NACUANOTES
May 15, 2012
Vol. 10 No. 8

TOPIC:

THE LEAHY-SMITH AMERICA INVENTS ACT

INTRODUCTION:

In 2004, a committee of the National Academy of Sciences issued a report recommending significant changes to the U.S. patent system, including shifting to a first-inventor-to-file priority system and allowing post-issuance administrative challenges. [1] After seven years of debate among the major stakeholders, the Leahy-Smith America Invents Act ("AIA") was signed into law on September 16, 2011, implementing these and a number of other major reforms.

This NACUANOTE summarizes the main changes under the AIA and offers some initial commentary on how these changes might impact colleges and universities, and how academic institutions might choose to adapt. Greater understanding of the AIA's impact on the academy will likely emerge after the U.S. Patent and Trademark Office issues implementing regulations, and further down the road, through Federal Circuit decisions construing the new law. It should be noted that while NACUANOTES are typically written for a general audience, this Note assumes a higher level of familiarity with patent law concepts. [2]

DISCUSSION:

I. Filing and Prosecuting Patents

A. First Inventor to File

The signature change of the AIA is to revamp the United States' basic paradigm for deciding who gets the patent when two separate inventors (or groups of co-inventors) have created the same invention. Under current U.S. law, the patent goes to the person who invented first. Under the AIA, however, the U.S. will join most of the rest of the world in awarding the patent to the inventor who filed the patent application first – known as the "first-inventor-to-file" system. [3] This new system will take effect beginning March 16, 2013.

This change puts a premium on filing early. To the extent that academic institutions wait longer to file, the new law could force a change in strategy. Currently, institutions have an incentive to delay filing applications for earlier stage inventions, giving the institution a later priority date and, therefore, longer patent life. Under current law, which awards the patent to the "first to invent," the first inventor can delay filing for a short time without losing the patent. Not so under the AIA. The premium going forward will be on early filing, as a later filer could supplant the earlier inventor's patent.

This change in strategy will require institutions to rethink their technology transfer processes as well. Institutions will now be motivated to enhance communication between researchers and technology transfer offices, identify inventions promptly, and minimize delays in filing patent applications. Likewise, it will no longer be a reasonable strategy to delay filing until the institution finds a licensee willing to shoulder the cost of patent prosecution. All of these shifts will likely increase patent costs for technology transfer offices.

The AIA will apply to patents with any claims having priority dates after March 16, 2013. [4] Yet the current statutory provision giving priority to the first to invent also applies to the entire patent so long as one claim was filed before March 16, 2013. [5] These effective date rules appear to conflict in the case of patents whose claims span the March 16 effective date, such as continuations-in-part. [6] How the USPTO plans to address this situation remains to be seen.

B. Prior Art & The One-Year Grace Period

While the change to a first-inventor-to-file system was made primarily to harmonize U.S. law with that of the rest of the world, the AIA carried forth the United States' one-year grace period for prior art, although with significant changes and restrictions from its previous version. [7] Most significantly, the only prior art that will be subject to the one-year grace period (i.e., the only prior art that will not be patent-defeating) will be prior art of the inventor herself, or that of co-inventors or people who obtained the content of the publication from the inventor. Prior art of others will defeat the patent, unless the inventor published the same prior art first. [8]

Consider the implications of this change in grace period for university faculty seeking to publish. Under the current regime, if several teams around the country are independently working on the same technological advance, publication by any one of them creates a one-year window for all of them to file a patent application. [9] If the multiple teams file for the same subject matter, the dispute is resolved through an evidence-based interference determining which one invented first.

Under the AIA, in the same situation, publication by any one of the inventors working on the same technology gives that inventor priority. Her publication will be patent-defeating prior art for the other teams, even if one of them had made the invention first. Only the author can file a patent application within one year. Later publication of the same content by others would not be prior art against her. The grace period will thus be narrower, and publication will be a more powerful weapon against competing inventors. The end result is a greater incentive to publish.

However, this shift in incentives may not be as significant as it appears. Under both the old and new regimes, the grace period is recognized only in the United States; prior publication is patent-defeating in the rest of the world. Most inventions have significant foreign commercial potential, so it is generally important to file before publishing regardless. Fortunately, the AIA preserves provisional applications, so it will remain relatively easy to prepare a quick patent application in advance of publication.

The AIA also introduced other changes to the scope of prior art. Currently, it is not considered prior art in the United States if the technology was in public use, on sale, or otherwise available to the public in other countries. [10] Under the AIA, such foreign availability will constitute prior art. [11] Currently, any knowledge or use of the technology in the United States constitutes prior art. [12] Under the AIA, only public use or availability to the public constitutes prior art. [13] The impact of these changes remains to be seen, as they will likely be subject to considerable judicial interpretation in coming years.

C. Abandonment

Another change introduced by the AIA is that abandonment of an invention will no longer be statutorily patent-defeating. The current law, 35 U.S.C. § 102(c), which provides, “A person shall be entitled to a patent unless . . . he has abandoned the invention,” has no counterpart in the AIA. So universities no longer fear a challenge to a patent based upon delays in filing the patent application.

D. CREATE Act

The AIA carries forward the concept of the CREATE Act of 2004, which promoted joint research activities by providing that the prior art of the collaborators could not be used against each other to invalidate inventions arising out of the collaboration. Currently, in order to receive this protection, the joint research agreement must have been in effect prior to the invention; under the AIA, the agreement will need only be in effect prior to the date of filing.

This will provide an extra opportunity for technology transfer offices to ensure that appropriate joint research agreements are in place before filing patents arising out of collaborative research. When an invention is disclosed with co-inventors who are not institutional employees, the Technology Transfer Office (“TTO”) should check whether there is a joint research agreement in place that meets CREATE Act requirements—i.e., whose scope clearly describes the research that yielded the invention—before filing the patent application. If an adequate agreement is not in place, the TTO should make sure one is drafted or revised before filing the patent application. [14]

E. Novelty & Obviousness

Under the AIA, novelty and obviousness will be measured at time of filing rather than at time of invention. [15] This is unlikely to matter much, given the strong imperative under the AIA to file promptly after invention. Nevertheless, if after invention but before filing, another person publishes an article disclosing related subject matter, it might create a novelty bar under [§102(a)(1)] or an obviousness bar under [§103]. This creates yet another incentive for universities to optimize systems for prompt disclosure of inventions and prompt filing of inventions with commercial potential.

F. Inventor’s Oath or Declaration

Currently, the applicant-inventor must make an oath stating that “he believes himself to be the original and first inventor,” and declaring his country of citizenship. [16] If the inventor refuses to execute a patent application or cannot be found, then an assignee (or someone who has a right of assignment or otherwise has sufficient proprietary interest in the matter) may execute the application. [17] In that case, “the oath may be so varied in form that it can be made by” the assignee. [18] The patent is nevertheless issued in the name of the inventor. [19]

Effective September 16, 2012, the oath may be made via statements in the assignment document; a separate filing is no longer required. [20] If the inventor refuses to make the oath or cannot be found, the assignee may apply for the patent [21] and provide a “substitute statement” explaining why the inventor is not executing the oath, and containing any additional information required by the USPTO. [22] Third parties can also file if the inventor is deceased or incapacitated—i.e., a legal representative is no longer required. [23] The patent in these cases is granted to the real party in interest, rather than to the inventor. [24]

Other changes include dropping the citizenship declaration, and not requiring a new oath in continuations and continuations-in-part. [25] What practical impact will this have? First, because the assignee can now obtain the required oath through an assignment, it is no longer necessary for the University to obtain the faculty member’s signature upon filing a patent. This can ease an

administrative burden (especially when the inventor is no longer at the university, or is uncooperative), and, for better or worse, it removes a step that keeps the inventor informed of the progress of patent prosecution. [26]

Another impact is that the oath can now be filed any time before a notice of allowance, [27] rather than at the beginning of the patent prosecution process. But USPTO proposed rules ignore this liberalization and continue to require the oath to be filed before examination begins. [28]

G. Human Organism Prohibition

An uncodified section of the AIA provides: “Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism.” [29] The provision is effective immediately. [30]

The USPTO Manual of Patenting Examination Procedure (“MPEP”) has long provided that “[i]f the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under 35 U.S.C. § 101 must be made indicating that the claimed invention is directed to nonstatutory subject matter.” [31] One might question whether the differences in verbiage between the MPEP and the AIA reflect a Congressional intent to broaden the restriction. After all, a claim “directed to” a “human organism” (as per the AIA) might cover a broader range of potential inventions than an invention that “as a whole encompasses a human being” (as per the MPEP).

The USPTO is taking the position, however, that the AIA provision is merely a codification of the existing PTO practice that inventions that encompass a human being are not patentable, and that it “does not change existing law.” [32] The provision is viewed as codifying the Weldon Amendment to appropriations bills, which has generally been interpreted as limited to prohibitions on claims related to cloned embryos rather than, say, methods of in vitro fertilization or procedures pertaining to stem cells. [33]

II. Reviews, Reexams, and Challenges

A. Pre-Issuance Third Party Submissions

Patent regulations currently permit the USPTO to receive third party submissions of patents or other publications during a two-month period after publication of an application for the purpose of allowing the public to submit prior art that the examiner would discover on his own with an ideal prior art search. [34] This practice contributes to the quality of issued patents and balances the requirements that a patent should issue only if it appears that the applicant is entitled to a patent under the law (35 U.S.C. §§ 131 and 151) with the requirement that no protest or other form of pre-issuance opposition may be initiated after publication without the express written consent of the applicant (35 U.S.C. § 122(c)). [35] To ensure that the submission does not amount to a protest or pre-grant opposition without consent, the third party does not have the right to insist that the examiner consider any of the patents or publications submitted. [36]

The AIA adds a new section (e) to 35 U.S.C. § 122 that expands the kinds of information that can be submitted by third parties and also the time for submitting. Any third party may submit for consideration and inclusion in the record a patent application, any patent, published patent application, or other printed publication of potential relevance to the examination of the application if such materials are submitted before the earlier of (1) notice of allowance or (2) the later of six months after the publication of the application by the USPTO or the date of first rejection of a claim. A proposed rule, section 1.290 pursuant to 37 CFR Part 1, [37] points out a distinction in the statutory language of 35 U.S.C. § 122(c) and the new (e) with respect to publication of the

application. Namely, 35 U.S.C. § 122(c) refers to "publication of the application" whereas the new 35 U.S.C. § 122(e) refers to an application "first published under section 122 by the Office." The proposed rule clarifies that an earlier World Intellectual Property Organization ("WIPO") publication of an international application, for example, would not be considered a publication that would initiate the time period for filing a third party submission.

Of greater significance perhaps is that submitters of prior art under 35 U.S.C. § 122(e) may now provide information explaining the relevance of the prior art to the pending application. The new 35 U.S.C. § 122(e) states that the submission must be accompanied by a "concise description of the asserted relevance of each submitted document." Thus, the submitter has a much enhanced opportunity to convince the examiner that prior art bars issuance of the patent.

These provisions become effective on September 16, 2012 and apply to any patent application filed before, on or after that date.

B. Derivation Proceedings

In the current first-to-invent regime, disputes between independent inventors claiming the same invention are resolved through interference proceedings, in which each party attempts to prove that its inventor created the claimed invention first. Under the AIA, timing of inventorship is irrelevant—what matters is which inventor (or assignee) filed first. This eliminates the need for interference proceedings, which are therefore abolished. However, if the inventor of the earlier-filed patent application "derived" the invention from the inventor of the later-filed patent application, then the later filer will prevail. The later filer makes this assertion by initiating a "derivation proceeding."

In other words, if a university is planning to file a patent application on an invention, but some other entity, such as a collaborator or sponsor, takes the invention and files first, there may be a remedy. And similarly, a collaborator could challenge a university patent filing, claiming the university "derived" the invention from the collaborator.

The Act provides little guidance as to what derivation is; standards are to be prescribed in regulation. USPTO proposed regulations interpret derivation to mean that the earlier filer was not an inventor at all, stating that "derivation proceedings were created to ensure that the first person to file the application is actually a true inventor." [38] To succeed, the petitioner must establish that the later filer communicated the invention to the earlier applicant, and that the earlier applicant filed without authorization. [39]

Derivation proceedings will likely be rarer than interferences have been. Under current law, an interference can be filed against an independent inventor of the same invention, so long as the challenger can make a claim to having created the invention first. A derivation under the AIA, by contrast, may be filed only against an inventor who *obtained* the invention from the challenger. A truly independent inventor who files first will not be subject to a derivation claim.

The time limit to file a derivation petition is one year after the first publication of "a claim to an invention that is the same or substantially the same as the earlier application's claim to the invention." This language is confusing, and could be construed as meaning that the one-year clock starts with publication of the true inventor's later-filed application. But the USPTO proposed regulations recast the standard as: the one-year clock starts with "publication by the earlier applicant of a claim to the same or substantially the same invention" as that of the petitioner. [40]

The petition must specify the basis for concluding that the earlier filer derived her invention from the petitioner without authorization. It must be submitted under oath and supported by substantial evidence. The USPTO will review the petition and decide whether to institute a derivation proceeding before the newly created Patent Trial and Appeal Board ("PTAB"). [41] There are no provisions for

discovery from the earlier filer.

If both patents have issued, [42] the AIA authorizes a civil lawsuit to assert a claim of derivation against the owner of the earlier filed patent. [43] The action must be filed within one year of the issuance of the derived patent.

The intersection of these two provisions appears to be as follows:

- If both applications are pending, then section 135 authorizes a derivation proceeding by the actual inventor before the PTAB within one year of publication of the derived patent application. The actual inventor must have her own patent application pending at the time she files the petition.

- Once the deriver's patent issues, the actual inventor has one year to file a civil action, but only if her own patent issues.

- If the actual inventor's patent has already issued, and the deriver's earlier-filed application is still pending, neither section 135 nor section 291 applies. So in that case, the actual inventor must wait to see if the alleged deriver's patent issues. If it does, the actual inventor then has one year to file a civil action. (Of course, during the interim, the actual inventor may have recourse to some of the other opportunities to challenge the deriver's patent by providing input to the USPTO, as explained elsewhere in this NACUANOTE).

Appeals of PTAB derivation decisions are made to the Federal Circuit, [44] but any adverse party can make an election under 35 U.S.C. § 146 to remove the matter to federal district court for a *de novo* consideration.

C. Post-Grant Proceedings

United States patent law has long been criticized for the lack of a post-grant "opposition" process, such as that of the European Patent Office ("EPO"), pursuant to which a third party may administratively contest the validity of a patent after the patent issues. The proponents of such a system argue that it provides a low cost alternative to litigation and a more thorough and efficient review, since third party competitors often have more useful information than the USPTO about the technological value of inventions and the state of the art. Thus, it is argued that a post-grant review will benefit not only the patent owner and petitioner but also conserve governmental resources by providing a less expensive way for competitors to share information directly with the USPTO. [45]

Prior to the enactment of the AIA, there were two principal ways in which a patent could be challenged post grant in the United States. The most frequent has been by filing a lawsuit in federal district court, which can be prohibitively expensive and which favors the patent owner by presuming the validity of the patent and by requiring a "clear and convincing" standard of proof of invalidity.

The administrative alternative to litigation is the reexamination proceeding, which, until 1999, was *ex parte* and its efficacy was limited by the fact that the patentee had the exclusive right to communicate with the examiner and the challenger had very limited involvement. [46] In 1999, the law was amended to permit *inter partes* reexamination, a solution that was designed to be closer to the European opposition model, but that also has proved to be less than optimal as an alternative to litigation for challenging granted patents.

The new law provides an expanded process for challenging patent validity at the USPTO by including two new proceedings: post-grant review and *inter partes* review.

The post-grant review process enables anyone, including patent litigation defendants, to challenge issued patents in an expedited and cost-effective proceeding within nine months of the patent issue. And the new *inter partes* review will replace the current *inter partes* reexamination with a procedure that can be invoked at any time during the life of the patent after nine months from date of issue. *Ex parte* reexamination will still be available, but *inter partes* reexamination will be abolished one year after enactment of the new law. [47]

Post-grant review will be available during the first nine months after issuance (or broadening reissuance) of a patent and will permit third party challenges based on any ground for invalidity that would be available in litigation. [48] *Inter partes* review will be available after the first nine months from issuance and for the remainder of a patent's period of enforceability, but is limited to challenges for lack of novelty or obviousness based on patents or printed publications. [49]

For patents that are at least nine months old, *inter partes* review will be available on September 16, 2012, after which date *inter partes* reexamination will no longer be available. Post-grant review will be available for patents with a priority date on or after March 16, 2013. [50] However, with an average date of issuance three-to-five years after filing, post-grant review will not be available for most patents until 2015 or 2016.

D. Post-Grant Review

Post-grant review is initiated when a person who is not the owner of the patent files a petition with the Director of the USPTO [51] no later than nine months after the grant of the patent or the issuance of a reissue patent. The petition may challenge one or more claims of a patent on any ground that could be raised under paragraphs (2) or (3) of §282(b) (any ground for invalidity of the patent or claim). [52] The petitioner may submit factual evidence and expert opinions in support of the allegations of the petition.

The patent owner has the right to file a preliminary response to the petition that sets forth reasons, limited to failure of the petition to meet any requirements of Chapter 32, why no post-grant review should be instituted. The Director will authorize post-grant review only upon a finding that it is more likely than not that at least one of the claims challenged is unpatentable. There is no right of appeal from the Director's decision to grant the review. [53] A significant additional basis for review is a showing by the petitioner that the petition raises a novel or unsettled legal question that is important to other patents or patent applications. [54] The review process must be completed within one year from the date the Director grants review, with an extension of up to six months for good cause. [55]

E. *Inter Partes* Review

A petition for *inter partes* review may be filed after the later of nine months from patent grant or termination of a post-grant review proceeding. The permissible grounds for challenge are more narrow than post-grant review as they are limited to claims of invalidity based on lack of novelty or obviousness demonstrated in patents or printed publications. The petitioner must show only that there is a reasonable likelihood of prevailing on at least one claim. [56] Although this standard for review is nominally different from that for *ex partes* review, it is unclear whether there is an actual or intended difference between the phrase "reasonable likelihood of prevailing" used in the *inter partes* provision and "more likely than not to prevail" in the *ex partes* provision.

Prior to the enactment of the AIA, 35 U.S.C. § 312(a) provided, as a standard for granting an *inter partes* reexamination request, that the Director determine whether a substantial new question of patentability ("SNQ") affecting any claim of the patent concerned was raised by the petition. The new section 6(c)(3)(A) of the AIA amended 35 U.S.C. §§ 312 and 313 to delete any reference to the "SNQ" standard, and to provide instead language requiring the information presented in a request for *inter partes* review to show that there is a "reasonable likelihood that the requestor will prevail with

respect to at least one of the claims challenged." [57]

Unlike under reexamination, the parties involved in *inter partes* review have the ability to settle and terminate the review up until the time the USPTO decides the merits of the proceedings. The patent owner has an opportunity to object to the review based on the petitioner's failure to meet any requirement of Chapter 31, but the Director's decision to grant review is not appealable. [58] Reviews under both post-grant and *inter partes* procedures will be conducted by the newly created Patent Trial and Appeal Board, whose decisions are appealable to the Court of Appeals for the Federal Circuit. [59]

It remains to be seen how well these new post-grant administrative remedies work for universities in resolving questions of patent validity. Throughout the six years that it has taken for Congress to enact patent reform legislation, there has never been consensus on this question. Some fear that the post grant processes merely add more means for patents to be attacked, keeping new technology from the market and making it difficult for small companies to compete. Some have predicted that large corporations will use the new procedures to file post-grant oppositions for the purpose of delaying potential damages for infringing.

However, in a joint letter to Congress dated June 22, 2011, a group of prominent higher education associations confirmed their support for the AIA by stating that the legislation "represents the successful culmination of a thorough, balanced effort to update the U.S. patent system to support more effectively the nation's economic competitiveness and job creation in the increasingly competitive global economic environment of the 21st century." [60]

F. Transitional Business Method Post-Grant Review

Largely in response to businesses such as financial institutions that are being sued with increasing frequency for infringing business method patents, section 18 of the AIA establishes a transitional post-grant review of the validity of covered business method patents which will employ the standards and procedures of post-grant review described above, but will apply to business method patents existing as of September 16, 2012, without the nine-month limitation. Once it takes effect, this provision applies to already-granted business method patents. Consequently, it could have an impact on a lawsuit pending today if the case remains active until September 16, 2012. The transitional provisions will expire September 16, 2019.

The term "covered business method patent" is defined as "a patent that claims a method or corresponding apparatus for performing data processing or other operations used in the practice, administration, or management of a financial product or service, except that the term does not include patents for technological inventions." [61] The USPTO is charged with promulgating regulations for determining whether a patent is for a "technological invention."

In order to invoke the business method review, the petitioner must have been sued for infringing the patent involved or been "charged" with infringing the patent. The term "charged" is not defined, but could refer to a proceeding before the International Trade Commission ("ITC"), for example. Presumably, this term also will receive further attention in the forthcoming regulations. The petitioner, if a defendant in a civil action, may request the court to grant a stay pending post-grant review, but either party may file an interlocutory appeal to the Court of Appeals for the Federal Circuit. [62] If post-grant review occurs and fails, the petitioner is estopped from asserting in a civil action that a claim is invalid on any ground actually raised during the transitional proceeding that resulted in a final written decision.

G. Estoppel

As when filing a civil complaint, under both post-grant and *inter partes* review, petitioners should

raise with the ITC or USPTO all viable grounds for invalidating the patent, since failing to do so will prevent the petitioner from raising them in a later civil action. [63] Comments filed with the USPTO on the planned implementation of the AIA questioned the fact that, under both post-grant and *inter partes* procedures, estoppel does not expressly exclude claims that were filed in earlier reexamination proceedings. The new *inter partes* review estoppel provision provides:

> 315 (e) Estoppel
> (1) PROCEEDINGS BEFORE THE OFFICE. The petitioner in an *inter partes* review of a claim in a patent under this chapter that results in a final written decision under §381(a), or the real party in interest or privy of the petitioner, may not request or maintain a proceeding before the Office with respect to that claim on any ground that the petitioner raised or reasonably could have raised during the *inter partes* review. [64]

Some commenters point out that this provision does not expressly prohibit an *inter partes* review based on, for example, the same issue presented in an earlier *inter partes* reexamination. [65] If the parties were allowed to file later *inter partes* review petitions on the same grounds as an earlier *inter partes* reexamination, this would seem to be at odds with two of the principal reasons that Congress included the estoppel provisions—the economical use of USPTO resources and the expense to patent owners of being forced to participate in duplicative proceedings.

Another anomaly is that patents issuing after September 16, 2012 and before 2016 will not be subject to *inter partes* review for the first nine months after issuance and will also be ineligible for post-grant review because of their effective filing dates. As stated above, post-grant review is limited to patents issued on applications that were filed on or after March 16, 2013 (first to file) and it is likely to take several years for those patents to issue. For those patents, there will be several years when the only means to challenge invalidity will be litigation.

H. Relationship of Post-Grant Review/*Inter Partes* Review and Civil Litigation

The AIA's new sections 315 and 325 provide that neither review can proceed simultaneously with the petitioner's civil action. If the petitioner files a civil action challenging the validity of a claim of the patent under review, the civil action will be stayed unless and until the patent owner moves to lift the stay or files a civil action or counterclaim alleging that the petitioner has infringed the patent. A defendant's counterclaim of patent invalidity filed in a civil action for infringement does not bar the defendant from also seeking administrative review. [66] However, an *inter partes* review petition will not be granted if it is filed more than one year after the petitioner is sued for infringement.

A substantive difference between the new administrative proceedings and civil litigation is that under post-grant/*inter partes* review there is no presumption of patent validity. This aspect of the review is similar to the EPO opposition and provides an obvious advantage to the petitioner, but is consistent with the intent of Congress to correct or limit the number of improperly granted patents. It is also presumed to reduce the number of declaratory judgment actions filed in court. [67] And, even when civil actions are filed, complainants may not assert issues that they "raised or reasonably could have raised" in any post-grant proceeding or *inter partes* review.

The Intellectual Property Owners Association ("IPO") has submitted to the USPTO proposed rules on the AIA drafted by a committee appointed jointly by IPO, the American Bar Association, and the American Intellectual Property Law Association. The IPO points out that the new proceedings augment alternatives already available to those wanting to challenge the validity of patents. A petitioner will be able to choose among the alternatives based on their own resources and the perceived efficacies of the respective options. In addition, they will have had, in the case of a post-grant review petition, the opportunity to monitor the progress of the patent prosecution; will be familiar with allowed claims; and will then have an additional nine months in which to prepare the

petition. With respect to *inter partes* review, the petitioner will have had even longer to prepare.

In contrast, patent owners have no ability to choose where and when they will defend their patent rights and could be forced to defend against multiple challengers in more than one of the new procedures. The IPO suggests that implementing regulations should balance the congressional intent that the new proceedings serve as a "viable alternative to expensive and protracted patent litigation" [68] while ensuring fairness to the patent owner. Accordingly, they have proposed rules that, among other things, set a timeline for post-grant and *inter partes* proceedings that will afford the patent owner three months to file a preliminary response and will allow the patent owner six months for discovery after order on post-grant review while allowing only three months for the petitioner's rebuttal discovery period.

It is too early in the rulemaking process to predict whether the USPTO will in fact adopt rules designed to favor the patent owner, but USPTO will definitely be adopting rules of practice, addressing the structure and timing for the new proceedings, which are merely outlined in the statute. These rules and the costs associated with the new proceedings will largely determine the extent to which the new law provides a meaningful alternative to litigation.

I. Supplemental Examination

Prior to enactment of the AIA, patent owners could amend or correct issued patents in one of two ways: requesting a certificate of correction, or reissuing under Chapter 25. [69] Both of these remedies were limited in the kind of information and the issues that the patent owner could address. The AIA adds to these remedies a new subsection (a) of 35 U.S.C. § 257, "Request for Supplemental Examination," pursuant to which the patent owner may petition to consider, reconsider, or correct information believed by the patent owner to be relevant to the issued patent. [70] Such information can be new information, information that was previously considered by the USPTO, or information that the patentee wants to correct. [71] The new law does not limit the submitted information to patents or printed publications as required under the *ex parte* reexamination rules of Chapter 30. If the new information raises a "substantial new question of patentability," the USPTO will issue a certificate ordering an *ex parte* reexamination, which will be conducted with special dispatch pursuant to the procedures established by Chapter 30. [72] Consequently, a patent owner may raise issues relating to novelty, obviousness, or inequitable conduct and have these addressed through the reexamination process pursuant to a supplemental examination request. [73] If the request for supplemental examination does not raise a "substantial new question of patentability," no reexamination is ordered, and the USPTO will simply issue a certificate to that effect.

One of the advantages of the supplemental examination procedure for patent owners is that the AIA specifically provides that a patent cannot be held unenforceable based upon information that was considered during a supplemental examination of the patent, assuming an exception does not apply. [74] Thus, unlike previous options for correcting a patent, the supplemental examination may provide a process for curing an earlier error regarding the patent, including an error which is alleged to constitute inequitable conduct. [75] If the error is corrected in supplemental reexamination before an inequitable conduct allegation is brought, and subject to the exceptions listed below, it can preclude patent invalidity based upon allegation of inequitable conduct. [76]

There are, however, limits on the use of the process to address issues raised in litigation. The provision that a patent cannot be found unenforceable based on information considered during supplemental reexamination does not apply to issues raised in the supplemental examination which were also pled with particularity in a civil action or set forth with particularity in a notice under section 355(j)(2)(B)(iv)(11) of the Federal Food, Drug, and Cosmetic Act prior to the request for supplemental examination. Further, this provision does not apply in an action brought under section 337(a) of the Tariff Act of 1930 or a civil action for patent infringement under 35 U.S.C. § 281, unless the supplemental examination and any ordered reexamination are concluded before the date on

which the action is brought. [77]

The USPTO will conduct the supplemental examination within three months of a request that meets their requirements. Thus, the procedure may be faster than filing a reissue application. The changes in 35 U.S.C. § 257 will take effect on September 16, 2012 and apply to every patent issued before or after that date.

III. Infringement

A. Best Mode Defense

Under current law, a specification for a patent must "set forth the best mode contemplated by the inventor of carrying out his invention." [78] The AIA eliminates an accused infringer's ability to use the best mode requirement to defend an infringement action. Failure to disclose the best mode is no longer a basis upon which any claim of a patent may be "canceled or held invalid or otherwise unenforceable." [79] This provision was effective as of September 16, 2011.

B. Defense to Infringement Based on Prior Commercial Use

Under previous law, prior commercial use was a defense for infringement of patents for "methods of doing or conducting business" only. The AIA significantly expanded this defense, extending it to cover patents for any "process,. . . machine, manufacture, or composition of matter used in a manufacturing or other commercial process." [80] Note that this effectively applies only to trade secrets—prior uses that are public are protected to an even greater extent in that they preclude patenting by others under [§102(a)(1)] (no patent for invention in public use before the filing date).

The defense applies only if the defendant engaged in commercial use at least one year before the patent application filing date (or, if earlier, one year before certain disclosures of the invention to the public by the inventor). Commercial use can be internal commercial use, an arm's length sale, or arm's length commercial transfer. Importantly for universities, nonprofit research or nonprofit laboratory use counts as commercial use, [81] so institutions can take advantage of this provision in fending off the growing number of research-tool claims we face under *Madey v. Duke*. [82]

The defense may soon become even broader. The Senate Judiciary Committee has held hearings on whether to eliminate the one-year look-back and expand the defense to any entity making substantial preparations to use the technology.

Equally important, this defense contains a blanket exception when universities or their licensees are the plaintiffs. It cannot be used against inventions owned by U.S. institutions of higher education, [83] or under obligation of assignment thereto, or by their dedicated tech transfer organizations. Thus, universities and their licensees can enforce university inventions even against companies that had made prior commercial use of the technology.

This exception was the result of advocacy by academic institutions concerned that the expansion of prior use rights would inhibit academic publication. The fear was that publications could be used by industry to develop and use university technology for commercial purposes, and the companies that did so quickly enough would then not need to take a license to the resulting patents. The exception addresses that concern.

This exception has its own exception, however. It does not apply if any activity required to reduce the invention to practice could not have been undertaken using federal funds. [84] This is presumably aimed at the Dickey-Wicker prohibition on funding destruction of embryos, although it is

not so limited in its terms.

The provision is in effect immediately as to any patent granted after the date of enactment.

C. Advice of Counsel

The AIA adds [35 U.S.C. § 298], providing that a patentee may not use an infringer's failure to obtain advice of counsel or failure to present advice of counsel to court as evidence of willful or induced infringement. This clarifies confusing existing Federal Circuit precedent holding that failure to obtain advice of counsel doesn't give rise to an inference of willful or induced infringement, but may be nonetheless probative of willful infringement [85] and similarly is relevant to assessing intent to induce infringement. [86]

This may be helpful to universities defending against infringement claims, as most institutions do not have the resources to routinely obtain non-infringement opinions of counsel. The situation is most likely to arise in a Duke v. Madey-type research-tool claim from a patentee or assignee. Currently, when confronted with an allegation of infringement, some institutions may feel compelled to obtain formal opinions of counsel to avoid risk of willful infringement and consequent exposure to enhanced damages and attorney fees. Under new [§298], a more informal review may be deemed sufficient in some circumstances.

The new rule is effective for any patents issued after September 16, 2012.

IV. Miscellaneous

A. Fees for Patent Services

Although the new law includes an immediate surcharge of 15% on all fees, including maintenance fees, and an additional fee of $400.00 for non-electronic filing of applications, it contains provisions that will reduce fees for non-profits, small companies, and universities. [87] The AIA retains the 50% fee reduction for applicants that qualify as "small entities" as defined by 35 U.S.C. § 41(h)(1) and adds a new fee reduction of 75% for "micro entities" for filing, searching, examining, issuing, appealing, and maintaining patent applications. A "micro entity" is defined to include an inventor applicant employed by, or who has a duty to assign to, an "institution of higher education." [88]

A new schedule of fees for patent services is provided in section 11 of the Act. [89] Even with the higher fees, universities will benefit from the new law. An example is the basic utility patent filing fee which has increased from $165 to $330. Under the AIA, that same filing fee will now be only $95 for a university. A search fee which would have cost a university $270 before will now cost $155. These savings will be advantageous to those institutions with limited resources for filing and prosecuting patents. They will also be good for technology transfer and innovation, since universities will be able to pass the savings along to their small entity licensees.

B. Funding Agreements

The AIA improves Bayh-Dole's provisions pertaining to retention of commercialization revenues for operators of Government-owned-contractor-operated facilities. [90] As before, the first 5% of net revenues are to be used for the research, development and educational mission and objectives of the facility, as are a portion of the amounts in excess of 5%. But previously, the retained portion above the 5% threshold was only 25%; now it is 85%. This provision became effective on September 16, 2011, although there may be timing issues regarding revenues earned prior to the effective date but received afterward.

CONCLUSION:

The America Invents Act was a long time coming, and it addresses many of the aspects of U.S. patent law that conflicted with the systems in other countries, while still preserving a number of the unique features of the American system. The new provisions will no doubt raise additional issues and questions in the years to come, and it will take regulatory development and litigation to sort them out. Already, various stakeholders are working hard to influence the so-called technical amendments that will be needed in the coming year to smooth out some wrinkles and unintended consequences of the new law.

As the AIA rolls out in stages between September 2011 and May 2013, the U.S. Supreme Court continues to hear patent cases at a rate unseen in our lifetimes, with decisions on business method patents, laws of nature, and other basic patent concepts, unsettling the landscape further. These are fraught but exciting times for those of us affected by patent law!

FOOTNOTES:

FN1.
S. Merrill, R. Levin & M. Myers, "A Patent System for the 21st Century," National Academies Press (2004).

FN2.
For a more basic background on patent law and treatment of *pre-AIA* patent law in the higher education context, *see* Rita Hao, Intellectual Property Basics: Copyright, Trademark, Patent, Trade Secret, Publicity Rights, NACUA Annual Conference (2009); M. Sharon Webb, Patents Made Painless, NACUA Fall CLE Workshop (2002). The USPTO also maintains a website devoted to Implementation of the new America Invents Act, at http://www.uspto.gov/aia_implementation/index.jsp.

FN3.
[35 U.S.C. § 102(a)(2)]. Throughout this NACUANOTE, square brackets will be used to denote citations to AIA-mandated code revisions that are not yet in effect at the time of publication.

FN4.
AIA, § 3(n)(1).

FN5.
AIA, § 3(n)(2).

FN6.
For a discussion of the complexities and uncertainties the AIA creates for continuation-in-part applications, see C. Brinckerhoff, "The First-to-File Poison Pill," PharmaPatents Blog (October 4, 2011).

FN7.
"Prior art" refers to earlier publications and uses of the same invention—normally, a patent will not be issued if there is prior art. But in the U.S., there has been a "grace period" that allows a patent to

issue under certain circumstances, so long as the application is filed within one year of the prior art. 35 U.S.C. § 102.

FN8.
[35 U.S.C. §§ 102(a)(1), 102(b)(1)(A)]. There is some ambiguity as to how closely the inventor's invention and prior art must match the third party's prior art, in order for the grace period to work.

FN9.
35 U.S.C. § 102(b). Note also, the technology disclosed in the filing must have been invented prior to the date of publication; someone who independently invents it again, after that date, is not eligible to file a patent application. 35 U.S.C. § 102(a).

FN10.
See 35 U.S.C. § 102(b).

FN11.
[35 U.S.C. § 102(a)(1)].

FN12.
35 U.S.C. § 102(a).

FN13.
[35 U.S.C. § 102(a)(1)].

FN14.
The CREATE Act provisions are currently codified at 35 U.S.C. § 103(c); under the AIA they will be codified at [35 U.S.C. §§ 100(h), 102(c)] with the caption "Common Ownership under Joint Research Agreements."

FN15.
[35 U.S.C. §§ 102, 103].

FN16.
35 U.S.C. § 115.

FN17.
35 U.S.C. § 118.

FN18.
35 U.S.C. § 115.

FN19.
35 U.S.C. § 118.

FN20.
[35 U.S.C. § 115(e)].

FN21.
[35 U.S.C. § 118].

FN22.
[35 U.S.C. § 115(d)(3)].

FN23.

[35 U.S.C. § 115].

FN24.
[35 U.S.C. § 118].

FN25.
[35 U.S.C. § 115(g)].

FN26.
See Noonan, AIA Overview: Changes in Requirements for the Inventor's Oath or Declaration, Patent Docs Blog (October 27, 2011).

FN27.
[35 U.S.C. § 115(f)]. A notice of allowance is the announcement of the USPTO's decision to award a patent, contingent upon timely payment of an issue fee by the applicant. 35 U.S.C. § 151.

FN28.
77 Fed. Reg. 984 (Jan. 6, 2012).

FN29.
AIA § 33(a).

FN30.
AIA § 33(b).

FN31.
MPEP-2105.

FN32.
Memorandum, Sept. 20, 2011, from Robert Bahr, Sr. Patent Counsel and Acting Assoc. Comm'r or Patent Examination Policy, to Patent Examining Corps re "Claims Directed to or Encompassing a Human Organism."

FN33.
2003 Cong. Rec. E2235, quoting Rep. Weldon as stating that his amendment "simply restates [USPTO] policy." See also 2011 Cong. Rec. E1184, quoting Rep. Lamar Smith: " … nothing in this section should be construed to limit the ability of the PTO to issue a patent containing claims directed to or encompassing:

"1. any chemical compound or composition, whether obtained from animals or human beings or produced synthetically, and whether identical to or distinct from a chemical structure as found in an animal or human being, including but not limited to nucleic acids, polypeptides, proteins, antibodies and hormones;

"2. cells, tissue, organs or other bodily components produced through human intervention, whether obtained from animals, human beings, or other sources; including but not limited to stem cells, stem cell derived tissues, stem cell lines, and viable synthetic organs;

"3. methods for creating, modifying, or treating human organisms, including but not limited to methods for creating embryos through in vitro fertilization, methods of somatic cell nuclear transfer, medical or genetic therapies, methods for enhancing fertility, and methods for implanting embryos;

"4. a nonhuman organism incorporating one or more genes taken from a human organism, including

but not limited to a transgenic plant or animal, or animal models used for scientific research."

FN34.
37 CFR 1.99.

FN35.
MPEP 1134.01.

FN36.
Id.

FN37.
77 Fed.Reg. 448, 451 (Jan.5, 2012).

FN38.
77 Fed. Reg. 7028, 7029 (Feb. 10, 2012).

FN39.
Proposed 37 C.F.R. 42.405, 77 Fed. Reg. 7028, 7040 (Feb. 10, 2012).

FN40.
77 Fed. Reg. 7028, 7030 (Feb. 10, 2012).

FN41.
[35 U.S.C. § 135].

FN42.
Note that the PTO cannot effectively track and compare all the patents it is issuing, so it may well issue patents on two applications that claim substantially the same invention.

FN43.
[35 U.S.C. § 291].

FN44.
[35 U.S.C. § 141(d)].

FN45.
Lemley, Mark A, Lichtman, Douglas Gary and Sampat, Bhaven N., "What to do About Bad Patents, Regulation, Vol. 28, No.4, pp. 10-13, Winter 2005-2006.

FN46.
Graham, Stuart J.H. and Harhoff, Dietmar, "Separating Patent Wheat from Chaff: Would the U.S. Benefit from Adopting a Patent Post-Grant Review?" (October 14, 2009) (available at Social Science Research Network).

FN47.
35 U.S.C. §§ 321-329 (Post-Grant Review) and §§ 311-319 (*Inter Partes* Review).

FN48.
Id. at § 321(a)-(c*).*

FN49.
Id. at § 311(b).

FN50.

Although the effective date is September 16, 2012 under AIA §6(f)(2)(A), §3(n)(1) limits consideration to patents issued from applications filed under the first inventor to file system, i.e. with a priority date on or after March 16, 2013.

FN51.
Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office. 35 U.S.C § 3(1).

FN52.
Id. at § 321(a)-(c).

FN53.
Id. at § 324(a).

FN54.
Id at § 324(b).

FN55.
Id. at § 316(a)(11).

FN56.
The USPTO has issued rules effective September 16, 2011 that makes the new "reasonable likelihood" standard applicable to all requests for *inter partes* reexamination.

FN57.
35 U.S.C. § 314(a). With respect to the new standard, House Rep. 112-98(Part 1), 112th Cong., 1st Sess., provides, in connection with *inter partes* review: "The threshold for initiating an *inter partes* review is elevated from 'significant new question of patentability'—a standard that currently allows 95% of all request to be granted—to a standard requiring petitioners to present information showing that their challenge has a reasonable likelihood of success." H.R. Rep. No. 112-98 (Part 1), at 47.

FN58.
35 U.S.C. § 311-324.

FN59.
Id. at §319 and §329.

FN60.
See Letter from Association of American Universityes, American Council on Education, Association of American Medical Colleges, Association of Public and Land-grant Universities, Association of University Technology Managers and the Council on Governmental Relations (June 22, 2011).

FN61.
AIA, § 18(d)(1).

FN62.
AIA, § 18(b).

FN63.
Id. at § 315(e) and § 325(e).

FN64.
This language is identical to that in § 325(e) for Post Grant Review.

FN65.

http://www.uspto.gov/aia_implementation/comments.jsp.

FN66.
Id. at § 315(a) and § 325(a).

FN67.
Id. at § 315(b).

FN68.
Nov. 18, 2011, letter to David J. Kappos submitted via aia_implementation@uspto.gov.

FN69.
35 U.S.C. §§ 251-256.

FN70.
Id. at § 257(a).

FN71.
The USPTO has stated that the information "may include, for example, issues of patentability under 35 U.S.C. 101 and 112." See, Federal Register Vol. 77, No.16, p. 3666.

FN72.
See, Federal Register Vol.77, No. 16, p. 3668.

FN73.
Id.

FN74.
Id. at § 257(c)(1).

FN75.
This means of absolving inequitable conduct was an attempt by Congress to remedy the strain on the patent system produced by numerous inequitable conduct claims as a defense to infringement, and to limit unnecessary and counterproductive litigation costs. See, House Report on H.R. 1249 (June 29, 2011), pages 40 and 50 available at http://www.uspto.gov/aia_implementation/resources.jsp.

FN76.
35 U.S.C. § 257(c)(2)(A).

FN77.
Id.

FN78.
Id. at § 112.

FN79.
Id. at § 282(3)(A).

FN80.
35 U.S.C. § 273.

FN81.
35 U.S.C. § 273(c)(2).

FN82.
Madey v. Duke, 307 F.3d 1351 (Fed. Cir. 2002). This case made clear that universities do not have a broad "experimental use" defense to patent infringement. Patent holders can therefore assert their patents and prevent universities from using patented technology in their research activities without a license.

FN83.
As defined in 20 U.S.C. 1001(a).

FN84.
35 U.S.C. § 273(e)(5)(B).

FN85.
In re Seagate Technology, LLC, 497 F.3d 1360 (Fed. Cir. 2007) (Failure to obtain or introduce evidence of legal advice regarding possible infringement does not give rise to an inference of infringement, but it is crucial to the analysis).

FN86.
Broadcom v. Qualcomm, 543 F.3d 683 (Fed. Cir. 2008) (Upholding jury instruction permitting consideration of whether infringement defendant sought opinion of counsel as one element in specific intent determination, but prohibiting negative inference).

FN87.
The $400 filing fee is not applicable to design, plant, or provisional applications. §10, AIA.

FN88.
35 U.S.C. § 123.

FN89.
Codified at 35 U.S.C. § 41(a) and (b).

FN90.
35 U.S.C. § 202(c)(7)(E)(i).

AUTHORS:

Robert Bienstock, Associate General Counsel, Yale University

Judith L. Curry, Associate General Counsel, North Carolina State University

The authors wish to acknowledge and thank Greg Hartwig and Lynda Fitzpatrick at Michael Best & Friedrich LLP; Erin Bobay at Myers, Bigel, Sibley & Sajovec P.A.; Wes Blakeslee at Johns Hopkins University; and Greg Brown at the University of Minnesota for their thoughtful review and comments during the drafting of this NACUANOTE.

"To advance the effective practice of higher education attorneys for the benefit of the colleges and universities they serve."