DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard
Rockville, MD 20852

November 5, 2012

Mail Stop Comments-Patents
Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, Virginia 22313-1450

Attn: Mary C. Till, Senior Legal Advisor, Office of Patent Legal Administration

Dear Ms. Till:

The written remarks presented herein are directed to the United States Patent and Trademark Office's (USPTO) Request for Comments to the Examination Guidelines for Implementing the First-Inventor-to-File Provisions of the Leahy-Smith America Invents Act (AIA) (hereafter "the Guidelines") and the USPTO's proposed rules RIN 0651-AC77 (hereinafter "the Rules"), both published at 77 Fed. Reg. 43,759-43,773 (July 26, 2012). These comments represent the views of the National Institutes of Health (NIH).[1]

NIH commends the USPTO for its considerable efforts over the past fourteen months to engage stakeholders in the implementation of the AIA. To that end, NIH has concerns with two provisions within the Guidelines.

I. The Guidelines Are Inconsistent with 35 U.S.C. § 102(a) by Limiting the Grace Period to Identical Subject Matter

NIH opposes the USPTO's interpretation of the prior art exceptions under 35 U.S.C. §§ 102(b)(1)(B) and 102(b)(2)(B). The USPTO's interpretation appears to require near absolute identity of prior disclosures, inconsistent with 35 U.S.C. § 102(a). By precluding prior disclosures with "mere insubstantial changes, or only trivial or obvious variations" from falling within the exceptions, the Guidelines effectively vitiate the statutory grace period.

[1] NIH is the lead agency within the Department of Health and Human Services (HHS) in matters of technology transfer. In addition to providing patent and licensing services to all Institutes and Centers within NIH and the U.S. Food and Drug Administration (FDA), it is the lead agency responsible for coordinating and facilitating technology transfer policy functions for NIH, FDA, and Centers for Disease Control and Prevention (CDC).

With respect to a prior disclosure in a scientific journal or other non-patent context, NIH notes that U.S. patent laws afford a distinct – arguably more expansive -- view of "inventions" than such types of disclosures. Journal articles may be subject to peer review and other non-patent requirements, distinct from a patent application. As such, the proposed guideline unfairly penalizes inventors who publish their research before filing an application, even though the AIA, as affirmed through Congressional testimony, was intended to support this practice.

Even when the prior disclosure is a patent application, the Guidelines are problematic. For example, an application may include claims that are added or amended or changes to the specification, even though the disclosure in the prior application is the same. Under the Guidelines, the prior application would fall outside the grace period; even continuation and divisional patent applications, in which the specification is generally the same, may be impacted, as the claims in such applications are, by definition, different.

As the USPTO prepares final guidelines on the grace period, NIH respectfully requests that the final guidelines rely more closely with the intent of Congress and the AIA by removing the requirement for near identity of disclosure.

II. The Guidelines for Proposed Rule 37 C.F.R. § 1.130 Propose a Heightened, Impracticable Standard for Establishing that a Prior Disclosure is the Work of the Inventors.

The Guidelines for Proposed Rule 37 C.F.R. § 1.130 provide that an affidavit or declaration including an "unequivocal" statement of the inventor or joint inventor that he/she invented the subject matter of the disclosure and accompanied by a "reasonable explanation" may be required to traverse a rejection based on that disclosure. While the Guidelines cite *In re DeBaun*, 687 F.2d 459, 463 (C.C.P.A. 1982), the "unequivocal" or "reasonable explanation" terms are not expressly defined therein. Indeed, the Guidelines appear to impose a different and heightened standard from pre-AIA practice in similar circumstances, under current 37 C.F.R. § 1.131 and consistent with *In re Katz*, 687 F.2d 450 (C.C.P.A. 1982).

While these comments express concerns for the Guidelines for 37 C.F.R. § 1.130, NIH supports the proposed rules associated therewith. More specifically, the NIH supports Proposed Rules 37 C.F.R. §§ 1.77(b) and 1.130, noting that it is more likely that inventors will require Section 1.130, as many publications include authors who are not inventors. Indeed, absent adoption of Proposed Rule 37 C.F.R. § 1.130, there is effectively no grace period because there will be no means to establish that a disclosure is entitled to the prior art exception.

However, the Guidelines work to undermine the proposed rules such that the NIH believes that the USPTO should continue to apply pre-AIA practice with respect to the associated affidavits and declarations.

Thank you for the opportunity to present our views. Please contact us if we can be of further assistance.

Sincerely,

Mark L. Rohrbaugh, Ph.D., J.D.
Director, NIH Office of Technology Transfer