

Intellectual Property

Expert Analysis

Supreme Court Set to Tackle ‘Secret’ Patented Sales Under AIA

In June, the U.S. Supreme Court agreed to hear the case of *Hel-sinn Healthcare v. Teva Pharmaceuticals USA*, in which the court will address the scope and impact of the “on sale bar” of the patent statute as it applies under the America Invents Act (AIA). The decision could have a significant impact on patenting, R&D and commercial strategy for U.S. operating companies that typically seek patent protection for their products and services.

Background: The Pre-AIA on Sale Bar

The on sale bar is a provision of the U.S. patent laws which dictates, in essence, that inventions that were “on sale” prior to the invention’s patent application filing date cannot be patented. Historically, even secret on sale activities had been considered bars to pat-

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entability. *Pfaff v. Wells Electronics*, 525 U.S. 55 (1998). Other secret activities were treated similarly.

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For example, a judicially-created extension of the statutory bars—characterized as a “forfeiture” doctrine—was applied to private and prolonged commercial uses by an inventor. *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516, 520 (CA2 1946).

These decisions were principally based on policies discouraging secret commercial uses of new

inventions, because, contrary to the quid-pro-quo of our patent system, such uses deny the public the benefit of the invention, and yet could effectively extend the term of the patent grant beyond that provided by Congress (assuming the inventor eventually files for a patent). As the Supreme Court noted, quoting Judge Learned Hand, “it is a condition upon an inventor’s right to a patent that he shall not exploit his discovery competitively after it is ready for patenting; he must content himself with either secrecy, or legal monopoly.” *Pfaff v. Wells Electronics*, 525 U.S. 55 (1998) (quoting *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516, 520 (CA2 1946)).

Congress Rewrites The on Sale Bar

In 2011, President Obama signed into law the America Invents Act (AIA), the most sweeping reform to U.S. patent laws in over half a

century. It has largely been effective at achieving its goals of harmonizing U.S. patent laws with those abroad, and curbing frivolous patent litigation. But, as part of these changes, the AIA also included revised on sale bar language that has since been widely debated as open to multiple interpretations.

Specifically, the revised Section 102(a)(1) provides that a person will be entitled to a patent unless “the claimed invention was patented, described in a printed

However, another reading, which arguably better aligns with legislative history of the AIA as explained by the sponsors of these provisions, is different: the intention of the language is to overturn that case law that created prior art effects by secret use or sale of an invention. Under this view, the “or otherwise available to the public” language is a wholesale qualifier, which modifies the list of items preceding it, thereby restricting prior art on sale and public use activities to only those that are “available to the public.” As Senator Kyl explained on the Senate floor during discussion of the AIA:

As Chairman [Lamar] Smith most recently explained in his June 22 remarks, “contrary to the current precedent, in order to trigger the bar in new 102(a) in our legislation, an action must make the patented subject matter “available to the public” before the effective filing date.” ... When the committee included the words “or otherwise available to the public” in section 102(a), the word “otherwise” made clear that the preceding items are things that are of the same quality or nature. As a result, the precedent events and things are limited to those that make the invention “available to the public.” ... Once an invention has entered the public domain, by any means, it can no longer be withdrawn by anyone. But public uses and

sales are prior art only if they make the invention available to the public.

Senator Kyl also explained “that the interpretation of 102 that some opponents appear to advance—that non-disclosing uses and sales would remain prior art, and would fall outside the 102(b) grace period—is utterly irrational.” Congressional Record, Senate, Sept. 8, 2011, at S5431.

These statements echo comments made months earlier by others in Congress:

One of the implications of the point we are making is that subsection 102(a) was drafted in part to do away with precedent under current law that private offers for sale or private uses or secret processes practiced in the United States that result in a product or service that is then made public may be deemed patent-defeating prior art. That will no longer be the case. In effect, the [AIA] imposes an overarching requirement for availability to the public.

Congressional Record Volume 157, Number 35 (Wednesday, March 9, 2011), Senate, S1496-S1497.

The competing views on this language and the legislative history set up a classic statutory interpretation question, and it was only

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publication, or in public use, on sale, or otherwise available to the public before the filing date of the claimed invention.” (Emphasis supplied.) Some have interpreted the italicized language as merely a catch-all, seeking to capture other unspecified types of disclosures to the public, but not as modifying the items preceding it (“or in public use, on sale”). According to this reading, the case law regarding the secret uses and/or sales would remain intact, and those sorts of secret activities would remain patent-defeating.

a matter of time until this question would be taken up by the courts.

'Helsinn Healthcare v. Teva Pharmaceuticals USA'

Helsinn originally brought suit against Teva alleging that the filing of Teva's Abbreviated New Drug Application (ANDA) constituted an infringement of various claims of Helsinn's patents directed to intravenous formulations for reducing chemotherapy-induced nausea. Teva raised an invalidity defense based on the on sale bar, in light of Helsinn's offer to sell the patented invention before the critical date (in which the offer itself did not disclose the patented feature). Although the district court agreed that there was an offer for sale before the critical date, it found that the AIA had changed 35 U.S.C. Section 102(b) to limit the bar to only *public* sales or offers for sale. The district court rejected Teva's invalidity defense on that basis.

The case drew widespread interest on appeal to the Federal Circuit. A number of amicus briefs were filed in support of Helsinn's position, including by Congressman Lamar Smith, a lead sponsor of the AIA legislation (i.e., H.R. 1249, the "Leahy-Smith America Invents Act"), who has relied heavily on the

legislative history. However, others expressed an opposing view, including a group of 42 IP law professors who filed an amicus brief supporting Teva, arguing that the legislative history relied on by Helsinn is a "weak form of legislative history," comprising merely a "prepackaged 'conversation'" on the Senate floor the day *after* the Senate had passed the AIA, and which reflected only the individual views of a few select lawmakers.

The Federal Circuit reversed, detailing the prior precedent, analyzing the legislative history, and ultimately rejecting arguments by Helsinn that the AIA changed the law. The court there concluded that, at best, the legislative history may indicate Congress' intent to change the law for a public *use* (where that use of the invention did not disclose the invention to the public), but not for *on sale* scenarios.

Helsinn appealed to the Supreme Court. A number of amici filed briefs urging the Supreme Court to take up the case, including AIPLA, IPO and other IP rights organizations, and Congressman Lamar Smith. Smith argued that the text of the statute is plain, and that, in light of the legislative history, Congress clearly intended to change the law.

On June 25, 2018, the Supreme Court granted cert. The Question Presented is as follows: "Whether, under the Leahy-Smith America Invents Act, an inventor's sale of an invention to a third party that is obligated to keep the invention confidential qualifies as prior art for purposes of determining the patentability of the invention."

Briefing is now underway, with argument expected during the October 2018 term and a decision likely in late Spring 2019.

If the dispute at the Federal Circuit is any indication, a number of stakeholders will submit amicus briefs, and the case will be closely watched as one that could have a significant impact on the way companies do business going forward, particularly for operating companies that sell products or services protected by their patents. Should the Supreme Court reverse, and finally abolish the old on sale bar, new, accelerated avenues for commercialization may be on the horizon for companies patenting and doing business in the U.S.