

The Bayh-Dole Act of 1980: Frequently Asked Questions



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35 U.S. Code Chapter 18 - PATENT RIGHTS IN INVENTIONS MADE WITH FEDERAL ASSISTANCE

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 Statement in Bayh-Dole Act).

1. What is the Bayh-Dole Act?

Co-sponsored by Senators Birch Bayh of Indiana and Robert Dole of Kansas, The Patent and Trademark Law Amendments Act of 1980, more commonly known as the Bayh-Dole Act or simply “Bayh-Dole,” is legislation that shifted the ownership of inventions made with federally funded research. Before Bayh-Dole, inventors were obligated to assign inventions made using federal funding to the federal government. Bayh-Dole grants ownership to the inventors, and permits a university, small business, or nonprofit institution to elect to pursue ownership in preference to the government.

2. What does Bayh-Dole say about the ownership of inventions and technologies?

Pursuant to Bayh-Dole, universities and other nonprofit organizations that receive federal funding, may “elect to retain title to any subject invention.”ⁱ In 2011, the Supreme Court clarified in *Stanford v. Roche* that title in a patented invention vests first in the inventor.ⁱⁱ In that case, Stanford University sued Roche for patent infringement. Stanford claimed that an HIV test kit invented by a Stanford professor belonged to the university and not to Roche, even though Roche had signed a contract with the professor that granted the company ownership of any of his inventions. Stanford’s main claim to ownership was that Bayh-Dole trumped any contract signed by a professor with an external company. However, the Supreme Court ruled in favor of Roche, noting that the act “does not have any language automatically vesting ownership with Universities.”ⁱⁱⁱ

Assignment of title is a common condition of employment at universities and research institutions, so while this case provided important clarification of existing law, it had minimal practical impact.^{iv}

3. Does Bayh-Dole apply to all research conducted at universities?

The act applies to any invention “conceived or first actually reduced to practice” in the course of research funded with federal dollars.^v Implementing regulations make clear that where a non-government sponsor establishes a project that falls outside the “planned and committed activities” of a government-funded project, inventions made in the performance of that work would not be subject to Bayh-Dole.^{vi} Examples of research

that may be exempt from Bayh-Dole include non-government funded fellowships and industry-sponsored research projects.

4. What requirements does Bayh-Dole place on universities?

The implementing regulations of the Bayh-Dole Act outline the requirements for inventions arising from federally funded research projects.^{vii} Some key requirements include the following:

- Execute written agreements with faculty and technical staff requiring disclosure of inventions. 37 C.F.R. § 401.14(f)(2).
- Report each new invention to the federal funding agency within two months of the invention being reported to the funding recipient. 37 C.F.R. 401.14(c)(1)
- Decide whether to retain ownership (i.e., elect to own the invention) of the technology and notify the agency of any decision to retain title within two years of the date of disclosure. 37 C.F.R. 401.14(c)(2).
- File for patent protection within one year of electing to retain title. 37 C.F.R. 401.14(c)(3).
- Provide a license to the government to also practice the subject invention. 37 C.F.R. 401.14(b).
- Keep government informed of progress in patenting or commercializing the invention. 37 C.F.R. 401.14(f); 401.14(h).

5. What are march-in rights, and what does Bayh-Dole say about them? Has the government ever exercised its march-in rights?

“March-in rights” refer to the rights granted under Bayh-Dole that allow the federal funding agency to grant additional licenses to a “responsible applicant” if the agency determines that one of four triggering circumstances has occurred.^{viii} Specifically, the agency must determine whether action is necessary:

1. “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. “to alleviate health or safety needs which are not reasonably satisfied” by the rights-holders;
3. “to meet requirements for public use specified by Federal regulations”; or
4. because the rights-holders have violated U.S. manufacturing preference rules, if applicable.

The National Institutes of Health (NIH) has been petitioned on five separate occasions to exercise its march-in rights and has declined to do so each time.^{ix}

6. Does Bayh-Dole allow patenting of research tools and resources?

The legislation applies to any invention conceived or reduced to practice in research supported by federal funds.^x Accordingly, Bayh-Dole places no restrictions on a university’s ability to patent and license research tools such as new DNA sequences, protein structures, and disease pathways.^{xi} However, as acknowledged in the NIH Research Tools Policy, “[t]he right of Recipients to retain title to inventions made with NIH funds comes with the corresponding obligations to promote utilization, commercialization, and public availability of these inventions.”^{xii} The NIH Research Tools Policy goes on to explain:

“The Bayh-Dole Act encourages Recipients to patent and license subject inventions as one means of fulfilling these obligations. However, the use of patents and exclusive licenses is not the only, nor in some cases the most appropriate, means of implementing the Act. Where the subject invention is useful primarily as a research tool, inappropriate licensing practices are likely to thwart rather than promote utilization, commercialization and public availability of the invention.”

Issued in 1999, this policy represents an effort to ensure better balance between commercial interests and public interests, “to provide NIH funding recipients with guidance concerning appropriate terms for disseminating and train.fastercures.org

acquiring unique research resources developed with federal funds, and ... assist recipients in complying with their obligations under the Bayh-Dole Act.”^{xiii}

7. What have the impacts of Bayh-Dole been?

Bayh-Dole has both passionate supporters and detractors. Advocates argue that it has brought the results of federally funded research out of the laboratory and into the clinic. Critics say it has increased the time and cost of research because it “has negatively affected the practice and norms of science, created “anticommons” problems, contributed to patent hold-ups, and led to unnecessary increases in consumer prices.”^{xiv}

The Association of University Technology Managers (AUTM) reports that in 1979, one year before Bayh-Dole was passed, only 30 universities had a technology transfer office^{xv}; by 2013, data released by AUTM indicate that more than 200 U.S. institutions with tech transfer offices responded to its annual survey.^{xvi} AUTM data also show that levels of invention disclosures, patent applications, patent issuances, and licensing have increased steadily since Bayh-Dole’s enactment, and that universities created 10,000 companies since Bayh-Dole was enacted, 4,000 of which are still operating. University licensing income increased from \$7.3 million in 1981 to \$3.4 billion in 2008,^{xvii} and university patent licensing supported 3 million jobs between 1996 and 2010, an average of 200,000 jobs per year.^{xviii}

Individual universities can generate large revenue streams in the event they own the rights to a patent covering a commercially successful product. A 2013 study released by the Brookings Institution, however, showed that most universities do not break even on their technology transfers; on average, 87 percent have finished in the red over the last 20 years.^{xix} The same study shows that most of the revenue accrues to a small subset of universities—the top 10 percent of earners accumulate nearly 75 percent of the revenue.^{xx} Licensing revenue is also correlated with the number of employees in a university’s technology transfer office and university research expenses.^{xxi}

ⁱ 35 U.S.C. § 202(a).

ⁱⁱ *Stanford v. Roche*, 131 S. Ct. 2188 (2011).

https://scholar.google.com/scholar_case?case=14519543602869990622&hl=en&as_sdt=6&as_vis=1&oi=scholar (accessed July 22, 2015).

ⁱⁱⁱ *Id.*

^{iv} Patently-O. Supreme Court: Inventors Can Retain Rights Even for Federally Funded Inventions.

<http://patentlyo.com/patent/2011/06/stanford-v-roche-563-u-s-2011-in-a-split-decision-the-supreme-court-has-ruled-that-a-federally-funded-contractor.html> (accessed July 22, 2015).

^v 35 U.S.C. § 201(d).

^{vi} See e.g., 37 C.F.R. § 401.1(a)(1).

^{vii} See e.g., 37 C.F.R. § 401.1(a)(1). See also, The “Intellectual Property Policy” section of the NIH Grants and Funding website, <http://grants.nih.gov/grants/intell-property.htm> (accessed July 22, 2015).

^{viii} 35 U.S.C. § 203.

^{ix} O’Brien, William. “March-In Rights Under Bayh-Dole: The NIH’s Paper Tiger?” *Seton Hall Law Review*: Vol. 43, Iss. 4, Article 8. 2013. Web. 23 May 2014. <http://scholarship.shu.edu/cgi/viewcontent.cgi?article=1488&context=shlr> (accessed July 22, 2015).

^x 35 U.S.C. § 201(e).

^{xi} Schacht, Wendy. “The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology.” Congressional Research Service, Dec. 3, 2010. <http://www.fas.org/sgp/crs/misc/RL32076.pdf> (accessed July 22, 2015).

^{xii} NIH Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources, 64 Fed. Reg. 72090, 72093 (Dec. 23, 1999). http://grants.nih.gov/grants/intell-property_64FR72090.pdf (accessed July 22, 2015).

^{xiii} *Id.* at 72090.

^{xiv} Sweeney, Michael. “Correcting Bayh-Dole’s Inefficiencies for the Taxpayer.” *Northwestern Journal of Law and Technology*, Winter 2012. <http://scholarlycommons.law.northwestern.edu/cgi/viewcontent.cgi?article=1166&context=njtip> (accessed July 22, 2015).

^{xv} Valdivia, Walter D. “University Start-Ups: Critical for Improving Technology Transfer.” *Center for Technology Innovation at Brookings*. Brookings Institution, November 2013. Pg 6 Web. 27 May 2014.

http://www.brookings.edu/~media/research/files/papers/2013/11/start%20ups%20tech%20transfer%20valdivia/valdivia_tech%20transfer_v29_no%20embargo.pdf (accessed July 22, 2015).

^{xvi} See Highlights of AUTM's U.S. Licensing Activity Survey, FY2013. Available at:

http://www.autm.net/AM/Template.cfm?Section=FY_2013_Licensing_Activity_Survey&Template=/CM/ContentDisplay.cfm&ContentID=13870 (accessed July 22, 2015).

^{xvii} Loise, Vicki and Ashley Stevens. "The Bayh-Dole Act Turns 30." *Les Nouvelles*, December 2010.

http://www.bu.edu/otd/files/2011/02/The_Bayh-Dole_Act_Turns_30.pdf (accessed July 22, 2015).

^{xviii} Biotechnology Industry Organization. *The Economic Contribution of University/Nonprofit Inventions in the United States: 1996–2010*. June 20, 2012. <https://www.bio.org/sites/default/files/Bio%20Economic%20Impact%202012%20June%2020.pdf> (accessed July 22, 2015).

^{xix} Valdivia, Walter D, *supra* at 9.

^{xx} *Id.*

^{xxi} *Id.* at 6.