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MAY 5, 2017

Federal Circuit Clarifies Post-AIA On-Sale Bar Doctrine

Since the enactment of the America Invents Act (AIA), the status and the scope of the on-sale bar under 35 U.S.C. § 102 has been unsettled. The Federal Circuit's recent decision in *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA Inc.* provides some clarification, holding that the public sale of an invention triggers the on-sale bar under post-AIA § 102, even if the details of the invention were not publicly disclosed.

Before the enactment of the AIA, § 102 barred the issuance of a patent for an invention that was "in public use or on sale in this country, more than one year prior to the date of the application for patent." The Federal Circuit had previously held that the on-sale provision of the statute encompassed private sales and offers for sale that were otherwise unknown to the public, and accordingly, such secret sales and offers for sale made more than one year before the filing of a patent application would bar the issuance of a patent for the invention.

Under the AIA, § 102 was amended to bar the issuance of a patent for an invention that was "in public use, on sale, *or otherwise available to the public* before the effective filing date of the claimed invention." The addition of the phrase "or otherwise available to the public" following the on-sale provision provided an implication that the on-sale provision now referred only to sales in which the invention was made known to the public, raising a question about whether secret or nonpublic sales were still encompassed by § 102. Accompanying legislative history to the statute, including floor statements from Senators Patrick Leahy (D-VT) and Jon Kyl (R-AZ), supported the interpretation that secret or nonpublic sales of an invention were no longer encompassed by the on-sale bar of § 102. While the U.S. Patent and Trademark Office (USPTO) also adopted this interpretation in its Manual of Patent Examining Procedure,[1] the Federal Circuit had not directly addressed the scope of the on-sale bar of post-AIA § 102 until the recent decision in *Helsinn*.

In *Helsinn*, Helsinn Healthcare applied for and obtained a patent for a drug that is used to counteract the side effects of chemotherapy. However, more than one year before filing the patent application, Helsinn Healthcare entered into an agreement with a marketing and distribution company to sell the drug. While the agreement itself was made public in both a press release and a Securities and Exchange Commission filing, the details of the invention, including the specific dosage of the drug, were not made public.

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[1] MPEP 2152.02(d) states: "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."

Addressing whether this sale invalidated the patent under the post-AIA on-sale bar, the Federal Circuit held that, because the existence of the sale was made public, even though the details of the invention were not publicly disclosed, the on-sale bar was triggered, and the sale was encompassed within § 102. With this ruling, the Federal Circuit confirmed that publicly disclosed sales or offers for sale are encompassed within the post-AIA on-sale bar, even when the details of the invention remain secret.

The decision in *Helsinn*, however, admittedly stopped short of confirming that the AIA did not substantively change the circumstances in which the on-sale bar will apply. In particular, the opinion was careful to note that the holding is not generally applicable to all offers for sale or distribution agreements but merely addresses the unique facts of *Helsinn*. The Federal Circuit left open the question of whether a purely secret sale or offer for sale, in which the existence of the sale and the details of the invention remain secret, would be encompassed within the on-sale bar of post-AIA § 102. Moreover, in distinguishing the senators' floor statements, the Federal Circuit also noted that such statements addressed situations in which certain secret uses of an invention had been held to be an invalidating public use before enactment of the AIA. Because the facts of *Helsinn* did not involve a secret use of an invention, the *Helsinn* court declined to address whether the AIA had changed the law for such secret uses of an invention being an invalidating public use. The holding in *Helsinn* does, however, indicate that the AIA did not change the scope of § 102 as broadly as some commentators and the USPTO initially believed.

Takeaway

While the contours and scope of post-AIA § 102 will continue to be defined, *Helsinn* indicates that the AIA did not substantially change the applicability of the on-sale bar to publicly disclosed sales and offers for sale of products that embody an invention, regardless of whether the details of the invention itself were made public. As was the case before the AIA, all early sales and offers for sale should be carefully considered when deciding whether to file a patent application.

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