

Bayh-Dole Obligations to Disclose Federal Funding in Patented Inventions

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Legal, Regulatory, and Contractual Obligations¹

The Bayh-Dole Act and federal regulations and guidelines make clear several obligations for contractors in the disclosure of government rights in subject inventions, including: (1) a requirement to disclose that federal funding contributed to an invention; (2) contractual requirements for disclosure; and (3) required language to be inserted in patent applications and the patents, stating the role of federal funding and the government's rights.

First, contractors are required to disclose subject inventions discovered with federal funding in a timely manner and with sufficient detail to describe the invention.

Under 35 U.S.C. § 202(c)(1), any contractor that receives funding from the federal government is required to “disclose each subject invention to the Federal agency within a reasonable time after it becomes known to contractor personnel responsible for the administration of patent matters.”²

Under 37 C.F.R. § 401.3(a), each federal funding agreement shall contain the “standard patent rights clause” found at 37 C.F.R. § 401.14(a), barring specific circumstances and exceptions.³ Subsection (c)(1) of the patent rights clause outlines the disclosure requirements, including a two month time limit on the disclosure of patents and a requirement that the disclosure have sufficient detail:⁴

37 C.F.R. § 401.14(a)(c)(1)

(c) Invention Disclosure, Election of Title and Filing of Patent Application by *Contractor*

(1) The *contractor* will disclose each subject invention to the *Federal Agency* within two months after the inventor discloses it in writing to *contractor* personnel responsible for patent matters. The disclosure to the *agency* shall be in the form of a written report and shall identify the contract under which the invention was made and the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or

¹ See: <https://www.keionline.org/bayh-dole/failure-to-disclose>

² The statute defines a “subject invention” at 35 U.S.C. § 201(e) as “any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement,” and defines a contractor at 35 U.S.C. § 201(c) as “any person, small business firm, or nonprofit organization that is party to a funding agreement.”

³ The exceptions do not contain reference to the disclosure requirements.

⁴ Italics in original.

electrical characteristics of the invention. The disclosure shall also identify any publication, on sale or public use of the invention and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure. In addition, after disclosure to the *agency*, the *Contractor* will promptly notify the *agency* of the acceptance of any manuscript describing the invention for publication or of any on sale or public use planned by the *contractor*.

...

(4) Requests for extension of the time for disclosure, election, and filing under subparagraphs (1), (2), and (3) may, at the discretion of the *agency*, be granted.

Second, in implementing this regulation, agencies may require disclosure through documentation and/or via iEdison, an online electronic system for reporting inventions and patents discovered under federal grants, or via other documents to be submitted.⁵ iEdison is run by the National Institutes of Health (NIH), but is used by a wide variety of agencies, including:

Agency for Health Care Research and Quality (AHRQ)
Agricultural Research Service (ARS)
Agency for Toxic Substances and Disease Registry (ATSDR)
Air Force Office of Scientific Research (AFOSR)
Air Force Research Laboratory Information Directorate (AFRL/RI)
Air Force Materiel Command Legal Office (AFMCLO/JAZ)
Army Medical Research and Materiel Command (ARMY/MRMC)
Army Natick Soldier Systems Center (ARMY/SSC)
Army Research Laboratory (ARMY/ARL)
Army Research Office (ARMY/ARO)
Army Space and Missile Defense Command (ARMY/SMDC)
Centers for Disease Control and Prevention (CDC)
Defense Advanced Research Projects Agency (DARPA)
Defense Microelectronics Activity (DMEA)
Defense Threat Reduction Agency (DTRA)
Department of Energy (DOE)
Department of Homeland Security
Science and Technology Directorate (DHS/S&T)
Department of Transportation (DOT)
Economic Development Administration (EDA)
Environmental Protection Agency (EPA)
Food and Drug Administration (FDA)
Indian Health Service (IHS)

⁵ iEdison.gov

International Trade Administration (ITA)
National Institute of Food and Agriculture (NIFA)
National Institutes of Health (NIH)
National Institute of Standards and Technology (NIST)
National Oceanic and Atmospheric Administration (NOAA)
National Science Foundation (NSF)
Nuclear Regulatory Commission (NRC)
Office of Naval Research (ONR)
U.S. Agency for International Development (USAID)
United States Forest Service (USFS)

iEdison was created in 1995 in the wake of findings by the Office of Inspector General of the Department of Health and Human Services that the NIH was not sufficiently overseeing and monitoring compliance with Bayh-Dole requirements, including disclosure.⁶

By way of example of how agencies require disclosure, the NIH requires contractors to disclose subject inventions via iEdison, as well as via HHS Form 568, entitled, “Final Invention Statement and Certification (For Grant or Award),” available at: <https://grants.nih.gov/grants/hhs568.pdf>.

The NIH specifies the required information on a FAQ related to the use of iEdison, and also notes that contractors should disclose the subject invention even if they have, in the past, failed to report the invention within the two month period:⁷

5. What information is required to report a subject invention?

The invention disclosure must include the following information:

- Either the EIR Number, Invention Docket Number, or both.
- Invention Title
- Names of all of the inventors and the institutions with which they are associated
- Invention Report Date
- Description of the Invention that must meet the standards set forth per 37 CFR Sec. 401.14 (a)(c)(1):

“ . . . be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of

⁶ <https://oig.hhs.gov/oei/reports/oei-03-91-00930.pdf>

⁷ Available at: https://era.nih.gov/iedison/iedison_faqs.cfm#VIII5 (accessed Jan. 6, 2017).

the invention.”37 C.F.R. 401.14(a)(c)(1)”

-Primary Funding Agency

-All funding agreement numbers and names of the funding agencies

- Any publication, on sale or public use of the invention and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure

9. If I upload a patent application, can that patent application satisfy the Invention Disclosure Report requirement?

Yes, so long as the EIR Number or Invention Docket Number is included on the submission, the patent record containing the patent/patent application number has been reported in iEdison, and you upload proof that the patent application was filed with the USPTO, e.g., a USPTO submission receipt.

10. What should a grantee/contractor do if a subject invention hasn't been reported to the awarding agency within the required 2 month period?

Always report the invention, even if it is late. The invention report date should be the date the inventor notified the awardee institution of the subject invention. Provide an explanation in the "Explanatory Notes" section of the invention record.

On February 17, 2016, NIH issued a notice entitled “Reminder: All Subject Inventions Must Be Reported on the HHS 568 - Final Invention Statement and Certification (For Grant or Award) and in iEdison.” The notice explained that failure to disclose the subject invention via both iEdison and Form 568 could result in the loss of rights in the invention.⁸

Finally, under 35 U.S.C. § 202(c)(6) and 37 C.F.R. § 1.77(b)(3), contractors are required to state within the patent application that the federal government contributed funding to support the discovery of the invention and that the government retains certain rights:

35 U.S.C. § 202(c)(6)

(c) Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate the following:

...

⁸ National Institutes of Health, Reminder: All Subject Inventions Must Be Reported on the HHS 568 - Final Invention Statement and Certification (For Grant or Award) and in iEdison, NOT-OD-16-066 (Feb. 17, 2016), NIH Guide Notice, <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-066.html>.

(6) An obligation on the part of the contractor, in the event a United States patent application is filed by or on its behalf or by any assignee of the contractor, to include within the specification of such application and any patent issuing thereon, a statement specifying that the invention was made with Government support and that the Government has certain rights in the invention.

35 C.F.R. § 1.77(b)(3)

(b) The specification should include the following sections in order:

...

(3) Statement regarding federally sponsored research or development.

The Manual of Patent Examining Procedure contains the following recommended language:

“This invention was made with government support under (identify the contract) awarded by (identify the Federal agency). The government has certain rights in the invention.”⁹

Remedies for Non-Disclosure

Non-disclosure Permits the Federal Government to Receive Title to the Invention

Failure to disclose subject inventions pursuant to 35 U.S.C. § 202(c)(1) permits the Federal Government to “**receive title to any subject invention not disclosed to it within such time**” (emphasis added).

The patent rights clause at 37 C.F.R. § 401.14(a) specifies this right to claim title in subsection (d):

37 C.F.R. § 401.14(a)

(d) Conditions when the Government May Obtain Title

The contractor will convey to the Federal agency, upon written request, title to any subject invention—

(1) If the contractor fails to disclose or elect title to the subject invention within the times specified in (c), above, or elects not to retain title; provided that the agency may only request title within 60 days after learning of the failure of the contractor to disclose or elect within the specified times.

⁹ MPEP (9th ed. Rev. 07.2015, Nov. 2015), § 310.

...

In the past, the Federal Government has utilized its authority to claim title in subject inventions that have not been properly disclosed, as in the case of *Campbell Plastics Engineering & Mfg., Inc. v. Brownlee*, 389 F.3d 1243 (Fed. Cir. 2004) (finding that federal government claim of title in invention was legitimate under federal acquisition regulations and supported by the Bayh Dole Act where disclosure submissions were “piecemeal” and violated the contractual agreement with the government); see also *Central Admixture Pharmacy Services, Inc. v. Advanced Cardiac Solutions, P.C.*, 482 F.3d 1347, 1352-53 (Fed. Cir. 2007) (“Critically, *Campbell Plastics* holds that a Bayh–Dole violation grants the government *discretionary* authority to take title. . . . When a violation occurs, the government can choose to take action; thus, title to the patent may be avoidable.”).

In *Campbell Plastics*, the court found that the contract was clear and unambiguous, but moreover the government’s claim to title was “buttressed by the policy considerations behind the Bayh Dole Act.” *Id.* at 1248. These include, specifically under 35 U.S.C. § 200, the need “to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions.”

Correction of the Patent Will Establish Other Enforceable Rights For the Federal Government

Even if the Government permits the continued use of its invention, forcing a correction to the patent will create enforceable obligations and rights designed to protect the public interest. These rights can be used as leverage to force concessions in pricing.

Local Manufacturing

Under 35 U.S.C. § 204, for example, there is a requirement (waivable in individual cases) that the subject invention be manufactured substantially in the United States.¹⁰

35 U.S.C. § 204

Notwithstanding any other provision of this chapter, no small business firm or nonprofit organization which receives title to any subject invention and no assignee of any such small business firm or nonprofit organization shall grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Federal agency under whose

¹⁰ See also the patents rights clause regarding preference for United States industry at 37 C.F.R. § 401.14(a)(i).

funding agreement the invention was made upon a showing by the small business firm, nonprofit organization, or assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

Practical Application

Government rights in a subject invention also implicates the requirement repeated in numerous sections of the Bayh-Dole Act that there be “practical application” of the invention, including once in 35 U.S.C. § 203 on march-in rights, and nine times in 35 U.S.C. § 209 on licensing federally-owned inventions. “Practical application” is defined under 35 U.S.C. § 201(f) to mean “manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized **and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.**” (Emphasis added.)

The phrase “available to the public on reasonable terms” to is a statutory obligation in the Bayh-Dole Act that only has meaning if the invention is available at a reasonable price, and while the NIH has been loath to enforce this requirement, the Congress is increasingly focused on a practical implementation of such an obligation. For example, in 2017, the Senate Armed Services Committee adopted a directive in a committee report to require enforcement of this obligation when the prices of a medical technology were higher in the United States than the median price charged in seven countries with large economies with at least 50 percent of U.S. per capita income.¹¹ There is also U.S. and international case law, as well as statutes in the U.K. and South Africa, defining the phrase “reasonable terms” to include the price of a product of service.¹²

March-In Rights and the Royalty-Free Right

Under 35 U.S.C. § 203(a), the government may require the grant of a license to a third party, or may grant such a license itself, if any of four conditions are met, including the obligation of practical application:

35 U.S.C. § 203

¹¹ 115TH Congress, 1st Session, 2017, Senate Report 115–125. National Defense Authorization Act for Fiscal Year 2018. Report to accompany S. 1519, page 173.

¹² See KEI 10 March 2017 Comments on Army Exclusive License on Zika Virus Vaccine Patents to Sanofi, available at https://www.keionline.org/wp-content/uploads/2017/03/KEI-March_10_2017-3rd-Comments-Zika.pdf.

(a) With respect to any subject invention in which a small business firm or nonprofit organization has acquired title under this chapter, the Federal agency under whose funding agreement the subject invention was made shall have the right, in accordance with such procedures as are provided in regulations promulgated hereunder to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, to grant such a license itself, if the Federal agency determines that such—

- (1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;
- (2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;
- (3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or
- (4) action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.

The government also retains a perpetual non-exclusive royalty-free license in the invention, written into any funding agreement under 35 U.S.C. § 202(c)(4), and again iterated as a required term and condition for any license of a federally-owned invention under § 209(d)(1). The royalty-free right, as opposed to the march-in rights, has no precondition and can be used at any time, for any reason.

35 U.S.C. § 202

...

(c) Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate the following:

...

(4)

With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world: Provided, That the funding agreement may provide for such additional rights, including the right to assign or have assigned foreign patent rights in the subject invention, as are determined by the agency as necessary for meeting the obligations of the United States under any treaty, international agreement, arrangement of cooperation, memorandum of understanding, or similar arrangement, including military agreement relating to weapons development and production.

35 U.S.C. § 209

...

(d) Terms and Conditions.—Any licenses granted under section 207(a)(2) shall contain such terms and conditions as the granting agency considers appropriate, and shall include provisions—

(1)

retaining a nontransferable, irrevocable, paid-up license for any Federal agency to practice the invention or have the invention practiced throughout the world by or on behalf of the Government of the United States;

...

Both of these rights provide significant leverage to the United States, as they could be used to allow affordable competition. Even the viable threat of use of either of these rights might be sufficient to prompt price reductions or other concessions increasing access while decreasing price.

In some cases there may be more than one patent in a particular medicine, and not all patents may have government rights. In the event that there is at least one patent with government rights, the government could potentially use the royalty-free right in conjunction with the government use provision of 28 U.S.C. § 1498. While § 1498 has been used many times by the military, interest in using the government use law alone on medical technologies has been complicated by uncertainty as to the extent of compensation owed.¹³ Using the royalty-free right and § 1498 together would lessen the amount of compensation owed to the patent holder.

¹³ See, e.g. May 12, 2015 letter from Senator Bernard Sanders to Secretary of the US Department of Veterans Affairs, Robert McDonald. <https://www.keionline.org/wp-content/uploads/2015/05/12may2015-Sanders-McDonald-Veterans-1498.pdf>; and <https://www.keionline.org/22842>.