Supreme Court in Helsinn: Secret Sales Can Qualify as Prior Art Under the AIA

by Kirk Coombs

Prior to the Leahy-Smith America Invents Act (AIA), 35 U.S.C. §102 entitled a person to a patent unless, among other things, "the invention was … in public use or on sale in this country, more than one year prior to the date of the application for patent." 35 U. S. C. §102(b) (pre-AIA). It was established that an invention was "on sale" within the meaning §102(b) when it was "the subject of a commercial offer for sale" and "ready for patenting," *Pfaff* v. *Wells Electronics*, *Inc*., 525 U. S. 55, 67 (1998), regardless of whether the sale made the details of the invention available to the public. As such, a "secret sale" in the United States more than one year prior to the date of the application for patent would be a bar to patentability. After enactment of the AIA, §102 now entitles a person to a patent unless, among other things, the invention was "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) (post-AIA).

The question before the Supreme Court in *Helsinn Healthcare S. A. v. Teva Pharmaceuticals USA, Inc., et al.,* 586 U.S. __ (2019) was whether, under the AIA, an inventor's sale of an invention to a third party who is obligated to keep the invention confidential qualifies as prior art for purposes of determining the patentability of the invention.

Petitioner Helsinn Healthcare S. A. is a Swiss pharmaceutical company that makes Aloxi, a drug that treats chemotherapy-induced nausea and vomiting. Helsinn found a marketing partner, MGI Pharma, Inc. (MGI), a Minnesota pharmaceutical company that markets and distributes drugs in the United States. Helsinn and MGI entered into two agreements, a license agreement and a supply and purchase agreement—both of which were announced in a joint press release and a Form 8–K filing by MGI with the Securities and Exchange Commission. Neither the 8–K filing, nor the press releases, disclosed the specific dosage formulations (0.25 mg and 0.75 mg doses of palonosetron) covered by the agreements. Nearly two years after Helsinn and MGI entered into the agreements, Helsinn filed a provisional patent application covering these dosage formulations, and then followed with four nonprovisional applications—including one which issued in May 2013 as U.S. Patent No. 8,598,219 ('219 patent) covering a fixed dose of 0.25 mg of palonosetron. In 2011,

respondents Teva Pharmaceutical Industries, Ltd., and Teva Pharmaceuticals USA, Inc. (collectively Teva), sought approval to market a generic 0.25 mg palonosetron product. Helsinn sued Teva for infringing its patents, including the ’219 patent. Teva countered that the ’219 patent was invalid under the “on sale” provision of the AIA.

The District Court determined that the “on sale” provision did not apply, concluding that, under the AIA, an invention is not “on sale” unless the sale or offer in question made the claimed invention available to the public. *Helsinn Healthcare S. A. v. Dr. Reddy’s Labs. Ltd.,* 2016 WL 832089, *45, *51 (D NJ, Mar. 3, 2016). Because the public disclosure of the agreements between Helsinn and MGI did not disclose the 0.25 mg dose, the court determined that the invention was not “on sale” before the critical date. *Id*., at *51–*52. The Federal Circuit reversed, 855 F. 3d 1356, 1360 (2017), concluding that “if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale” to fall within the AIA’s on-sale bar. *Id*., at 1371. Because the sale between Helsinn and MGI was publicly disclosed, it held that the on-sale bar applied. *Id*., at 1364, 1371.

On January 22, 2019, the Supreme Court affirmed in a unanimous decision, concluding 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. In particular, it held that “[a] commercial sale to a third party who is required to keep the invention confidential may place the invention “on sale” under §102(a).” The Court summarized its reasoning as follows:

“The patent statute in force immediately before the AIA included an on-sale bar. This Court’s precedent interpreting that provision supports the view that a sale or offer of sale need not make an invention available to the public to constitute invalidating prior art. See, *e.g.*, *Pfaff* v. *Wells Electronics, Inc.*, 525 U. S. 55, 67. The Federal Circuit had made explicit what was implicit in this Court’s pre-AIA precedent, holding that “secret sales” could invalidate a patent. *Special Devices, Inc.* v. *OEA, Inc.*, 270 F. 3d 1353, 1357. Given this settled pre-AIA precedent, the Court applies the presumption that when Congress reenacted the same “on sale” language in the AIA, it adopted the earlier judicial construction of that phrase. The addition of the catchall phrase “or otherwise available to the public” is not enough of a

change for the Court to conclude that Congress intended to alter the meaning of "on sale." *Paroline* v. *United States*, 572 U. S. 434, and *Federal Maritime Comm'n* v. *Seatrain Lines, Inc.*, 411 U. S. 726, distinguished. Pp. 5–9."