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Axinn IP Update: U.S. Supreme Court Ruling Leaves On-Sale Bar Unchanged

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January 23, 2019
Axinn Update

On January 22, 2019, the U.S. Supreme Court held that the America Invents Act ("AIA") did not change the scope of the on-sale bar. *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 586 U.S. ___ (2019). In a unanimous decision authored by Justice Thomas, the Supreme Court held that the sale of an invention to a third party who is contractually obligated to keep the invention confidential places the invention "on sale" within the meaning of 35 U.S.C. § 102(a)(1) (barring a person from receiving a patent on 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 issue at the center of this case involves the execution of a supply agreement for the marketing and sale of a patented product. The District Court held that the AIA's on-sale bar did not apply to the public disclosure of the sales agreement because the sales agreement did not disclose the claimed invention to the public. *Helsinn Healthcare S.A. v. Dr. Reddy's Labs. Ltd.*, 2016 WL 832089, *45, *51 (D.N.J. Mar. 3, 2016). Although the District Court acknowledged that secret sales precluded patentability under the pre-AIA on-sale bar, it concluded that the language "or otherwise available to the public" following the on-sale bar in the AIA modified the on-sale bar. *Id.* at *49.

The Federal Circuit reversed, holding that the AIA's on-sale bar applied even though "the details of the invention" were not made public in the sales agreement (*Helsinn Healthcare S.A. v.*

Teva Pharms. USA, Inc., 855 F.3d 1356, 1371 (2017)), and Helsinn petitioned the Supreme Court for cert.

The Supreme Court affirmed the Federal Circuit opinion, and more than a century of Supreme Court and Federal Circuit precedent on the meaning of "on sale," holding that an invention is "on sale" when it is subject to a commercial offer for sale and ready for patenting even when the sale does not make the details of the invention available to the public. *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 586 U.S. ___, slip op. at 6-7 (2019). In addressing the added language in the AIA, the Supreme Court stated that "[t]he addition of 'or otherwise available to the public' is simply not enough of a change for us to conclude that Congress intended to alter the meaning of the reenacted term 'on sale.'" *Id.* at 8.

Although the Supreme Court reaffirmed the rule that has largely been in place for quite some time, this decision highlights that companies need to be extremely diligent in filing patent applications very early in the product development process. This is particularly important for life sciences companies, who often rely on partners and contract manufacturers throughout the research and development process. Contact the authors of this update or any of Axinn's Intellectual Property partners for more information.

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