Bayh-Dole Act Obligations for Universities

<u>Importance of reporting inventions in sufficient time to permit the filing of</u> patent applications prior to U.S. or foreign statutory bars.

USC has a long history of research that translates into public benefit. These endeavors typically begin with faculty led research programs, often funded by external sponsors, that produce intellectual property (IP) that is protected by the University via patents or copyright. This memorandum provides an overview of University and Federal policies and procedures concerning disclosure of Intellectual Property (IP), and the importance of timely disclosure of IP at USC.

Key Takeaways:

- Compliance with both USC and Federal policies requires prompt disclosure of inventions and software to the USC Stevens Center for Innovation via its online portal Sophia.
- Disclosure to USC Stevens of funded inventions should be made at least 75 days prior to any
 public publication or presentation so that USC can fulfill its obligation to notify government
 sponsors.
- Failure to comply with any Bayh-Dole regulations and/or associated sponsor policies on intellectual property may result in the loss of patent rights or a withholding of additional grant funds.

Under the USC Intellectual Property Policy, with some exceptions called out within the policy, the University owns IP that is produced by its employees in the course and scope of their employment. This includes IP that is produced with the use of University facilities or funds, and IP that is produced by employees of the University in the performance of a written agreement between the University and a sponsor. (See USC IP Policy at: https://policy.usc.edu/files/2014/02/intellectual property.pdf).

The <u>Bayh-Dole Act</u> governs rights in inventions made with U.S. federal government funding. Among other requirements, the Act imposes invention disclosure obligations on the funded researchers, permits the University to elect to retain title (subject to a worldwide, non-exclusive license to the U.S. government), and requires the University to pursue patent protection and commercialization so long as it retains title.

The National Institute of Standards and Technology recently instituted a new requirement that employees supported by federal grants and contracts provide a written present assignment of their grant/contract produced Intellectual Property (IP) to their institution, along with an agreement in writing to promptly disclose their IP. Employees meet this requirement through a one-time response to an email invitation sent from the "IP-ACT" system at USC.

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Benefits of disclosure and technology transfer include:

- development of products and services that benefit the public;
- economic development through job creation and new companies;
- attraction of corporate research support;

licensing revenue to further research, and to benefit inventors;

By disclosing IP to the university and participating in the protection of the IP via patents or copyrights, USC may be able to commercialize your innovations. If successful, you and your co-inventors/creators will receive a share of the licensing income that is received by USC. Specifics of how income is divided can be found in Section 4 of the USC IP Policy.

How Do I Comply with the Assignment Requirement?

If you are a named investigator, and/or budgeted to receive income and/or paid from a federally funded project, you will be invited via email to log into the "IP-ACT" system and accept USC's IP assignment and disclosure terms. Once you accept, you have satisfied the requirement for all future federal grants and contracts.

Acceptance is required for all named project personnel prior to establishment or modification of federal awards. In addition, students and others who were not named in the award must complete these steps prior to being set up on payroll.

When and How Do I Disclose Intellectual Property?

Invention disclosures should be made at least 75 days prior to any public publication or presentation via Sophia, so that USC can fulfill its obligation to notify the government at least 60 days prior to any statutory patent bar or to comply with its obligations under a corporate sponsored agreement. Disclosure of inventions and software should be made to the USC Stevens Center for Innovation via its online portal Sophia. Even if investigators fail to report within the required timeline they are encouraged to disclose as soon as they are able to in order to demonstrate good faith efforts in complying with federal regulations.

Why is Prompt Disclosure Important?

Failure to comply with any Bayh-Dole regulations and/or associated sponsor policies on intellectual property may result in the loss of patent rights or a withholding of additional grant funds.

Any publication of an inventions that is enabling (to one skilled in the art of the innovation) will prevent the filing of a patent in most international jurisdictions. Given the value of international patent protection to industry partners, the publication of an invention before appropriate disclosure and appropriate provisional filing can have a negative impact on commercialization. Additionally, on March 13, 2013 the America Invents Act was made effective which transitioned the U.S. from a "first to invent" patent system to a "First Inventor to File" system. Given this new framework it has become important to establish an early priority date when deciding to pursue patent protection. (https://www.congress.gov/bill/112th-congress/senate-bill/23)

What Do I Need to Disclose?

Any "Subject Invention". A "subject invention" is any invention or discovery that is *or may be* patentable (or otherwise protectable), conceived <u>or</u> reduced to practice in the performance of work under a funding agreement at USC (reference: Title 35 of the United States Code). Subject inventions include any novel variety of plant that is or may be protectable under the Plant Variety

Protection Act (7 U.S.C. 2321 *et seq.*). Because software is potentially patentable, and if not copyrightable, software too must be disclosed. **When in doubt, file an invention disclosure through Sophia so a determination can be made.**

A complete list of the reporting requirements under the Bayh-Dole Act can be found at 37 CFR 401.14 (https://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title37/37cfr401 main 02.tpl)

Resources:

USC Intellectual Property Policy
Guidance on How to Distribute USC-Owned Software
NIH Intellectual Property Policy
Revision of NSF Grants General Conditions
Memo on Commercialization of Technology at USC
Intellectual Property Guidance for Students