

Legal & Regulatory Update

Staking an advantage in an AIA world: Practical patent tips for biotechnology companies

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ABSTRACT

With passage of the Leahy-Smith America Invents Act (AIA), new rules and procedures related to the application of prior art now apply to patenting under a "first-inventor-to-file" system. This article summarizes certain key prior art provisions that biotechnology companies should be aware of and details practical steps that can be implemented to help stake a competitive advantage under the new law including the use of patent liaisons, early provisional and patent application filings, and in certain circumstances, defensive publication of patentable subject matter.

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INTRODUCTION

THE LEAHY-SMITH INVENTS Act, informally known as the "AIA," was signed into law September 16, 2011, and represented the first major overhaul of the United States patent system in over 60 years.¹ From opinion pieces to detailed technical analysis, an overwhelming amount of literature has already been written on the intricacies of the new law.² This has led to an information glut, and consequentially, many managers, CEOs, scientists and even patent counsel are left without clear directions for responding to the new law. As detailed below, however, practical steps can be taken to gain a competitive advantage in a company's intellectual property (IP) space by implementing simple steps including early patent filing, strategic defensive disclosures and the use of "patent liaisons."

REASSESS AND ADDRESS

The most significant shift resulting from passage of the AIA altered the U.S. patent law from a first-to-invent (FTI) to a first-inventor-to-file (FIF) system. While the policy debate on the merits of this sea change show no signs of waning, beyond debate is the need for biotechnology companies to reassess their intellectual property policies and procedures from both an offensive vantage point (e.g., the filing, prosecution and enforcement of patents) and a defensive one (e.g., patent challenges and defensive disclosures).³ A central issue relates to the AIA's provisions regarding novelty, i.e., the circumstances under which the claimed subject matter of a patent is deemed to have been already known to the public before the filing date of a patent. The AIA's novelty provisions are set forth in the Patent Law at section 102(a), which is reproduced in part below in Box A.⁴

Subject to very important but narrow exceptions, these new novelty provisions of the AIA establish a strict standard by which nearly any public disclosure of a claimed invention will obviate patentability. The exceptions, detailed in the following section 102(b), entitle the inventor to a 1-year grace period for the first public disclosure of the claimed subject matter.⁵ Notably, the

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**Box A: 35 U.S.C. § 102(a)
(Conditions for patentability; novelty)**

“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

(2) the claimed invention was described in a patent ... or in an application for patent published ... in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.”

grace period also applies to other parties' disclosures if the inventor was first to publically disclose the invention. The House Report on these new prior art laws succinctly summarizes the new reach: “Prior art will ... typically include all art that publicly exists prior to the filing date, other than disclosure by the inventor within 1 year of filing.”⁶ Moreover, in contrast to pre-AIA law, there no longer are geographic exceptions to applicable prior art: art, as well as public use and on-sale activities, anywhere in the world can now be used.⁷

What this means practically is that if a company scientist invents something new before anyone else, but is not first to either publicly disclose or file a patent application, a competitor can obtain a patent notwithstanding the later invention date. A corporation must address this change in the law by implementing new policies, as discussed next.

FILE PATENT APPLICATIONS EARLY

Passage of the AIA led to criticism that the new patent law would provide a disadvantage to smaller companies.⁸ Arguably, larger companies would have the resources to form and maintain high-throughput internal patenting and invention disclosure procedures leading to rapid filing of patent applications. Because the law no longer awards patents to the first inventor-to-file, a company with an efficient means for capturing patentable subject matter and filing a patent application could conceivably race to the Patent Office before a smaller competitor.

Smaller companies can nonetheless compete with minimal resources by instilling a corporate “publish, file or perish” mandate.⁹ The goal is simple: move patentable subject matter quickly to the Patent Office, or

in some cases, publish to stake an early line in the sand and capture incremental IP space. Successful implementation requires establishing in-house procedures to ensure ideas are captured early and then disclosed in usable form for drafting as a patent application or public disclosure. This requires managed oversight of the disclosure process. The goal being to decrease the lag time from the point of an inventor's conception of an idea to in-house disclosure, followed by public or Patent Office filing, with the latter preferable. Borrowing from the legislative mandate for *inter partes* review of patents, such disclosure or filing should be made with “special dispatch.”¹⁰ One relatively low-cost means for implementation involves centralizing responsibility for IP disclosure, which can be done using an IP liaison.

A CENTRAL AUTHORITY: THE INTELLECTUAL PROPERTY LIAISON

An IP liaison is so named because the post functions to facilitate a close working relationship between scientists, management, and patent counsel.¹¹ Moreover, the liaison will serve to ensure that inventions are properly documented, witnessed and recorded, in part by reaching out to department heads and obtaining regular updates on potential patentable subject matter. For example, the team head for a group in a particular technical field may provide a monthly update of potential new IP disclosures and developments on prior disclosures. Where new potential IP space can be captured, the liaison will then identify likely inventors and task them with the creation of an invention disclosure form (IDF) recording pertinent facts related to the scope of the invention.¹² Because the liaison is aware of disclosures among different departments, he/she can also determine whether cross-patenting is a possibility.¹³

The liaison will in turn work with patent counsel to analyze completed IDFs for patenting readiness by initiating preliminary prior art evaluations. Subsequently, the liaison will either recommend the drafting of a patent application, a defensive publication, or communicate with team heads where further research and development is needed to obtain patentability. The IP liaison's role can also be expanded to allow coordinated efforts to identify areas of virgin IP space that can be captured. Such IP space is characterized by a dearth of prior art in the technical field under study by laboratory heads.¹⁴ Lastly, the IP liaison can serve as a repository for template invention disclosure forms and patent applications. By managing control over such forms and applications, the liaison can ensure uniformity in the disclosure and patenting process. Most

Box B: An IP Liaison can not only ensure that best practices are followed, but that patent disclosures and applications are efficiently drafted and submitted among other duties.

The IP Liaison: Roles & Responsibilities		
Point Person and Go-Between for Inventors, Department Heads, Managers and Patent Counsel	Assist in Drafting Invention Disclosure Forms (IDFs) and Patent Applications	Monitor Patent Prosecution
Monitor Department Heads Vis-à-Vis Intellectual Property Issues	Oversee Brain-Storming Sessions for Capturing IP Space	Monitor and Disseminate Patent and Prior Art Data
Maintain Template Invention Disclosure Forms (IDFs) and Patent Applications	Create and Maintain IP Databases	Perform IP Training
Ensure Best-IP Practices Compliance	Provide IP Updates on Regulatory Issues	Monitor Competitor IP and Track In-House IP Projects
Locate and Capture “Free” Patent Space in Key Technical Fields	Bolster Recognition of the Importance of IP Protection	Develop In-House IP Policy

importantly, the liaison can distribute template invention disclosure forms and employ a uniform disclosure process. This will improve efficiency in communicating with patent counsel without impacting the quality of patent applications. The various roles and responsibilities that may be assigned to an in-house IP liaison are summarized in Box B.

Under the AIA regime, patenting is now a race to the Patent Office. Optimizing the disclosure process, which can be implemented using patent liaisons, is an important step to getting there first. The suitability of various forms of disclosure under the new AIA regime is considered next.

USE OF PROVISIONAL PATENT APPLICATIONS AND PUBLIC DISCLOSURES

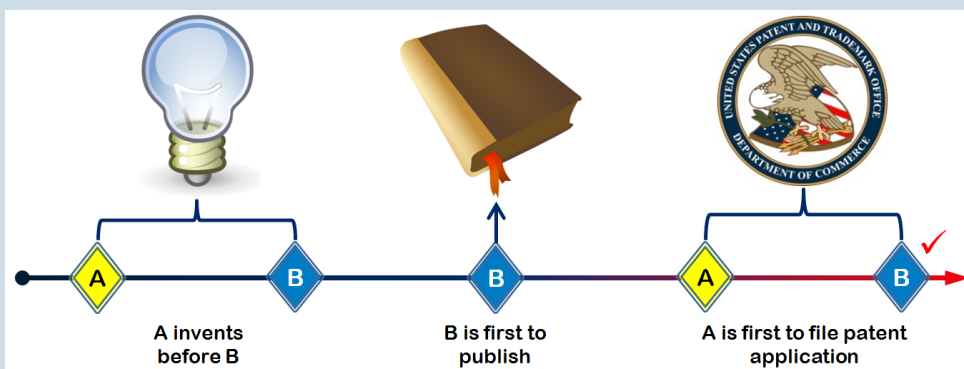
Under the AIA, applications with a claimed invention having an effective filing date on or after March 16, 2012 are generally subject to the new framework with respect to prior art. As detailed above and codified in section 102 of the Patent Law, publications, patents, sales and uses, that are public before an applicant’s effective filing date can be invalidating prior art.¹⁵ Moreover, certain patent publications by another that are filed before the applicant’s effective filing date can also be prior art. It is therefore critical that a corporation determine whether to take advantage of the one-year grace period for making prior art disclosures. This is because pre-filing disclosure can serve to overcome the earlier filing of an application to the *same* subject matter by a competitor (or other intervening

prior art), as illustrated below in Box C.¹⁶ Box C also highlights that the relative dates of invention under the AIA no longer determine the scope of applicable prior art.

Under the AIA’s First Inventor-to-File rules, in the absence of pre-filing disclosure,¹⁷ the AIA favors the first filer among multiple filings with the Patent Office toward the same invention. Thus, the effective filing date of a patent application—not the conception date of an invention—is the *sine qua non* determinative of the applicable prior art. Provisional filings provide a convenient means for helping ensure an early effective filing date. Because provisional filings are low-cost, even cash-strapped companies can stake a line in the sand.¹⁸ Because an applicant has one year to file a final non-provisional application, an initial provisional filing can *and should* be supplemented with additional provisional filings in a rolling manner that add additional disclosure or address any issues with prior disclosures.

As an alternative to provisional patent applications, a corporation can also consider the use of other public disclosures to offset the chance that a competitor will be first-to-file. These disclosures can include the use of low-cost “grey literature”—informally published but publically available written materials (like white papers)—or press releases and tradeshow abstracts/materials. While provisional applications do not become publically accessible until after the filing of a non-provisional application and publication of that application, other public disclosures are generally immediately available.¹⁹ A corporation will have to consider whether early public disclosure is preferable to disclosure by means of a provisional filing.²⁰ The former may be preferable where it is clear that patent protection is not desired; public disclosure in this case serves

Box C: Under the AIA, Inventor A loses to Inventor B despite an earlier invention date and patent filing because Inventor B was first to publish (disclose) the claimed invention.



a defensive purpose by setting forth potentially invalidating prior art. In contrast, a provisional application avoids the risk that comes with public disclosure, i.e., that the public disclosure will fail to meet an exception under the prior art provisions and become prior art to a company's own patent application. Close consultation with IP counsel on these alternatives is paramount.

MONITOR COMPETITOR PATENTING, KNOW THE PRIOR ART AND DISCLOSE

Among the key provisions of the AIA related to prior art, the AIA now provides for expanded options for pre-grant oppositions.²¹ In particular, third-parties can now submit prior art from any part of the world related to a patent application within certain timeframes, as well as any statements made by the applicant to the Patent Office or before a federal court. Moreover, such submissions may include explanations of the pertinence of the prior art.

Because a corporation should include in its IP due diligence a continuing analysis of the prior art landscape related to any target or competitor technology, such materials are useful not only in the planning and prosecution of a corporation's patent applications, but may be used offensively against competitors. Defensively, early disclosure of potential prior art before the Patent Office can be used to offset the risk that the prior art will be used successfully by a competitor in a pre-grant filing.

INFORM, INFORM, INFORM

A sea change in patent law has occurred. But far from a one-off event, continued changes are on the horizon as

the Patent Office and the courts begin interpreting and implementing the law to actual patent cases. This article has provided some practical advice with respect to a small subset of the new AIA law. A corporation should ensure that its employees are continuously informed and updated on patent law developments, and that its scientists adhere to good patent disclosure practices. Implementation of a patent liaison and appreciation of the role of prior art under the AIA is one solid step in the right direction. Continued vigilance and early patent application filing is the next.

ENDNOTES

1. Leahy-Smith America Invents Act, H.R. 1249 (112th Congress, First Session), enacted (President Obama) 16 September 2011, available online at <http://www.gpo.gov/fdsys/pkg/PLAW-112publ29/content-detail.html> (accessed 24 February 2014).
2. See, e.g., American Intellectual Property Law Association (2012) Summary of the America Invents Act. <http://www.aipla.org/advocacy/congress/aia/Pages/summary.aspx>, accessed 26 February 2014 (providing a succinct summary of key provisions); Uthaman, S., Lu, D., and Kowalski, T. (2012) Post-grant review: The good, the bad and the ugly for biotechnology companies. *Journal of Commercial Biotechnology* 18(1): 97–99 (discussing new opposition procedures); Intellectual Property Owners Association (2011) Comparison of Selected Sections of Pre-AIA and AIA U.S. Patent Law https://www.ipo.org/wp-content/uploads/2013/03/Patent_Reform_Chart_Comparison_of_AIA_and_Pre-AIA_Laws_FINAL.pdf, accessed 26 February 2014.

3. See, e.g., Fox, J. (2011) America Invents Act receives cautious welcome. *Nature Biotechnology*. 29: 953–954; Rondeau, G. (2011) “America Invents Act” patent law overhaul: the benefits and the drawbacks. *Lexology*. 17 November. <http://www.lexology.com/library/detail.aspx?g=5f772592-7ac2-41bc-becb-d3ff5c8ed192>, accessed 26 February 2014.
4. The full text of Title 35 of the United States Code (U.S.C.), Section (§) 102 (enacted 2012) is available online at http://www.law.cornell.edu/uscode/text/35/102?qt-us_code_tabs=0 (accessed 26 February 2014).
5. See 35 U.S.C. § 102(b) (setting forth exceptions for disclosures made 1 year or less before the effective filing date of the claimed invention and for disclosures appearing in applications and patents).
6. Commonly owned disclosures, i.e., subject matter disclosed in the published application or patent and the claimed invention were owned by or subject to an obligation of assignment to the same person, made within a U.S. patent, patent application, or PCT application are also excepted as prior art.
7. It is not yet clear whether private use and on-sale activities may be considered prior art “available to the public” under the new § 102. See 35 U.S.C. § 102(a).
8. See, e.g., Rao N. (2013) Opinion: AIA Does Not Discriminate. *The Scientist*. 21 August. <http://www.the-scientist.com/?articles.view/articleNo/37133/title/Opinion--AIA-Does-Not-Discriminate/>, accessed 26 February 2014 (arguing that the AIA does not discriminate against academics and small biotech firms).
9. The “paradox of large organisations,” in which companies with great assets are successfully out-competed by smaller and newer companies has been previously described, and suggests it is managerial efficiency and not assets, that determine winners in the marketplace. See Luke Johnston (2011) The biggest groups are ill with inefficiency. *Financial Times*. 5 April. <http://www.ft.com/intl/cms/s/0/863409bc-5fca-11e0-a718-00144feab49a.html#axzz2uMzj3yLQ>, accessed 25 February 2014
10. See 35 U.S.C. § 305 (Conduct of reexamination proceedings).
11. See Knight, J. (2013) Patent strategy for researchers and research managers, 3rd ed. Chichester, West Sussex, U.K.: John Wiley at ch. 3 (discussing use of patent liaisons).
12. Some have argued that practices under the pre-AIA world related to documentation of an invention’s conception and reduction-to-practice are of lesser import now that a first-inventor-to-file system has been implemented. Nonetheless, good practices should still be adhered to for use in potential derivation proceedings and to ensure that the scope of an invention is accurately and quickly translated into a fulsome patent application. See, e.g., Lu, D., Kowalkski, T., Uthaman, S. (2012) Are laboratory notebooks necessary in a first inventor to file world? *Journal of Commercial Biotechnology*. 18(3): 67–68.
13. For example, one department may have ideas relating to improved gene amplification techniques, and another department may have ideas relating to improved gene silencing techniques. The IP liaison can help determine whether potential IP space can be captured involving a combination of those techniques. The resulting combination patents are more likely to survive prior art challenges where a motivation to combine those techniques has not been previously demonstrated or suggested.
14. See e.g., Rzucidlo, G. and Miller, S. (2008) Aggressive Intellectual Property Strategies. In Friedman, Y. (ed.) *Best Practices in Biotechnology Business Development*, ed. Yali Friedman, US: Logos Press, pp. 61–80 (discussing the use of strategic patenting to capture free IP space).
15. The “effective filing date” of a claimed invention is defined to be the earlier of the actual filing date of a nonprovisional application and the date to which the nonprovisional application claimed domestic benefit or foreign priority of another application describing the claimed subject matter. See AIA Frequently Asked Questions (2013). USPTO, 30 October. http://www.uspto.gov/aia_implementation/faqs_first_inventor.jsp, accessed 26 February 2014.
16. See 35 U.S.C. § 102(b)(2)(B) (setting forth that as to a later filed application, an earlier-filed application or patent is not prior art under § 102(a) if the inventor(s) of the later filed application publically disclosed the claimed invention within the 1-year grace period and prior to the effective filing date of the earlier filed application). Importantly, patent counsel should be consulted when considering a pre-filing disclosure because such disclosures can have other consequences such as affecting patenting rights in foreign jurisdictions or serving as prior art against a company’s own later filed patent applications where a disclosure does not meet a prior art exception.
17. Importantly, the grace period does not apply where the difference between the subject matter in the prior art disclosure that is relied upon under 35 USC § 102(a) and the publically disclosed subject matter of the inventor are different (*even if the difference is trivial or obvious*).

18. Such filings should be as complete as possible to ensure that later claimed subject matter will be entitled to the earlier effective filing date.
19. See 35 U.S.C. § 122 (Confidential status of applications; publication of patent applications).
20. Disclosures should be made carefully and with the advice of counsel, as the prior art exceptions under 35 U.S.C. § 102(a) do not apply where the disclosure of the prior art and the subject matter relied upon under § 102(a) is not identical. Otherwise, a defensive publication by a company may inadvertently become prior art to a company's own patent application!
21. See, e.g., *supra*, Uthaman (2012) Post-grant review: The good, the bad and the ugly for biotechnology companies.