

**From:** Norton, Leah

**Sent:** Friday, October 05, 2012 4:24 PM

**To:** fitf\_guidance

**Cc:** fitf\_rules

**Subject:** Proposed Examination Guidelines on First Inventor to File Provisions. (Docket No. PTO-P-2012-0024; 77FedReg43759) - Comments from Higher Education Associations

Attached please find comments from the higher education associations in response to the Federal Register notice on the USPTO proposed Examination Guidelines on First Inventor to File Provisions. (Docket No. PTO-P-2012-0024; 77FedReg43759). Our comments also involve the companion First Inventor to File Rules published simultaneously (Docket No. PTO—P-2012-0015; 77FedReg43742).

Thank you,

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October 5, 2012

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Re: Docket No. PTO-P-2012-0024 (77FedReg43759)

The Association of American Universities (AAU) is an association of 59 U.S. and two Canadian preeminent research universities organized to develop and implement effective national and institutional policies supporting research and scholarship, graduate and undergraduate education, and public service in research universities. The American Council on Education (ACE) represents the presidents of 1,800 U.S. accredited, degree-granting institutions, which include two- and four-year colleges, private and public universities, and nonprofit and for-profit entities. The Association of American Medical Colleges (AAMC) is a not-for-profit association representing all 138 accredited U.S. medical schools; nearly 400 major teaching hospitals and health systems, and 89 academic and scientific societies. The Association of Public and Land-grant Universities (APLU) is a research and advocacy organization of public research universities, land-grant institutions, and state university systems with member campuses in all 50 states, U.S. territories and the District of Columbia. The Association of University Technology Managers' (AUTM) is a global network of members from more than 350 universities, research institutions, teaching hospitals and government agencies as well as hundreds of companies involved with managing and licensing innovations derived from academic and nonprofit research. The Council on Governmental Relations (COGR) is an association of 190 U.S. research universities and their affiliated academic medical centers and research institutes that concerns itself with the impact of federal regulations, policies and practices on the performance of research and other sponsored activities conducted at its member institutions.

These six associations have collaborated throughout the patent reform process that successfully concluded with the enactment of the AIA. We appreciate the opportunity to comment on the U.S. Patent and Trademark Office's (USPTO) proposed implementation of the First Inventor to File

Provisions of the American Invents Act (AIA). Our comments are directed primarily at the proposed Examination Guidelines (Docket No. PTO-P-2012-0024; 77FedReg43759). Our comments also involve the companion First Inventor to File Rules published simultaneously (Docket No. PTO—P-2012-0015; 77FedReg43742).

Our associations strongly supported the goal of patent reform to enhance the capacity of the US patent system to promote innovation and economic competitiveness. Given the heterogeneous nature of the US patent community, however, achieving balanced, effective patent reform required that we support compromises among the stakeholders to achieve improvement of the patent system overall. During the six-year legislative patent reform process, we agreed to a number of compromises where we deviated from our preferred outcome for what we judged to be the larger benefit to the patent system. One of those compromises was the move from the previous a First to Invent (FTI) to a First Inventor to File (FITF) system for determining patent priority.

Universities have operated effectively under FTI, which has fit well with the primary research mission of universities to expand the frontiers of knowledge through the conduct and broad public dissemination of the results of fundamental research. An FTI-based system also effectively supports the typical academic publication process. Our researchers often publish as soon as their results and data warrant a manuscript submission; such prompt and open dissemination supports the university mission of broad dissemination of new knowledge and also advances the professional interests of academic researchers. In such cases, universities often can only consider later whether that research has produced patentable inventions that can be developed into useful products and processes for the benefit of society. Under FTI with its reliable grace period, universities were able to meet the dual goals of knowledge dissemination and creation of valuable intellectual property needed to support commercial investment.

Despite the advantages of a FTI patent priority system for universities, we understood the multiple benefits of a FITF system for US patent policy overall – global harmonization, greater objectivity, reduced litigation through elimination of patent interferences, and more. To accommodate FITF to university research and publishing, we requested three provisions to accompany the move to FITF. These were a strong inventor’s oath or declaration, continuation of the ability to file provisional patent applications, and, of particular importance to universities, an effective grace period, which is critical to enable the U.S. patent system to accommodate the university mission of broadly disseminating new knowledge and bringing the benefits of academic discoveries to the public.

We have several concerns with the proposed Examination Guidelines, the most serious concerning the treatment of the grace period. At the outset of the patent reform process, we worked in good faith with Congress and other interested parties to establish an effective grace period aligned with the new FITF system. A broadly negotiated grace period comparable in its intent to the existing system was put in place early in that process. We believed that the issue was satisfactorily resolved by establishing what we understood to be a procedure whereby a disclosure such as a faculty member’s publication in a scholarly journal or a conference presentation would shield that disclosure from being treated as prior art for up to 12 months and would also nullify any subsequent similar disclosure, including obvious variants, from being treated as prior art.

Earlier this year we learned that some interpret the grace period statutory language in the AIA as being much narrower than throughout the patent reform process we had understood it to be – specifically, that the AIA grace period language might not shield inventors’ disclosures from subsequent disclosures of obvious variants. Had this interpretation been advanced during patent

reform, our associations would have worked vigorously to reclaim our compromise condition of an effective grace period as part of the transition to a FITF system.

We were surprised and disappointed to see that the proposed Examination Guidelines adopt what appears to us to be an exceedingly narrow interpretation of the grace period language in the AIA. The Guidelines state that the prior art exception in 35 USC 102(b)(1)(B) and (b)(2)(B) requires that the subject matter in the prior art relied upon under 102(a) be the same "subject matter" as the subject matter previously publicly disclosed by the inventor in order for the 102(b) shielding exceptions to apply to the inventor's disclosure. Further, the Examiner Guidelines go on to state: "Even if the only differences between the subject matter in the prior art disclosure that is relied upon under 35 USC 102(a) and the subject matter publicly disclosed by the inventor ... are mere insubstantial changes or only trivial or obvious variants, the (grace period exception) does not apply."

We view this language to be a gratuitous and unwarranted extrapolation beyond an objective translation of statute into regulation. In our view this language constitutes substantive rule-making and exceeds the authority of USPTO. The AIA does not use the term "same" subject matter and is ambiguous on the point. The language in the Examination Guidelines quoted above seems almost to invite someone who finds the disclosed invention problematic to copy the disclosure, introduce a "mere insubstantial change" or "trivial or obvious variant" and publish the resultant product, perhaps just on a website, to establish patent-defeating prior art under 102(a), eviscerating the clear intention of the grace period to encourage early publication.

This extra-textual extrapolation of the statutory language also diametrically contradicts the legislative history expressing the intent of Congress; consider the comments of the House and Senate Judiciary Committee chairs:

- House Judiciary Committee Chairman Lamar Smith, during 2011 congressional debates:  
"Accusations that the bill doesn't preserve the one-year grace period are simply not true. The grace period protects the ability of an inventor to discuss or write about his ideas for a patent up to one year before he or they file for patent protection. Without the grace period, an individual who does this defeats his own patent. Since the publicly disseminated information constitutes prior art, it renders the invention non-novel and obvious."
- Senate Judiciary Committee Chairman Patrick Leahy:  
"...actions that constitute prior art under subsection 102(a) necessarily trigger subsection 102(b)'s protection....and, what would otherwise have been section 102(a) prior art, would be excluded as prior art by the grace period provided by subsection 102(b)."

In our view, USPTO in the Examination Guidelines proposes an interpretation of the AIA grace period statutory language that substantially narrows its scope without any clear legal or policy basis. Absent satisfactory resolution of this problem, we are concerned that universities might discourage faculty researchers working in areas likely to produce patentable inventions from disclosing the results of their research through journal articles and conference presentations lest such disclosures lead to subsequent disclosures of patent-defeating obvious variants. Moreover, even in the absence of such an institutional response, the proposed Guidelines likely will alter the behavior of individual faculty researchers to the detriment of early dissemination of research.

Such an impact of the USPTO's interpretation of the AIA grace period language would be directly counter to the university mission of broad and prompt dissemination of the results of university fundamental research, depriving the scientific and scholarly communities and the broader public of new knowledge. The consequences of this interpretation would also run counter to longstanding US science policy – and, indeed, a basic objective of patent law – that supports such broad dissemination. This is precisely the outcome that we sought to avoid throughout the patent reform process.

The conflicting interpretations of the AIA grace period language may indicate the desirability of a statutory fix to carry out the original intent of extending an effective grace period from prior law into the AIA. But in the current uncertain context of the grace period statutory language, we believe the proposed USPTO language of “mere insubstantial changes, or only trivial or obvious variations” is extreme and prejudicial.

We request that USPTO eliminate this language and suggest that the Office instead consider using language such as “subject matter commensurate with the claimed invention” or other less prejudicial language with regard to the 102(b) exceptions in the Examination Guidelines. We also encourage the Office to give careful consideration to alternative language submitted by the University of California in its comments on the USPTO proposed first inventor to file rules and guidelines. Fundamentally, we encourage USPTO to adopt language that interprets the AIA grace period statutory language in a manner that effectively implements the clear intention of Congress.

Our associations' second major concern is the proposed treatment of authorship of grace period disclosures, which we believe militates against academic publishing. University research is increasingly multi- and interdisciplinary, frequently and desirably including multiple authors. In addition, personnel such as research assistants frequently are included in scientific publications as authors. In the case of a multiple-author publication disclosing an invention and leading to a patent application, the distinction between authors and inventors will not be clear until claims are filed in patent applications. Rules for authorship of scholarly publications are different from rules for determining inventorship under patent law. The proposed Guidelines correctly note that the situation in which an application names fewer inventors than a prior publication names authors creates ambiguity about the identity of the inventors. But the Guidelines appear to adopt a default position that a publication having more authors than the subsequent patent application has inventors is categorically rejected as a grace period inventor disclosure, leading to a rejection. An overrule of such a rejection would require an “unequivocal” statement from inventors and an absence of any (emphasis added) evidence to the contrary.

The Office is helpfully proposing in a separate action (RIN 0651 – AC77) to revise the rules of practice to allow patent applicants to include a statement of any grace period inventor disclosures in the patent application specification that a grace period disclosure is by the inventor or inventors. According to the Examination Guidelines, however, this revised procedure will apply only if the disclosure does not contain additional authors. We believe that the default position should shift to the authors and inventors, allowing an inventor affidavit at the time of application to affirm a grace period disclosure and preclude rejection and to be reversed only by subsequent irrefutable evidence. This procedure would accord Office procedures with the realities of academic publishing and the intent of the grace period. It also is more consistent with the basic premise in AIA 102(a) that a person is entitled to a patent unless PTO can demonstrate that the applicant(s) did not meet the statutory requirements.

The USPTO notice asks for comments on the extent to which public availability plays a role in “on sale” prior art as defined in 35 USC 102(a)(1). We recognize that there is an extensive body of pre-AIA case law and legislative history on this matter. We believe that non-public offers for sale should not be considered prior art precisely because they are not public. In addition, the stipulation under current law that an offer to license is not considered an offer to sell should be continued. Such license offers typically occur under confidentiality agreements and are not publicly available within the generally understood meaning of the term. We urge USPTO, however, to consider the effect of new mechanisms such as crowdfunding and other web-based platforms on this matter. While the Examination Guidelines suggest these might be considered as “otherwise available prior art,” such a categorization may well depend on the particular platform in question, and we urge some flexibility in this regard.

We applaud the enormous accomplishment of the enactment of the AIA and commend the Office for its exceptionally effective, thoughtful, and consultative process of implementing this landmark legislation. We look forward to continuing to work with the Office in a collegial and collaborative fashion to address the concerns we have raised as this process continues.