



The Bayh-Dole Act

Forty Years of Technology Transfer Under the Bayh-Dole Act and What May Come Next



Diz Locaria

Partner | +1 202.344.8013 | DLocaria@Venable.com

Chris Griesedieck

Associate | +1 202.344.4771 | CGGriesedieck@Venable.com

Spencer Williams

Associate | +1 202.344.4268 | SPWilliams@Venable.com

VENABLE LLP

History of the Bayh-Dole Act

40 Years of Technology Transfer

History of the Bayh-Dole Act

- **Patent and Trademark Law Amendments Act, a.k.a. the Bayh-Dole Act**
 - Sponsored by Birch Bayh of Indiana and Robert “Bob” Dole of Kansas
 - Passed in 1980
 - Codified in 35 U.S.C. § 200-212
- **Pre-Bayh-Dole**
 - Universities performed 14% of the research & development in the U.S. (similar to today)
 - Fewer than 5% of the 28,000 patents held by federal agencies had been licensed
 - 26 different federal agency policies regarding the use of results from federally funded research

History of the Bayh-Dole Act

- It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; 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; and to minimize the costs of administering policies in this area.

– 35 U.S.C. § 200, Policy and Objective

History of the Bayh-Dole Act

- Effect of the Bayh-Dole Act according to various sources
 - Bolstered economic output by \$1.3 trillion
 - Supported 4.2 million jobs
 - Helped lead to more than 11,000 start-up companies
 - E.g., Google
 - 380,000 inventions and 80,000 patents in the last 25 years
 - In 2012 alone, 591 new products originating from university research entered the market
 - Universities have expanded or created technology transfer offices

The Bayh-Dole Act's Basic Mechanics

Shared Public and Private Rights in Subject Inventions

The Bayh-Dole Act's Basic Mechanics

- **Relevant Authorities to Consult**

- **Statute:** Pub. L. No. 96-517, 94 Stat. 3015, 3019-28 (1980), as amended, commonly known as the Bayh-Dole Act, codified at 35 U.S.C. §§ 200-212
- **Regulations:** 37 C.F.R. §§ 401.1-401.17 (“Rights to Inventions Made by Nonprofit Organizations and Small Business Firms under Government Grants, Contracts, and Cooperative Agreements”)
- **Grant Terms and Conditions:** E.g., DEPARTMENT OF COMMERCE FINANCIAL ASSISTANCE STANDARD TERMS AND CONDITIONS, U.S. Dep’t of Commerce (Apr. 30, 2019), *available at* http://www.osec.doc.gov/oam/grants_management/policy/
- **Government Guidance:** E.g., DEPARTMENT OF COMMERCE GRANTS AND COOPERATIVE AGREEMENTS MANUAL, U.S. Dep’t of Commerce (Jan. 25, 2018), *available at* http://www.osec.doc.gov/oam/grants_management/policy/

The Bayh-Dole Act's Basic Mechanics

- General Rule: “Title to intangible property...acquired under a Federal award vests upon acquisition in the” non-federal entity (NFE). 2 C.F.R. § 200.315(a).
- Bayh-Dole Act Quasi-Exception: The federal government and NFE have shared rights in subject inventions, or any invention “conceived or first actually reduced to practice in the performance of work under a funding agreement.” 37 C.F.R. § 401.2(d); 37 C.F.R. § 401.1(a).
 - The Bayh-Dole Act does not generally apply to inventions other than subject inventions (i.e., inventions made outside of the research activities of a government-funded project).
 - A “funding agreement” is “any contract, grant, or cooperative agreement entered into between any Federal agency, other than the Tennessee Valley Authority, and any [NFE] for the performance of experimental, developmental, or research work funded in whole or in part by the Federal government,” including any assignment, substitution of parties, or subcontract for that work. 37 C.F.R. § 401.2(a).

The Bayh-Dole Act's Basic Mechanics

- NFE's Rights in Subject Inventions
 - NFEs “may retain the entire right, title, and interest throughout the world to each subject invention subject to the provisions of” the clause at 37 C.F.R. § 401.14 (which comprises the standard clause inserted into funding agreements to implement Bayh-Dole) and 35 U.S.C. § 203 (which provides for the government’s “march-in” rights, described below). 37 C.F.R. § 401.14(b).
 - Key Point: These rights are limited and can be lost without diligence.
- Government's Rights in Subject Inventions
 - “With respect to any subject invention in which the [NFE] retains title, the Federal government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject invention throughout the world.” 37 C.F.R. § 401.14(b).
 - Key Point: Grant recipients have obligations to help protect this license.

The Bayh-Dole Act's Basic Mechanics

- NFE's Obligations to Protect the Government's Rights
 - Must “disclose each subject invention to the Federal Agency **within two months** after the inventor discloses it in writing to [NFE] personnel responsible for patent matters.” 37 C.F.R. § 401.14(c)(1).
 - Must “execute or [] have executed and promptly deliver to the Federal agency all instruments necessary” to (1) “establish or confirm the rights the Government has throughout the world in those subject inventions to which the [NFE] elects to retain title,” and (2) “convey title to the Federal agency when” required under the standard clause (discussed below). 37 C.F.R. § 401.14(f)(1).
 - Must “require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters...each subject invention made under contract,” and “assign to the [NFE] the entire right, title and interest in and to each subject invention made under contract.” 37 C.F.R. § 401.14(f)(2).
 - At least 60 days before the statutory deadline, must provide notice for each subject invention “of any decision...[n]ot to continue the prosecution of a non-provisional patent application; not to pay a maintenance, annuity or renewal fee; not to defend in a reexamination or opposition proceeding on a patent, in any country,” or any decision to participate in certain USPTO proceedings. 37 C.F.R. § 401.14(f)(3).

The Bayh-Dole Act's Basic Mechanics

- NFE's Obligations to Protect the Government's Rights, Cont'd.
 - Must include in specifications of U.S. patent applications for subject inventions: “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.” 37 C.F.R. § 401.14(f)(4).
 - Must include a version of the standard Bayh-Dole clause, “suitably modified to identify the parties,” in “all subcontracts, regardless of tier, for experimental, developmental or research work to be performed by a small business firm or domestic nonprofit organization subcontractor.” 37 C.F.R. § 401.14(g)(1).
 - Must “submit on request periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining such utilization” by the [NFE] or its “licensees or assignees.” 37 C.F.R. § 401.14(h).



Protecting Your Patent Rights under the Bayh-Dole Act

Following the Rules and Avoiding the Numerous Possible Pitfalls

Protecting Your Rights under the Bayh-Dole Act

- Successful preservation of one's patent rights in subject inventions requires understanding both:
 - The potential for limitations on and even loss of one's "Entire Right, Title, and Interest" in subject inventions, and
 - Required steps to avoid these pitfalls.

Protecting Your Rights under the Bayh-Dole Act

- Limits on and Loss of “Entire Right, Title, and Interest” in Subject Inventions
 - Improper Designation of Invention as Subject Invention.
 - Inventions made in performance of a non-government-sponsored project “which, although closely related, falls outside the planned and committed activities of a government-funded project and does not diminish or distract from the performance of such activities...” 37 C.F.R. §§ 401.1(a)(1).
 - Inventions “made outside of the research activities of a government-funded project” (e.g., “instrument purchased with government funds is later used, without interference with or cost to the government-funded project, in making an invention all expenses of which involve only non-government funds,”). 37 C.F.R. §§ 401.1(a)(2).
 - Remember, the test is whether the invention was “conceived or first actually reduced to practice” in performance of government project.

Protecting Your Rights under the Bayh-Dole Act

- Limits on and Loss of “Entire Right, Title, and Interest” in Subject Inventions, Cont’d.
 - Additional Provisions in Funding Agreements Requiring Licensing of Non-Subject Inventions to Third Parties.
 - Funding agreements generally may not contain any “provision allowing a Federal agency to require the licensing to third parties of inventions owned by the [NFE] that are not subject inventions.” 37 C.F.R. § 401.12(a).
 - An agency may nonetheless do so when “such provision has been approved by the agency head and a written justification has been signed by the agency head” concluding that “the use of the invention by others is necessary for the practice of a subject invention or for the use of a work object of the funding agreement and that such action is necessary to achieve practical application of the subject invention or work object.” 37 C.F.R. § 401.12(a)-(b).
 - “Practical application” means “to manufacture in the case of a composition of 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.” 37 C.F.R. § 401.2(e).

Protecting Your Rights under the Bayh-Dole Act

- Limits on and Loss of “Entire Right, Title, and Interest” in Subject Inventions, Cont’d.
 - Forfeiture or Loss of Title in Subject Invention Through NFE Inaction
 - An NFE “will convey to the Federal agency, upon written request, title to any subject invention” if the NFE (37 C.F.R. § 401.14(d)):
 - “fails to disclose or elect title to the subject invention within the times specified” by the Bayh-Dole regulations,
 - “elects not to retain title,” or
 - in any country in which the NFE (1) “fails to file patent applications within the times specified” by the Bayh-Dole Act regulations, or (2) “decides not to continue the prosecution of any non-provisional patent application for, to pay a maintenance, annuity or renewal fee on, or to defend in a reexamination or opposition proceeding on, a patent on a subject invention.”

Protecting Your Rights under the Bayh-Dole Act

- Limits on and Loss of “Entire Right, Title, and Interest” in Subject Inventions, Cont’d.
 - Revocation or Modification of License to Use Subject Invention to Which Government Has Taken Title
 - Even where the government takes title to a subject invention, the NFE “will retain a nonexclusive royalty-free license throughout the world...except if the [NFE] fails to disclose the invention within the times specified in” the standard clause. 37 C.F.R. § 401.14(e)(1).
 - This license “may be revoked or modified by the funding Federal agency to the extent necessary to achieve expeditious practical application of the subject invention pursuant to an application for an exclusive license” by another entity, although the license “will not be revoked in that field of use or the geographical areas” in which the NFE (1) “has achieved practical application,” and (2) “continues to make the benefits of the invention reasonably accessible to the public.” 37 C.F.R. § 401.14(e)(2).

Protecting Your Rights under the Bayh-Dole Act

- Limits on and Loss of “Entire Right, Title, and Interest” in Subject Inventions, Cont’d.
 - Alternative Provisions in Funding Agreements Creating Exceptions to Normal Bayh-Dole Rights for NFEs
 - In some cases, the Bayh-Dole Act regulations permit federal awarding agencies to include in funding agreements “alternative provisions” to the standard clause at 37 C.F.R. § 401.14.
 - For example, “[i]n exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of” the Bayh-Dole Act. 37 C.F.R. § 401.3(a)(2). The policy goals of the Bayh-Dole Act, stated at 35 U.S.C. § 200, are broad.
 - The agency must “provide the [NFE] with an opportunity to receive greater rights” if the NFE later shows an adequate plan to bring the subject invention to practical application (i.e., deferred determinations). 37 C.F.R. § 401.3(b).

Protecting Your Rights under the Bayh-Dole Act

- Limits on and Loss of “Entire Right, Title, and Interest” in Subject Inventions, Cont’d.
 - Modification and Tailoring of the Standard Clause
 - Agencies have discretion to modify the standard clause in certain ways, including but not limited to (37 C.F.R. § 401.5):
 - Requiring the clause to be flowed down to all subcontractors, not just small business firms and nonprofit organization subcontractors;
 - Incorporating other applicable government-wide regulations on patents such as those found in the Federal Acquisition Regulation;
 - Retaining the right to “unilaterally amend” the funding agreement to identify treaties entered into “after the effective date” of the agreement and “effectuate those license or other rights...necessary for the government to meet its obligations to” foreign governments and international organizations.

Protecting Your Rights under the Bayh-Dole Act

- Limits on and Loss of “Entire Right, Title, and Interest” in Subject Inventions, Cont’d.
 - Government’s Exercise of Its March-In Rights
 - The government has “march-in” rights with respect to subject inventions, such that “the Federal agency under whose funding agreement the subject invention was made shall have the right...to require the [NFE], 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...” 35 U.S.C. § 203(a).
 - If the NFE or its “assignee, or exclusive licensee refuses such a request[,] the Federal agency has the right to grant such a license itself if the Federal agency” makes one of a series of determinations, including on the basis of practical application, health or safety, public use, or preference to United States industry. 37 C.F.R. § 401.14(j)(1)-(4).

Protecting Your Rights under the Bayh-Dole Act

- Limits on and Loss of “Entire Right, Title, and Interest” in Subject Inventions, Cont’d.
 - Nonprofit NFEs – Assignment, Small Business Preference, and Royalties Restrictions
 - “Rights to a subject invention in the United States may not be assigned [by a nonprofit NFE] without the approval of the Federal agency,” with the exception that assignment “to an organization which has as one of its primary functions the management of inventions” is acceptable, provided that “such assignee will be subject to the same provisions as the” NFE. 37 C.F.R. § 401.14(k)(1).
 - Such NFEs must “make efforts that are reasonable under the circumstances to attract licensees of subject inventions that are small business firms” and “give a preference to a small business firm when licensing a subject invention” if certain conditions are met. 37 C.F.R. § 401.14(k)(4); *see also* 37 C.F.R. § 401.7(a).
 - Such NFEs must “share royalties collected on a subject invention with the inventor, including Federal employee co-inventors (when the agency deems it appropriate) when the subject invention is assigned” by the agency to the NFE under 35 U.S.C. § 202(e) and 37 CFR § 401.10.” 37 C.F.R. § 401.14(k)(2). Moreover, “[t]he balance of any royalties or income earned by the [NFE] with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions, will be utilized for the support of scientific research or education[.]” 37 C.F.R. § 401.14(k)(3).

Protecting Your Rights under the Bayh-Dole Act

- Limits on and Loss of “Entire Right, Title, and Interest” in Subject Inventions, Cont’d.
 - United States Domestic Preference
 - The standard clause requires the NFE to agree that neither it “nor any assignee will grant to any person the exclusive right to use or sell any subject inventions 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.” 37 C.F.R. § 401.14(i).
 - A federal agency may waive this requirement in individual cases “upon a showing by the [NFE] or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms” or that “under the circumstances domestic manufacture is not commercially feasible.” *Id.*

Protecting Your Rights under the Bayh-Dole Act

- Limits on and Loss of “Entire Right, Title, and Interest” in Subject Inventions, Cont’d.
 - That was a lot.
 - What steps can I take to avoid those potential limitations on or losses of my organization’s patent rights?

Protecting Your Rights under the Bayh-Dole Act

- Preserving Your Patent Rights

- Comply with the Standard Clause and Your Obligations to Protect the Government’s Rights, Including Timely Disclosure and Election of Title.

- As noted, failure to timely disclose a subject invention (**two months**) can be extremely costly, resulting in loss of not just title, but also licensing rights.
 - An NFE must also “elect in writing whether or not to retain title to any such invention by notifying the Federal agency **within two years** of disclosure to the Federal agency.” 37 C.F.R. § 401.14(c)(2) (emphasis added). An agency may shorten the election notification period “to a date that is no more than 60 days prior to the end of the” one year statutory period (i.e., the period wherein valid patent protection can still be obtained in the United States) in “any case where a patent, a printed publication, public use, sale, or other availability to the public has initiated” that statutory period. *Id.* An agency may grant an extension of the time for election at its discretion. 37 C.F.R. § 401.14(c)(5).

Protecting Your Rights under the Bayh-Dole Act

- Preserving Your Patent Rights, Cont'd.
 - Timely File Your Patent Applications or Risk Losing Title.
 - An NFE must “file its initial patent application on a subject invention to which it elects to retain title **within one year** after election of title or, if earlier, prior to the end of any statutory period wherein valid patent protection can be obtained in the United States after a publication, on sale, or public use.” 37 C.F.R. § 401.14(c)(3).
 - “If the [NFE] files a provisional application as its initial patent application, it shall file a non-provisional application **within 10 months** of the filing of the provisional application.” *Id.* Additional timeliness requirements apply to patent applications in other countries or international patent offices. *See id.*
 - An agency may grant an extension of the time for filing at its discretion. 37 C.F.R. § 401.14(c)(5). When an NFE “has requested an extension for filing a non-provisional application after filing a provisional application, a one-year extension will be granted unless the Federal agency notifies the [NFE] within 60 days of receiving the request.” *Id.*

Protecting Your Rights under the Bayh-Dole Act

- Preserving Your Patent Rights, Cont'd.
 - Apply Confidential Markings to Protect Proprietary Information.
 - The Bayh-Dole regulations and the Uniform Guidance include specific requirements with respect to the government’s safeguarding of confidential information related to patents and inventions. *See* 37 C.F.R. §§ 401.6(e) (march-in proceedings), 401.8(b) (utilization reports), 401.13(c) (invention disclosure, patent applications, and utilization reports). Nonetheless, the Bayh-Dole regulations also state that NFEs “will continue to provide confidential markings to help prevent inadvertent release outside the agency.” 37 C.F.R. § 401.8(b).
 - In addition, the Uniform Guidance establishes federal agencies’ approach to disclosure under the Freedom of Information Act (FOIA) of information related to intangible property. *See* 2 C.F.R. § 200.315(e).

Protecting Your Rights under the Bayh-Dole Act

- Preserving Your Patent Rights, Cont'd.
 - Know When You May Dispute an Adverse Determination.
 - The Bayh-Dole regulations allow NFEs to dispute and/or appeal multiple decisions related to their patent rights, including determinations that:
 - An invention is a subject invention; *see* 37 C.F.R. §§ 401.1(a)(2), 401.11(d);
 - March-in is appropriate; *see* 37 C.F.R. §§ 401.1(c), 401.6, 401.11;
 - An alternative provision to the standard clause should be used; *see* 37 C.F.R. §§ 401.3(e), 401.4, 401.15(d);
 - No extension of time for disclosure of a subject invention, election of title, or filing of a patent application will be granted; *see* 37 C.F.R. § 401.11(b)(1);

Protecting Your Rights under the Bayh-Dole Act

- Preserving Your Patent Rights, Cont'd.
 - Know When You May Dispute an Adverse Determination, Cont'd.
 - The Bayh-Dole regulations allow NFEs to dispute and/or appeal multiple decisions related to their patent rights, including determinations that:
 - An NFE should convey title in a subject invention to an agency; *see* 37 C.F.R. §§ 401.11(b)(2), 401.15(d);
 - No waiver of the United States preference will be issued; *see* 37 C.F.R. § 401.11(b)(3);
 - A requested assignment of patent rights will be denied; *see* 37 C.F.R. § 401.11(b)(4);
 - An NFE's remaining license after the government obtains title will be modified or revoked; *see* 37 C.F.R. § 401.14(e)(3); and
 - A request for greater rights in a deferred determination proceeding will not be granted; *see* 37 C.F.R. § 401.15(d).

Current Criticisms and Responses to the Bayh-Dole Act

Drug Pricing, March-In Rights, and More

Criticisms and Responses to the Bayh-Dole Act

- Intellectual Property Hoarding
- Pharmaceutical Prices & March-In Rights

Criticisms and Responses to the Bayh-Dole Act

- Intellectual Property Hoarding
 - Criticism: Universities are selling patents to patent assertion entities (a.k.a. Patent Trolls).
 - Response: Nine Points to Consider in Licensing Technology
 - 1 - Universities should reserve the right to practice licensed inventions and to allow other nonprofit and government organizations to do so
 - 2 - Exclusive licenses should be structured in a manner that encourages technology development and use
 - 3 - Strive to minimize the licensing of “future improvements”
 - 4 - Universities should anticipate and help to manage technology transfer-related conflicts of interest
 - 5 - Ensure broad access to research tools
 - 6 - Enforcement action should be carefully considered
 - 7 - Be mindful of export regulations
 - 8 - Be mindful of the implications of working with patent aggregators
 - 9 - Consider including provisions that address unmet needs, such as those of neglected patient populations or geographic areas, giving particular attention to improved therapeutics, diagnostics, and agricultural technologies for the developing world

Criticisms and Responses to the Bayh-Dole Act

- Pharmaceutical Prices & March-In Rights
 - Idea: Breaking drug patents by exercising the government’s march-in rights to lower prices
 - 2016 Letter to Secretary of Health and Human Services and the Director of the National Institutes of Health urging the administration to exercise march-in rights.
 - In the Bayh-Dole Act’s 40 years, the only federal agency to receive a petition to exercise its march-in rights is the NIH.
 - Response: Lowering pharmaceutical prices through the Bayh-Dole Act’s march-in rights does not satisfy the statutory triggers.

Criticisms and Responses to the Bayh-Dole Act

- Pharmaceutical Prices & March-In Rights
 - March-In Rights – Four statutory triggers
 - 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;
 - **Action is necessary to alleviate health or safety needs** which are not reasonably satisfied by the contractor, assignee, or their licensees;
 - 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
 - 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.

35 U.S.C. § 203

Criticisms and Responses to the Bayh-Dole Act

- Pharmaceutical Prices & March-In Rights
 - NIH response to a 2004 petition to exercise march-in rights:
 - Finally, the issue of the cost or pricing of drugs that include inventive technologies made using federal funds is one which has attracted the attention of Congress in several contexts that are much broader than the one at hand. In addition, because the market dynamics for all products developed pursuant to licensing rights under the Bayh-Dole Act could be altered if prices on such products were directed in any way by NIH, the NIH agrees with the public testimony that suggested that the extraordinary remedy of march-in is not an appropriate means of controlling prices. The issue of drug pricing has global implications and, thus, is appropriately left for Congress to address legislatively.

Criticisms and Responses to the Bayh-Dole Act

- Pharmaceutical Prices & March-In Rights
 - While every petition has so far been denied, the outbreak of COVID-19 has led to a renewed interest in exercising march-in rights.
 - “In the context of a pandemic like COVID-19, the ‘health or safety needs’ language would appear to provide a possible basis for the exercise of march-in rights, should the federal agency determine that compulsory licensing is necessary to address public health needs unmet by a federal contractor.”

Congressional Research Service, *COVID-19 Medical Countermeasures: Intellectual Property and Affordability*, LSB10422 (Mar. 18, 2020).



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