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PATENTS

This article examines how the AIA affects the patenting of trade secrets in the biotechnology and electronics/software industries, defenses to infringement of such patents, and whether the U.S. Supreme Court might step in and interpret the AIA as not allowing the patenting of trade secret processes.

A Best Kept Secret: AIA Allows Patenting of Trade Secrets



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Introduction

Increased market competition and recent Supreme Court decisions limiting subject matter patent eligibility have caused many companies to question whether they should file for patent protection, rely on trade secret protection, or both. The America Invents

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Act (AIA) ostensibly overruled *Metallizing Engineering*,¹ which prohibited the patenting of a trade secret process of making a commercial product. After the AIA, a commercial process could be kept as a trade secret and later patented.

AIA Adds “Or Otherwise Available To The Public” to Section 102

On September 16, 2011, the AIA was signed into law.² The AIA was intended to more closely align U.S. patent laws with the rest of the world, improve patent quality, provide a more efficient system to challenge patents, and reduce unwarranted litigation.³ To this end, the AIA replaced the first-to-invent law with a first-inventor-to-file law.⁴ As part of this change, the AIA eliminated two forms of secret prior art deemed unrec-

¹ *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516, 520 (2d Cir. 1946).

² Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29 (2011).

³ See H.R. Rep. No. 112-98, at 38-42 (2011).

⁴ See 35 U.S.C. § 102(a) (2006); 35 U.S.C. § 102 (2012).

essary under a first-inventor-to-file system: secret art derived from another's invention and secret prior inventions by another.⁵ AIA 102(a) reads in part:

[a] person shall be entitled to a patent unless 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 invention⁶

With this change, Congress intended to eliminate an inventor's own secret prior art, including secret sales and secret commercial activity.⁷ While the AIA maintained much of the prior-art language from pre-AIA § 102(b), it added the phrase "or otherwise available to the public."⁸ But this new phrase could be interpreted in two ways – to provide that the scope of invalidating prior art was **expanded** to include other prior art that was "otherwise available to the public" (e.g., a speech to an audience not under an obligation of confidentiality), or **narrowed** to limit what was considered to be in public use or on sale to activities that were "otherwise available to the public." This ambiguity has raised the question of whether the courts will interpret "or otherwise available to the public" to limit the scope of "in public use" and thereby overturn *Metallizing Engineering*.

Prior to the AIA, the courts did not require an invention to be available to the public for it to be "in public use" and a bar under § 102. Instead, courts interpreted "public use" to be any non-experimental use that was either accessible to the public or constituted a commercial exploitation of the invention.⁹ In *Metalizing Engineering*, a prior secret use of a process to make a commercial product was held by the court to be invalidating prior art. Judge Learned Hand explained that an inventor was not permitted to commercially exploit his invention and later obtain a patent only "when the danger of competition should force him" because this "would materially retard the progress of science and the useful arts."¹⁰

The Courts Will Likely Interpret "Or Otherwise Available To The Public" As Narrowing The Scope Of Prior Art

When the meaning of AIA 102(a) is tested, the courts will look to the legislative history of the AIA, the textual canons of statutory construction, the statutory construction of similarly worded language in other statutes, and the opinions of the U.S. Patent and Trademark Office and those of commentators. All of these indicia will point to a narrowing of AIA 102(a).

⁵ See 35 U.S.C. § 102(f)-(g) (2006); M.P.E.P. §§ 2137-38 (9th ed. Mar. 2014). Following the AIA, 35 U.S.C. § 102 is still used to define the scope of prior art. See 78 FED. REG. 11059, 11070 (Feb. 14, 2013) ("[T]he AIA sets forth what qualifies as prior art in two paragraphs of 35 U.S.C. 102(a).").

⁶ 35 U.S.C. § 102 (2012) (emphasis added).

⁷ 157 CONG. REC. S1496 (Mar. 9, 2011) (statement of Sen. Patrick Leahy).

⁸ 35 U.S.C. § 102(a)(1) (2012).

⁹ See, e.g., *Egbert v. Lippmann*, 104 U.S. 333, 336 (1881).

¹⁰ *Metallizing Engineering* 153 F.2d at 518 (quoting *Pennock v. Dialogue*, 27 U.S. 1, 19 (1829) (internal quotation marks omitted)). The doctrine described by Judge Hand in *Metallizing Engineering* is generally referred to as the forfeiture doctrine.

The phrase "or otherwise available to the public" was added to § 102 in the Senate's 2007 bill.¹¹ During Senate debate over the Patent Reform Act of 2011, then-Sen. Jon Kyl (R-Ariz.), a co-sponsor of the AIA, provided a number of reasons for changing § 102's definition of "prior art" to include "otherwise available to the public" and explanations for why the court should consider the added language limiting:

New section 102(a)(1) makes two important changes to the definition of non-patent prior art. First, it lifts current law's geographic limits on what uses, knowledge, or sales constitute prior art. And second, it limits all non-patent prior art to that which is available to the public. . . . The word "otherwise" makes clear that the preceding clauses describe things that are of the same quality or nature as the final clause—that is, *although different categories of prior art are listed, all of them are limited to that which makes the invention "available to the public."* As the committee report notes at page 9, "the phrase 'available to the public' is added to clarify the broad scope of relevant prior art, as well as to emphasize the fact that it [i.e., the relevant prior art] must be publicly available." . . .

The Committee's understanding of the effect of adding the words "or otherwise available to the public" is confirmed by judicial construction of this phraseology. Courts have consistently found that when the words "or otherwise" or "or other" are used to add a modifier at the end of a string of clauses, the modifier thus added restricts the meaning of the preceding clauses. [citing cases].

Moreover, the fact that the clause "or otherwise available to the public" is set off from its preceding clauses by a comma confirms that it *applies to both "public use" and "on sale."* . . . Thus new section 102(a)(1) imposes a public-availability standard on the definition of all prior art enumerated by the bill—an understanding on which the remainder of the bill is predicated.

The present bill's *elimination of the patent forfeiture doctrines* in favor of a general public availability standard also limits and reconciles the various purposes that previously have been ascribed to section 102's definition of prior art. Current 102(b), which imposes the forfeiture doctrines, has been described as being "primarily concerned with the policy that encourages an inventor to enter the patent system promptly," And the "overriding concern of the on-sale bar" has been described as "an inventor's attempt to commercialize his invention beyond the statutory term," . . .

By adopting the first-to-file system, however, the present bill already provides ample incentive for an inventor to enter the patent system promptly. There is no need to also require forfeiture of patents simply because the inventor has made some use of the invention that has not made the invention available to the public. And the current on-sale bar imposes penalties not demanded by any legitimate public interest. There is no reason to fear "commercialization"

¹¹ See 154 Cong. Rec. S1145 (2007); S. Rep. 110-259 at 42 (Jan. 24, 2008).

that merely consists of a secret sale or offer for sale but that does not operate to disclose the invention to the public.

The *current forfeiture doctrines* have become traps for unwary inventors and impose extreme results to no real purpose. [discussing cases]. . .

The present bill's new section 102(a) precludes extreme results such as these and eliminates the use of the definition of prior art to pursue varied goals such as encouraging prompt filing or limiting commercialization. Instead, *the new definition of prior art will serve only one purpose: "to prevent the withdrawal by an inventor of that which was already in the possession of the public,"* . . . The new definition is "grounded on the principle that once an invention is in the public domain, it is no longer patentable by anyone," . . .

I emphasize these points about the bill's imposition of a general public availability standard and its *elimination of secret prior art* because they are no small matter. A contrary construction of section 102(a)(1), which allowed private and non-disclosing uses and sales to constitute invalidating prior art, would be fairly disastrous for the U.S. patent system.¹²

Comments made by Sens. Patrick Leahy (D-Vt.) and Orrin Hatch (R-Utah) supported Kyl. Hatch stated that in order for an inventor's disclosure to constitute prior art under AIA 102(a), the disclosure must be "both made available to the public and enabled."¹³ Leahy agreed, stating that new paragraph 102(a)(1) imposes an overarching requirement for availability to the public.¹⁴

In June 2011, following Kyl's comments, the House amended the bill to strengthen prior user rights under § 273.¹⁵ On the day the AIA was passed, Kyl reiterated that his previous remarks on March 8, 2011 "obviously apply to the [amended] bill as well."¹⁶

The Supreme Court has cautioned that an individual senator's comments in support of legislation are not controlling.¹⁷ This principle may hold true even if the senator is the bill's sponsor.¹⁸ In analyzing the legislative history of a statute, a legislator's remarks must be

considered alongside congressional reports and "statements of other Congressmen."¹⁹ If a legislator's interpretation is refuted by these reports or statements, a court may accord little weight to that legislator's interpretation.²⁰ Kyl's comments were not inconsistent with congressional reports or otherwise challenged by a contrary point of view. Accordingly, in analyzing the legislative history of AIA § 102(a), a court would probably attach weight to the comments advanced by Kyl.

Textual canons of statutory construction also support a narrowing of AIA 102. The "last antecedent rule" is one often-cited textual canon.²¹ The last antecedent rule states that "[r]eferential and qualifying words and phrases, where no contrary intention appears, refer solely to the last antecedent."²² Accordingly, a proviso is usually construed to apply only to the provision or clause immediately preceding it.²³ This rule is not uniformly binding, however, and may be trumped by the "punctuation rule."²⁴ The punctuation rule provides that "evidence that a qualifying phrase is supposed to apply to all antecedents instead of only to the immediately preceding one may be found in the fact that it is separated from the antecedents by a comma."²⁵ This suggests that the phrase "or otherwise available to the public" applies to all of the antecedents that precede it and not simply to the immediately preceding antecedent. Thus, the punctuation rule indicates that the "or otherwise" qualifying phrase modifies "in public use," along with the other recited forms of prior art.

And, there is at least one reported decision by the U.S. Supreme Court holding that a similar phraseology ("or otherwise involves conduct that presents a serious potential risk of physical injury to another") in the Armed Career Criminal Act applied to all antecedents.²⁶

The U.S. Patent and Trademark Office has also supported an interpretation of AIA § 102 to be narrowing.²⁷

While the courts should interpret AIA 102(a) to be narrowing, thereby overruling the forfeiture doctrine under *Metalizing Engineering*, the U.S. Supreme Court may ultimately decide otherwise and find that the statute is clear on its face – thereby expanding the scope of invalidating prior art.

AIA Also Strengthened Prior User Rights

Prior to the AIA, 35 U.S.C. § 273 provided a very limited prior-user rights defense.²⁸ The AIA greatly expanded this defense to cover any "process, or . . . machine, manufacture, or composition of matter used in a manufacturing or other commercial process" that had been commercially used at least one year prior to either

¹² 157 Cong. Rec. S1335, 1370-1371 (daily ed. Mar. 8, 2011) (statement of Sen. Jon Kyl) (emphasis added) (internal citations omitted). See also 157 Cong. Rec. S5319-S5321 (daily ed. Sept. 6, 2011) (stating that "[a]nother one of the bill's clear improvements over current law is its streamlined definition of the term 'prior art'. Public uses and sales of an invention will remain prior art, but only if they make the invention available to the public. An inventor's confidential sale of his invention, his demonstration of its use to a private group, or a third party's unrestricted but private use of the invention will no longer constitute private art. Only the sale or offer for sale of the invention to the relevant public or its use in a way that makes it publicly accessible will constitute prior art.")

¹³ 157 Cong. Rec. S1496 (daily ed. Mar. 9, 2011) (statement of Sen. Orrin Hatch).

¹⁴ *Id.* (statement of Sen. Patrick Leahy).

¹⁵ See H.R. Rep. No. 112-98 (June 1, 2011); H.R. Rep. No. 112-111 (June 21, 2011).

¹⁶ 157 Cong. Rec. S5402, S5429 (daily ed. Sept. 8, 2011) (statement of Sen. Jon Kyl).

¹⁷ *Mims v. Arrow Fin. Servs., LLC*, 132 S. Ct. 740, 752 (2012) (citing *Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc.*, 447 U.S. 102, 118 (1980)).

¹⁸ *Id.*

¹⁹ *Chrysler Corp. v. Brown*, 441 U.S. 281, 311 (1979).

²⁰ See *id.*

²¹ WILLIAM ESKRIDGE, JR. ET AL., *Cases and Materials on Legislation: Statutes and the Creation of Public Policy* 857. WEST ACADEMIC PUBLISHING, (2007).

²² NORMAN J. SINGER, *SUTHERLAND STATUTES & STATUTORY CONSTRUCTION* 369. THOMSON/WEST GROUP, (2000).

²³ *Id.* at 371.

²⁴ Eskridge, p. 858.

²⁵ Singer, p. 373.

²⁶ *James v. U.S.*, 550 U.S. 192, 196 (2007) (quoting Armed Career Criminal Act (ACCA), 18 U.S.C. § 924(e)(B) (2000 ed.)).

²⁷ See Edward Manzo, *The Impact of the America Invents Act on Trade Secrets*, 13 J. MARSHALL REV. INTELL. PROP. 497, 507-08 (2014).

²⁸ 35 U.S.C. § 273 (2006).

(1) “the effective filing date of the claimed invention” or (2) “the date on which the claimed invention was disclosed to the public in a manner that qualified for the [§ 102(b) prior art exception].”²⁹

Under 35 U.S.C. § 273(e)(1)(A), the defense extends beyond the direct user of a trade secret to include those who “performed or directed the performance of the commercial use,” as well as to “an entity that controls, is controlled by, or is under common control with such person.”³⁰ This would include contractors, vendors and corporate parents and subsidiaries charged with induced or contributory infringement.

The “prior-user rights” defense may also be asserted by a third-party to the trade secret as a successor-in-interest. Under § 273(e)(1)(B), the defense is personal and cannot be “licensed or assigned or transferred to another person” unless it is a “good-faith assignment or transfer. . . of the entire enterprise or line of business to which the defense relates.”³¹ This defense is further limited under § 273(e)(1)(C) geographically to only those sites where the trade secret was “in use before the later of the effective filing date of the claimed invention or the date of the assignment or transfer of such enterprise or line of business.”³²

Balancing Trade Secret And Patent Protection

There are a number of factors to consider when weighing the risks and advantages of patents and trade secrets. It is important to have a strong trade secret protection program in place during the early stages of development. This will protect information that offers a competitive advantage, such as a new product or process, as well as “negative know-how” and knowledge about what does not work or is less than optimal. During the development phase, decision points should be added to determine if the inventive idea is ready for commercialization, and if a new method of protection might be needed. When making a decision to file for patent protection, one may ask: (1) what is the value of keeping the invention secret, (2) is the invention at risk of reverse engineering, (3) what will be the impact if the trade secret is patented and disclosed, and (4) does the trade secret represent patent eligible subject matter? While not an exhaustive list, these questions can help a company weigh its risks and opportunities.

What Does AIA § 102(a) Mean For The Biotechnology Industry?

Information that biotechnology companies keep as trade secrets has increased. This information includes details regarding clinical trial design and strategy; cell growth conditions; analytical, manufacturing and purification processes; and features of producer cell lines.³³ This increase may be attributed, at least in part, to increased market competition, especially with biosimilars.³⁴ While some of this information may not qualify

²⁹ 35 U.S.C. § 273 (2012).

³⁰ 35 U.S.C. § 273(e)(1)(A) (2012).

³¹ 35 U.S.C. § 273(e)(1)(B) (2012).

³² 35 U.S.C. § 273(e)(1)(C) (2012).

³³ See *Best Kept Secrets*, 32 NATURE BIOTECH. 499 (2014).

³⁴ *Id.*

for a patent under 35 U.S.C. §§ 101, 102 and 103, companies should be aware that AIA § 102(a) will not prevent the patenting of trade secrets that have been commercialized previously.

Under the Biosimilars Price Competition and Innovation Act of 2009 (“BPCIA”), a pioneer product receives 12 years of exclusivity.³⁵ After that, a generic competitor is permitted to rely on the FDA’s finding that the pioneer product was safe, pure and potent, based on the trade secrets disclosed in the pioneer application.³⁶ Thus, a biotechnology company may choose to file patent applications on trade secret processes in advance of the expiration of the 12-year period of exclusivity. This may be a nasty surprise for a generic biosimilar company if the patented process is the only way to manufacture a true biosimilar. Thus, a generic biosimilar company should consider starting work early on the making and testing of a biosimilar drug in the hopes of invoking the prior-user-rights defense should the innovator file a patent application.

What Does AIA 102(a) Mean For The Electrical/Software Industry?

The Supreme Court’s 2014 *Alice Corp. v. CLS Bank* decision substantially limited the patenting of abstract ideas in business method and software patents.³⁷ Other court decisions, a decrease in district court litigation and an increase in PTAB reviews³⁸ have caused companies to question whether they should file for patent protection, rely on trade secret protection, or both.

In the electronics industry, companies should ask two questions when considering whether to file a patent application. First, is the inventive idea patentable? Second, is the inventive idea vulnerable to reverse engineering once commercialized? Inventions that are resistant to reverse engineering are good candidates for trade secret protection, while inventions that are vulnerable to reverse engineering are good candidates for patent protection.

Product life cycles in the electronics industry are typically much shorter than those in the biotechnology industry—so there is much less probability that long-held trade secrets will be patented, in view of the pace at which the electronics industry develops technology. By the time long-held trade secrets are filed in patent applications, the sheer volume of intervening prior art would likely render such filings unpatentable.

Trade secret and patent protection may be combined to protect a software method and process as a patent, and protect the software’s source code as a trade secret. Trade secret protection can also be combined with federal copyright protection for software.

³⁵ Richard Epstein, *The Constitutional Protection of Trade Secrets and Patents under the Biologics Price Competition and Innovation Act of 2009*, 66 FOOD & DRUG L. J. 284, 286-87 (2011).

³⁶ *Id.*

³⁷ *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347 (2014) (holding certain methods or processes drawn to an abstract idea are not patentable simply because they are implemented with a computer).

³⁸ Brian Howard, *Patent Case Trends and the Business of Litigation*, Lex Machina, <https://lexmachina.com/patent-case-trends-business-litigation/>, (February 5, 2015).

Conclusion

The AIA has substantially narrowed the scope of prior art to include only what is available to the public. This allows the patenting of trade secrets years after they have been exploited commercially, possibly leading to some unpleasant surprises for companies who have carried out freedom-to-operate studies, only to

find out that the innovator filed a patent application many years after the invention was first commercialized.

*A white paper with detailed legal research on this topic may be obtained by contacting the authors at resmond@skgf.com or donf@skgf.com.