Knowledge Ecology International (KEI)
1621 Connecticut Avenue, NW
Suite 500
Washington, DC 20009
http://keionline.org

January 27, 2020

Dr. Courtney Silverthorn
Deputy Director, Technology Partnerships Office,
National Institute of Standards and Technology
Technology Partnerships Office
100 Bureau Drive, MS 2200, Gaithersburg, MD 20899,
mailto:courtney.silverthorn@nist.gov

Re: Request for Information Regarding the Interagency Edison System for Reporting Federally Funded Inventions, 84 FR 68128, Docket No. 191126-0092

NIST has published a request for comments regarding the iEdison reporting system that asks the following three questions:

1. What, if any, current features of iEdison does your organization believe should be retained in any updated version?

2. What challenges, if any, is your organization experiencing in reporting inventions in the iEdison system? Where practicable, please provide specific descriptions and/or screenshots of user interface screens or error messages.

3. What improvements could be made to the iEdison system that would reduce your organization's reporting burdens, improve its experience, and facilitate your organization's ability to comply with reporting requirements?

The notice appears to be directly primarily at awardees who use the web-accessible program to report federally-funded subject inventions, elect rights, request extensions of time requirements, request waivers, demonstrate progress, inform the government of its limited use rights, upload requested documents, and perform other reporting tasks as required by their funding agency.

KEI is offering comments from the point of view of the general public and the taxpayers who fund the grants. In particular, KEI requests certain enhancements to the iEdison system, including reporting regarding several patent-related issues, economic data on the costs of government-funded clinical trials, and the creation of opportunities for the public to query the iEdison database for some information that is of public interest.

1. Reporting regarding several patent-related issues.

a. At present, companies often fail to make disclosures of public funding on initial patent applications. In some cases, such omissions are addressed via late reports to the iEdison system, or the United States Patent and Trademark Office (USPTO). The USPTO notices may include a formal Certificate of Correction (CofC), and/or a modified assignment of rights. The iEdison system should have a complete record of any CofC or modified assignments of rights.

b. The iEdison system should include data regarding the listing of patents in the FDA Orange Book.

c. The iEdison system should include data regarding any patents that are asserted to be relevant to the sale of a specific biologic drug, cell or gene therapy, vaccine or biomedical diagnostic test.

d. The iEdison system should include copies of both the full text and a version redacted for public viewing, of any license to any federally funded patents.

e. The iEdison system should indicate if any patented invention is related to any human-use clinical trial of a drug, vaccine, cell or gene therapy or biomedical diagnostic test, and identify the trial by clinicaltrials.gov identifier (NCT Number).

2. Economic data on the costs of government-funded clinical trials

When any grant is used to fund a clinical trial, the awardee should provide the following information:

a. The name and clinicaltrials.gov identifier (NCT Number) for the trial.
b. The expected total cost of the trial.

c. The federal government's contribution, in that year, to the costs of the trial.
d. The contribution, if any, to the cost of the trial, by any other parties.
e. Any actual or expected reimbursements/cost sharing, by U.S. or foreign health care reimbursement entities, such as those under PHS Act section 2709(a), as added by the Affordable Care Act, to the costs of the trials.
f. The number of subjects enrolled in the trial, for that year.

3. Creation of opportunities for the public to query the iEdison database for some information that is of public interest.

At present, iEdison is designed for use by federal employees and federal grantees or contractors. The database should be enhanced to permit the public to search and submit queries to iEdison directly, on topics of public interest, or arrangements should be made to make some information available through the NIH RePORT or RePORTER databases.

The following are some of the items the public should have access to:

a. The dates that a subject invention was disclosed via the iEdison system.
b. Copies of any USPTO Certificate of Correction or changes in assignments of interest that correct earlier failures to disclose federal funding.
c. Copies of all licenses and assignments of interest in the patents.
d. Request for waivers of U.S. manufacturing, and subsequent determination on the waiver request by the funding organization.
e. Whether or not any specific drug, vaccine, cell or gene therapy or biomedical diagnostic test that uses the subject invention under a patent license has been approved for marketing by the FDA.
f. An estimate of the annual cost to the federal government health programs for purchasing any product or service identified in e.
g. All data on the costs of clinical trials, described in 2, above.
h. Information about the geographical scope of the patent rights, including the names of the countries where twin applications have been filed or granted; numbers, dates, and other identifiers for patents or published applications filed in other countries; and whether a Patent Cooperation Treaty (PCT) application has been filed, and its application or publication number.
i. Legal events that have occurred following the issuance of the patent, such as patent term extensions and term adjustments; granted pediatric exclusivity; as well as any judicial or administrative proceeding relating to the issued patent.

j. Any request by or to the federal government for exercise of the government's royalty free right in the patents, or to use the Bayh-Dole march-in rights in the patents.

Sincerely,

James Love
Knowledge Ecology International
james.love@keionline.org

Luis Gil Abinador
Knowledge Ecology International