

# Supreme Court Says America Invents Act Did Not Alter On-Sale Bar

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## Squib of Holding and Key Implication:

The United States Supreme Court, in *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*, held on January 22, 2019 that “a commercial sale to a third party who is required to keep the invention confidential may place the invention ‘on sale’ under the America Invents Act.”

While the full effect of the ruling remains to be seen, it makes clear that the universe of prior art includes an inventor’s sale of an invention to a third party who must keep the details of the invention confidential.

## Background of AIA and the Change

Every patent statute since 1836 has included an on-sale bar. The patent statute in force immediately before the AIA prevented an inventor from receiving a patent if, “more than one year prior to the date of the application for patent in the United States,” “the invention was . . . on sale” in the United States. 35 U. S. C. §102(b) (2006 ed., Supp. IV).

The AIA similarly precludes a person from obtaining a patent on an invention that was “on sale” before the effective filing date of the patent application. However, the AIA amended the on-sale bar to include the catchall phrase “[or otherwise available to the public](#).” The full statutory provision reads:

- 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.”

The question for the Supreme Court in *Helsinn Healthcare* was how—if at all—the addition of the catchall phrase altered the scope of the on-sale bar. Specifically, the parties asked the Court whether “secret sales”—sales where the technical details of the invention are kept confidential—trigger the on-sale bar to patentability. The Supreme Court, rather effortlessly, concluded that they do.

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## Background of the Case

Helsinn Healthcare makes a treatment for chemotherapy-induced nausea and vomiting using the chemical palonosetron. While Helsinn was developing its palonosetron product, it entered into two agreements with another company that granted that company the right to distribute, promote, market, and sell a 0.25 mg dose of palonosetron in the United States.

Importantly, the agreements required that the company keep confidential all proprietary information received under the agreements. Nearly two years later, in January 2003, Helsinn filed a provisional patent application to cover the 0.25 mg dose of palonosetron. And, over the next 10 years, Helsinn filed four additional patent applications that claimed priority to the January 2003 date. Helsinn filed its fourth patent—the '219 patent, the patent at issue in the case—in 2013. Thus, the AIA governed the resolution of the legal issues.

In 2011, Teva Pharmaceuticals sought approval to market a generic 0.25 mg palonosetron product. Helsinn sued Teva for infringing its '219 patent. Teva countered that the '219 patent was invalid under the “on sale” provision of the AIA because the 0.25 mg dose was “on sale” more than one year before Helsinn filed the provisional patent application in 2003.

The District Court held that the AIA’s “on sale” provision did not apply because the public disclosure of the agreements did not disclose the 0.25 mg dose. On appeal, the Federal Circuit [reversed](#). The Federal Circuit held that under the AIA, public disclosure of the *existence* of a commercial sale was sufficient to trigger the on-sale bar to patentability, even if the invention that was the subject of the sale remained secret and was not “available to the public.”

## The Supreme Court

At the Supreme Court, Helsinn [argued](#) that the Federal Circuit’s decision was “untethered to the statutory text” of the patent laws because the AIA’s inclusion of the residual phrase “or otherwise available to the public” required that sales make the claimed invention “available to the public” to qualify as prior art.

Helsinn pointed to substantial extra-textual evidence to support its position. During debate over the AIA, for example, the House and Senate explained that they were adding the phrase to emphasize that prior art must be publicly available and specifically to clarify that “[secret collaborative agreements, which are not available to the public, are not prior art.](#)”

Moreover, following the AIA’s enactment, the Patent and Trademark Office (PTO) issued revised guidelines for examining patent applications that instructed its examiners that, under the AIA, a sale “[must make the invention available to the public](#)” to be prior art. The PTO further explained that sales “among individuals having an obligation of confidentiality to the inventor” do not qualify as prior art under the AIA. In 2014, the PTO incorporated its interpretation into the Manual of Patent Examining Procedures, stating that the catch-all phrase “[indicates that \[Section 102\(a\)\(1\)\] does not cover secret sales or offers for sale.](#)”

In addition to textual and other support, Helsinn also had the backing of the United States. The Office of the Solicitor General [filed a supporting brief as amicus curiae](#) and participated in oral argument in support of Helsinn’s position.

Nevertheless, the Supreme Court had little trouble rejecting Helsinn’s argument. Indeed, the opinion seems to have been a rather easy one. Not only was it unanimous, it ran only nine pages (with just four and bit dedicated to legal analysis) and was issued just seven weeks after oral argument.

The Court’s decision involved two analytical moves. First, the Court [established](#) that “our precedents suggest that a sale or offer of sale need not make an invention available to the public” to constitute invalidating prior art. The Supreme Court concluded that the Federal Circuit’s decision merely made explicit what was implicit in the Supreme Court’s pre-AIA case law—that “secret sales” could invalidate a patent. Thus, said the Court, “[i]n light of this settled pre-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.”

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The Court's second analytical move was to ask whether the addition of the catchall phrase "or otherwise available to the public" was enough of a change for the Court to conclude that Congress intended to alter the meaning of "on sale." The Court concluded that the addition was not enough.

The Court observed that the relevant AIA provision retained the exact language used in its predecessor statute ("on sale") and added only a new catchall clause ("or otherwise available to the public"). The Court then observed that even the United States [noted at oral argument](#) that adding the phrase "or otherwise available to the public" to the statute "would be a fairly oblique way of attempting to overturn" that "settled body of law."

In all, the Court, led by Justice Thomas, concluded that whatever changes the AIA wrought upon the patent laws, it did not displace the long-standing rule that commercial exploitation of a patentable invention "bars" a later patent—even if the inventor manages to sell the patentable item without disclosing the details of the invention to the public.

White & Case will continue to monitor all developments stemming from the Court's decision in *Helsinn Healthcare*.

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