult with patent counsel and consider filing a patent application before entering into these commercial agreements - regardless of whether the details of the agreements and the existence of the agreements are confidential.
4. Patent applicants and patent owners proceeding under the AIA who are aware of a previous agreement or transaction that might trigger the on-sale bar should consult with counsel regarding their obligations under the duty of disclosure provisions of 37 C.F.R. § 1.56.
5. Finally, the U.S. is in the minority when it comes to what is considered prior art as most other jurisdictions (including Europe and Japan) require that prior art be “public.” This divergence in law should be considered in international patent portfolio prosecution and strategy.

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