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Generics Win SCOTUS Suit: Secret Drug Sales Start Patent-Filing Clock

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In a win for the generic drug industry, the Supreme Court unanimously ruled Tuesday (Jan. 22) that secret sales of inventions start the one-year clock to file patents. In the *Helsinn Healthcare v. Teva Pharmaceuticals* opinion, written by Justice Clarence Thomas, the court said the 2011 Leahy-Smith America Invents Act, which overhauled patent law, didn't change the trigger for the patent-filing clock.

The decision was a loss for the Trump administration and the brand-drug lobby, which had backed brand-drug maker Helsinn.

The Supreme Court upheld the U.S. Court of Appeals for the Federal Circuit's decision. The ruling invalidates a patent, which would have run until 2024, on Helsinn's flagship drug that treats nausea caused by chemotherapy.

Before the America Invents Act, confidential sales started the patent-filing clock, and brands argued that the 2011 patent law changed that aspect of patent law. Thomas, however, said changes to that provision of the law were not significant enough to overturn decades of court precedent.

"In light of this settled pre-AIA precedent on the meaning of 'on sale,' we presume that when Congress reenacted the same language in the AIA, it adopted the earlier judicial construction of that phrase," Thomas wrote.

The attorney for the federal government filed an amicus brief supporting Helsinn, and Thomas turned part of the attorney's argument against the brand-drug manufacturer. Thomas held that the slight language changes were not substantial enough to exempt confidential sales from starting the patent filing clock.

"As amicus United States noted at oral argument, 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,'" Thomas wrote.

Mark Lemley, a professor at Stanford Law School and the director of the school's law, science and technology program, said the decision was important because the court turned down an opportunity to fundamentally change patent law.

"That's good news for patent law; a decision going the other way would have thrown a monkey wrench into our system of prior art," Lemley said.

The Supreme Court contradicted the U.S. Patent and Trademark Office's interpretation of the America Invents Act. The Patent and Trademark Office told its examiners that a sale "must make the invention available to the public" to be considered prior art.

"The PTO is not entitled to deference by the courts in the way they interpret statutes," Sarah Kagan, an attorney with Banner & Witcoff, said. "While it is interesting, I guess they got it wrong too."

Small and mid-sized pharmaceutical companies that relied on the Patent Office's interpretation of the law to time patent filings may be hurt by the ruling, said Michael Pomianek, an attorney at Wolf Greenfield. Pomianek said small and mid-sized pharmaceutical companies are more likely to partner with large companies when they develop, market and distribute new drugs. Pomianek's firm counseled companies to file patents in accordance with requirements from before the America Invents Act, but he said some companies may have taken a more aggressive strategy.

“There was hope and expectation that had given way with the Patent Office that [the America Invents Act] would facilitate new opportunity, which now has shown to be a false promise,” Pomianek said.

Generic drug lobby Association for Accessible Medicines filed a brief supporting generic-drug maker Teva and is pleased with the court’s decision.

“AAM applauds today’s unanimous decision of the Supreme Court that upholds the plain meaning of the on-sale bar in the patent statute,” AAM General Counsel Jeff Francer said. “Today’s decision reflects the clear intent of Congress to avoid patent gaming by allowing a company to sell technology publicly and later obtain a patent on it.”

AAM said that not imposing the one-year patent filing requirement after secret sales could have delayed generic drugs’ entry to market.

The federal government, Biotechnology Innovation Organization, Pharmaceutical Research and Manufacturers of America and former Rep. Lamar Smith (R-TX), who co-sponsored America Invents Act, filed amicus briefs in support of Helsinn.

Hans Sauer, the vice president for intellectual property for BIO, said the ruling is problematic because it only affects small and mid-size pharmaceutical companies, which are already worse off because the America Invents Act stipulates that international sales start the patent-filing clock.

“We were disappointed at the result, and disappointed at the shallowness of the opinion. It’s not very detailed, and there’s a lot more that could have been said. We still have to digest what happened, but we are worse off than before [the America Invents Act] passed,” Sauer said. -- *Rachel Cohrs* (rcohrs@iwpnews.com)

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