Haley Guiliano

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Helsinn v. Teva – The evolution of the On Sale Bar; Pre-AIA to AIA

With the passage of the America Invents Act (AIA), the U.S. moved from a First-To-Invent system to a First-Inventor-To-File system in order to harmonize the U.S. patent system with that of the rest of the world. The AIA altered the language of the statutes pertaining to the on-sale bar which, as it turns out, has made it less straightforward, to determine what actions might constitute a "sale" or an "offer for sale."

The on-sale bar is a challenge, in particular, to the biopharmaceutical industry where it can take 10-15 years for a drug to come to market. Several simultaneously moving processes have to come together in terms of regulation, marketing, distribution, etc. For example, small biopharmaceutical companies that may lack resources or infrastructure to develop a drug, need to form partnerships with manufacturers and distributors early in development, to come to market as soon as possible after FDA approval. Partaking in such activities may inadvertently put such companies at risk of violating the on-sale bar.

The Federal Circuitry has addressed these issues in *Helsinn v. Teva*. The main question is: If the partners make a deal – say the distributor pays for the right to sell the drug (if it gets approved) – and the partners publicize the existence of the deal (but not the full details of the drug), does the deal bar a patent filed more than one year later? In *Helsinn v. Teva*, the Federal Circuit issued its first opinion on the "new" on sale bar in May 2017.

Interpretation of the on-sale bar under Section § 102 of the Patent Act

Pre-AIA § 102(b) reads:

> "A person shall be entitled to a patent unless … (b) the invention was … on sale in this country more than one year prior to the date of application for patent in the United States"

Under the AIA, § 102(a)(1) now reads:

> "A person shall be entitled to a patent unless . . . (1) the claimed invention was … on sale (anywhere in the world), or otherwise available to the public before the [critical date]"

Under pre-AIA § 102(b), even secret/private sales in the U.S. that do not disclose the invention can bar patentability. However, it is unclear whether the AIA altered the law such that secret/private sales would still bar patentability. The U.S. Patent and Trademark Office (USPTO) has now examined thousands of applications under the new law which contains the ambiguous provision "otherwise available to the public" without guidance from the courts as to the true meaning of this provision.

The USPTO interprets the "otherwise available to the public" provisions to require that the details of the claimed invention be publicly disclosed in terms of the sale before the on-sale bar is triggered.

Type of sale more than 1 year prior to the critical date	Discloses claimed invention?	Is it prior art under pre-AIA?	Is it prior art under AIA?
Public	Yes	Yes	Yes
Public	No	Yes	No per USPTO; Yes per CAFC
Secret	No	Yes	Yes per CAFC in *Helsinn v. Teva*; Final outcome to be determined

Helsinn v. Teva provides some clarity on this issue although it appears that this decision indicates that the AIA did not change the pre-AIA law pertaining to sales as prior art. The outstanding questions that remain are:

1. Does the "or otherwise available to the public" clause added by the AIA mean that, to be "on sale", the invention must be "on sale" in such a manner as to be "available to the public," and, if so, what does it mean for a sale to be "available to the public"?
2. What is the trigger date – the date of the sale or the date that it was disclosed to the public?

Under pre-AIA law, the Federal Circuit precedent interpreted the pre-AIA on-sale bar as potentially applicable to any sale, even those not available to the public. *See, e.g.*, Meds. Co. v. Hospira, Inc., 827 F.3d 1363, 1376 (Fed. Cir. 2016) "confidential transactions [are] patent invalidating sales under § 102(b)." So secret sales (which inherently do not disclose the invention) bar patentability.

Helsinn v. Teva

In the late 1990s, Helsinn, an oncology company, was developing Aloxi (palonosetron), a drug formulation for treating chemotherapy-induced nausea and vomiting. The formulation, then in clinical trials, included an unexpectedly low dose of the known drug. Helsinn had never marketed a drug in the U.S., and found a partner (MGI Pharma) to do so. In 2001 (2 years before applying for its patents), Helsinn and MGI entered into a License Agreement (under which Helsinn licensed the formulation to MGI for an up-front fee and royalties) and a Supply and Purchase Agreement (under which Helsinn agreed to supply MGI the formulation, if it received FDA approval). Helsinn and MGI publicized the existence of the agreements (in press releases and SEC filings). However, they kept the details of the low-dose formulation confidential (only a redacted version in MGI's 8-K filing was released to the public). The dose and the price details were not revealed. More than a year after the deal, Helsinn applied for, and obtained, three patents on its new formulation subject to pre-AIA, and one patent subject to the AIA.

In 2011, Helsinn brought suit against Teva alleging that the filing of Teva's Abbreviated New Drug Application ("ANDA") constituted an infringement of various claims of those patents. Teva in turn challenges the validity of these patents based on the on-sale bar and alleges that Helsinn violated the on-sale bar. The district court upheld all 4 of Helsinn's patents. It ruled that the AIA patent was valid since the "sale" was not "available to the public." The Patent Trial and Appeal Board denied institution of a post-grant review (PGR) on the same basis.

The District Court upheld Helsinn's AIA Patent

The District Court ruled that the "AIA changed the meaning of the on-sale bar which now requires ***a public*** sale or offer for sale of the claimed invention". The District Court interprets this to mean that a sale is public only if it publicly discloses the details of the invention. In this case, the details of the invention were not disclosed in the Helsinn-MGI

agreement, and so the sale was not public.

The Federal Court reversed the District Court Decision; holds Helsinn's AIA Patent invalid

- Unhappy with the District Court decision, Teva appealed to the Court of Appeals for the Federal Circuit. Helsinn argued that the AIA on-sale bar does not encompass secret sales and requires that a sale make the invention available to the public. The Federal Circuit disagreed with that decision, stating that Helsinn's argument primarily relies on floor statements by Congress members that are not reliable indicators of Congressional intent to do away with secret sales under the new law. Quoting Senators Leahy and Kyl, the Federal Circuit rules that:

"At most, the floor statements show an intent to do away with precedent under pre-AIA § 102 law pertaining to ***secret use*** and we decline to address it." Further, the FC states that the floor statements did not identify ***sale*** cases that could be overturned and that secret use does not impact this case.

- Further, the Federal Circuit disagreed with Helsinn's assertion that the AIA on-sale bar does not apply unless the sale "discloses the invention to the public", saying that such a disclosure would work a "foundational change in the theory of the on-sale bar".
- The Federal Circuit indicated that in *Pennock v. Dialogue* (1829), if an inventor is permitted to hold back the secrets of his invention, he could retain the monopoly over the invention until the danger of competition forces him to secure a patent.
- The Federal Circuit further stated that in prior cases, the on-sale bar was applied even though there was no delivery of the claimed invention or when delivery is set after the critical date, or even when, upon delivery, members of the public could not ascertain the claimed invention. So, the public sale itself puts the patented product in the hands of the public.
- The Federal Circuit also opined that "If Congress has intended to work such a sweeping change to on-sale jurisprudence, it would have done so by clear language."
- The Federal Circuit concluded by saying that distribution agreements will not always be invalidating under 102(b), but in this case, the Sales and Purchase Agreement between Helsinn and MGI is invalidating.
- In conclusion the Federal Circuit rules that if the existence of a sale is public, its details need not be publicly disclosed to trigger AIA 102(a).

The Future of the On-Sale Bar

After the Federal Circuit decision, it is unclear what changed in the law with respect to sales as prior art. Helsinn has filed a writ of certiorari and has appealed to the Supreme Court to review the Federal Circuit's decision. The main question presented in the Writ is:

Whether, under the Leahy-Smith America Invents Act, an inventor's sale of an invention to a third party that is obligated to keep the invention confidential qualifies as prior art for purposes of determining the patentability of the invention.

- Senators Leahy and Smith, the founders of the AIA have supported Helsinn's petition which delves deeply into a historical perspective of the On-Sale bar, along with legislative history, guidelines and public policy considerations. The Writ highlights that the Federal Circuit decision is wrong. Congress did intend to get the US patent system in line with the rest of the world and that it wanted to get rid of secret sales as invalidating prior art. Outside the US, there is an absolute novelty requirement which require that a patent application for invention have a filing date that precedes any prior art activities (including sales), or else the invention set forth in the patent application fails the novelty requirement
- The Writ also states that "…no party or amicus argued that the disclosure of the fact of a sale is legally relevant. The distinction between "disclosed secret sales" and "undisclosed secret sales" was an invention of the Federal Circuit, and, for all the reasons discussed, it has no basis in the text of the statute. This Court should not reward the Federal Circuit's attempt to shield its decision from further review by portraying it as narrow"

Under the new AIA law, if there is a secret sale of the claimed invention by inventor A before the critical date, it would not count as prior art. At the same time, since this is a FITF system (different from the FTF system for countries that require absolute novelty), inventor A is taking a risk by not filing as soon as possible after the sale, because even though the sale is secret and would not invalidate a future patent per AIA, if inventor B comes along in the intervening period and files a patent app on the same claimed invention, inventor A would have no rights.

Key Takeaways

The final outcome in *Helsinn v. Teva* is yet to be decided. As of now, the AIA does not appear to have materially changed the meaning of the on-sale bar under U.S.C § 102 of the Patent Act. In the meantime, it is best to file patent applications early, preferably prior to making a sale, and in any case within a year of any kind of sale. It is best practice not to rely on the one year grace period. Further, there are possible incentives to maintaining the secrecy of a sale. However, clients should consult IP counsel before entering agreements with third parties.