



UNITED STATES DEPARTMENT OF COMMERCE
Office of the General Counsel
Washington, D.C. 20230

OFFICE OF THE CHIEF COUNSEL FOR NIST

September 1, 2010

Thomas A. Kalil
Deputy Director for Policy
Office of Science and Technology Policy
Executive Office of the President
725 17th Street, Room 5228
Washington, DC 20502

Re: Facilitating Technology Transfer under the Bayh-Dole Act

Dear Tom:

You have asked for the views of this office regarding whether innovative approaches to facilitate transfer of technology developed through Federal funding awards are consistent with the requirements of the Bayh-Dole Act, 35 USC § 200 *et seq.* (Bayh-Dole). In particular, it has been proposed that the rate of Technology Transfer might be increased if grantees were to more widely employ elements of e-commerce, permitting creative and flexible licensing strategies to promote the practical application of Government-funded research.

The Department of Commerce is the Executive Branch agency responsible, through the Secretary of Commerce, for issuing regulations and establishing standard funding agreement provisions applicable to Federal agencies implementing Bayh-Dole. 35 USC § 206. The Secretary has delegated the authority to promulgate regulations (found at 37 CFR Part 401) to the Director of the National Institute of Standards and Technology ("NIST"). DOO 30-2A § 3.02(g).

The Department of Commerce seeks to promote U.S. commercial interests, including fostering and encouraging innovation and entrepreneurship. The Federal investment in research and development serves as an engine to keep the United States a leader in technology advancement and innovation, and stimulates economic growth. Technology Transfer promotes the commercialization of Government-funded research and development, fostering the transfer of new technologies into products for commercial and public benefit. Improving the effectiveness of Technology Transfer, then, is critical to achieving these objectives.

Bayh-Dole Policy

The stated policy and objective of Congress in enacting Bayh-Dole is “. . . 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 USC § 200.

Bayh-Dole Permits Contractors to Retain Ownership of Inventions

To accomplish that policy and objective, Bayh-Dole obligates nonprofit organizations and small business firms (“contractors”¹) to disclose each “subject invention” (that is, each “invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement,” 35 USC § 201(e)) “within a reasonable time” after the invention becomes known to the contractor, 35 USC § 202(c)(1), and permits contractors to elect to retain title to a subject invention within a reasonable time after disclosure, 35 USC § 202(a). Under certain defined circumstances, Bayh-Dole permits the Government to “restrict or eliminate” the contractor’s right to elect to retain title, 35 USC §§ 202(a), 202(b), and under such circumstances, rights vest in the Government.

Regulations implementing 35 USC § 202 through 204 are codified at 37 CFR Part 401, “Rights to Inventions Made by Nonprofit Organizations and Small Business Firms under Government Grants, Contracts, and Co-operative Agreements,” apply to all Federal agencies. 37 CFR § 401.1(b). These regulations govern all “subject inventions,” 37 CFR § 401.2(d), even if the Federal government is not the sole source of funding for either the conception or the reduction to practice. 37 CFR § 401.1(a). The following discussion of these regulations is not intended to be exhaustive, but to illustrate the nature of the regulatory requirements, most of which apply to funding agreements made by Federal funding agencies.

¹ The Presidential Memorandum to the Heads of Executive Departments and Agencies of February 18, 1983, expanded the definition of “contractor” under Bayh-Dole to include all recipients of federally funded research and development contracts, regardless of size.

Funding Agencies Must Use “Standard Patent Rights Clauses”

Bayh-Dole and its implementing regulations require Federal funding agencies to employ certain “standard clauses” in funding agreements awarded to contractors, except under certain specified conditions. 37 CFR § 401.3. Through these “standard clauses,” set forth at 37 CFR § 401.14(a), contractors are obligated to take certain actions to properly manage subject inventions. These actions include disclosing each subject invention to the Federal agency within two months after the contractor’s inventor discloses it in writing to contractor personnel responsible for patent matters, 37 CFR § 401.14(a)(c)(1); electing in writing whether or not to retain title to any subject invention by notifying the Federal agency within two years of disclosure, 37 CFR § 401.14(a)(c)(2); filing an initial patent application on a subject invention as to which the contractor elects to retain title within one year after election, 37 CFR § 401.14(a)(c)(3); executing and promptly delivering to the Federal agency all instruments necessary to establish or confirm the rights the Government has throughout the world in those subject inventions to which the contractor elects to retain title, 37 CFR § 401.14(a)(f)(1); requiring, by written agreement, the contractor’s employees to disclose promptly in writing each subject invention made under contract, 37 CFR § 401.14(a)(f)(2); notifying the Federal agency of any decision not to continue the prosecution of a patent application, 37 CFR § 401.14(a)(f)(3); and including in the specification of any United States patent applications and any patent issuing thereon covering a subject invention, a statement that the invention was made with Government support under the grant or contract awarded by the Federal agency, and that the Government has certain rights in the invention, 37 CFR § 401.14(a)(f)(4).

In addition, contractors are obligated to include the requirements of the standard clauses in any subcontracts under the contractor’s award, 37 CFR § 401.14(a)(g); to submit periodic reports as requested on the utilization of a subject invention or on efforts at obtaining such utilization that are being made by the contractor or its licensees or assignees, 37 CFR § 401.14(a)(h); and to agree that neither the contractor 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 CFR § 401.14(a)(i).

Under 37 CFR § 401.14(a)(j), the “March-in Right” clause, a contractor agrees that where it has acquired title, the Federal agency has the right 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 a request, the Federal agency has the right to grant such a license itself where it makes certain specified determinations.

The “standard clauses” also impose certain requirements on contractors, such as universities, that are 501(c)(3) non-profit organizations. Under 37 CFR § 401.14(a)(k), a non-profit contractor agrees that it may not assign its rights in a subject invention without the approval of the Federal agency (other than to a patent management organization); that it will share royalties with inventors; that it will utilize the balance of royalties after expenses for the support of scientific research or education; and that it will make reasonable efforts to attract, and will give preference to, licensees that are small business firms.

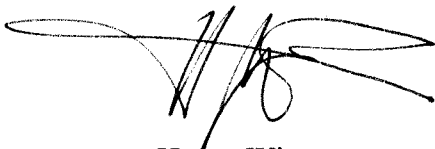
Bayh-Dole Does Not Prescribe Any Particular Licensing Scheme

It can be seen that while many of the regulations under Bayh-Dole address obligations imposed by Federal funding agencies on contractors, some of the obligations contractors assume when they elect to take title to federally funded subject inventions also relate to and affect rights granted and obligations imposed by those contractors through licensing of subject inventions. Any license granted by a contractor, then, must conform to the statutory requirements of Bayh-Dole and to the regulations promulgated thereunder.

However, neither Bayh-Dole nor its implementing regulations imposes upon contractors any particular approach to be used in licensing subject inventions. Provided that a contractor’s granted license satisfies the provisions of the Bayh-Dole Act and its implementing regulations, there is no constraint on a federally funded contractor’s ability to enable Technology Transfer, whether through e-commerce or other creative approaches, especially where such mechanisms can facilitate reduction of transaction costs associated with licensing and promote the translation of federally funded technology.

I hope that this has addressed your questions about the ability of contractors to employ different approaches in licensing inventions developed through Federal funding. I thank you for your inquiry, and encourage you to contact my office if we can be of any other assistance to you and to the Office of Science and Technology Policy regarding Technology Transfer under Bayh-Dole.

Sincerely,

A handwritten signature in black ink, appearing to read 'H. Wixon', with a large, sweeping flourish extending to the left.

Henry Wixon
Chief Counsel for NIST