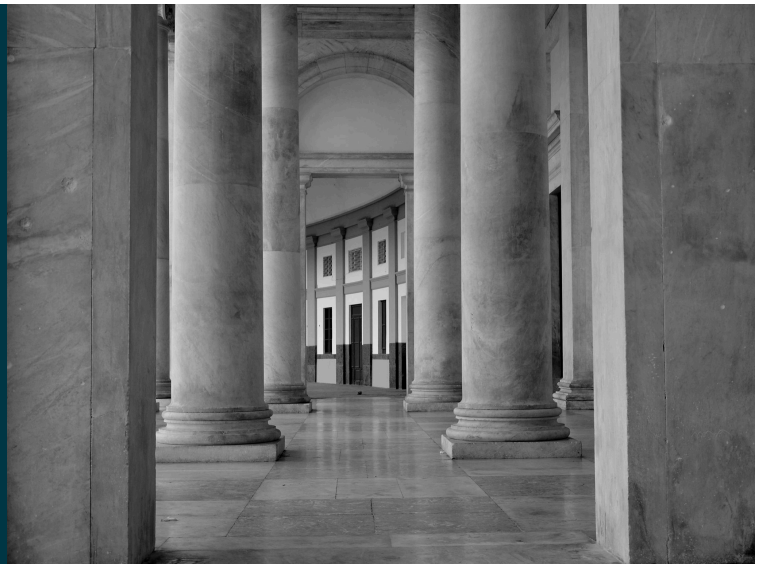
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U.S. Supreme Court Patent Case Ruling: Commercial Sale and Prior Art

ALERTS

January 22, 2019

On January 22, 2019, in a unanimous ruling in *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*,the U.S. Supreme Court maintained that "a commercial sale to a third party who is required to keep the invention confidential may place the invention 'on sale' under" 35 U.S.C. § 102(a) of the Patent Act.[1]

Because the Supreme Court's interpretation of "on sale"—prior to the enactment of the Leahy-Smith America Invents Act (AIA)—supports the view that an invalidating sale does not need to make details of the invention available to the public, the Court affirmed the Federal Circuit's decision holding that Congress adopted the pre-AIA judicial construction of that phrase when it retained the "on sale" language in the AIA.[2]

Background

Petitioner Helsinn Healthcare S.A. (Helsinn) makes Aloxi with the active ingredient palonosetron, a drug for the treatment of chemotherapy-induced nausea and vomiting. In 2001, MGI Pharma, Inc. (MGI) entered into various agreements with Helsinn in order to market and distribute Helsinn's .25 mg and .75 mg doses of palonosetron. While Helsinn and MGI announced the agreements in a joint press release and MGI also reported the agreements to the U.S. Securities and Exchange Commission, neither Helsinn nor MGI disclosed the details of the invention to the public.

Nearly two years after the parties entered into the agreements, on January 30, 2003, Helsinn filed a provisional patent application covering the .25 mg and .75 mg dosages of palonosetron. In the following years, Helsinn filed four patent applications that claimed priority to the provisional patent application. The patent at issue (the '219 patent) was governed by the AIA statute.

In 2011, respondents Teva Pharmaceutical Industries, Ltd., and Teva Pharmaceuticals USA, Inc. (Teva) sought approval under the Hatch-Waxman Act to market a generic .25 mg palonosetron product. When Helsinn sued for patent infringement, Teva argued that the '219 patent was invalid under the "on sale" provision of the AIA. Specifically, Teva argued that the 2001 agreements between Helsinn and MGI constituted a "sale" more than one year before the effective filing date of January 30, 2003. Interpreting the AIA, the district court held that because the details of the invention were not publicly disclosed, the invention was not "on sale" before the critical date. On appeal, the Federal Circuit reversed the district court's decision because the fact of a sale was publicly disclosed. The Supreme Court granted certiorari.

The Court's Analysis

Writing for a unanimous court, Justice Thomas started with the language of the AIA, which bars a person from receiving a patent when the claimed invention is "in public use, on sale, or otherwise available to the

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public."[3] Justice Thomas noted that the "AIA, as relevant here, retained the on sale bar and added the catchall phrase 'or otherwise available to the public.'"[4] Thus, the "on sale" provision should be interpreted consistent with the Court's *Pfaff v. Wells Electronics* decision. Justice Thomas noted that the Supreme Court in *Pfaff* decided that an invention was "on sale" when it was "the subject of a commercial offer for sale" and "ready for patenting."[5] *Pfaff* suggests that a "sale or offer of sale need not make an invention available to the public."[6] Moreover, "secret sales" can invalidate a patent.[7] Therefore, the Court concluded that the same judicial construction applied to the meaning of "on sale" in established pre-AIA precedent should apply to the AIA.[8] Thus, the Court held that an "inventor's sale of an invention to a third party who is obligated to keep the invention confidential can qualify as prior art under § 102(a)," even if the invention itself is not made available to the public.[9]

Takeaways

The Court's decision confirms that the interpretation of the "on sale" phrase of 35 U.S.C. § 102(a) under the AIA should follow established pre-AIA precedent and that a commercial sale to a third party that includes a confidential agreement may qualify as "on sale" even if details of the invention are not made public.

As such, entities should file a patent application prior to entering into commercial agreements involving an invention, even if the details of the invention are kept secret or confidential, to ensure patent protection.

For more information about the Supreme Court's ruling, please contact any member of the patent litigation practice at Wilson Sonsini Goodrich & Rosati.

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[1] Slip Op. at 1-2.

[2] Slip Op. at 1.

[3] 35 U.S.C. § 102(a)(1).

[4] Slip Op. at 6.

[5] *Pfaff v. Wells Electronics, Inc.*, 525 U. S. 55, 67 (1998).

[6] *Id.*

[7] *Id.* at 7.

[8] *Id.*

[9] *Id.* at 8-9.

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