

AIA On-Sale Bar, otherwise Reinterpreted

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The U.S. Supreme Court heard oral arguments on December 4, 2018, in *Helsinn Healthcare SA v. Teva Pharmaceuticals USA Inc.* as to whether the “on-sale” bar under the America Invents Act (“AIA”) renders an inventor’s private sale to a third party as prior art for purposes of determining patentability.

35 U.S.C. §102(a)(1) of the AIA provides in pertinent part that a “person shall be entitled to a patent unless — (1) 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.” (Emphasis added). An important aspect of the question in front of the Supreme Court is whether the details of the product that is “on sale” have to be public to render the sales activity as prior art for purposes of determining patentability.

Helsinn Healthcare is the owner of a patent covering methods of administering Aloxi®, an intravenous formulation of palonosetron for reducing chemotherapy-induced nausea and vomiting. During discovery in a Hatch-Waxman litigation, Teva, the ANDA applicant, asserted invalidity of the patent under the on-sale bar based on a supply and purchase agreement and a license agreement between Helsinn and MGI Pharma Inc. that was subject to a nondisclosure agreement. The district court of New Jersey held that the AIA modified the statute and now only public sales trigger the on-sale bar. Sales under a nondisclosure agreement, such as the one in *Helsinn*, were found by the district court not to qualify as prior art under the post-AIA on-sale bar. The Federal Circuit disagreed that AIA changed the long history of jurisprudence on the “on sale” bar, and held that the existence of a sale, regardless of whether the details of the invention are disclosed to the public or not, renders the patent invalid. Helsinn appealed to the Supreme Court.

During oral argument, Helsinn argued that the phrase “on sale,” according to the plain text of Section §102(a), means the invention is made available for sale to public, hence, a secret sale to a third party and unavailable to the public would not fall under the post-AIA on sale bar. Teva, on the other hand, argued that “on sale” encompasses an offer for sale regardless of whether the sale was public or private, as long as an inventor has expressed willingness to commercialize the product. Along this vein, Justices Breyer and Kavanaugh questioned Helsinn on the commercial exploitation aspect of the secret sale, quoting Judge Learned Hand’s reasoning that commercial exploitation by the inventor may serve as prior art because the patent statute does not intend to encourage secrecy, but rather, encourages disclosure to the public to gain patent protection.

Both parties and the justices focused heavily on statutory interpretation. Helsinn maintained that the catch-all provision (*i.e.*, “or otherwise available to the public”) modifies all the specific items before it, including “on sale.” While Teva told the Court the new catch-all phrase has no effect on the items before it, and was simply added to ensure that other forms of public disclosures, such as conference presentations and online virtual collaborations, would be covered by the statute. Justice Kagan expressed sympathy to Helsinn’s argument by repeatedly asking Teva’s counsel to explain why the conjunction “otherwise” would not change the meaning of the items before it. Her

hypothetical involving brownies, pecan pies, and otherwise nutty desserts drew rare laughter from the bench and the audience.

The parties also advanced legislative history arguments related to their respective statutory interpretations. Helsinn argued that the legislators clearly intended to impose a public-availability requirement by adding the catch-all provision. Teva, on the other hand, argued that Congress would have chosen clearer ways of implementing their intent if it wanted to change the term's meaning. Justice Kavanaugh, in questioning Helsinn's counsel about congressional intent, called the catch-all provision a "terrible clarification." He commented that the legislative history needs to be viewed in its entirety, and pointed out that Congress had repeatedly tried to delete the on-sale bar from the statute, but failed.

While it remains to be seen how the Supreme Court will decide this important issue, the decision will have far-reaching consequences to many technology companies. If the Court agrees with Helsinn and finds that a private sale does not violate the on-sale bar, many small pharmaceutical companies that lack the funding or the experience to bring their products to market would be able to contract with larger companies under the protection of a nondisclosure agreement so as to acquire the necessary resources to develop their product and implement steps to bring it to market through other parties before pursuing patent protection. As Teva and some amici briefs pointed out, however, such a rule without limits could be prone to abuse by an inventor who commercially exploits the invention and then artificially extends his monopoly by obtaining a patent. Additionally, certain contracts that constituted a sale may no longer be prior art, and companies wishing to attack the validity of a patent may find there is one fewer weapon in the invalidity arsenal.