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Patent Rights in Inventions Made with Federal Assistance: The Bayh-Dole Act

Michael V. Seitzinger
Legislative Attorney
American Law Division

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SUMMARY

A major statute concerning patent rights in inventions made with federal assistance and the first patent policy statute applicable to all federal agencies is referred to as the Bayh-Dole Act. This Act was passed in 1980 and amended in 1984. In order to accomplish the stated congressional objectives, the Act set up a system for allocating rights in inventions which result from research contracts or grants between federal government agencies and small businesses, nonprofit organizations, and universities.

Until passage of the Bayh-Dole Act, there had in many instances been the presumption that the government was the owner of any invention resulting from a research funding agreement with a small business, nonprofit organization, or university. Under Bayh-Dole any nonprofit organization, university, or small business firm having a research funding agreement with the federal government may elect to retain title to any subject invention. The election to take title must occur within a reasonable time after required disclosure by the contractor to the federal agency.

If title is retained by the nonprofit organization or small business firm, the federal agency still has certain rights. For example, it has 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. Also, the federal agency has march-in rights, meaning that it has the right to require the contractor, an assignee, or exclusive licensee concerning the subject invention to grant a nonexclusive, partially exclusive, or exclusive license in the invention if the agency determines, for example, that the contractor or assignee has not taken or is not expected to take within a reasonable time steps to achieve practical application of the invention.

Bayh-Dole contains a number of other provisions which have as their purpose increasing the development of technology in the United States. For example, the nonprofit organization is also required to share royalties with the inventor. Certain amounts of the royalty payments are required to be used for research and development.

In 1983 President Reagan issued a patent policy statement that government policy should, to the extent permitted by law, treat all contractors in the way that Bayh-Dole treats small businesses, nonprofit organizations, and universities. Further, in 1987 President Reagan issued an executive order entitled "Facilitating Access to Science and Technology." Section 1 of the Executive Order concerns patent rights in inventions made with federal assistance.

Patent Rights in Inventions Made with Federal Assistance: The Bayh-Dole Act

The United States Constitution provides:

> The Congress shall have Power...[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.[1]

Out of this general clause have come a number of federal statutes concerning the granting of patents, or exclusive rights for a certain period of time, to the inventors of discoveries. Many of these patent statutes derive from legislation enacted in the early years of the nation's history. However, legislation concerning the disposition of patent rights in inventions made with federal assistance is of relatively recent origin.

A major statute concerning patent rights in inventions made with federal assistance and the first patent policy statute applicable to all federal agencies is referred to as the Bayh-Dole Act.[2] This Act was passed in 1980 and amended in 1984.[3] It has the following as its stated objectives:

> to use the patent system to promote the utilization of inventions arising from federally supported research and 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; 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 sufficent 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.[4]

In order to accomplish these objectives, the Act set up a system for allocating rights in inventions which result from research contracts or grants between

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1 U.S. Const., Art. I, § 8, cl. 8.

2 P.L. 96-517, 96th Cong., 2d Sess. (1980), *codified at* 35 U.S.C. §§ 200 *et seq.*

3 P.L. 98-620, 98th Cong., 2d Sess. (1984).

4 35 U.S.C. § 200.

federal government agencies and small businesses, nonprofit organizations, or universities.

Until passage of the Bayh-Dole Act, each agency had had its own patent policy and in many instances there had been the presumption that the government was the owner of any invention resulting from a research funding agreement or grant with a small business, nonprofit organization, or university. For example, section 152 of the Atomic Energy Act of 1954[5] and section 9 of the Federal Nonnuclear Energy Research and Development Act of 1974[6] provide that the federal government shall own any invention or discovery resulting from a

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[5] "Any invention or discovery, useful in the production or utilization of special nuclear material or atomic energy, made or conceived in the course of or under any contract, subcontract, or arrangement entered into with or for the benefit of the Commission, regardless of whether the contract, subcontract, or arrangement involved the expenditure of funds by the Commission shall be vested in, and be the property of, the Commission, except that the Commission may waive its claim to any such invention or discovery under such circumstances as the Commission may deem appropriate, consistent with the policy of this section." 42 U.S.C. § 2182.

[6] "Whenever any invention is made or conceived in the course of or under any contract of the Secretary, other than nuclear energy research, development, and demonstration pursuant to the Atomic Energy Act of 1954 (42 U.S.C. 2011 et seq.) and the Secretary determines that--

> (1) the person who made the invention was employed or assigned to perform research, development, or demonstration work and the invention is related to the work he was employed or assigned to perform, or that it was within the scope of his employment duties, whether or not it was made during working hours, or with a contribution by the Government of the use of Government facilities, equipment materials, allocated funds, information proprietary to the Government, or services of Government employees during working hours; or
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> (2) the person who made the invention was not employed or assigned to perform research, development, or demonstration work, but the invention is nevertheless related to the contract or to the work or duties he was employed or assigned to perform, and was made during working hours, or with a contribution from the Government of the sort referred to in clause (1),
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> title to such invention shall vest in the United States, and if patents on such invention are issued they shall be issued to the United States, unless in particular circumstances the Secretary waives all or any part of the rights of the United States to such invention in conformity with the provisions of this section." 42 U.S.C. § 5908.

contract. This type of provision concerning federal government contracts was quite common until passage of the Bayh-Dole Act.[7]

Under Bayh-Dole any nonprofit organization,[8] including a university, or small business firm[9] having a funding agreement[10] with the federal government may elect to retain title to any subject invention.[11] The election to take title must occur within a reasonable time after required disclosure by the contractor to the

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[7] Congress appears to have intended that Bayh-Dole change the earlier title-taking policy. For example, Rep. Brooks, who dissented from the legislation, stated:

> The major problem I have with H.R. 6933 is that it violates a basic provision of the unwritten contract between the citizens of this country and their government; namely, that what the government acquires through the expenditure of its citizens' taxes, the government owns. Assigning automatic patent rights and exclusive licenses to companies or organizations for inventions developed at government expense is a pure giveaway of rights that properly belong to the people. H.R. Rep. No. 96-1307, 96th Cong., 2d Sess. (1980), part 2, *reprinted in* 1980 USCCAN 6511.

[8] The term "nonprofit organization" means universities and other institutions of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a State nonprofit organization statute. 35 U.S.C. § 201(i).

[9] The term "small business firm" means a small business concern as defined at section 2 of Public Law 85-536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration. 35 U.S.C. § 201(h).

[10] The term "funding agreement" means any contract, grant, or cooperative agreement entered into between any Federal agency, other than the Tennessee Valley Authority, and any contractor for the performance of experimental, developmental, or research work funded in whole or in part by the Federal Government. Such term includes any assignment, substitution of parties, or subcontract of any type entered into for the performance of experimental, developmental, or research work under a funding agreement as herein defined. 35 U.S.C. § 201(b).

[11] 35 U.S.C. § 202(a). "Subject invention" is defined as "any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement: *Provided*, That in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act (7 U.S.C. 2401(d)) must also occur during the period of contract performance." 35 U.S.C. § 201(e).

federal agency.[12] If disclosure within a reasonable time does not occur, the federal government may receive title to the subject invention.[13]

Although the right to retain title by the nonprofit organization, university, or small business firm is the general rule, the funding agreement may provide otherwise in certain circumstances. These circumstances include the following: 1. when the contractor is not located in the United States or is subject to the control of a foreign government; 2. in 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 Act; 3. when it is determined by a government authority which is authorized by statute or executive order to conduct foreign intelligence or counter-intelligence activities that the restriction or elimination of the right to retain title to any subject invention is necessary to protect the security of such activities; or 4. when the funding agreement includes the operation of a government-owned, contractor-operated facility of the Department of Energy primarily dedicated to that Department's naval nuclear propulsion or weapons related programs and all funding agreement limitations on the contractor's right to elect title to a subject invention are limited to inventions occurring under the above two programs of the Department of Energy.[14]

If title is retained by the nonprofit organization, university, or small business firm, the federal agency still has certain rights. For example, it has 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."[15] Also, the federal agency has march-in rights, meaning that it has the right to require the contractor, assignee, or exclusive licensee to grant a nonexclusive, partially exclusive, or exclusive license in the invention if the agency determines, for example, that the contractor or assignee has not taken or is not expected to take within a reasonable time steps to achieve practical application of the invention. If the contractor, assignee, or exclusive licensee refuses this request, the agency itself may grant the license.[16] Further, the federal agency must in most cases approve the assignment by a nonprofit organization of rights in the invention in the United States.[17]

The recipient of the federal funds is restricted in certain ways from assigning rights in the subject invention. For example, a nonprofit organization is

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12 35 U.S.C. § 202(a) and (c)(1).

13 35 U.S.C. § 202(c)(1).

14 35 U.S.C. § 202(a).

15 35 U.S.C. § 202(c)(4).

16 35 U.S.C. § 203(1).

17 35 U.S.C. § 202(c)(7)(A).

prohibited from licensing the subject invention to other than a small business firm except where it proves infeasible after a reasonable inquiry.[18] A nonprofit organization or small business firm receiving title to an invention resulting from federal funds is prohibited from granting to any person the exclusive right to use or sell the invention in the United States unless the person agrees that any products "embodying the subject invention or produced through the use of the subject invention" will be substantially manufactured in the United States.[19] However, the federal agency under whose funding agreement the invention was made may waive the requirement upon a showing that the nonprofit organization or small business firm used reasonable but unsuccessful efforts to grant licenses to licensees that would be likely to manufacture substantially within the United States or that under the circumstances domestic manufacture is not commercially feasible.[20]

Bayh-Dole contains a number of other provisions which have as their purpose increasing the development of technology in the United States. It was believed by many in Congress that the United States was falling behind in innovation and commercialization of technology and that to remain competitive in the global economy economic incentives should be provided to research facilities and inventors.

> The crisis in U.S. productivity and the governmental role in it has not gone unnoticed, however. In May of 1978 the President called for a major policy review of industrial innovation as the key to increased productivity in the United States. This White House call to action resulted in the creation of an advisory Committee of more than 150 senior representatives from the industrial, public interest, labor, scientific, and academic communities. The work of the Advisory Committee was overseen by a cabinet level coordinating committee chaired by the Secretary of Commerce. The Committee studied all the areas in which federal government policy impacts on productivity and innovation in the private sector. These fields of inquiry included: economic and trade policy; environmental, health and safety regulations; anti-trust enforcement; federal procurement policies; and federal patent and information policies.
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> When the advisory committee issued its 300 page report last year, a key segment contained recommendations on government patent policy. These recommendations, in turn, were received by the President, and formed the basis of a major legislative proposal which was conveyed to the Congress. Special emphasis was placed on the

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18 35 U.S.C. § 202(c)(7)(D).

19 35 U.S.C. § 204.

20 35 U.S.C. § 204.

> role of the patent system and the patent policy regarding government funded research in promoting industrial innovation.[21]

In addition to allowing the nonprofit organizations, including universities, potentially to profit by holding title to the patent, the nonprofit organization is also required by Bayh-Dole to share royalties with the inventor.[22] There is a requirement that, except for a contract for the operation of a Government-owned, contractor-operated facility, the balance of any royalties or income earned by the contractor concerning subject inventions, after payment of expenses incidental to the administration of the subject inventions, shall be used for the support of scientific research or education.[23] With respect to an operating contract for the operation of a Government-owned, contractor-operated facility, there is a requirement that, after payment of patenting costs, licensing costs, payments to inventors, and other expenses incidental to the administration of subject inventions, 100 percent of the balance of any royalties or income earned and retained by the contractor during any fiscal year up to an amount equal to 5 percent of the annual budget of the facility is required to be used by the contractor for scientific research, development, and education consistent with the research and development mission and objectives of the facility. However, if the balance exceeds 5 percent of the annual budget of the facility, 75 percent of the excess is required to be paid to the Treasury of the United States and the remaining 25 percent is required to be used for the licensing of the subject inventions. To the extent that it provides the most effective technology transfer, the licensing of the subject inventions is required to be administered by contractor employees on location at the facility.[24] If a contractor does not elect to retain title to a subject invention, the federal agency may grant a request for retention of rights by the inventor.[25]

In 1983 President Reagan issued a patent policy statement that government policy should, to the extent permitted by law, treat all contractors in the way that Bayh-Dole treats small businesses, nonprofit organizations, and universities.

> To the extent permitted by law, agency policy with respect to the disposition of any invention made in the performance of a federally-

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21 H.R. Rep. 96-1307, 96th Cong., 2d Sess., part 1 (1980), *reprinted in* 1980 USCCAN 6461.

22 "Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate the following:...(7) In the case of a nonprofit organization,...(B) a requirement that the contractor share royalties with the inventor." 35 U.S.C. § 202(c)(7)(B).

23 35 U.S.C. § 202(c)(7)(C).

24 35 U.S.C. § 202(c)(7)(E).

25 35 U.S.C. § 202(d).

> funded research and development contract, grant or cooperative agreement award shall be the same or substantially the same as applied to small business firms and nonprofit organizations under Chapter 38 of Title 35 of the United States Code.[26]

In 1987 President Reagan issued an Executive Order entitled "Facilitating Access to Science and Technology."[27] In the statement accompanying the order, the President stated:

> It is important not only to ensure that we maintain American preeminence in generating new knowledge and know-how in advanced technologies, but also that we encourage the swiftest possible transfer of federally developed science and technology to the private sector. All of the provisions of this Executive Order are designed to keep the United States on the leading edge of international competition.[28]

Section 1 of the Executive Order, part of which concerns patent rights in inventions made with federal assistance, states:

> (a) The head of each Executive department and agency, to the extent permitted by law, shall encourage and facilitate collaboration among Federal laboratories, State and local governments, universities, and the private sector, particularly small business, in order to assist in the transfer of technology to the marketplace.
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> (b) The head of each Executive department and agency shall, within overall funding allocations and to the extent permitted by law:
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> (1) delegate authority to its government-owned, government-operated Federal laboratories:
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> (A) to enter into cooperative research and development agreements with other Federal laboratories, State and local governments, universities, and the private sector; and
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> (B) to license, assign, or waive rights to intellectual property developed by the laboratory either under such cooperative research or development agreements and from within individual laboratories.
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> (2) identify and encourage persons to act as conduits between and among Federal laboratories, universities, and the private sector for the transfer of technology developed from federally funded research and development efforts;

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[26] Presidential Memorandum to the Heads of Executive Departments and Agencies on Government Patent Policy, 1983 Pub. Papers 248 (Feb. 18, 1983).

[27] E.O. 12,591, 3 C.F.R. 220, *reprinted in* 15 U.S.C.A. § 3710 (April 10, 1987).

[28] Statement by the President issued by the Office of the Press Secretary, April 10, 1987.

(3) ensure that State and local governments, universities, and the private sector are provided with information on the technology, expertise, and facilities available in Federal laboratories;

(4) promote the commercialization, in accord with my Memorandum to the Heads of Executive Departments and Agencies of February 18, 1983, of patentable results of federally funded research by granting to all contractors, regardless of size, the title to patents made in whole or in part with Federal funds, in exchange for royalty-free use by or on behalf of the government;

(5) administer all patents and licenses to inventions made with federal assistance, which are owned by the non-profit contractor or grantee, in accordance with Section 202(c)(7) of Title 35 of the United States Code as amended by Public Law 98-620 [section 202(c)(7) of title 35, Patents], without regard to limitations on licensing found in that section prior to amendment or in Institutional Patent Agreements now in effect that were entered into before that law was enacted on November 8, 1984, unless in the case of an invention that has not been marketed, the funding agency determines, based on information in its files, that the contractor or grantee has not taken adequate steps to market the inventions, in accordance with applicable law or an Institutional Patent Agreement;

(6) implement, as expeditiously as practicable, royalty-sharing programs with inventors who were employees of the agency at the time their inventions were made, and cash award programs; and

(7) cooperate, under policy guidance provided by the Office of Federal Procurement Policy, with the heads of other affected departments and agencies in the development of a uniform policy permitting Federal contractors to retain rights to software, engineering drawings, and other technical data generated by Federal grants and contracts, in exchange for royalty-free use by or on behalf of the government.

Over the years there has been significant praise of Bayh-Dole for spurring innovation and commercialization of United States technology. There has also been criticism of the Act. For example Rep. Brooks, in his dissent to the Act, stated that inventions resulting from taxpayer money belong to the taxpayers.[29] Some recent criticism has stemmed from the Scripps Research Institute's consideration of giving licensing rights in Scripps's future discoveries in cardiovascular medicine, immunology, and oncology to a Swiss firm, Sandoz, in exchange for $30 million a year for ten years. The National Institutes of Health (NIH) provides 60% of Scripps's budget. Scripps has apparently not gone forward with such an arrangement.

Several bills in the 103d Congress would amend the Bayh-Dole Act. Among these are H.R. 3590 and S. 1537, which, although primarily amending the

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[29] *See* fn 7.

Stevenson-Wydler Technology Innovation Act of 1980,[30] would also affect the Bayh-Dole Act by changing the distribution of income received by a federal agency or laboratory from the licensing or assignment of intellectual property under 35 U.S.C. section 207. These bills would require in certain cases, among other things, a kind of predetermined "direct" financial payback to the government. H.R. 1334 would require that a cooperative research and development agreement (CRADA) and other cooperative research arrangements concerning biomedical research relating to the development of a tangible product could not be conducted or supported by any agency of NIH unless regulations are in effect to ensure that, if the product is made available to the public: 1. the research entity will make certain that the commercial parties involved will make the product available at a "reasonable price" and 2. that the commercial parties will pay to NIH royalties which are reasonably related to the amounts spent by NIH.

Michael V. Seitzinger
Legislative Attorney

[30] P.L. 96-480, 96th Cong., 2d Sess., *codified at* 15 U.S.C. §§ 3701 *et seq.*