IP Alert: Does Secret Prior Art Survive in the AIA? Twelve Interested Parties Weigh In

Does Secret Prior Art Survive in the AIA? Twelve Interested Parties Weigh In

By Sarah A. Kagan

In May, a panel of the U.S. Court of Appeals for the Federal Circuit applied an on-sale bar under the America Invents Act (AIA) to Helsinn's U.S. Patent No. 8,598,219 (Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc., Case Nos. 2016-1284, 2016-1787). Unlike the district court, the Federal Circuit panel imported pre-AIA on-sale bar case law into its consideration of the AIA, holding that Congress had not clearly overruled Federal Circuit precedent in its enactment. Helsinn petitioned unsuccessfully for en banc rehearing, after which it petitioned for a writ of certiorari to the Supreme Court. Ten parties filed amicus curiae briefs supporting the granting of the petition.[1] Most, but not all, supported Helsinn's position on the merits. All brief-filers except opponent Teva urged that the meaning of "on sale" in AIA § 102(a)(1) was an important question of law and settling its meaning would be economically important for future innovators needing to structure their business activities and for investors and industry members needing to assess validity of patents. Teva argued that the facts decided below precluded consideration of the legal question raised in the petition. The Court granted certiorari on June 25, 2018.

The '219 patent is directed to a dosage formulation of palonosetron, a drug used to combat nausea induced by chemotherapy. More than a year before filing its application, the patent owner licensed and contracted with MGI Pharmaceuticals to purchase and distribute the dosage formulation. Although the contract required MGI to keep the dosage formulation confidential, MGI disclosed the existence of the contract in an SEC filing, as it was required

to do by law. It redacted the confidential information so that there was no breach of its duty of confidentiality. Thus, the existence of the contract but not the identity of the dosage formulation became public.

The Federal Circuit panel reversed the district court and held that the retention of the term "on sale" in AIA § 102(a)(1) from pre-AIA § 102(b) indicates that Congress did not intend to wipe the slate clean. Rather it intended that all prior on-sale case law would be adopted.

The question presented by the petition is: "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." In short, the petition asks whether sale of an invention that does not disclose the invention to the public qualifies as prior art under the AIA. The relevant portion of the statue reads:

> NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless—
>
> (1) 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; or....

Although a new set of briefs will be filed on the merits (filing period ending October 9, 2018), the briefs on the petition for certiorari likely foreshadow the arguments to be made in the briefs. We highlight arguments from the 12 briefs below.

The Parties' Briefs

Helsinn pointed out that the panel's methodology was faulty because it failed to analyze the new statute itself. Rather, the panel analyzed the legislative history for clear and unambiguous statements that it intended to overrule particular cases. From a policy perspective, Helsinn urged that a first-to-file system, as undisputedly adopted in the AIA, is inconsistent with use of secret prior art. It also urged that harmonization, which was one of the goals of the AIA, would be thwarted by retaining use of secret prior art, which no other country uses.

Opponent Teva urged that the new clause in § 102(a)(1), "or otherwise available to the public," does not modify "on sale," but rather simply adds an additional category, including oral disclosures and disclosures, via new technology to the list of forms of prior art, beyond merely printed publications. Therefore, in its reading of the statute, sales do not need to make the invention available to the public to qualify as prior art.

Teva also urged that prior draft versions of the legislation entirely eliminated the words "on sale" and contained a catch-all phrase like "otherwise available to the public." The final legislation added back "in public use, on sale" before the catch-all phrase. The petitioner, Teva argued, is urging an erroneous statutory construction that renders "on sale" superfluous.

Teva argued that the construction that Helsinn urges is contrary to the U.S. Constitution, which recites securing exclusive rights for "limited times" to inventors. According to Teva, permitting sales of inventions more than one year prior to filing an application would allow inventors to extend exclusivity beyond the "limited time."

The Amicus Briefs

The AIPLA added an interesting twist to the statutory interpretation dispute. It argued that just as the last nine words of § 102(a)(1) ("before the effective filing date of the claimed invention") indisputably apply to all prior listed categories of prior art, so should the beginning of the same clause ("or otherwise available to the public"). The entire clause modifies the entire list that precedes it, contrary to Teva's reading.

Amicus BIO attempted to mitigate the risk that the Supreme Court would agree with the Federal Circuit that the AIA was not clear enough in expressing its intention to overrule prior case law on the on-sale bar. BIO framed the change in the statute as merely adding another prong to overlay on the old case law, i.e., that the prior art event must cause public availability. In this way it sought to obtain a change in the understanding of the law without needing to have the Supreme Court agree that Congress intended to repeal all prior on-sale case law.

Many amici pointed to the inconsistency between the Patent and Trademark Office guidelines for the examining corps and the Federal Circuit panel's interpretation of the statue. See, e.g., briefs of BIO and IPO. The Patent and Trademark Office guidelines, however, are entitled to little deference for statutory construction.

BIO's amicus brief pointed to an apparent inconsistency between § 102(a)(1) as interpreted by the Federal Circuit and 35 U.S.C. § 273 ("Defense to infringement based on prior commercial use"). Section 273 provides a defense to a charge of infringement to an entity that commercially used or sold the claimed subject matter at least one year before the effective filing date or disclosure date.[2] Why would the AIA provide such a personal defense if those very actions (according to the Federal Circuit ruling) would invalidate a patent under § 102(a)(1)?[3]

Helsinn used in its petition a statutory construction canon known as the series-modifier canon or last antecedent canon. Helsinn applied the canon to urge that the phrase "available to the public" applied to all three of the members of the prior series, i.e., "in public use, on sale, or otherwise." Amicus U.S. Inventor, Inc., in its brief, applied a different canon. It dismissed the application of the last antecedent canon, because Helsinn wrongly involved identifying "available to the public" as modifying "otherwise" when in fact, U.S. Inventor, Inc. said, "otherwise" modified "available to the public." In any event, it urged that the canon known as noscitur sociis (the company it keeps) would be a better aid in construing the statute. Applying this canon, this amicus urged that "on sale" should be interpreted as similar to its closest neighbors, i.e., "in public use" and "otherwise available to the public." Thus "on sale" should also require public availability.

Just one amicus brief was filed by an entity that was neither an intellectual property law organization nor industry trade association. This brief was filed by Congressman Lamar Alexander, chair of the House Committee on the Judiciary and the lead sponsor of the AIA. His brief provides a comprehensive review of the legislation and how the parts fit together. One key change the amicus points to is that AIA § 102(a)(1) is inventor-agnostic, i.e., it does not distinguish between acts done by the inventor and those done by third parties, as the old law did. The amicus points to the change in title from "Loss of Rights" to "Prior art," noting that the three loss of right provisions (§ 102(c),(d),(f)) involving inventor actions have been repealed. The amicus also points to the use of the term "claimed invention" and

addition of its explicit definition rather than use of the term "invention" in the pre-AIA statute. The amicus asserts that the Federal Circuit decision overlooked this term in construing a "sale" as not requiring disclosure of the claimed invention.

2. Intent to Change

The Naples Roundtable, a non-profit devoted to improving and strengthening the U.S. patent system, criticized the panel decision for having overlooked the statutory purpose of the AIA. It pointed to two "Sense of the Congress" provisions that are part of the act. These purposes, it argued, should have informed the determination of whether there was Congressional intent to retain or change the meaning of "on sale." The first statutory purpose (AIA § 3(p)) was toward global harmonization. The second statutory purpose (AIA § 3(o)) was toward certainty in scope of protection. Both these objectives would be served by adopting a new construction divorced from the baggage of pre-AIA case law, the Roundtable urged.

PhaRMA described pre-AIA case law as composed of two different parts: Supreme Court and Federal Circuit. The Supreme Court, it urged, has only found an on-sale bar where the invention has been publicly disclosed. The Federal Circuit, in contrast, has extended the scope to include sales that do not disclose the invention. The AIA was meant to reign in the Federal Circuit, this amicus urged, by adding the phrase "or otherwise available to the public" to § 102(a)(1).

3. Policy Considerations

The AIPLA urged that the large number of changes to the statute rebuts any presumption that Congress intended to retain the prior interpretation of portions of the statute.

Many amici argued that the Federal Circuit panel's holding would disproportionately affect small innovator companies that must cooperate with other entities to get their products to market, as compared to large, vertically integrated companies. See, e.g., briefs of BIO, Bar of the District of Columbia, Mass Bio Council, and U.S. Inventor, Inc. While not terribly persuasive on its own, this might provide some real world context to the Court regarding the possible effects of its holding.

Many amici pointed to the policy notion that an on-sale bar is not necessary with a first-to-file system, since the system gives a powerful incentive to file early. See, e.g., brief of amicus Lamar Smith.

Many amici discussed the approximately one million patents that have been issued under the Patent and Trademark Office's post-AIA guidelines requiring an on-sale rejection to include a public disclosure of the invention. While this may have demonstrated that the meaning of the statue was ambiguous and needed clarification, it is unlikely to move the Supreme Court to a particular construction. The Supreme Court was not swayed by similar arguments raised in the Section 101 statutory-subject-matter cases. Broadly invalidating thousands of patents did not deter the Court when it clarified the scope of patent eligible subject matter in such cases as Mayo[4] and Myriad.[5]

4. Other Reasons to Hear the Case

The IPO pointed to an apparent inconsistency between the Federal Circuit panel decision and a 2016 en banc Federal Circuit decision in Medicines Company v. Hospira, Inc., Nos. 2014-1469, 2014-1504. IPO urged that Medicines distinguished between actual commercial

marketing of the invention (an on-sale bar) and preparation for potential or eventual marketing (not an on-sale bar). IPO urged that the Federal Circuit narrowed the Medicines holding by making pre-marketing sales into an on-sale bar if the mere existence of the sale was public. Medicines, however, seemed to turn on what was for sale (manufacturing services), not what was claimed (product of manufacture).

MassBio pointed out the irony in the Federal Circuit panel's claimed reluctance to make a fundamental change to the pre-AIA on-sale bar. MassBio characterized the panel holding as actually changing the pre-AIA law so that if the sale itself were publicly known, a disclosure of the invention was not required to make an on-sale bar.

The merits briefs of the parties will no doubt incorporate and respond to the best of the amicus briefs in support of the petition for writ of certiorari. We will continue to monitor this case and its developments.

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[1] American Intellectual Property Law Association (AIPLA), Boston Patent Law Association (BPLA), the Biotechnology Innovation Organization (BIO), Bar Association of the District of Columbia (BADC), Intellectual Property Owners Association (IPO), Congressman Lamar Smith, Massachusetts Biotechnology Council (MassBio), The Naples Roundtable, Pharmaceutical Research and Manufacturers of America (PhaRMA), and US Inventor, Inc.

[2] A person shall be entitled to a defense under section 282(b) with respect to subject matter consisting of a process, or consisting of a machine, manufacture, or composition of matter used in a manufacturing or other commercial process, that would otherwise infringe a claimed invention being asserted against the person if—

> (1) such person, acting in good faith, commercially used the subject matter in the United States, either in connection with an internal commercial use or an actual arm's length sale or other arm's length commercial transfer of a useful end result of such commercial use; and
>
> (2) such commercial use occurred at least 1 year before the earlier of either—
>
> > (A) the effective filing date of the claimed invention; or
> >
> > (B) the date on which the claimed invention was disclosed to the public in a manner that qualified for the exception from prior art under section 102(b).

[3] Perhaps confusing this question is the reference in Section 273 to Section 282(b), which describes invalidity as a defense.

[4] Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66 (2012)

[5] Association for Molecular Pathology., v. Myriad Genetics, Inc., 569 U.S. 576 (2013)

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