

On January 22, 2019, the Supreme Court held that an offer for sale or sale of a product embodying an invention is prior art and triggers the on-sale bar against receiving a patent under 35 U.S.C. § 102 (post- America Invents Act) even if the offer or sale did not disclose the invention to the public. *Helsinn Healthcare S.A. v. Teva Pharma. USA, Inc.*, Case No. 17-1229, 2019 WL 271945 (2019).

The on-sale bar is a venerable and centuries-old doctrine prohibiting the issuance of a patent for an invention that the patent applicant offered for sale or sold more than a year before the priority date of the patent application, even if the invention itself remained secret. Some commentators have theorized that the AIA weakened the on-sale bar such that secret sales would no longer invalidate a subsequent patent application, thus allowing entry into agreements for the licensing, sale, or distribution of inventions more than a year before filing a patent application. *Helsinn*—against a tide of speculation—rejected that theory, holding that a *public offer for sale* or a *public sale* of a product embodying the patented invention can trigger the on-sale bar *regardless* of whether the details of the invention remain cloaked in secrecy or under the protection of a confidentiality agreement.

The issue faced by the *Helsinn* Court concerned whether or not the plaintiff, Helsinn Healthcare S.A. (“Helsinn”)’s patents covering a medication for treating certain side-effects of chemotherapy were invalid under the on-sale bar. Helsinn’s relevant patents all hinged upon inclusion of certain dosages of palonesetron hydrochloride (“the Ingredient”). In early 2001, Helsinn entered into agreements with a third party for the distribution and marketing of the drug in exchange for an upfront payment and future royalties. The agreements identified the critical concentrations of the Ingredient, but those details were redacted in publicly available copies of the agreements and thus never disclosed to the public at large.

Helsinn filed its first relevant patent application nearly two years later, in January of 2003. Helsinn eventually obtained four patents covering the invention, three of which were governed by the pre-AIA patent regime, and one—the ’219 Patent—was filed late enough to be governed by the post-AIA regime. The District Court held that the ’219 Patent was valid because the AIA “changed the meaning of the on- sale bar and § 102(a) now ‘requires a *public sale* or offer for sale of the claimed invention.’” *Helsinn Healthcare S.A. v. Teva Pharma. USA, Inc.*, 855 F.3d 1356, 1363 (Fed. Cir. 2017). This decision read the phrasing of post-AIA § 102(b) (“*otherwise* available to the public”) to imply that the preceding condition, “on sale,”

needed to disclose the invention to the public in order to trigger the on-sale bar.

The Federal Circuit reversed, relying on long-standing precedent that an offer would trigger the on-sale bar even if the seller never consummated the sale or delivered the product (thus barring the patent regardless of whether the seller ever disclosed the invention to the public), and that Congress, presumably acting with knowledge of this body of established precedent, would not have effected such a sweeping change of on-sale bar jurisprudence without clear language evincing that goal. *Id.* at 1370–71. The Supreme Court, in a rare departure from form, affirmed the Federal Circuit’s holding. *Helsinn*, 2019 WL 271945, at \*5. Note, however, that the Federal Circuit expressly declined to consider whether offers or sales that were not publicly known (so-called “secret sales”) would trigger the AIA on-sale bar.