

Secret Sales Trigger "On Sale Bar" Under the AIA

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The Supreme Court clarified this week in *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.* that the "On Sale Bar" — which prohibits patents on inventions that are sold or offered for sale before the patent application filing date — applies to private offers for sale, as well as public offers.

Before the American Invents Act, it was clear that the On Sale Bar applied to both private and public offers for sale. The Supreme Court defined an "on sale" invention over 20 years ago in *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 67 (1998), holding an invention was "on sale" when it was "the subject of a commercial offer for sale" and "ready for patenting." Though that decision did not address the public or private nature of the offer, the Federal Circuit later held that even secret offers for sale fell within the On Sale Bar. (See *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1357 (Fed. Cir. 2001).)

The American Invents Act, which was enacted in 2012, introduced ambiguity into this settled precedent by stating that: "A person shall be entitled to a patent unless ... the claimed invention was ... 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) Focusing on the "or otherwise available to the public" language, some litigants argued that under the statute, the On Sale Bar applied only when the offer for sale publicly disclosed the invention details.

Helsinn Healthcare addressed a situation in which the allegedly disqualifying sale offer was not public. In that case, Helsinn Healthcare developed a new dosage for an antiemetic drug and Phase III clinical trials to test the new dosage. Anticipating that these trials would succeed, Helsinn sought partners to assist in marketing and distributing the soon-to-be-approved drug. It ultimately entered into marketing and distribution agreements with an outside company. The agreements were announced in a joint press release, but the details of the drug trials, including the claimed dosages, remained private.

Nearly two years after executing these agreements, Helsinn filed a provisional patent application for the new dosage invention. Helsinn later obtained a patent that claimed priority to this provisional application. When Teva Pharmaceuticals sought FDA approval to market a generic version of the drug using the patented dosages, Helsinn sued for patent infringement. Teva argued that the patent was invalid under the On Sale Bar because the two agreements predated the patent application. Helsinn argued that these agreements did not trigger the On Sale Bar because they were not "public" sales offers under the American Invents Act.

The District Court rejected Teva's On Sale Bar defense, holding that the American Invents Act changed the On Sale Bar so that it could be triggered only by public offers for sale. The court found that Helsinn's agreements were not public offers for sale because, while Helsinn publicly announced the sales' existence, it did not publicly disclose the invention details.

On appeal, the Federal Circuit reversed the District Court, holding that an offer for sale could trigger the On Sale Bar even if these details were not disclosed publicly.

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The Supreme Court granted *certiorari*, and affirmed the Federal Circuit. In an opinion by Justice Thomas, the Court reasoned that term "on sale" had a settled meaning before Congress drafted the American Invents Act, and when it used the term "on sale" in the statute, Congress presumably intended to adopt that meaning. The drafter's decision to follow the term "on sale" with the phrase "or otherwise available to the public" did not reflect a clear intent to change the meaning of the term "on sale."

The *Helsinn Healthcare* decision re-emphasizes the need to exercise caution before taking any steps to commercialize an invention before filing a patent application. Even where, as here, parties keep the invention details confidential, an offer to sell can render the invention unpatentable. Please contact the authors of this alert or your Miller Canfield attorney to discuss further.