

AIA On-Sale Bar and USPTO's Practices After Helsinn

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In the recently decided *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*, the Federal Circuit tackled the issue of when on-sale bars can apply under the America Invents Act (“AIA”). No. 2016-1284 (Fed. Cir. May 1, 2017). Although the decision addresses situations involving public sales of inventions, questions about situations involving private or secret sales remain open.

Prior to enactment of the AIA, §102 included an on-sale bar if “the invention was . . . on sale in this country, more than one year prior to the date of the application for patent in the United States.” 35 U.S.C. § 102(b) (Pre-AIA). Under the AIA, modified §102 also includes an on-sale bar that applies if “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) (Post-AIA). Disagreements in parties’ understandings of the effect of the AIA’s modification of §102, as it relates to applicability of the on-sale bar, were recently on display in *Helsinn*.

Helsinn sued Teva for infringement. *Helsinn*, No. 2016-1284 at 3. Facts established at trial include: (i) the invention was sold more than one year before the application for patent, (ii) the existence of the sale was public, and (iii) the terms of the sale did not make the technical details of the invention publicly available. *Id.* at 6-8. Teva argued that, like the pre-AIA bar that applies to public and private sales, the AIA on-sale bar also applies to *Helsinn*’s sale. *Id.* at 19. On the other hand, *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 in order to trigger application of the on-sale bar.” *Id.* *Helsinn* relied on the “otherwise available to the public” phrase in modified §102 to support its argument that the AIA on-sale bar should not apply. *Id.* at 22. According to *Helsinn*, regardless of whether the existence of the sale itself is public or remains secret, it is necessary that terms of the sale make the invention publicly available before the AIA on-sale bar can apply. *Id.*

The Federal Circuit rejected *Helsinn*’s argument based on *Pennock v. Dialogue*, a precedent set by the Supreme Court long before the AIA. *Id.* at 23. *Pennock* also involved a situation in which existence of the sale was public, but the terms of sale did not make details of the invention publicly available. *Id.* The Supreme Court found *Pennock*’s public sale invalidating based mostly on a policy concern that failing to do so would lead to impediments in progress of science and useful arts. *Id.* The Federal Circuit relied on *Pennock* to conclude that, “if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale” for the AIA on-sale bar to apply. *Id.* at 27.

However, the Federal Circuit did not address the situation in which existence of the sale remains secret. *Id.* at 21. The Federal Circuit declined to address this situation explaining that it was not pertinent because *Helsinn*’s sale of its invention was indisputably public. *Id.* Therefore, although the court clarified that the AIA on-sale bar can apply when existence of a sale is public, it provides little guidance in situations where the existence of the sale remains secret.

Interestingly, the Federal Circuit’s ruling squarely contradicts the USPTO’s position on AIA on-sale bars to sales that are public. The MPEP states the USPTO’s position:

The phrase “on sale” in AIA 35 U.S.C. 102(a)(1) is treated as having the same meaning as “on sale” in pre-AIA 35 U.S.C. 102(b), **except that the sale must make the invention available to the public.**

MPEP §2152.02(d) (emphasis added). The USPTO argued at the Federal Circuit in support of Helsinn’s arguments, which were rejected. The Helsinn ruling places the USPTO in the difficult position of deciding whether to continue to apply its stated position or whether to change its position to align with the Federal Circuit in the near term. Nonetheless, the USPTO is likely to defer its decision on the matter until all appeals in the Helsinn case have been exhausted.

If the Helsinn ruling stands after all appeals are exhausted, the USPTO’s position would become obsolete. In addition, it would call into question the validity of any patents relying on the USPTO’s understanding of the on-sale bar.

With respect to sales that are secret, there is no clarity on whether the AIA on-sale bar can apply because the Federal Circuit declined to address that situation. Interestingly, the MPEP also states the USPTO’s position regarding AIA on-sale bars to sales that are secret:

AIA 35 U.S.C. 102(a)(1) uses the same “on sale” term as pre-AIA 35 U.S.C. 102(b). **The “or otherwise available to the public” residual clause of AIA 35 U.S.C. 102(a)(1), however, indicates that AIA 35 U.S.C. 102(a)(1) does not cover secret sales or offers for sale.** For example, an activity (such as a sale, offer for sale, or other commercial activity) is secret (non-public) if it is among individuals having an obligation of confidentiality to the inventor.

MPEP §2152.02(d) (emphasis added). The secret sale issue remains open for litigation. Applicants, patent owners, and practitioners will be interested to see how secret sales are handled by the USPTO and courts in the meantime.

Conclusions

The Helsinn decision informs us that the AIA on-sale bar can apply to all public sales, whether or not the terms of a public sale disclose details of the invention. But, it is not yet clear whether the AIA on-sale bar can apply to secret sales. Assuming Helsinn stands, applicants and practitioners should understand that a public sale (or an offer to sell) starts the clock ticking on the one-year grace period. Conservative practitioners may adopt a similar view even when a sale (or offer to sell) remains secret to avoid being susceptible to the AIA on-sale bar, at least until a future case clarifies otherwise.

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