



Helsinn—Supreme Court Unanimously Confirms AIA “On Sale” Does Not Require “On Public Sale”

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On January 22, 2019, the Supreme Court unanimously ruled that the provision of the America Invents Act (“AIA”) barring an inventor from obtaining a patent for an invention that was “in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention” means exactly what it meant under the provision’s pre-AIA counterpart—an invention is “on sale” when it is “the subject of a commercial offer for sale” and “ready for patenting.” *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*, No. 17-1229, slip op. at 1 (U.S. Jan. 22, 2019) (quoting *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 67 (1998)).

At issue in *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.* was “whether 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 [AIA] § 102(a).” *Id.* at 1.

Helsinn manufactures Aloxi (palonosetron), which treats nausea and vomiting associated with chemotherapy. *Id.* at 2. In order to market its product, Helsinn partnered with MGI Pharma and the two entities entered into a license agreement and a separate supply and purchase agreement. *Id.* The license agreement provided for MGI to market, distribute, and sell the 0.25 mg and 0.75 mg doses of palonosetron in exchange for MGI’s upfront payments and future royalties; the supply and purchase agreement provided for MGI to purchase palonosetron from Helsinn exclusively in exchange for Helsinn’s promise to supply as much palonosetron as MGI required. *Id.* Both agreements required MGI to maintain the confidentiality of Helsinn’s proprietary information. *Id.*

The deal was announced in a joint press release as well as in MGI’s required SEC Form 8-K filing. *Id.* Neither the press release nor the Form 8-K filing disclosed the specific dosage formulations that were the subject of the license and supply and purchase agreements. *Id.* at 2-3.

Two years passed before Helsinn filed a provisional patent application directed to the 0.25 mg and 0.75 mg doses of palonosetron. *Id.* at 3. Over the course of ten years, Helsinn filed four patent applications that claimed priority to the provisional application. *Id.* The fourth application eventually issued as U.S. Patent No. 8,598219 (“’219 patent”), which was directed to a 0.25 mg dose of palonosetron in solution. *Id.*

Teva, a generic drug manufacturer, subsequently filed an application with the FDA to market a generic version of palonosetron. *Id.* Helsinn sued Teva for allegedly infringing its patents, including the ’219 patent, and Teva countered by arguing that the ’219 patent was invalid because the alleged invention was “on sale” more than a year before Helsinn filed the provisional patent application to which the ’219 patent claims priority. *Id.*

The AIA provides that “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). The pre-AIA counterpart included similar language: “A person shall be entitled to a patent unless . . . the invention was patented or described in a printed publication in this or a foreign country or in public use or *on sale* in this country, more than one year prior to the date of the application for patent in the United States.” 35 U. S. C. §§ 102(a)-(b) (2006 ed.) (emphasis added).

The District Court ruled that AIA’s “on sale” provision did not apply because the Helsinn and MGI agreements did not make the later-claimed invention available to the public. *Helsinn*, slip op. at 4.



The Federal Circuit reversed, concluding that the AIA provision did apply because the agreements were disclosed publicly even if the details of the agreements were not. *Id.* Thus, according to the Federal Circuit, the details of an invention need not be publicly disclosed for a sale to bar an inventor from obtaining a patent. *Id.*

The Supreme Court granted certiorari “to determine 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.” *Id.* at 4-5. The Court determined that “such a sale can qualify as prior art.” *Id.* at 5.

The Court explained that the on-sale bar “reflects Congress’ ‘reluctance to allow an inventor to remove existing knowledge from public use’ by obtaining a patent covering that knowledge.” *Id.* (quoting *Pfaff*, 525 U.S. at 64). The AIA carried over from the previous patent statute the on-sale bar provision but added the catchall phrase “or otherwise available to the public.” 35 U.S.C. § 102(a)(1) (2012 ed.). The Court determined that the addition of this catchall phrase did not alter the meaning of the “on sale” bar to include a requirement that the sale be public. *Helsinn*, slip op. at 6.

The Court reasoned that Congress had enacted the AIA “against the backdrop of a substantial body of law interpreting § 102’s on-sale bar.” *Id.* Indeed, the Court held in 1998 that the pre-AIA provision applied when an invention is “the subject of a commercial offer for sale” and “ready for patenting.” *Id.* (quoting *Pfaff*, 525 U.S. at 67). The Court explained that, “[a]lthough this Court has never addressed the precise question presented in this case, our precedents suggest that a sale or offer of sale need not make an invention available to the public. For instance, we held in *Pfaff* that an offer for sale could cause an inventor to lose the right to patent, without regard to whether the offer discloses each detail of the invention.” *Id.* Further, the Federal Circuit has made this explicit, holding that “secret sales” can invalidate a patent. *Id.* at 7.

In light of this precedent, the Court “presume[d] that when Congress reenacted the same language in the AIA, it adopted the earlier judicial construction of that phrase.” *Id.* The Court agreed with *amicus* United States that “if ‘on sale’ had a settled meaning before the AIA was adopted, then adding the phrase ‘or otherwise available to the public’ to the statute ‘would be a fairly oblique way of attempting to overturn’ that ‘settled body of law.’” *Id.* at 7-8 (quoting Tr. of Oral Arg. 28). The Court concluded 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.

This is the first patent-related Supreme Court opinion to be handed down in 2019. The decision (1) provides clarity on the nature of the on sale bar under the AIA, especially as a unanimous decision; (2) confirms that the on sale bar in the AIA was not changed to require a public component by the AIA and that the prior law on the on sale bar continues as authoritative; and (3) should serve as fair warning to patent applicants to file promptly to have an effective filing date before any sale, public or confidential.

Locke Lord will continue to monitor the Supreme Court’s jurisprudence over the course of the year.

For more information on the matters discussed in this *Locke Lord QuickStudy*, please contact the authors.

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