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Unanimous Supreme Court: The America Invents Act Did Not Change The Law On Secret Sales

Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc. et al., 586 U.S. ___ (2019).

The patent laws and regulations of many countries around the world require absolute novelty of a claimed invention in order for a patent to be granted. In those countries, an inventor's public disclosure, use, or offer for sale of the invention (including an article of manufacture embodying the invention), which occurs prior to the filing of a patent application claiming the invention, will destroy any potential patent rights that may otherwise have been awarded. In contrast, the patent laws of the United States have long included a grace period, whereby the invention may be "on sale" for up to 12 months prior to the filing date of the patent application claiming the invention. 35 U.S.C. §102(b)(1).

The sweeping 2011 patent reform legislation known as The Leahy-Smith America Invents Act ("AIA") greatly harmonized the patent laws of the United States with the laws of much of the rest of the world, yet retained the unique grace period for an inventor's own prior activities. The AIA did, however, add new language to the statute that cast doubt about whether or not secret sales would trigger the start of the grace period. Specifically, the AIA amended the novelty statute in the U.S. to recite the following, "A person shall be entitled to a patent unless…the claimed invention was patented, described in a printed publication, or in public use, on sale, ***or otherwise available to the public*** before the effective filing date of the claimed invention." 35 U.S.C. §102(a)(1) (emphasis added).

Prior to the enactment of the AIA, it had long been settled by the courts that the 12-month statutory clock for filing a patent application would be triggered by sales of all types, including secret sales. The courts did not want, for example, an inventor to profit from his or her invention for years in secret prior to filing for a patent application—which could unjustly award a monopoly right to one who had concealed the invention from the public. The limited monopoly right that accompanies the award of a patent is a bargain between the inventor and the government, whereby the inventor must disclose the details of the invention to the public in return for a limited period of exclusivity, now twenty years from filing. In the 1998 case of *Pfaff v. Wells Electronics, Inc.*, the Supreme Court set forth a two-part test to determine whether or not an invention was "on sale" under Section 102: (i) the invention was the subject of a commercial offer for sale; and (ii) the invention was ready for patenting at the time of the offer for sale. 525 U.S. 55 (1998). The Court did not require that the details of the invention be public, only that the offer for sale be public for the statutory bar to apply.

In the case at hand, Helsinn entered into an agreement with a third party for the distribution of a 0.25 mg dose and a 0.75 mg dose of palonosetron (a potential anti-nausea treatment for chemotherapy patients) in the United States. The agreement was publicly announced by both companies more than 12-months prior to Helsinn's earliest filed patent application claiming the specific formulations and effective doses of the drug. Helsinn was awarded a series of patents on its drugs, the latest of which was covered by the AIA, and thus the new statutory language relating to novelty-destroying activities of the inventor. Teva applied to the FDA to market a generic version of Helsinn's patented drug, and Helsinn sued for infringement of the patents at issue. Teva counterclaimed that the asserted patents were invalid because the patented drug was "on sale" more than 12-months prior to the earliest filing date of the patents at issue.

In a surprising decision in 2016, the United States District Court for the District of New Jersey ruled that Congress modified the law when amending the novelty statute by requiring that sale must make the invention available to the public. *Helsinn Healthcare S.A. v. Dr. Reddy's Labs. Ltd*., 2016 WL 832089, *45 (D. N.J. Mar. 3, 2016). Thus, the on-sale bar did not apply to the patent that was subject to the AIA-amended novelty statute because the details of Helsinn's invention were not available to the public via the press release. On appeal, the Federal Circuit reversed, favoring years of legal precedent concerning secret sales over a single, somewhat ambiguous clause in the new novelty statute.

The Supreme Court unanimously affirmed the decision of the Federal Circuit, finding that the new language added to the statute was a catchall provision which did not modify the Court's prior interpretations of the statute in view of the absence of any express indication from Congress that it was overruling the Court's on-sale bar body of law.

Practically speaking, it is generally not advisable for an inventor or assignee to rely upon the 12-month grace period in the U.S., because any public activity, disclosure, sale, or offer for sale is conservatively assumed to result in a loss of all non-U.S. patent rights. The transition to a "first-to-file" regime in the U.S., and the holding of the Helsinn case at issue, reinforce the necessity of filing early in the research and development process. This is especially true for large organizations, where, for example, the marketing department may well be working ahead of the intellectual property department and unwittingly creating statutory bars to patentability.

If you have any questions about patenting an invention, both domestically and outside of the U.S., then please contact an attorney at Wood Phillips.