White Paper:

What Innovators Need to Know – *and Need to Do* – under the America Invents Act

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Introduction

American Innovators for Patent Reform, working in conjunction with patent attorneys Carlos A. Fisher and Timothy D. Casey and patent agent Juan C. Quiroz, is pleased to provide this White Paper as a resource for inventors, patent owners, attorneys, businesspeople and others who will be affected by the changes the America Invents Act (the "AIA") brings to U.S. patent law.

Executive Summary

Part I of this paper, authored by attorney Timothy D. Casey and agent Juan C. Quiroz of SilverSky Group in Reno, Nevada, covers information that is vital for inventors, business owners and attorneys to know before applying for a patent, or during the prosecution of a patent application. This section covers:

- The change from a "first-to-invent" to a "first-to-file" patent system
- "Derivation proceedings," a weak substitute for first-to-invent in which an inventor can attempt to prove the theft of a patented invention
- Changes in public disclosure, statutory bars to patentability, and the loss of the one-year grace period for filing a patent application or provisional patent application
- Ways to prevent the loss of patenting rights to another inventor
- The role of provisional applications in securing the priority date under a first-to-file system, and what to include in such an application
- How virtual marking benefits patent owners, and how to use it
- Patent office fee schedule changes and the new "micro entity" status
- How the new challenge provisions for issued patents make effective patent prosecution even more vital

Part II of this paper, authored by attorney Carlos A. Fisher of Stout, Uxa, Buyan, & Mullins LLP in Irvine, California, is primarily concerned with what patent owners need to know about enforcing their patent rights and ensuring their ownership of patented inventions under the AIA. Topics covered include:

- Patent ownership issues, including the impact of the prior user's rights provision, the "common ownership" exception and the new "derivation proceeding" for alleging the theft of an invention
- Steps that universities and employers should take to ensure that patents produced by student researchers or employees are promptly and properly assigned
- New patent review procedures under the AIA, and how they differ from existing patent examination or review options
- New guidelines for third parties wishing to submit prior art relevant to the examination of a patent application
- The AIA's new rules for patent infringement lawsuits that target multiple defendants—the "anti-joinder" provision

This white paper was designed to act as a helpful overview and guide to the changes and issues ushered in by the America Invents Act, but it is not legal advice and is not a substitute for competent legal counsel.

Part I: A Practical Guide to Protecting Patentable Inventions under the AIA

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Overview

In many ways the America Invents Act turns what many of us know about patent law on its head. For example, we will lose our first-to-invent system and what has been a clear one-year statutory bar period. The loss of the first-to-invent system is particularly significant because it gave an inventor the ability to (1) "swear behind" an alleged prior art reference that was published less than one year prior to the priority date of the inventor, and (2) prove the inventor was the first to invent the idea being protected ("interference").

While interferences were very rare and seldom benefited the second to file, even if that person was the first to invent, the loss of the ability to swear behind a cited reference will have a huge impact on prosecution practice. These changes, and many others changing aspects of patent law, will require both practitioners and clients (referred to herein as "we" or "you") to change how you disclose inventions, how soon and what type of application you file, and how you prepare and prosecute those applications.

This information is intended to provide practical advice to inventors, small businesses and universities that already know something about patents, and the attorneys and agents that provide services to such organizations and inventors, as to how to behave under the AIA so as to protect patent rights.[2] While the laws changed by the AIA are numerous, we will focus on how the AIA changes the filing system to a first-to-file system, risk mitigation associated with public disclosures of inventions, the use of provisional applications, disclosing the best mode in a patent application, marking of products with patent numbers, the Patent Ombudsman Program, changes to filing fees and the new micro-entity definition, and new challenge provisions during the pendency of patent applications and after issuance of patents.

I. Loss of One-year Grace Period; New Statutory Bar

The AIA became law on September 16, 2011. While some provisions, such as fee increases, were effective immediately, the majority of the provisions will not become effective until a year or more later, although their effect might be felt as early as March 16, 2012. In particular, the switch from a first-to-invent to a first-to-file system does not become effective until March 16, 2013, but inventor activity that might not have created a statutory bar in the past now could. Hence, the impact of this law will begin to take effect as of March 16, 2012.

[1] SilverSky Group worked closely with a broad coalition of organizations and individuals during a multi-year legislative process, in a not always successful attempt to improve various aspects of what became the AIA. While we are not thrilled with various provisions of the AIA, it is now the law and we move on. Nevertheless, the opinions expressed in this article are those of Timothy D. Casey and Juan C. Quiroz and do not necessarily reflect those of SilverSky Group, LLC.

[2] As a practical guide, this article is not otherwise footnoted. If you would like more information on any subject mentioned or if there are questions regarding the source of any statement made herein, please contact Timothy D. Casey at tcasey@silverskygroup.com.

For example, if an invention is disclosed on March 17, 2012, and that disclosure creates a statutory bar under the AIA, but would not have under existing law, and a patent application is not filed on that invention until March 16, 2013, that application would be statutorily barred under the AIA when it would not have been under current law.

Ambiguity of Provision May Take Years to Resolve

While we can adjust to new bars under the AIA, if we understand them, many relevant provisions of the AIA are poorly worded and do not match the wording under current law, making such determinations difficult. For example, the legislative proponents of the AIA claimed that secret offers for sale of a product or service would not create a bar under the AIA, but the AIA does not clearly state this fact. Legislative history was introduced in both the House and Senate to clarify this and other points, but such history will not be binding upon courts hearing appeals of rejected applications or invalidated patents until some five to ten years from now. Hence, it will be many years before we have a clear understanding of the meaning of the new law.

II. Derivation Proceedings Replace "First-to-Invent"

The adoption of a first-to-file system brings the U.S. patent system more in line with the rest of the world, but in doing so inventors face the risk of losing patent protection to other entities who win the race to the USPTO. This change also poses the risk of having an inventor's idea stolen if the idea is disclosed prior to filing.

Interference

For example, theoretically under current law, an inventor can disclose an invention prior to filing and if a third party steals and attempts to patent the invention, the original inventor can invoke an interference to prevent the thief from getting the patent by proving prior conception and a diligent reduction to practice of the invention. Under the AIA, if an inventor discloses an invention to a third party who then steals the invention, there is a good chance the first person to file will get the patent, regardless of the true inventor.

Derivation Proceeding

While the AIA introduces something called a "derivation proceeding" to allegedly enable inventors to prove someone "derived" (i.e., stole) an invention from them, the AIA does not provide any evidentiary tools (such as discovery) that would enable inventors to gather the evidence necessary to prove such theft. Hence, unless an inventor just so happens to have clear proof of the theft, it will be virtually impossible to gather the evidence necessary to prove that the invention was stolen.

III. Preventing Public Disclosure and Subsequent Loss of Patentability

Under the new law, any public disclosure of an invention will start the bar period running and put the inventor at risk. One solution is to use a non-disclosure agreement (NDA) prior to the disclosure so as to avoid a "public disclosure".

Using an NDA to Protect Inventions

It is important that the NDA include a provision preventing the recipient from filing a patent application based on any of the confidential information received under the NDA. As noted above, the derivation proceedings under the AIA do not include any discovery mechanisms, making it difficult to obtain evidence to prove that a stolen idea was derived from an inventor. By including such a provision in an NDA, a separate breach of contract action could possibly be pursued that will make it possible to obtain through civil litigation what was not possible to obtain through the AIA.

Patent Applications: File Early and Update Frequently to Protect Patent Rights

It is also highly recommended that you file a patent application as early as possible and continue filing applications related to that idea as further developments occur. While this practice may be more expensive and extensive than practices under current law, it will help prevent the loss of patent rights.

Filing a Written and Enabling Disclosure of the Invention

Prior to a public disclosure, inventors can also publish a written and enabling disclosure of an invention, followed by the timely filing of a provisional or non-provisional patent application, to prevent others from claiming the invention as their own. The key to remember here is that each patent application filed needs to be enabling, meaning that it needs to include as much detail as possible so as to enable others to practice the invention from the disclosure. Failure to file an enabling disclosure will make a filing ineffective for preserving the invention disclosed and could make that filing prior art to other filings you might make to correct that problem.

In view of the risk of loss due to a public disclosure, certain business practices that were frequently performed prior to filing for patent protection need to stop, such as marketing an invention to test market acceptance, obtaining financing for a business through public disclosure, attending a public investor presentation, participating in a business plan competition, or publicly marketing a business plan to potential inventors. Under the AIA, each of these practices poses a potential risk of loss and should not be performed until after filing an enabling provisional application, at least.

IV. What to Include in Provisional Patent Applications

Provisional applications can be an effective means of ensuring that a true inventor is the first to file for patent protection under the AIA. A fully enabling provisional application will preserve a priority date (an early filing date upon which subsequent applications can be based) as of the filing date of the provisional application. However, a provisional application only preserves a priority date for what is disclosed in that application, and such a provisional application is only good for one year (at which time it must be converted to a non-provisional application).

Provisional Applications Should Be Detailed and Complete as Possible

It is not sufficient for a provisional application to include a vague recitation of an idea. Instead, the provisional application must include relevant details that explain exactly how the idea is to be practiced. It is a common mistake for provisional applications to be comprised of a cover sheet, a few photographs or hand drawn figures, and a mish mash of hastily gathered material that provides little or no description of the invention. Under no circumstances should a provisional application be filed without a suitable description of the invention.

Preferably, a provisional application should include everything that would normally be included in a non-provisional application, with the exception that a provisional application can include informal drawings and an incomplete claim set. This means that you should expect to pay at least a few thousand dollars to file a truly effective provisional, and that is not something you should do yourself or through an Internet-based service.

V. Best Mode

Regarding providing an enabling description of an invention, applicants for patent applications can take advantage of the new AIA provision that does not penalize inventors for failure to disclose the best mode of practicing their invention. Under current law, inventors are required to disclose their best mode, i.e., their preferred embodiment for practicing an idea they seek to patent. This remains a criterion under the AIA, only the AIA removes any penalty associated with failing to disclose the best mode of an invention.

New Best Mode Rules Allow Use of Both Patent and Trade Secret Protection

While the AIA maintains the tradition of requiring an inventor to disclose his best way of practicing his invention, there is no consequence if the inventor fails to do so. This means inventors must disclose a way of practicing an invention, but it need not be the best way. Therefore, inventors can maintain the best way of practicing an invention as a trade secret, even though the inventor may have otherwise disclosed the invention in the patent application.

By not disclosing the best mode, an inventor can prevent others from practicing the worst way of practicing the invention, through a patent, while preventing others from practicing the best mode, through trade secret protection. It should be noted that a patent application must still be enabling, and if there is significant difference between the best mode of practicing the invention that is not disclosed and the worst way of practicing the invention that is disclosed, the patent application may not afford any protection to the best mode of practicing the invention.

VI. New Virtual Marking Provision: An Advantage for Patent Owners

The AIA also introduces a new virtual marking provision that benefits patent owners. Under current law, if a patent owner fails to properly mark a product or service with the patent numbers corresponding to that product or service, the patent owner may be subject to civil litigation. Failing to properly mark a product or service may also prevent the patent owner from collecting damages on patents that were not included in the marking list. The AIA resolves these concerns by (1) removing the need to mark every product or service with the corresponding patent numbers, and (2) not penalizing patent owners when they fail to comply with the marking requirements.

Using a Website for Virtual Marking

In particular, a patent owner need only maintain a webpage that includes some or all of the patent numbers associated with its products or services, and even if those patent numbers are not accurate, there is no consequence. Hence, patent owners can now avoid the cost of updating products, collateral or other material with accurate patent and pending application numbers, and avoid the cost of listing the wrong numbers.

Patent owners can also follow the strategy of simply labeling products or services with “patent pending” or “patented”, forcing competitors to do the research as to which patents are associated with those particular products or services, yet listing them on their website and therefore getting full protection.

VII. Patent Office Fee Changes under AIA

A significant AIA change already in effect is the increase in fees charged by the USPTO. A 15% surcharge increase has been added to all general statutory fees and maintenance fees; a $400 fee has been added for all applications not filed electronically; and a $4,800 fee has been added to the cost of filing any application with expedited processing (reduced by 50% for small entities having less than 500 employees). This new form of expedited application has no special additional requirements, such as the age of the inventor or performing your own search and examination prior to filing, aside from the fee.

New Micro-Entity Status

In an attempt to help individual inventors, the AIA defines a new "micro-entity" for USPTO fees. Under the new definition, applicants who (1) have not filed more than four patent applications in the past and (2) do not have a household (or equivalent) income in excess of three times the national average, which was $50,000 in 2009, may qualify for a 75% reduction in USPTO fees. However, even though the USPTO has already implemented the increase in fees, at the time of this writing, the USPTO had still not yet offered the micro-entity discount on any fees.

VIII. Patent Ombudsman Program

In a further attempt to aid small businesses and independent inventors, the AIA includes the Patent Ombudsman Program, a new program wherein a USPTO official is able to help pro se patent applicants through the patenting process.

Contacting USPTO Support Staff: Caution Advised

While the goals of the program are ideal, we urge pro se patent applicants and others to be extremely cautious regarding advice received from USPTO officials. It is unfortunately common to receive incorrect advice from USPTO officials supporting the various help desks and in support role functions, and it is not unusual to receive contradictory answers from multiple different USPTO sources. It is therefore important to understand this risk when calling for help at the USPTO because even if the advice given is wrong, the USPTO will not waive a deadline or release you of some obligation because you followed their advice. The USPTO is truly an "at your own risk" agency.

IX. Third Party Challenges for Pending Patent Applications

The AIA also creates a new opportunity to challenge pending patent applications and many new ways to challenge issued patents. Under current law, while a patent application is pending, a third party can submit patents or publications relevant to the patent application. However, this law is fairly useless because such submissions cannot include any explanation of the patents, publications, or any other information, and must be submitted within two months after publication of the application, which is not enough time to prepare such a submission.

Under the AIA, the time period for third party submissions is increased to the later of the first rejection of any claim or six months after publication of the patent application. The AIA also allows third party submissions to include an explanation regarding the relevance of the evidence submitted, and the evidence submitted is not limited to patents or publications.

Avoiding Third Party Patent Challenges

For patent applicants only filing in the U.S., one possible solution for avoiding this new challenge provision is to opt out of having your patent application published when the patent application is filed. Opting out of publication can thereby be used to avoid having a competitor abuse the third party submission provisions. Opting out of publication can also be used to prevent an applicant's own published patent applications being used as prior art for continuing applications, at least until those prior applications issue as patents and are then published.

Applicants are reminded, however, that opting out of publication is not possible when filing internationally, or if a patent application claims priority to any patent application that has been published in the past. Finally, if a third party submission presents art that is truly relevant to the scope of the patent application, drafting claims that avoid the relevant art, even if the cited art is dismissed by the USPTO, can help prevent the likelihood of future challenge provisions on any issued patents.

X. New Review Options for Issued Patents

Once a patent is issued, under the AIA, the patent can be challenged on a multitude of new "challenge provisions," including supplemental examination and post-grant review, which are new, and *inter partes* review (IPR), a new type of challenge that takes the place of *inter partes* reexamination. The standard for instituting an *inter partes* reexamination was proof of a substantially new question of patentability with respect to any claim of the challenged patent, which the USPTO implemented to mean almost any proof questioning patentability. The new IPR standard of proof is higher in that it requires the petitioner (third party) to show that it would prevail with respect to at least one challenged claim. While this change is encouraging, it is more than offset by the new supplemental examination and post-grant review procedures that are likely to be as easy to institute as reexamination was in the past.

Effective Prosecution Helps Protect Patent against Challenges

All of these new challenge provisions make effective prosecution even more important. For example, even if the USPTO does not appreciate the relevance of a particular reference, it is important that the reference be distinguished or the scope of the claims be drafted to overcome that particular reference so that the reference cannot be effectively used in the future. For inventors, it is recommended that you take an active and hands-on approach to prosecution, including reviewing and discussing the scope of claims with your practitioner if there are concerns regarding the scope of the claims being too broad or easily invalidated.

It is also important to be wary of prosecution history estoppel, which can arise when a reference is distinguished in some way during prosecution. If the owner of any resulting patent wants to distinguish that reference in a different way or argue that it is not applicable, prior arguments might make that difficult to achieve.

Summary

Applicants can keep the best mode of practicing an invention as a trade secret without a penalty. Prior to any disclosures, applicants are encouraged to extensively use NDAs and to at least file an enabling provisional application. Programs such as the Patent Ombudsman Program aid pro se patent applicants, but pro se patent applicants are warned regarding the quality and inconsistency of advice provided by USPTO officials.

Patent owners are no longer penalized for not properly marking products or services with corresponding patents and patent application numbers, and patent owners need only maintain a webpage with marking information. The new challenge provisions can increase the prosecution costs of applicants, but preventive measures can reduce the risk of challenge provisions being used against a pending patent application or an issued patent, such as opting out of publication and drafting strong claims in view of all relevant art.

While the AIA significantly changes how we disclose and patent inventions today and includes a number of new burdens, there are some new tools introduced by the AIA as well that should be used, and regardless of whether you like the AIA or not, it is here for now and needs to be understood and accommodated to most effectively protect your ideas in the future.

Part II: Patent Ownership and the America Invents Act of 2011

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Overview

The America Invents Act of 2011 (the "AIA") represents the most major revision of the U.S. patent law since 1952. The AIA provisions affect the entire spectrum of patent law: Redefining the scope of prior art, providing for post-grant review, expanding the right of certain prior users to use patented technology with impunity, provide patent owners (as opposed to inventors) greater procedural flexibility than was previously available, and contain provisions clearly and preferentially favorable to certain industries, such as the pharmaceutical and financial services industries.

Furthermore, the AIA has changed the procedural law concerning patent litigation, potentially increasing costs of patent litigation by eliminating the ability of a patent owner to join multiple defendants in a single lawsuit under many circumstances.

This overview of the AIA is intended to address issues affecting patent owners, both with respect to the owner's role in patent prosecution and with respect to post-issue matters. These issues may affect a patent owner wishing to procure or protect its patents, as well as those patent owners wishing to consider affirmative actions against infringers and patent applicants attempting to design around the patent owner's patents.

Important practical considerations that flow from AIA include:

1. The critical need for increased, continuous, and vigilant surveillance of U.S, and foreign patent and non-patent literature for prior art and patenting activity relevant to the patent owner's patents and commercial activity.
2. The increased requirement for accurate and detailed record-keeping in research, development, and commercialization activities. Under the AIA's first-inventor-to-file system, laboratory notebooks will not be used to show prior invention, but may well be critical (along with other documentation, such as production and manufacturing records, standard operating procedures ("SOPs"), e-mails, letters, contracts etc.) to help prove derivation of an invention and to take advantage of the prior users' rights now available under the AIA.
3. The potential of immunizing against the prior-user defense by entering into research or other agreements with a university or other non-profit organization whereby potentially patentable subject matter is under an obligation to be assigned to the non-profit organization. The literal language of the statute does not require that the patentable subject matter be under an obligation to be assigned *solely* to the non-profit; thus the potential exists for co-ownership arrangements between industry and non-profits that can exploit this advantage. Of course, regardless of the ownership of the subject matter rights may be exclusively licensed to an industry collaborator and/or licensee.

[3] The opinions expressed in this article are those of Carlos A. Fisher, and do not necessarily reflect those of Stout, Uxa, Buyan, & Mullins LLP. © 2011 Carlos A. Fisher.

What follows is a summary of provisions of the AIA having particular applicability to patent owners and licensees.

I. Common Ownership Exception to Prior Art

The AIA contains provisions which will become effective March 16, 2013 under which descriptions of a claimed invention made in U.S. patents and U.S. published applications that name *another* inventor[4] and were "effectively filed"[5]before the effective filing date of the claimed invention are prior art to a subsequently claimed invention.[6] However, the exceptions to prior art under 35 U.S.C. 102(b)(2) provide that such disclosure is not prior art if the subject matter disclosed was obtained directly or indirectly from the inventor or a joint inventor[7], first disclosed by the inventor or a joint inventor[8], or if the subject matter disclosed in the publication and the claimed invention were owned, or under an obligation to assign to the same person *no later than the effective filing date of the claimed invention*.[9] This exception has no time limit, unlike the one-year "grace period" of 35 U.S.C. §102(b)(1). This exception, unlike former 35 U.S.C. §103(c)(which has been stricken in the AIA), applies to prior art for purposes of novelty as well as obviousness.

In particular, 35 U.S.C. §102(b)(2)(C) clearly provides advantages to patent owners who file applications only in the United States. If there are no prior-filed foreign or international patent publications (patents and published applications) that disclose the invention, then this exception to prior art permits the filing of continuation-in-part ("CIP") applications in the United States without tainting the CIP with the published disclosure of the parent application(s), so long as another inventor is named. It is often possible to claim inventions in a CIP application that have fewer or additional inventors than did the claimed invention in the parent application. Since, under the AIA, the "inventor" means *all* the inventors, any alteration to the named inventors in the CIP would constitute "another inventor", as required by 35 U.S.C. §102(b)(2).

This provision may also be a boon to entities such as universities or patent licensing companies, who have or acquire a large portfolio of patents and applications. *There is no requirement that the prior patent publication be a priority application of the application containing the claimed invention,* or that the publication have been filed or published after the enactment of effective dates of the AIA. Thus, such entities may file follow-up patent applications having a later priority date and drawn to subject matter related to the earlier filed application without the U.S. patent publications being prior art.

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[4] The term inventor means the "inventive entity;" that is, the individual or individuals who collectively invented or discovered the subject matter of the invention. *See* 35 U.S.C. §100(f).
[5] The effective filing date of a patent or application under the AIA is the filing date of the earliest U.S., foreign or international application for which the patent or application at issue is entitled to priority as to the subject matter at issue. *See* 35 U.S.C. §100(i).
[6] 35 U.S.C. §102(a)(2).
[7] 35 U.S.C. §102(b)(2)(A).
[8] 35 U.S.C. §102(b)(2)(B).
[9] 35 U.S.C. §102(b)(2)(C).

Additionally, common ownership under 35 U.S.C. §102(a)(2) is defined to include parties to joint research agreements.[10] Thus, the common ownership exception to prior art particularly benefits universities and companies collaborating with universities and also helps in the rarer instance that two private companies enter into a collaboration agreement. There is also an explicit inclusion of agreements entered into under the CREATE Act promoting cooperative R & D between universities and private industry as being within the spirit of common ownership, as defined in the AIA.

II. Derivation

In the event that an invention is "stolen" from an inventor, the AIA provides for administrative[11] and civil[12] procedures for patent owners to challenge a pending patent application or an issued patent, respectively, claiming an invention that was derived from an inventor of the petitioner's (plaintiff's) patent application (or patent).

In each case it is critical that patent owners be continuously aware of the status of published patents and patent applications related to their invention, and file patent applications on their inventions in a timely fashion to avoid losing their right to contest a derived invention. Additionally, companies should monitor the patenting activities of parties, if any, to whom the invention may have been disclosed. Although in this case, it is U.S. patents and publications that must be monitored, for purposes of patentability, a good competitive surveillance program should include published foreign patents and foreign/international applications as well.

Thus, an action against an application may only be taken if the petition is filed *within one year* of the earliest publication of a claim to an invention that is the same or substantially the same as the earlier applicant's claim to the invention.[13] The petitioner must therefore have a patent application pending in order to file a petition. If the petition is granted, the proceeding will be held before the Patent Trial and Appeal Board and can be terminated if the parties settle the dispute, so long as the agreement is consistent with the evidence of record.[14] It is therefore a good idea for a patent owner to attempt to seek a settlement with the owner of the disputed patent application, if possible, *before* filing a petition.

Similarly, a civil action may be filed by a patent owner against the owner of another patent that claims the same invention, has an earlier effective filing date, and was derived from the inventor of the plaintiff's patent.[15] But a civil action can only be filed *within one year* of the issue of the first patent containing a claim to a derived invention.[16] Thus, it is important for patent owners to keep constantly aware of issued patents in their field of commercial interest.

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[10] 35 U.S.C. §102(c). The requirements for common ownership under a joint research agreement ("JRA") are a) the disclosed subject matter was developed and the claimed invention was made by, or on behalf of, one or more parties to a joint research agreement that was in effect on or before the effective filing date; b) the claimed invention was made as a result of activities within the scope of the JRA, and the application for patent (against whom the publication would otherwise be prior art) discloses or is amended to disclose the names of the parties to the JRA.
[11] 35 U.S.C. §135.
[12] 35 U.S.C. §291.
[13] 35 U.S.C. §135(a).
[14] 35 U.S.C. §135(e).
[15] 35 U.S.C. §291(a).
[16] 35 U.S.C. §291(b).

III. Oath or Declaration

The AIA permits the patent owner to file a patent application, and have it examined, without an oath or declaration on record.[17] Moreover, if the inventor is under an obligation to assign the invention to the patent owner, but refuses to do so, it is now possible for the patent owner to file a substitute statement that fulfills the requirements of an oath or declaration, assuming that the request contains a description of the facts.[18] A substitute statement can be corrected, withdrawn, or replaced at any time, even after a patent has issued.[19]

Therefore, it remains particularly important for patent owners to have employment or similar agreements in place with all employees and contractors at the outset of the work that leads to the invention, as *the substitute specification can only be used in place of a signature of an uncooperative inventor if the inventor has an obligation to assign the invention.* Moreover, since a mere agreement to assign does not automatically vest title in a purported assignee, such agreements should contain language indicating that prospective inventor "agrees to assign and *hereby assigns*" the invention and patents and patent applications relating to the invention, as required by the United States Supreme Court in the recent decision *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc.*[20]

IV. Filing by Other than Inventor

The same considerations should be borne in mind when using a related provision that permits an assignee, or an entity to whom there is an obligation by the inventor (or all joint inventors) to assign the invention, to file the application directly.[21] To do so requires proof of a proprietary interest in the application (presumably by filing an assignment simultaneously with the patent application) and a showing that this is "appropriate" to preserve the right of the parties.[22] Exactly what additional showing will be necessary is unclear, and will require promulgation of the corresponding regulations by the USPTO. If a patent is granted on such an application it will be granted directly to the real party in interest (the assignee), with notice to the inventor.

As with the oath and declaration provisions, patent applicants should design and institute appropriate procedures for employees or contractors to permit the direct filing of patent applications by the company when necessary (e.g., when the inventor fails to sign the oath or declaration, or an assignment document). In such cases it is necessary to have in place an appropriately drafted employee agreement, consulting agreement, or other agreement containing provisions requiring the employee or contractor to assign all future inventions (and patent applications to be filed on such inventions) made during the course of employment, or other working engagement.[23] This provision is effective as to applications filed on or after September 16, 2012.

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[17] 35 U.S.C. §115(f).
[18] 35 U.S.C. §115(d).
[19] 35 U.S.C. §115(h)(1).
[20] 131 S. Ct. 2188 (2011).
[21] 35 U.S.C. §118.
[22] *Id.*
[23] *See* text accompanying note 18, *supra.*

V. Prior User's Rights

The extension of the prior user's right provisions beyond business method patents is a marquee feature of the AIA, and requires some detailed explanation. However, patent owners should keep in mind that to make use of a prior user's defense requires that detailed records be maintained demonstrating independent invention of permitted subject matter, "internal" commercial use of that subject matter, and sale of products comprising a "useful end product" of the use, and the continuous nature of that use. Thus, patent owners should take the time to develop, establish, and regularly audit procedures for maintaining such records. Since a prior use must have occurred at least one year before the effective filing date of a patent asserted against the prior user, it is also important to begin to implement such procedures as soon as possible.

The Basic Defense

The prior user's rights provisions became effective for all patents granted after September 16, 2011. These provisions permit a "person" (including a corporation) to assert a defense against a patent infringement lawsuit concerning subject matter consisting of 1) a process, or 2) a machine, manufacture of composition of matter, used in a manufacturing or other commercial process that would otherwise infringe a "claimed invention being asserted against the person" if the person acted in good faith and commercially used the subject matter in the U.S., either in connection with an "internal commercial use," or an actual arm's-length sale or other commercial transfer of a "useful end result" of such commercial use.[24]

The commercial use that immunizes such a person must have occurred *at least one year before* the earlier of the effective filing date of the claimed invention or the date the claimed invention was disclosed to the public such that it qualified for an exception from prior art under 35 USC 102(b) (i.e., disclosures by the inventor or from one who directly or indirectly obtained the subject matter from the inventor, or in a patent publication having common ownership with the patent at issue.) The *commercial use must be continuous*; if the commercial use is abandoned, then the defendant cannot rely on activities occurring before the date of abandonment to establish a defense against activities occurring on or after the date of abandonment.[25] Also, *the subject matter cannot have been derived from the inventor* (or persons in privity with the inventor e.g., as co-parties to a contract) of the claimed invention in the asserted patent.[26]

Attorney's Fees for Unreasonable Assertion of Defense

There is, however, a major caveat to asserting the defense. If the person pleading the defense is found to infringe the patent and fails to provide a reasonable basis for asserting the defense, the court must find the case "exceptional" under 35 U.S.C. 285, which permits the court to award attorney's fees to the plaintiff.

It is at this time unclear exactly what will constitute an unreasonable assertion of the defense. Given that it is necessary to prove the facts necessary to successfully maintain the defense by the stringent "clear and convincing evidence" standard, would the failure to meet this standard be in and of itself "unreasonable"? Such a definition of reasonableness would certainly discourage all but those having the most clear-cut evidence[27] from attempting to assert the defense. A lesser standard, such as a lack of substantial evidence showing that the requirements of the defense was met, would appear to be more in keeping with the spirit of the statute.

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[24] 35 U.S.C. §273(a).
[25] 35 U.S.C. §273(e)(4).
[26] 35 U.S.C. §273(e)(2).
[27] And would certainly give an advantage to entities such as pharmaceutical companies undergoing premarketing regulatory review and non-profit organizations, who benefit under 35 U.S.C. § 273(c)(1) & (2) from a statutory "waiver" of the need to show commercial use under certain circumstances. *See discussion infra.*

Personal Defense

The defense is personal to the person (and its affiliates controlling, controlled or under common control with such person) who performed or directed the qualifying commercial use, and cannot be licensed or sold.[28] However, it is subject to a limited transfer right; either a) to the patent owner as part of a settlement, or b) as an ancillary part of a *transfer of the entire enterprise or business line for other reasons*. Furthermore, the defense is only effective for commercial uses at sites where the subject matter is in use before the later of the effective filing date of the claimed invention, or the date of a qualifying assignment or transfer.

*The overall effect of the prior user rights provisions of the AIA is to encourage the maintenance of trade secrets, particularly by larger companies having the manpower and resources to maintain accurate records***.** As mentioned above, such records would ideally include, for example, corroborated dated laboratory notebooks, SOPs etc. proving a) dates of conception and reduction to practice of inventions, whether recognized as such at the time or not; b) the dates of first use of such inventions in an internal commercial use; and c) the dates of a first commercial sale of a useful end result of such commercial use, if applicable. It would also be important to have confidentiality obligations in place with all research, development, and manufacturing employees and contractors.

Note also that the effect of this defense is that it *actively discourages the filing of patent applications* by such entities, as the defense is only applicable to commercial uses occurring at least a year before the effective filing date of the patent, and very possibly up to two years or even more prior to that.[29]

Preferential Treatment

The AIA provides preferential treatment to two classes of potential prior users making it easier for them to establish "commercial use" under the prior user's right provisions.

a) Premarketing Regulatory Approval

The AIA establishes that a pharmaceutical company filing an application for premarketing regulatory review (e.g., FDA review of a proposed pharmaceutical or biologics product) establishes a "commercial use" within the meaning of new § 273. Thus, potentially patentable subject matter for which commercial sale or use is subject to a premarketing regulatory review period to establish safety and efficacy marketing approval is regarded as "commercially used" as defined under the prior user's rights provisions.[30]

This provision clearly and specifically exempts drug and biologics manufacturers having a product undergoing premarketing FDA review from patent infringement if the other requirements of new §273 are met.[31]

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[28] 35 U.S.C. §273(e)(1). However, the sale of a "useful end product" of the commercial use by such a person exhausts the patent owner's rights in the products (thereby permitting the resale and use of the product) as if it had been sold by the patent owner itself. 35 U.S.C. §273(d).

[29] *See* 35 U.S.C. §102(b)(2)(c).

[30] 35 U.S.C. § 273(c)(1).

[31] Note also that due to the requirements relating to an application for FDA marketing approval, the dates and specific standard operating procedures (SOPs) will generally be well-documented and easily available as evidence to prove the other elements of the prior user's defense. In this, pharmaceutical companies using 35 U.S.C. § 273(c)(1) will have an evidentiary advantage over other companies or entities, who may need to adopt altogether new procedures to document compliance with the elements (e.g., the date of the prior use, description of the subject matter, description of the allegedly commercial nature of the use, etc.) necessary to prove their right to the prior user's defense.

b) Non-Profit Entity Use

Under limited circumstances non-commercial use is also protected under the prior user's defense rights of the AIA. Thus, such non-commercial use, redefined as a "commercial use" under the AIA, is the prior use of otherwise infringing patented subject matter by a non-profit research laboratory *or other non-profit entities*, such as a university or hospital, for which the public is the intended beneficiary.[32] However, in addition to the other requirements mentioned above, the use must remain non-commercial in order for the defense to remain applicable.

This provision should be of value to universities and non-profit research labs, particularly (but not solely) with respect to tests, assays, and reagents used in the research laboratory that may be later patented, for example, by biomedical supply companies.[33] While state universities are already exempt from patent infringement unless waived pursuant to State sovereign immunity (*see Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank*[34]), this prior user's right would be extended to *any* non-profit institution or entity, whether State owned or not.

Prior Use is Not a Defense as to the Patent as a Whole

The prior use defense can be asserted with respect to the patent claim or claims that cover subject matter used in a qualifying commercial use for which the defense can be successfully maintained as required by 35 U.S.C. §273(a) and (b). Additionally, the defense can be asserted with respect to variations in the quantity of volume of use of the claimed subject matter.[35] All other claims of the patent remain enforceable as to their literal limitations against the defendant.[36]

Remarkably, however, the defense also pertains to subject matter commercially used and/or resulting in useful end products that comprise *improvements* to the claimed subject matter that do not infringe *specifically claimed* additional subject matter of the patent.[37] This means that the Doctrine of Equivalents cannot be asserted against a commercial user who has successfully asserted the prior user's defense against a specific patent claim or claims (at least with respect to the patent at issue); the immunized person can improve the subject matter by "designing around" and avoiding the literal language of the patent claims with impunity.[38]

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[32] 35 U.S.C. § 273(c)(2). Although apparently intended to benefit universities and hospitals and apply mainly to medical technology, the literal language of the AIA appears to encompass *any* subject matter used by *any* primarily public-benefitting, non-profit entity. Thus, charities, religious institutions, and other non-profits may also be able to benefit from the defined "commercial use" of this subsection.

[33] Although many of these companies do currently provide a free research license to non-profit university use of such reagents, they are not obligated to do so.

[34] 527 U.S. 627 (1999).

[35] 35 U.S.C. § 273(e)(3).

[36] *Id.*

[37] *Id.* i.e., in other independent or dependent claims.

[38] This should only be done advisedly and at the defendant's peril: if the patent owner has a pending continuation or divisional application claiming priority to the asserted patent, the claims in the continuing application could be amended to cover the improvement. A subsequently issued new patent could then be freshly asserted against the defendant, who would once again have the burden of showing he is entitled to the prior user's defense, now with regard to the new claim(s) as well.

University Exception

The prior user's defense is *not* available to a defendant who has commercially used subject matter as required by 35 U.S.C. §273(a) if the claimed invention was, at the time the invention was made, owned or subject to an obligation to assign to a college, university or technology transfer organization of a college or university. [39]

Notwithstanding this, the prior user defense is nevertheless available to a defendant against a university's allegation of patent infringement if any of the activities required to reduce the claimed subject matter to practice "could not have been undertaken" using Federal funds.[40] Presumably, *but not specified by the AIA*, the determination of whether such reduction to practice could occur using Federal funding is measured as of the time of such reduction to practice. This appears to have been inserted to prevent universities from benefiting from preferential statutory treatment if the creation of the subject matter violated any Federal funding prohibitions.[41]

The university exception to the prior user's defense clearly encourages research, development, and licensing of university-made inventions. Licensees of most university-owned patents will be able to sue infringers without the need to worry about the prior user's defense. An open question is whether the university exemption requires sole ownership by (or an obligation to solely assign to) a university; the language of the statute makes no such requirement and thus, on its face, appears to permit patents jointly owned by a university and another entity to enjoy the benefits of the university exception.

VI. Patent Marking

Marking patented products with the patent number provides notice to the public that the product is indeed patented, as well as greatly expanding the remedies available to the patentee for infringement of the patent. Effective as of September 16, 2011, the AIA has changed the patent law's patent marking provisions in a number of important ways, making it easier for patent owners to comply with the marking requirements without violating the law.

"Virtual" Marking

The amendments to 35 U.S.C. §287(a) now permit patented products to be marked with an Internet address (which must be accessible to the public without charge) that associates the patented product with the number of the patent. Virtual marking can also be used to mark a product "patent pending", although whether actually or virtually stated these words actually have no legal effect.[42] Thus, when the patent expires, or when new patents covering the product issue, the web page can be amended and products will be instantly marked with the updated information. This provision thus saves previously necessary expense associated with the changing of

[39] 35 U.S.C. 273(e)(5)(A).
[40] 35 U.S.C. 273(e)(5)(B).
[41] But note that such prohibitions appear and disappear with the political and legal winds. For example, the Clinton administration prohibited research of embryos created solely for research purposes in 1995. The Bush administration issued an executive order prohibiting Federal funding of embryonic stem cell research in 2001. This ban was lifted in 2009; Federal funding of embryo research has continued to be litigated over ever since.
[42] Unless, that is, there *is* no pending U.S. provisional or non-provisional patent application currently pending. In this case the manufacturer may be liable for false marking, pursuant to the provisions of 35 U.S.C. 292. Additionally, an indication that a product has a "patent pending" may dissuade competitors from attempting to design around the product or enter the market.

product labeling to update patent status information, as well as ensuring that products in the field can be altered to reflect the current patent status.[43]

Moreover, virtual marking facilitates the ability of the patentee to provide actual notice to the public of the patent. Upon a failure to mark (constructive notice) no damages can be recovered in an infringement action without a proof of actual notice to the infringer, and damages will only be available for infringement activities occurring after the date of such actual notice.

False Marking

The threat of lawsuits for false marking under 35 U.S.C. §292 has been a serious concern for patentees since the Court of Appeals for the Federal Circuit's 2009 decision in *Forest Group Inc. v. Bon Tool Co*.[44], under which damages of up to $500 per "falsely" marked item sold could be obtained in a *qui tam* action, which can be brought by any member of the public. This decision, which caused havoc as a flood of actions were filed against patentees who failed to remove the patent markings from their products when they expired, has now been completely reversed.

In a retroactive remedy, the AIA has amended Section 292 to a) remove the possibility of *qui tam* actions for false marking, and b) indicate that the marking of a product with a patent number that covered the product but has now expired is not false marking.[45] Additionally, the amendments provide that members of the public can now only bring an action for compensatory damages, and even then, only when there is actual competitive injury.

VII. Post-Grant Review

The AIA has attempted to provide for the ability of interested third parties to challenge issued patents in a number of ways. The major, wholly new, provision provided by the AIA is post-grant review.

The new post-grant review (PGR) provisions are not effective until March 16, 2013. Once effective, PGR is available only for patents having a priority date on or after this date. In addition, a patent remains eligible to be subject to PGR only during a nine-month window beginning on the issue date of the patent; a petition requesting PGR must be filed during this nine-month window.[46]

The PGR provisions permit any person other than the patent owner to file a petition for PGR in the USPTO requesting the cancellation of one or more claims as unpatentable. [47] The grounds available under PGR for contesting the patentability of the claim is not limited to patents and printed publications, as in *Inter Partes* Reexamination[48], but may include other grounds for denying patentability, such as non-publication prior art (such as public use and/or sale), lack of a written description sufficient to show that the inventor "possessed" the full scope of the claimed invention at the time the patent application was filed, lack of an enabling disclosure, and claim indefiniteness. Notably, the presumption of patent validity will not be effective with respect to PGR

[43] This latter fact is helpful, but less important now due to the associated changes to the false marking provision mentioned below.
[44] 590 F.3d 1295 (Fed. Cir. 2009)
[45] Not only is the amendment retroactive, but it applies to all cases pending or commenced on or after September 16, 2011. However, Constitutional issues have been raised to the retroactive cancellation of pending *qui tam* actions.
[46] 35 U.S.C. §321(c).
[47] 35 U.S.C. §321(a) & (b).
[48] *See e.g.,* 37 C.F.R. 1.915.

proceedings, in which the petitioner may prove that one or more claims are invalid by a mere preponderance of the evidence.[49]

The petition must identify the real parties in interest and must identify and provide detailed arguments and evidence challenging each disputed claim. The evidence accompanying the petition must include any copies of patents or printed publications relied upon and/or affidavits or declarations supporting factual evidence or expert opinions. The petitioner must provide copies of the petition and evidence to the owner.[50] The petition will be made public.[51]

The patent owner may file a preliminary response to the petition setting forth reasons that PGR should not be granted because the petition fails to meet any requirement of law.[52] The Patent Trial and Appeal Board will then decide whether there is sufficient basis in the petition to demonstrate, if the stated "information" is not rebutted, that it is more likely than not that one or more of the claims is unpatentable.[53] Novel or unsettled legal issues affecting other patents or patent applications (for example, continuations or divisionals of the patent at issue) may also be raised in the petition, and are considered in the determination whether to grant PGR.[54] The decision whether to grant PGR is final and unappealable before the USPTO, although it can presumably be appealed before the Federal district court or the Court of Appeals for the Federal Circuit.

No Simultaneous Civil Action and Post Grant Review if Petitioner is Plaintiff

It is not in the petitioner's interest to file a petition for PGR while pursuing a claim for patent invalidity against the patent in court. A petition for PGR will not be granted if a civil action by the petitioner or real party in interest challenging the validity of a claim is filed before the date the petition is filed.[55]

Conversely, if the petitioner or real party in interest files a civil action challenging the validity of a claim on or after the date they file a petition for PGR the civil action will be stayed until the patent owner moves the court to lift the stay, files an infringement action against the petitioner or real party in interest, or the petitioner or real party in interest moves the court to dismiss the stay.[56] Thus, the filing of a civil action when a petition is pending either stays litigation or places the patent owner in far greater control of the litigation than the petitioner or real party in interest. Additionally if a patent infringement lawsuit is filed within three months after the patent is granted, a court may not stay its consideration of the patent owner's motion for a preliminary injunction.[57]

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[49] 35 U.S.C. §326(d).
[50] 35 U.S.C. §322(a)(3).
[51] 35 U.S.C. §322(b).
[52] 35 U.S.C. §323. These reasons appear to be limited to formal and procedural reasons, since under 35 U.S.C. §324(a) the USPTO subsequently is to make a determination, assuming that the assertions made in the petition are *not rebutted,* whether the petition states a case for unpatentability by a preponderance of the evidence.
[53] 35 U.S.C. §324(a).
[54] 35 U.S.C. §324(b).
[55] 35 U.S.C. §325(a)(1).
[56] 35 U.S.C. §325(a)(2).
[57] 35 U.S.C. §325(b).

The statutory ban on simultaneous administrative and judicial actions applies to cases in which the petitioner or real party in interest is the plaintiff. If the petitioner or real party in interest files a counterclaim as a defendant challenging the validity of a patent claim, this will not be treated as preventing the filing of a PGR, nor will the previous filing of a PGR petition stay a civil action if such a counterclaim is filed in an infringement lawsuit.[58]

A final decision by the Patent Trial and Appeal Board in a PGR proceeding against a claim gives rise to estoppel, *preventing the petitioner or real party in interest from raising that issue, or an issue that could reasonably have been raised, in subsequent proceedings* before the USPTO or in a civil action.

PGR proceedings before the Patent Trial and Appeal Board will be rather costly: it is similar to a mini-trial, with discovery, sanctions for abuse of process, protective orders covering the submission of confidential information, oral hearings upon request by a party, etc. The patent owner will be able to amend the patent to either cancel a claim or to propose a reasonable number of substitute claims.[59]

The PGR provisions include an incentive to settle the dispute; the proceeding may be terminated upon the joint request of the parties at any time prior to a decision on the merits, and no estoppel will attach to the petitioner or real party in interest. Agreements between the parties must be filed in the USPTO, but will be treated as business confidential information upon a party's request.[60]

Upon a decision of the Patent Trial and Appeal Board, and when the time for appeal has passed, a certificate will be issued canceling any claim, amending any claim and affirming the patentability of any challenged claim.[61]

VIII. Citation of Prior Art

Patent Applications

Under the AIA, any third party may submit a patent, printed publication, or other printed publication of potential relevance to the examination of any application if the submission is made before the date of a notice of allowance or the later of six months after the date of first publication of the patent application, or the date of the first Office Action rejecting at least one claim of the application. The submission will be added to the record of the application; however, the submitter has no further part in the prosecution of the application. The submission requires a description of why the publication is relevant.[62] This provision becomes effective September 16, 2012, and applies to any patent application, whether filed before, on, or after this date.

Issued Patents

Any person may, at any time, cite patents and printed publications bearing on the patentability of any claim of an issued patent, or written statement (including other documents, pleadings and/or evidence) of the patent owner in litigation or a USPTO proceeding in which the patent owner took a position concerning the scope of a claim of any particular patent.[63]

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[58] 35 U.S.C. §325(a)(3).
[59] 35 U.S.C. §326(a).
[60] 35 U.S.C. §327(a) & (b).
[61] 35 U.S.C. §328(b).
[62] 35 U.S.C. §122(e).
[63] 35 U..S.C. §301(a) & (c).

Additionally, such person may file a written explanation of the relevance and manner of applying this evidence to one or more claim of the patent, and the citation, written statements and explanation will become part of the official file of the patent.[64] At the citing person's request, their identity will be kept confidential.

IX. Joining Defendants in a Single Infringement Lawsuit

The AIA has drastically amended the procedural law surrounding patent infringement lawsuits in a way that preferentially disadvantages the individual inventor, small companies, and non-practicing entities.[65] Any single patent lawsuit can only join multiple alleged infringers if the accused infringement "aris[es] out of the same transaction, occurrence, or series of transactions or occurrences relating to the making, using, importing into the United States, offering for sale, or selling of the same accused product or process." Furthermore, "accused infringers *may not* be joined in one action as defendants or counterclaim defendants, or have their actions consolidated for trial, based solely on allegations that they each have infringed the patent or patents in suit." The only exceptions to this rule are for pharmaceutical companies alleging an act of infringement occurring under 35 U.S.C. §271(e)(2), or where an accused infringer waives the joinder ban with respect to itself.

This change is effective now, and applies to any civil action commenced on or after September 16, 2011.

Conclusion

The AIA is a complex piece of legislation containing many undefined and vague terms and ambiguous language that will undoubtedly require either further Congressional refinement or judicial interpretation. However, it is at least clear that patent owners must begin now to familiarize themselves with the AIA and to establish competitive surveillance procedures to stay constantly abreast with the published patent literature, both foreign and U.S., both for patentability studies on their own invention disclosures, and in order to take advantage of derivation and Post Grant Review procedures.

Moreover, patent owners must be certain to consistently and promptly implement appropriate agreements with employees, contractors and consultants obligating them to assign their subsequent inventions, and their right to prepare and file patent applications on such inventions. Such agreements should contain the magic language "agrees to assign and *hereby assigns*" required by the United States Supreme Court in the recent decision *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc.*[66]

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[64] 35 U.S.C. §301(c).
[65] The latter of which are sometimes termed "patent trolls."
[66] 131 S. Ct. 2188 (2011).

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