

LAW WEEK COLORADO

SCOTUS: Wording Change Does Not Amount to Legal Change in Patent Case

Ruling returns interpretation of on-sale bar to patents to pre-AIA meaning



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The U.S. Supreme Court took less than two months to decide a nuanced patent case about whether the America Invents Act changed existing law around the timeframe for patenting inventions.

Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA Inc. asked the Supreme Court to decide whether the America Invents Act changed the on-sale bar in patent law — which requires an inventor to file for a patent within a year after offering an invention for sale — to no longer include confidential sales when it added the phrase “otherwise available to the public.” The Supreme Court’s opinion upholds the Court of Appeals for the Federal Circuit, which found the America Invents Act did not change the on-sale bar’s application to confidential sales.

The unanimous decision, penned

by Justice Clarence Thomas, returns the on-sale bar to its pre-AIA interpretation. The USPTO put out guidance several years ago that the wording change under the AIA meant the on-sale bar no longer applied to secret sales, and the district court’s ruling in the Helsinn case reflected that.

In the several years between the first ruling and the Supreme Court weighing in, some attorneys and companies may have made decisions about when to file for patents that the Supreme Court’s decision could now call into question.

CASE OVERVIEW

When it went into effect in 2012, the AIA changed the existing language of the on-sale bar to include that an invention is not patentable if it was on sale “or otherwise available to the public” for more than a year before the filing of a patent application. Helsinn argued that change shifted the meaning of the on-sale bar to no longer include secret sales. But Teva claimed the AIA did not change the on-sale bar when it introduced the new wording.

A “sale” does not necessarily mean a product bought by a consumer.

Helsinn’s appeal involves agreements for licensing as well as supply and purchase between the company and MGI Pharma. The companies announced the agreements publicly but did not include the pricing terms or the drug dosage Helsinn would develop and supply to MGI. Before the AIA was passed but more than a year after the agreements, Helsinn received three patents. The company received a fourth patent in 2013.

In 2011, Teva filed for permission from the FDA for a generic version of the drug. In the filing, Teva claimed Helsinn’s patents weren’t valid and that a generic version of the drug would not infringe, because the timing of the patents was outside the one-year window required by the on-sale bar.

Helsinn sued Teva for patent infringement in federal court in New Jersey. The court ruled in favor of Helsinn, and specifically rejected Teva’s argument that Helsinn’s most recent patent violated the on-sale bar. Under the AIA, the court reasoned, the sale had to be “public.” Because the announcement of the agreements between Helsinn and MGI didn’t disclose the drug dosage



JUSTIN KRIEGER

or pricing, the agreements didn’t count as a public sale.

But in a narrow decision, the Federal Circuit Court of Appeals reversed the district court’s ruling. It held the on-sale bar applies to sales that are publicly known, even if the details of the invention are kept secret. The Supreme Court heard the case early in December.

Justin Krieger, a partner at

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—Justin Krieger, partner, Kilpatrick Townsend & Stockton



Kilpatrick Townsend & Stockton, remembered one of Justice Elena Kagan's questions as a particularly poignant example of the court's wrestling with the scope of "otherwise available to the public." Kagan asked Teva's attorney William Jay if she would violate an injunction against buying "peanut butter cookies, pecan pie, brownies, or any dessert that otherwise contains nuts" by purchasing nutless brownies.

"Are you allowed to bring nutless brownies? That hypothetical I think really rang true for the court and for everybody else listening that, yeah, of course you can bring brownies that don't have nuts," Krieger said, because it seemed clear "otherwise contains nuts" modifies the desserts before it. "Yet at the end of the day, it rang hollow for the court."

Krieger said one particular statement made by Deputy Solicitor General Malcolm Stewart, who argued as an amicus for Helsinn, actually seemed like the final nail in Helsinn's coffin. Kagan asked Stewart whether, assuming the case law was settled before the AIA, the addition of "otherwise available to the public" is enough to unsettle it. Stewart said no, calling it a "fairly oblique" way of

overturning settled law, phrasing the the Supreme Court's opinion quoted.

"I think his answer to that really gave away the case," Krieger said. "That answer he gave, I think ... ultimately was likely the death knell for Helsinn and their arguments."

Stewart's answer may have been especially surprising because of guidance the USPTO issued after the AIA went into effect and changed the on-sale bar's language. The guidance interpreted the language change as meaning the on-sale bar no longer applied to confidential sales, and the district court's decision in the Helsinn case reflected that interpretation. It speaks to the thorny implications of having a period of uncertainty in the law while Helsinn's case worked its way through the courts.

Some attorneys, in-house counsel and business people "may have taken that and made decisions on when to apply for a patent application based on that guidance" and had a confidential sale offer more than a year before applying for a patent, said Ryan Fletcher, a partner at Merchant & Gould. "If that was the case, based on the Supreme Court's position, that would potentially be an invalidating sale [for] a patent

application."

Fletcher said companies may resist filing for patents before their products are ready because they don't want to burn several years of the 20 they get for market exclusivity while they ready it for market. But he said he believes it's better to take a more conservative approach and file for a patent as soon as possible.

"The repercussions can be catastrophic" if a company is on the wrong side of the statutory bar gamble, he said. You spent all this time and money investing in patent applications that now potentially may be invalid due to an on-sale bar."

Krieger said interpreting the on-sale bar to mean it applies to confidential sales likely increases discovery costs in litigation because it opens the door to discovery requests for secret sale offers that wouldn't otherwise be relevant.

The decision's implications seem to find their divide between haves and have-nots in small versus large companies. Krieger said he believes the Helsinn case likely impacts small and medium-sized drug companies financially differently than larger ones. Smaller companies are less likely to have the capital needed to

develop and bring a drug to market on their own before filing for a patent, so they'll enter third-party agreements for manufacturing and distribution like the ones at issue in the Helsinn case so they can finance their inventions.

"Helsinn was a family-owned company. They didn't have the money to go through all the regulatory approval that was needed here," he said. "So they didn't have a choice but to enter an agreement with MGI [to] supply and help keep them afloat while they're working through this whole [FDA regulatory] process."

He said the Helsinn's case underscores the importance of deciding whether to patent an invention or keep it a trade secret, because the one-year bar is the point of no return for patenting. Although there's also no going back after filing for a patent, because it requires disclosing the details.

"That old mindset in the U.S. that you can't change your mind after one year, that has returned," Krieger said. "So I think companies need to have a rigorous system in place to evaluate new developments in intellectual property, especially inventions." •

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