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'On Sale' Ruling Shows Need For Earlier Patent Applications

By **Matthew Bultman**

Law360 (January 22, 2019, 9:07 PM EST) -- The U.S. Supreme Court's decision not to revive a Helsinn patent on the nausea drug Aloxi has clarified the scope of the on-sale bar under the America Invents Act and underscored the need for inventors to file their patent applications as early as possible.

In a unanimous ruling, the justices affirmed a Federal Circuit decision finding that the patent for Aloxi was invalid based on license and purchase agreements that Helsinn Healthcare SA made with another drug company to help fund the drug's development.

Sales of an invention that occur more than a year before a patent application is filed can be used to invalidate that patent. Helsinn argued that the AIA narrowed this rule, known as the on-sale bar, to exclude sales in which the invention was required to be kept confidential.

Rejecting that argument Tuesday, the Supreme Court focused on six words the AIA added to the on-sale bar provision. The court said there wasn't "enough of a change" to conclude Congress intended to upend long-standing rules about what it means for an invention to be "on sale."

"It's clear that to the extent there is any congressional desire, or desire by industry, to change the on-sale bar and what is covered by it, then Congress is going to have to do so expressly and not through implication," Mark Remus, a shareholder at Brinks Gilson & Lione, said.

Questions about whether the AIA changed the scope of the on-sale bar have lingered since the law was passed in 2011, which has created some confusion about the steps companies can take to commercialize an invention and still be eligible to protect it with a patent.

The issue is especially important for smaller companies, like Helsinn, that may need to license inventions to others for testing during the development process.

"To the extent there was a lack of clarity about whether the AIA changed the on-sale bar, this decision decisively reduces that uncertainty," said Kenneth Weatherwax, a founding partner of Lowenstein & Weatherwax LLP.

The case stems from a dispute between Helsinn and Teva Pharmaceuticals USA Inc., which was accused of infringing the patent with its planned generic version of Aloxi, a treatment for chemotherapy-induced nausea and vomiting.

More than a year before filing for its patent, Helsinn had entered into license and purchase agreements with MGI Pharma. While the deal was announced in a news release and regulatory filings, MGI was obligated to keep secret the details of the invention.

Every patent statute for almost two centuries has included an on-sale bar. Helsinn's case turned on the phrase "or otherwise available to the public" in the AIA, and it argued that Congress added this new language to exclude secret sales from the prior art.

The drugmaker had some recognizable names in its corner, including Rep. Lamar Smith, R-Texas, a main sponsor of the AIA. The U.S. Patent and Trademark Office has also taken the position that the AIA's on-sale provision "does not cover secret sales or offers for sale."

"The battle that Helsinn was fighting — and it proved to be too high of a mountain to climb — was the large amount of precedent that existed both at the Federal Circuit and at the Supreme Court," Remus said.

In 1998, the Supreme Court in Pfaff v. Wells Electronics decided an invention was "on sale" when it was the "subject of a commercial offer for sale" and "ready for patenting." The court did not say the sale has to make the details of the invention available to the public.

Writing for the court Tuesday, Justice Clarence Thomas noted the Federal Circuit has long held that secret sales can invalidate a patent, making "explicit what was implicit in our precedents." Justice Thomas also highlighted comments the federal government made during arguments last month, when it conceded that adding the "otherwise" phrase would be a "fairly oblique way" of overturning years of settled law.

"If the court were construing 'on sale bar' today, without any history or any precedent, they might arrive at a different conclusion," Remus said.

"But ... where there is such a large body of law that Congress either was, or should have been, well aware of, their failure to take a more explicit position rejecting the prior position seemed to be a pretty telling indication that it was not Congress' intent to change the definition of on sale," he said.

While the Supreme Court's ruling effectively maintains the status quo regarding confidential sales, attorneys said it highlights the need for companies to patent their inventions early and not wait to file their applications.

"Companies are going to need to be diligent in filing early patent applications," Scott McBride, a shareholder at McAndrews Held & Malloy Ltd., said. "Confidentiality agreements governing sales aren't likely to save patent rights going forward."

Along similar lines, Matthew Bodenstein of Sterne Kessler Goldstein & Fox PLLC said patent lawyers need to be aware of where a product is in the development pipeline, as well as any agreements that the company might be working on to sell the product.

"[The ruling] puts the onus on patent attorneys, particularly in-house patent attorneys, to be aware of what their commercial team is doing and make sure that everyone is working together to avoid the problem that Helsinn ultimately ran into," he said.

These same considerations may not always be relevant outside the U.S., as no other major patent system includes private sales within the prior art. This had been a criticism of the Federal Circuit's interpretation of the on-sale bar, as Helsinn and its supporters emphasized one of the goals of the AIA was to bring U.S. patent law more in line with other countries.

The Supreme Court did not dissect this apparent discrepancy, which others have downplayed.

“The fact that one of the goals was to bring us closer [to other countries' laws] shouldn't be a way to undo what the Supreme Court confirmed is years of consistent application of the on-sale bar wall,” said Matthew Siegal, counsel at Dilworth & Barrese LLP.

“Like they said, if that was the intent, [Congress] should have been a little more explicit about that instead of swallowing it with that ‘or otherwise available’ language.”

--Editing by Philip Shea and Kelly Duncan.

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