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## **The “New” On-Sale Bar Under The AIA**

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## The “New” On-Sale Bar Under The AIA

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With the enactment of the Leahy-Smith America Invents Act (AIA) in 2011, the U.S. patent system experienced the most significant reform since the U.S. Patent Act was enacted some 65 years ago.<sup>2</sup> One aspect of the AIA that triggered the biggest discussion was the conversion under the U.S. Patent laws from a “first-to-invent” system to a “first-inventor-to-file” system.<sup>3</sup> One argument favoring a first-inventor-to-file system was that such system would focus on publicly available information rather than privately held knowledge. Generally, the step of transferring of knowledge was a public act.

An aspect of the AIA was that it amended § 102 regarding novelty and prior art. With respect to the on-sale bar, the difference in the statute is reflected in a comparison of 35 U.S.C. § 102(b) (pre-AIA) and § 102(a)(1) (post-AIA) as shown in the table below:<sup>4</sup>

<b>§ 102(b) (pre-AIA)</b>	<b>§ 102(a)(1) (post-AIA)</b>
<b>Conditions for patentability; novelty and loss of right of patent.</b> A person shall be entitled to a patent unless – (b) the invention was patented or described in a printed publication in this or a foreign country or <b><i>in public use</i></b> or <b><i>on sale</i></b> in this country, more than one year prior to the date of application for patent in the United States	<b>Conditions for patentability; novelty</b> (a) <b>Novelty; Prior Art</b> – A person shall be entitled to a patent unless – (1) the claimed invention was patented, described in a printed publication, or <b><i>in public use, on sale, or otherwise available to the public</i></b> before the effective filing date of the claimed invention

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<sup>2</sup> The White House Office of the Press Secretary, “President Obama Signs America Invents Act, Overhauling The Patent System To Stimulate Economic Growth, And Announces New Steps To Help Entrepreneurs Create Jobs,” <https://obamawhitehouse.archives.gov/the-press-office/2011/09/16/president-obama-signs-america-invents-act-overhauling-patent-system-stim> (Sept. 16, 2011).

<sup>3</sup> See, e.g., Garsson, R.S., Pham, C.H., “Uncle Sam Wants You to Be the First-Inventor-To-File for Nanotechnology Inventions,” *Nanotechnology Reviews*, 2012, Vol. 1, Issue 4, 383-386.

<sup>4</sup> 35 U.S.C. § 102(b) (pre-AIA) and § 102(a)(1) (post-AIA) (emphasis added).

The addition of the “otherwise available to the public” language to the phrase of “in public use or on sale,” thus began a debate as to whether this changed the patent laws regarding the on-sale bar under the AIA. While the USPTO soon thereafter promulgated rules for examination indicating that the standard for the on-sale bar had changed (and now required that the sale must make the invention available to the public),<sup>5</sup> in *Helsinn*,<sup>6</sup> the Federal Circuit has now opined upon the statutory meaning of “on sale” in § 102 (post-AIA) and held that the meaning of this term had not changed.

As of September 29, 2017 (the submission date of this paper), the Federal Circuit is still considering whether to grant Helsinn’s petition for rehearing *en banc*. Regardless of whether the Federal Circuit grants this petition (and issues any subsequent opinions), it is almost certain that a petition for *writ of certiorari* to the United States Supreme Court will follow. When the appeals for *Helsinn* are complete, there will be some finality regarding the scope of the “on-sale” bar and what impact, if any, occurred to it in view of Congress’ amendments to § 102 under the AIA. However, questions could still remain open as to whether a completely private/non-public offer to sell would count as prior art post-AIA.

Thus, from a patent prosecution point of view, it will continue to be prudent to counsel patent applicants to take steps to avoid the on-sale bar issue by promptly filing their patent applications. Indeed, while a minority position, there is an argument that the one-year grace period provided under § 102(b)(1) (post-AIA) may be inapplicable to certain forms of “on-sale” activities, so care should be taken to file patent applications before any such potentially invalidating sales activities.

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<sup>5</sup> M.P.E.P § 2152.02(d).

<sup>6</sup> *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 855 F.3d 1356 (Fed. Cir. 2017).

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