

## Intellectual property issues around nanotechnology

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# What nanotech inventors need to know about trade secrets and the prior user rights defense

**Abstract:** The America Invents Act (AIA) presents new challenges and strategy considerations for nanotechnology inventors and companies that seek to protect their intellectual property in the United States. Among the many notable changes, the AIA expands the “prior user rights” defense to infringement and broadens the classes of patents that are eligible for the new limited prior user rights defense. While this defense is limited in some instances, such as against universities, it could be invaluable in others, such as when a competitor independently discovers and patents the trade secret. In the world of nanotechnology, where inventions and products are increasingly complex, this protection can prove to be vitally important.

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## 1 Together, trade secrets and patents create strong IP protection

The term trade secret refers to information that is maintained in secrecy and has commercial value. The most recent definition of *trade secret* is set forth in Restatement (Third) of Unfair Competition [Restatement (Third) of Unfair Competition, § 39]:

A trade secret is any information that can be used in the operation of a business or other enterprise and that is sufficiently valuable and secret to afford an actual or potential economic advantage over others.

The Uniform Trade Secrets Act (UTSA), which has been adopted by 47 of the 50 States, defines *trade secret* as [UTSA, § 1(4)]. The UTSA has been adopted by all U.S. States except New York, North Carolina, and Massachusetts. Legislation to enact the UTSA is currently pending in Massachusetts. The UTSA has also been adopted by the District of Columbia, Puerto Rico, and the U.S. Virgin Islands. <http://www.uniformlaws.org/Act.aspx?title=Trade%20Secrets%20Act>]:

(4) “Trade secret” means information, including a formula, pattern, compilation, program, device, method, technique, or process, that: (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

In some instances, trade secret protection is not viable (such as when the nanotechnology invention is readily observable and can be reverse engineered when a product is released). However, due to the inherent nature of many nanotechnology inventions, the nanotechnology invention is often not readily observable or capable of being reversed engineered. In such instances, a decision must be made whether to protect the nanotechnology invention by filing a patent application or by maintaining the invention as a trade secret. Applying for patents on every one of the many inventions that go into today’s complex nanotechnology inventions can be time and cost prohibitive. In some cases, the resulting patents would be so specific that they would have limited commercial value. Moreover, trade secrets can typically be less costly to maintain, at least initially, as costs are not incurred for filing and prosecution of the trade secret.

Thus, certain nanotech inventions may be more effectively leveraged if they were held as trade secrets instead of being disclosed to the world through the patenting process. The significant risk in choosing the trade secret route is that a competitor could independently develop the technology and obtain patent protection that precludes the trade secret owner from using its own trade

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secret. Accordingly, the decision as to whether to protect a particular nanotechnology invention through a patent or a trade secret should generally be on a case-by-case basis, through the company's IP strategy, and after consultation with the company's technical staff and legal counsel.

In combination, patents and trade secrets are an important facet of IP strategy. Patents (which require full disclosure) and trade secrets (which are kept confidential) can complement one another: patents protect inventions and trade secrets protect collateral know-how. For example, as licensing has become the preferred approach for technology transfer, most technology licenses cover both patents and trade secrets. Using a patent strategy to protect aspects of an innovation program that can be reverse engineered while simultaneously using a trade secret strategy to protect aspects of the innovation program that can be difficult to reverse engineer together in a synergistic manner can result in potent IP protection. However, despite the ease of obtaining trade secret protection, it is often not exploited to the full effect. With the AIA's expansion of the prior user rights defense, that may change.

The expansion of the prior user rights defense may lead to greater reliance on trade secret protections for many commercial inventions, including those in the nanotech sector. A trade secret owner who thoroughly documents the commercial activity at issue should be able to withstand a claim of patent infringement if he or she meets the criteria for this defense [35 U.S.C. §273 ("Defense To Infringement Based On Prior Commercial Use")]. Thus, if an invention is retained as a trade secret, and a competitor replicates that invention through a patent application, the new prior user rights defense can play a key role in determining the outcome of a patent infringement lawsuit.

For instance, if Nanotech Company A was commercially using Nanotech Company B's patented invention by a sufficiently early date, that commercial use can inoculate Nanotech Company A against an infringement finding. Under the prior user rights defense, Nanotech Company A is free to continue using the invention without paying any royalties to Nanotech Company B who has patented it. Nanotech Company B can sue others for infringement, but Nanotech Company A is not liable.

## 2 The AIA expands the prior user rights defense

Prior to the AIA's enactment, the prior user rights defense was limited to business methods patent infringement

claims. Under that defense, a defendant could avoid liability if, acting in good faith, he or she "actually reduced the subject matter to practice at least one year before the effective filing date of such patent, and commercially used the subject matter before the effective filing date of such patent."

The AIA greatly expanded the scope of these rights. One of the reasons that Congress expanded the prior user rights defense was to bring the U.S. in line with other countries that provide a similar defense and level the competitive playing field. As Representative Lamar Smith (R-TX), one of the AIA's sponsors, explained in a June 2011 speech in the House of Representatives [Congressional Record Vol. 157, No. 94, (June 28, 2011), Extension of Remarks, E1219, America Invents Act, speech of Hon. Lamar Smith of June 22, 2011.]:

The inclusion of prior user rights is essential to ensure that those who have invented and used a technology but choose not to disclose that technology – generally to ensure that they not disclose their trade secrets to foreign competitors – are provided a defense against someone who later patents the technology.

The AIA extended the prior user rights defense from business method patents to patents for processes, machines, manufactures, and compositions of matter issued after September 16, 2011. According to the new provisions, if a company is sued for patent infringement, there is a new defense that could prove valuable.

First, the prior commercial use must take place more than 1 year before the effective filing date of the patent application or public disclosure by the patentee. The defending party must also show that the invention or process was, in good faith, commercially used in the US in an internal commercial use or other transfer that resulted in a commercial use. The onus is on the defending party to prove this prior user rights defense by "clear and convincing" evidence, which means the evidence must show that the prior user rights defense was "highly probable" (a higher evidentiary standard than proof by a preponderance of the evidence) [*Colorado v. New Mexico*, 453 U.S. 310, 316-317 (1984)].

At the same time, the AIA includes several limitations and exceptions to the prior user rights defense, including a prohibition against license, assignment or transfer of the defense, other than in connection with an assignment or transfer of the entire business to which the defense relates; the defense is geographically limited to cover only those sites where the invention was used before the critical date; and there is an explicit exception to the defense for patents owned by or assigned to universities or affiliated technology transfer organizations. These

limitations and exceptions to the prior user rights defense address the equitable interests of patentees, universities, and affiliated organizations [Report On The Prior User Rights Defense, United States Patent & Trademark Office ([http://www.uspto.gov/aia\\_implementation/20120113-pur\\_report.pdf](http://www.uspto.gov/aia_implementation/20120113-pur_report.pdf)), at 1].

### 3 Benefits of the prior user rights defense

Essentially, the AIA's expansion of prior user rights enhances the value of trade secrets. Generally, large companies have the resources to ensure that they file for a patent first and have dealt with first-inventor-to-file systems in other countries. As a result, independent inventors who begin to commercialize their inventions, but do not promptly file for a patent, seem to be the likely beneficiaries of the new prior user rights defense. With this in mind, there are several direct benefits that prior user rights defense offers:

- **New options.** The expanded prior user rights defense provides small and large nanotech companies with an additional option for IP protection. A company can choose to patent an invention or process, or if that company does not want to incur the expense of a patent, it now can elect to use the underlying invention or process in secret.
- **More economical.** Protecting an invention or process as a trade secret is significantly less expensive than patent prosecution and application, and certainly less expensive than the costs involving a patent infringement case. However, it is critical to remember that given the clear and convincing evidentiary standard for proving this defense, there will be a premium on thoroughly documenting the prior use. Lab notebooks, quality control documents, engineering drawings and specifications will all need to be preserved for the inventions and processes that a user elects not to patent.
- **Fewer defensive patent filings.** The prior user rights defense should reduce the number of “defensive” patent filings in which companies file patent applications simply to avoid being precluded from using or developing an invention, process, or technology. These defensive patents are a drain on the resources of businesses and a strain on an already over-burdened USPTO.

### 4 Meticulous documentation is critical to success

In some respects, the patent system's shift from a first-to-invent to a first-inventor-to-file system suggests that inventors do not have the same need to preserve invention records [Under the AIA, there still is a need to maintain this type of information to memorialize inventorship activities in case a derivation dispute arises as to whether the applicant of a first-filed patent application derived the invention from the inventor of a later-filed patent application. 35 U.S.C. § 135 (Derivation Proceedings)]. Such documentation was typically relied upon in interference proceedings to establish earlier dates of conception, reduction to practice, and diligence. However, preserving research and development documentation can still be important for the prior user rights defense.

In order to be able to assert the prior user rights defense, a trade secret holder must document reduction of the subject matter to practice at least 1 year before the effective filing date of the patent and support that reduction with commercial use before the effective filing date of such patent. Because the success of that defense will depend on the ability to show early commercial use of the invention, meticulous documentation will be needed.

Nanotech companies that want to take advantage of the prior user rights defense need to act now to preserve the factual evidence that will be used to establish their prior use. Startups and other companies that rely on their own internal, unpatented technology are well advised to document their development and implementation of the technology to ensure the earliest possible date for prior use. Specifically, companies should continually monitor and maintain their trade secret records, including as follows:

- Establish and follow a policy of maintaining detailed records and documentation, including those materials recording the conception, design, development, prototypes, testing, and initial release/commercial use of the technology.
- Document the company's commercial processes, particularly internal methods that are not readily apparent from company's products.
- Regularly create and maintain documentation showing ongoing commercial use of the technology.
- Have relevant personnel maintain laboratory notebooks that are periodically witnessed by others. These notebooks should record research activities of the technology throughout the design, test, and

development activities. In each notebook, the entries should be set forth in chronological order (without blank pages) and written in ink.

- Maintain computer printouts, photographs, receipts, order forms, cancelled checks, invoices, technical specifications, user manuals, operating procedures, and test results. These can be incorporated into the laboratory notebooks or maintained and preserved separately.
- Submit a full laboratory notebook to a central repository [or other custodial place(s)] for safekeeping. Another laboratory notebook can then be issued to the relevant personnel for future documentation.
- Archive/store computer data. These data should be time stamped to reflect when archived/stored.
- When the commercial use is performed (in part) by third parties (i.e., distributors, suppliers, end users), create and maintain documentation reflecting such third party commercial use activities, including documentation from the third parties.
- Designate a particular person (or group) that is responsible for implementing these procedures and to periodically audit and monitor that such procedures are being followed.

Such meticulous documenting will also reduce deterrents that would otherwise weigh against the raising of a prior user rights defense. Such documentation would support the defending party's prior user rights defense had a "reasonable basis." In the absence of a reasonable basis, the AIA makes clear the Court *shall* find the case exceptional for the purposes of awarding attorney fees against the defending party's unsuccessful prior user rights defense.

While the full impact of the prior user rights defense on the American patent landscape will not be known for many years (again, this defense is limited to only those patents that issued after September 16, 2011), it can be an asset for the many companies that innovate today's increasingly complex nanotechnology technologies.

Companies that take the time to document their prior commercial use will be in the best position to take advantage of the broader prior user rights defense offered by the AIA. Regardless, nanotech companies should view the prior user rights defense as a complement to their IP strategy, and they can and should continue to patent their inventions as they always have.

## Bionotes



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