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.

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

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

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

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

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 litigreW*o

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

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

not so limited in its terms.

CONCLUSION:

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. § 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.

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).

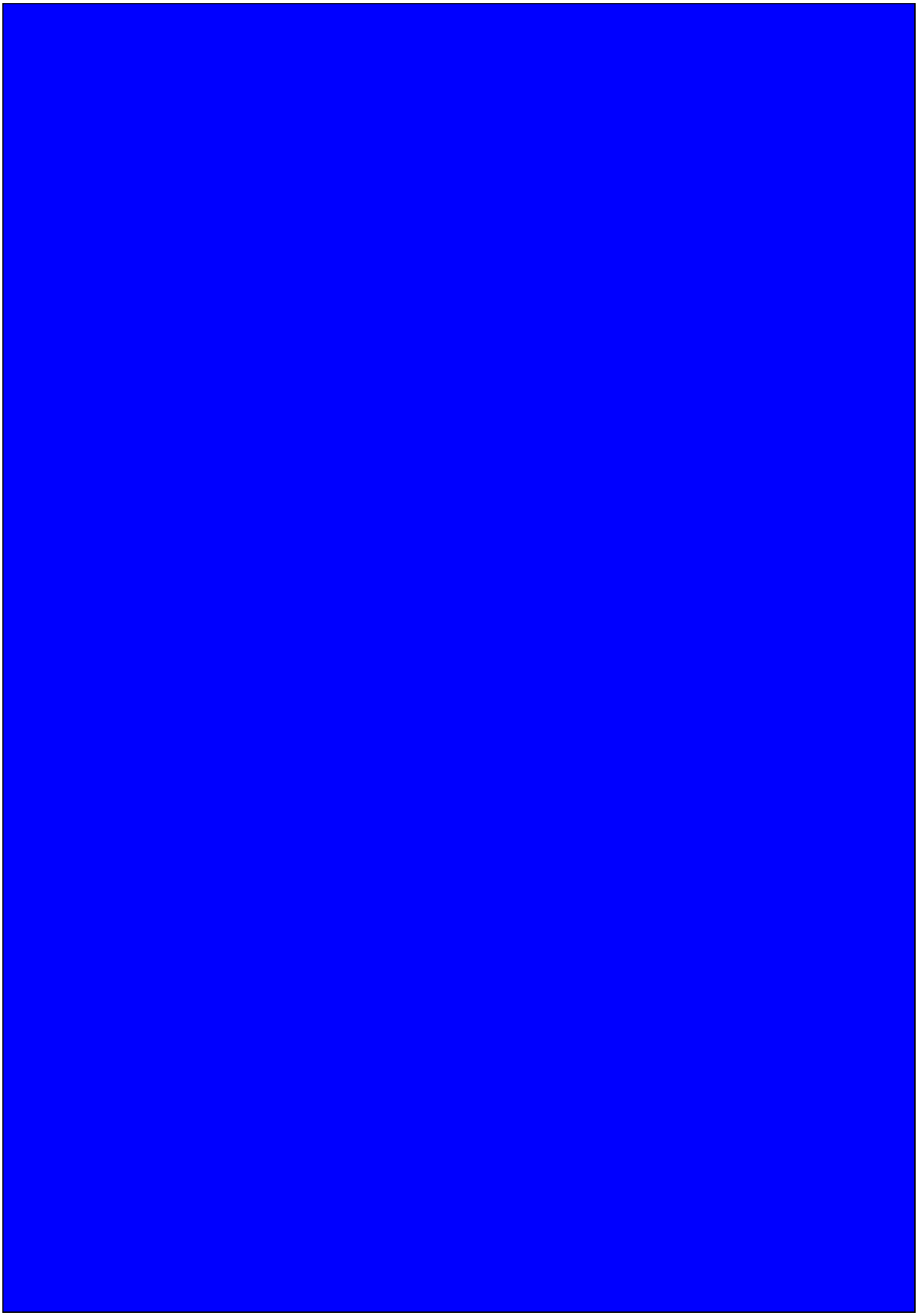
FN61.
AIA, § 18(d)(1).

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.



FN82.

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