BAYH DOLE ACT 35 U.S.C. §200 - 212

Sec. 200. - Policy and objective

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; 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

Sec. 201. - Definitions

As used in this chapter -

(a) The term "Federal agency" means any executive agency as defined in section 105 of title 5, United States Code, and the military departments as defined by section 102 of title 5, United States Code.

(b) 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.

(c) The term "contractor" means any person, small business firm, or nonprofit organization that is a party to a funding agreement.

(d) The term "invention" means any invention or discovery which is or may be patentable or otherwise protectable under this title or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321 et seq.).

(e) The term "subject invention" means 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) [1] of the Plant Variety Protection Act (7 U.S.C. 2401(d))) must also occur during the period of contract performance.

(f) The term "practical application" means to 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.

(g) The term "made" when used in relation to any invention means the conception or first actual reduction to practice of such invention.

(h) 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.

(i) 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 1986 (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

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[1] See References in Text note below.

Sec. 202. - Disposition of rights

(a) Each nonprofit organization or small business firm may, within a reasonable time after disclosure as required by paragraph (c)(1) of this section, elect to retain title to any subject invention: Provided, however, That a funding agreement may provide otherwise

(i) when the contractor is not located in the United States or does not have a place of business located in the United States or is subject to the control of a foreign government,

(ii) 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 this chapter

(iii) 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, iv) [1] 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 under this subparagraph 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.. (FOOTNOTE 2) The rights of the nonprofit organization or small business firm shall be subject to the provisions of paragraph (c) of this section and the other provisions of this chapter. [2] So in original.

(b)

(1) The rights of the Government under subsection (a) shall not be exercised by a Federal agency unless it first determines that at least one of the conditions identified in clauses (i) through (iv) of subsection (a) exists. Except in the case of subsection (a)(iii), the agency shall file with the Secretary of Commerce, within thirty days after the award of the applicable funding agreement, a copy of such determination. In the case of a determination under subsection (a)(ii), the statement shall include an analysis justifying the determination. In the case of determinations applicable to funding agreements with small business firms, copies shall also be sent to the Chief Counsel for Advocacy of the Small Business Administration. If the Secretary of Commerce believes that any individual determination or pattern of determinations is contrary to the policies and objectives of this chapter or otherwise not in conformance with this chapter, the Secretary shall so advise the head of the agency concerned and the Administrator of the Office of Federal Procurement Policy, and recommend corrective actions.

(2) Whenever the Administrator of the Office of Federal Procurement Policy has determined that one or more Federal agencies are utilizing the authority of clause (i) or (ii) of subsection (a) of this section in a manner that is contrary to the policies and objectives of this chapter, the Administrator is authorized to issue regulations describing classes of situations in which agencies may not exercise the authorities of those clauses.

(3) At least once every 5 years, the Comptroller General shall transmit a report to the Committees on the Judiciary of the Senate and House of Representatives on the manner in which this chapter is being implemented by the agencies and on such other aspects of Government patent policies and practices with respect to federally funded inventions as the Comptroller General believes appropriate.

(4) If the contractor believes that a determination is contrary to the policies and objectives of this chapter or constitutes an abuse of discretion by the agency, the determination shall be subject to the last paragraph of section 203(2).

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

(1) That the contractor 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, and that the Federal Government may receive title to any subject invention not disclosed to it within such time.

(2) That the contractor make a written election within two years after disclosure to the Federal agency (or such additional time as may be approved by the Federal agency) whether the contractor will retain title to a subject invention: Provided, That in any case where publication, on sale, or public use, has initiated the one year statutory period in which valid patent protection can still be obtained in the United States, the period for election may be shortened by the Federal agency to a date that is not more than sixty days prior to the end of the statutory period: And provided further, That the Federal Government may receive title to any subject invention in which the contractor does not elect to retain rights or fails to elect rights within such times.

(3) That a contractor electing rights in a subject invention agrees to file a patent application prior to any statutory bar date that may occur under this title due to publication, on sale, or public use, and shall thereafter file corresponding patent applications in other countries in which it wishes to retain title within reasonable times, and that the Federal Government may receive title to any subject inventions in the United States or other countries in which the contractor has not filed patent applications on the subject invention within such times.

(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; [3] 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.

(5) The right of the Federal agency to require periodic reporting on the utilization or efforts at obtaining utilization that are being made by the contractor or his licensees or assignees: Provided, That any such information as well as any information on utilization or efforts at obtaining utilization obtained as part of a proceeding under section 203 of this chapter shall be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5 of the United States Code.

(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.

(7) In the case of a nonprofit organization,

(A) a prohibition upon the assignment of rights to a subject invention in the United States without the approval of the Federal agency, except where such assignment is made to an organization which has as one of its primary functions the management of inventions (provided that such assignee shall be subject to the same provisions as the contractor);

(B) a requirement that the contractor share royalties with the inventor;

(C) except with respect to a funding agreement for the operation of a Government-owned-contractor-operated facility, a requirement that the balance of any royalties or income earned by the contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions, be utilized for the support of scientific research or education;

(D) a requirement that, except where it proves infeasible after a reasonable inquiry, in the licensing of subject inventions shall be given to small business firms; and

(E) with respect to a funding agreement for the operation of a Government-owned-contractor-operated facility, requirements

(i) 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, shall be used by the contractor for scientific research, development, and education consistent with the research and development mission and objectives of the facility, including activities that increase the licensing potential of other inventions of the facility; provided that if said balance exceeds 5 percent of the annual budget of the facility, that 75 percent of such excess shall be paid to the Treasury of the United States and the remaining 25 percent shall be used for the same purposes as described above in this clause (D); and

(ii) that, to the extent it provides the most effective technology transfer, the licensing of subject inventions shall be administered by contractor employees on location at the facility.

(8) The requirements of sections 203 and 204 of this chapter.

(d) If a contractor does not elect to retain title to a subject invention in cases subject to this section, the Federal agency may consider and after consultation with the contractor grant requests for retention of rights by the inventor subject to the provisions of this Act and regulations promulgated hereunder.

(e) In any case when a Federal employee is a coinventor of any invention made under a funding agreement with a nonprofit organization or small business firm, the Federal agency employing such coinventor is authorized to transfer or assign whatever rights it may acquire in the subject invention from its employee to the contractor subject to the conditions set forth in this chapter.

(f)

(1) No funding agreement with a small business firm or nonprofit organization shall contain a provision allowing a Federal agency to require the licensing to third parties of inventions owned by the contractor that are not subject inventions unless such provision has been approved by the head of the agency and a written justification has been signed by the head of the agency. Any such provision shall clearly state whether the licensing may be required in connection with the practice of a subject invention, a specifically identified work object, or both. The head of the agency may not delegate the authority to approve provisions or sign justifications required by this paragraph.

(2) A Federal agency shall not require the licensing of third parties under any such provision unless the head of the agency determines 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 the practical application of the subject invention or work object. Any such determination shall be on the record after an opportunity for an agency hearing. Any action commenced for judicial review of such determination shall be brought within sixty days after notification of such determination

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[1] So in original. Probably should be "(iv)".

[3] So in original. The semicolon probably should be a comma.

Sec. 203. - March-in rights

1. [1] 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 -

(a) 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;

(b) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;

(c) 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

(d) 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.

2. A determination pursuant to this section or section 202(b)(4) shall not be subject to the Contract Disputes Act (41 U.S.C. Sec. 601 et seq.). An administrative appeals procedure shall be established by regulations promulgated in accordance with section 206. Additionally, any contractor, inventor, assignee, or exclusive licensee adversely affected by a determination under this section may, at any time within sixty days after the determination is issued, file a petition in the United States Court of Federal Claims, which shall have jurisdiction to determine the appeal on the record and to affirm, reverse, remand or modify, ", (FOOTNOTE 2) as appropriate, the determination of the Federal agency. In cases described in paragraphs (a) and (c), the agency's determination shall be held in abeyance pending the exhaustion of appeals or petitions filed under the preceding sentence.

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[1] So in original. Probably should be "(1)".

[2] So in original. Quotation marks and comma probably should not appear

Sec. 204. - Preference for United States industry

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 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.

Sec. 205. - Confidentiality

Federal agencies are authorized to withhold from disclosure to the public information disclosing any invention in which the Federal Government owns or may own a right, title, or interest (including a nonexclusive license) for a reasonable time in order for a patent application to be filed. Furthermore, Federal agencies shall not be required to release copies of any document which is part of an application for patent filed with the United States Patent and Trademark Office or with any foreign patent office.

Sec. 206. - Uniform clauses and regulations

The Secretary of Commerce may issue regulations which may be made applicable to Federal agencies implementing the provisions of sections 202 through 204 of this chapter and shall establish standard funding agreement provisions required under this chapter. The regulations and the standard funding agreement shall be subject to public comment before their issuance

Sec. 207. - Domestic and foreign protection of federally owned inventions

(a) Each Federal agency is authorized to -

(1) apply for, obtain, and maintain patents or other forms of protection in the United States and in foreign countries on inventions in which the Federal Government owns a right, title, or interest;

(2) grant nonexclusive, exclusive, or partially exclusive licenses under federally owned patent applications, patents, or other forms of protection obtained, royalty-free or for royalties or other consideration, and on such terms and conditions, including the grant to the licensee of the right of enforcement pursuant to the provisions of chapter 29 of this title as determined appropriate in the public interest;

(3) undertake all other suitable and necessary steps to protect and administer rights to federally owned inventions on behalf of the Federal Government either directly or through contract; and

(4) transfer custody and administration, in whole or in part, to another Federal agency, of the right, title, or interest in any federally owned invention.

(b) For the purpose of assuring the effective management of Government-owned inventions, the Secretary of Commerce is authorized to -

(1) assist Federal agency efforts to promote the licensing and utilization of Government-owned inventions;

(2) assist Federal agencies in seeking protection and maintaining inventions in foreign countries, including the payment of fees and costs connected therewith; and

(3) consult with and advise Federal agencies as to areas of science and technology research and development with potential for commercial utilization

Sec. 208. - Regulations governing Federal licensing

The Secretary of Commerce is authorized to promulgate regulations specifying the terms and conditions upon which any federally owned invention, other than inventions owned by the Tennessee Valley Authority, may be licensed on a nonexclusive, partially exclusive, or exclusive basis

Sec. 209. - Restrictions on licensing of federally owned inventions

(a) No Federal agency shall grant any license under a patent or patent application on a federally owned invention unless the person requesting the license has supplied the agency with a plan for development and/or marketing of the invention, except that any such plan may be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5 of the United States Code.

(b) A Federal agency shall normally grant the right to use or sell any federally owned invention in the United States only to a licensee that agrees that any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States.

(c)

(1) Each Federal agency may grant exclusive or partially exclusive licenses in any invention covered by a federally owned domestic patent or patent application only if, after public notice and opportunity for filing written objections, it is determined that -

(A) the interests of the Federal Government and the public will best be served by the proposed license, in view of the applicant's intentions, plans, and ability to bring the invention to practical application or otherwise promote the invention's utilization by the public;

(B) the desired practical application has not been achieved, or is not likely expeditiously to be achieved, under any nonexclusive license which has been granted, or which may be granted, on the invention;

(C) exclusive or partially exclusive licensing is a reasonable and necessary incentive to call forth the investment of risk capital and expenditures to bring the invention to practical application or otherwise promote the invention's utilization by the public; and

(D) the proposed terms and scope of exclusivity are not greater than reasonably necessary to provide the incentive for bringing the invention to practical application or otherwise promote the invention's utilization by the public.

(2) A Federal agency shall not grant such exclusive or partially exclusive license under paragraph (1) of this subsection if it determines that the grant of such license will tend substantially to lessen competition or result in undue concentration in any section of the country in any line of commerce to which the technology to be licensed relates, or to create or maintain other situations inconsistent with the antitrust laws.

(3) First preference in the exclusive or partially exclusive licensing of federally owned inventions shall go to small business firms submitting plans that are determined by the agency to be within the capabilities of the firms and equally likely, if executed, to bring the invention to practical application as any plans submitted by applicants that are not small business firms.

(d) After consideration of whether the interests of the Federal Government or United States industry in foreign commerce will be enhanced, any Federal agency may grant exclusive or partially exclusive licenses in any invention covered by a foreign patent application or patent, after public notice and opportunity for filing written objections, except that a Federal agency shall not grant such exclusive or partially exclusive license if it determines that the grant of such license will tend substantially to lessen competition or result in undue concentration in any section of the United States in any line of commerce to which the technology to be licensed relates, or to create or maintain other situations inconsistent with antitrust laws.

(e) The Federal agency shall maintain a record of determinations to grant exclusive or partially exclusive licenses.

(f) Any grant of a license shall contain such terms and conditions as the Federal agency determines appropriate for the protection of the interests of the Federal Government and the public, including provisions for the following:

(1) periodic reporting on the utilization or efforts at obtaining utilization that are being made by the licensee with particular reference to the plan submitted: Provided, That any such information may be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5 of the United States Code;

(2) the right of the Federal agency to terminate such license in whole or in part if it determines that the licensee is not executing the plan submitted with its request for a license and the licensee cannot otherwise demonstrate to the satisfaction of the Federal agency that it has taken or can be expected to take within a reasonable time, effective steps to achieve practical application of the invention;

(3) the right of the Federal agency to terminate such license in whole or in part if the licensee is in breach of an agreement obtained pursuant to paragraph (b) of this section; and

(4) the right of the Federal agency to terminate the license in whole or in part if the agency determines that such action is necessary to meet requirements for public use specified by Federal regulations issued after the date of the license and such requirements are not reasonably satisfied by the licensee

Sec. 210. - Precedence of chapter

(a) This chapter shall take precedence over any other Act which would require a disposition of rights in subject inventions of small business firms or nonprofit organizations contractors in a manner that is inconsistent with this chapter, including but not necessarily limited to the following:

(1) section 10(a) of the Act of June 29, 1935, as added by title I of the Act of August 14, 1946 (7 U.S.C. 427i(a); 60 Stat. 1085);

(2) section 205(a) of the Act of August 14, 1946 (7 U.S.C. 1624(a); 60 Stat. 1090);

(3) section 501(c) of the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 951(c); 83 Stat. 742);

(4) section 30168(e) of title 49;

(5) section 12 of the National Science Foundation Act of 1950 (42 U.S.C. 1871(a); [1] 82 Stat. 360); (FOOTNOTE 1) See References in Text note below.

(6) section 152 of the Atomic Energy Act of 1954 (42 U.S.C. 2182; 68 Stat. 943);

(7) section 305 of the National Aeronautics and Space Act of 1958 (42 U.S.C. 2457);

(8) section 6 of the Coal Research Development Act of 1960 (30 U.S.C. 666; 74 Stat. 337);

(9) section 4 of the Helium Act Amendments of 1960 (50 U.S.C. 167b; 74 Stat. 920);

(10) section 32 of the Arms Control and Disarmament Act of 1961 (22 U.S.C. 2572; 75 Stat. 634);

(11) section 9 of the Federal Nonnuclear Energy Research and Development Act of 1974 (42 U.S.C. 5901; [2] 88 Stat. 1878);

(12) section 5(d) of the Consumer Product Safety Act (15 U.S.C. 2054(d); 86 Stat. 1211);

(13) section 3 of the Act of April 5, 1944 (30 U.S.C. 323; 58 Stat. 191); [1]

(14) section 8001(c)(3) of the Solid Waste Disposal Act (42 U.S.C. 6981(c); 90 Stat. 2829);

(15) section 219 of the Foreign Assistance Act of 1961 (22 U.S.C. 2179; 83 Stat. 806);

(16) section 427(b) of the Federal Mine Health and Safety Act of 1977 (30 U.S.C. 937(b); 86 Stat. 155);

(17) section 306(d) of the Surface Mining and Reclamation Act of 1977 (30 U.S.C. 1226(d); 91 Stat. 455); [1]

(18) section 21(d) of the Federal Fire Prevention and Control Act of 1974 (15 U.S.C. 2218(d); 88 Stat. 1548);

(19) section 6(b) of the Solar Photovoltaic Energy Research Development and Demonstration Act of 1978 (42 U.S.C. 5585(b); 92 Stat. 2516);

(20) section 12 of the Native Latex Commercialization and Economic Development Act of 1978 (7 U.S.C. 178(j); [3] 92 Stat. 2533); and

(21) section 408 of the Water Resources and Development Act of 1978 (42 U.S.C. 7879; 92 Stat. 1360). The Act creating this chapter shall be construed to take precedence over any future Act unless that Act specifically cites this Act and provides that it shall take precedence over this Act.

(b) Nothing in this chapter is intended to alter the effect of the laws cited in paragraph (a) of this section or any other laws with respect to the disposition of rights in inventions made in the

performance of funding agreements with persons other than nonprofit organizations or small business firms.

(c) Nothing in this chapter is intended to limit the authority of agencies to agree to the disposition of rights in inventions made in the performance of work under funding agreements with persons other than nonprofit organizations or small business firms in accordance with the Statement of Government Patent Policy issued on February 18, 1983, agency regulations, or other applicable regulations or to otherwise limit the authority of agencies to allow such persons to retain ownership of inventions except that all funding agreements, including those with other than small business firms and nonprofit organizations, shall include the requirements established in paragraph [4] 202(c)(4) and section 203 of this title.. [5] Any disposition of rights in inventions made in accordance with the Statement or implementing regulations, including any disposition occurring before enactment of this section, are hereby authorized. [5] So in original.

(d) Nothing in this chapter shall be construed to require the disclosure of intelligence sources or methods or to otherwise affect the authority granted to the Director of Central Intelligence by statute or Executive order for the protection of intelligence sources or methods.

(e) The provisions of the Stevenson-Wydler Technology Innovation Act of 1980 shall take precedence over the provisions of this chapter to the extent that they permit or require a disposition of rights in subject inventions which is inconsistent with this chapter

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[2] So in original. Should be "5908;".

[3] So in original. Should be "178j;".

[4] So in original. Probably should be "section".

Sec. 211. - Relationship to antitrust laws

Nothing in this chapter shall be deemed to convey to any person immunity from civil or criminal liability, or to create any defenses to actions, under any antitrust law

Sec. 212. - Disposition of rights in educational awards

No scholarship, fellowship, training grant, or other funding agreement made by a Federal agency primarily to an awardee for educational purposes will contain any provision giving the Federal agency any rights to inventions made by the awardee

THE BAYH-DOLE ACT
A GUIDE TO THE LAW AND IMPLEMENTING REGULATIONS

COUNCIL ON GOVERNMENTAL RELATIONS
September 1999

Introduction

The transfer of new technology from university laboratories to the private sector has a long history and has taken many different forms. The current national emphasis on this activity, however, can be dated to the 1980 enactment of P.L. 96-517, The Patent and Trademark Law Amendments Act, more commonly known as the Bayh-Dole Act, and amendments included in P.L. 98-620, enacted into law in 1984.

This brochure reviews the Bayh-Dole legislation, the implementing regulations that have evolved, and the major issues associated with complying with the law and related regulations. It also highlights the significant benefits of the Bayh-Dole Act that have occurred to date.

Background

Technology transfer--the transfer of research results from universities to the commercial marketplace for the public benefit--is closely linked to fundamental research activities in universities. Although a handful of U.S. universities were moving science from the laboratory to industrial commercialization as early as the 1920s, academic technology transfer as a formal concept, is said to have originated in a report entitled "Science - The Endless Frontier" that Vannevar Bush wrote for the President in 1945. At that time, the success of the Manhattan Project had demonstrated the importance of university research to the national defense. Vannevar Bush, however, also recognized the value of university research as a vehicle for enhancing the economy by increasing the flow of knowledge to industry through support of basic science. His report became instrumental in providing a substantial and continuing increase in funding of research by the federal government. It stimulated the formation of the National Institutes of Health (NIH), the National Science Foundation (NSF), and the Office of Naval Research (ONR). Due to the success of these and other agencies, the funding of basic research by the federal government is now considered to vital to the national interest.

In the 1960s and 1970s, there was much study and debate surrounding federal patent policies. A major concern was the lack of success by the federal government in promoting the adoption of new technologies by industry. There was no government-wide policy regarding ownership of inventions made by government contractors and grantees under federal funding. Inconsistencies in policies and practices among the various funding agencies resulted in a very limited flow of government-funded inventions to the private sector. In 1980, the federal government held title to approximately 28,000 patents. Fewer than 5% of these were licensed to industry for development of commercial products.[1]

This problem was due, in part, to restrictions imposed on the licensing of new technologies and reluctance on the part of the agencies to permit ownership of inventions to vest in universities and other grantees.[2] The government would not relinquish ownership of federally funded inventions to the inventing organization except in rare cases after petitions had moved through a lengthy and difficult waiver process. Instead, the government retained title and made these inventions available through non-exclusive licenses to anyone who wanted to practice them.

As a result, companies did not have exclusive rights under government patents to manufacture and sell resulting products. Understandably, companies were reluctant to invest in and develop new products if competitors could also acquire licenses and then manufacture and sell the same products. Accordingly, the government remained unsuccessful in attracting private industry to license government-owned patents. Although taxpayers were supporting the federal research enterprise, they were not benefiting from useful products or the economic development that would have occurred with the manufacture and sale of those products.

In 1980, however, legislators and the administration concluded that the public would benefit from a policy that permitted universities and small businesses to elect ownership of inventions made under federal funding and to become directly involved in the commercialization process. This new policy would also permit exclusive licensing when combined with diligent development and transfer of an invention to the marketplace for the public good. It was understood that stimulation of the U.S. economy would occur through the licensing of new inventions from universities to businesses that would, in turn, manufacture the resulting products in the U.S.

Evolution

With the passage of the Bayh-Dole Act, colleges and universities immediately began to develop and strengthen the internal expertise needed to effectively engage in the patenting and licensing of inventions. In many cases, institutions that had not been active in this area began to establish entirely new technology transfer offices, building teams with legal, business, and scientific backgrounds. These activities continue to accelerate nationally as the importance of the Bayh-Dole Act becomes fully appreciated. Evidence of this is reflected in the fact that the membership of the Association of University Technology Managers (AUTM) increased from 691 in 1989 to 2,178 in 1999. In 1979, the year before passage of the Bayh-Dole Act, the Association counted only 113 members. [3]

University technology transfer offices perform a wide variety of highly specialized functions related to the patenting and licensing of inventions. In addition, these offices also perform a vital function related to the formation of research partnerships with industry, and in negotiating the exchange of research materials and research tools.

In recent years, the wisdom of the new federal policy has become increasingly apparent. Growing numbers of universities have demonstrated that their newly formed technology transfer programs are effective in licensing inventions made with federal support to commercial partners. As a result, many new technologies have been diligently and successfully introduced into public use.

Another significant result of the Bayh-Dole Act is that it provides a strong incentive for university-industry research collaborations. At the national level, industry support for research and development at universities represents less than 7% of the total funding of university-based research. While small compared to the 60% provided by federal agencies, this private investment in the creativity of universities, including professors, students and staff, drives a form of technology transfer that is increasingly important to industry. The investment by industry rests on a secure footing because it is based on the principles and provisions of the Bayh-Dole Act.[4]

Some Perspective

The principles of the Bayh-Dole Act were the result of years of intense and emotional debate, dealing with fundamental concerns. The record shows that the debate included such issues as whether exclusive licenses would lead to monopolies and higher prices; whether taxpayers would get their fair share; whether foreign industry would benefit unduly; and whether ownership of inventions by a contractor is anti-competitive. Safeguards were hammered out in numerous legislative drafts. It is certain that the Act became much stronger because of the thorough debate that took place prior to its passage.

From the beginning, it was obvious that economic interests rather than academic science interests were the driving forces for the change in government policy. As early as October l963, President Kennedy had issued a Presidential Memorandum and Statement of Government Policy. This memorandum marked the beginning of an intense discussion about the effect that government patent policy had on commercial utilization of federally sponsored inventions, on industry participation in federally sponsored R & D programs, and on business competition in the marketplace.[5] It was not until industry, academe and the government recognized that their individual interests could be reconciled in the pursuit of commercialization that passage of the Bayh-Dole Act became possible and ended years of debate.

Until the Bayh-Dole Act became effective on July 1, 1981, the federal agencies kept tight control over intellectual property rights resulting from funded research, premised largely on traditional expectations rooted in the procurement process. After the passage of the Bayh-Dole Act, codifying and implementing it at the agency level was not an easy process. As the success of the Act became quickly apparent, subsequent legislative initiatives broadened its reach even further. These initiatives and the technical amendments involved are described in the Appendix.

Current Regulations

Regulations implementing federal patent and licensing policy regarding "Rights to Inventions Made by Nonprofit Organizations and Small Business Firms" are codified at 37 CFR Part 401. The Department of Commerce is designated as the federal agency to promote commercialization and to assume responsibility for maintaining these rules.[6] The following summarizes the significant aspects of these regulations:

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In order to assist grantees in their efforts to maintain compliance with regulatory compliance of the Act, some federal agencies have periodically issued guidance to the grantee community. An example is a question and answer document regarding invention reporting, printed in the NIH Guide to Grants and Contracts in l995. (NIH Guide, Vol.24, No.33, September 22, l995).

Results of the Bayh-Dole Act

University patenting and licensing efforts under the Bayh-Dole Act have fostered the commercialization of many new technological advances that impact the lives of millions of people across the nation. A recent national survey conducted by AUTM[10] reports that 70% of the active licenses of responding institutions are in the life sciences--yielding products and processes that diagnose disease, reduce pain and suffering, and save lives. Most of the inventions involved were the result of federal funding. While it would be impossible to list all such inventions, a few examples of technologies and products originating from federally funded university discoveries include:

- Artificial lung surfactant for use with newborn infants, University of California
- Cisplatin and carboplatin cancer therapeutics, Michigan State University
- Citracal® calcium supplement, University of Texas Southwestern Medical Center
- Haemophilus B conjugate vaccine, University of Rochester
- Metal Alkoxide Process for taxol production, Florida State University
- Neupogen® used in conjunction with chemotherapy, Memorial Sloan Kettering Cancer Institute
- Process for inserting DNA into eucaryotic cells and for producing proteinaceous materials, Columbia University
- Recombinant DNA technology, central to the biotechnology industry, Stanford University and University of California
- TRUSOPT® (dorzolamide) ophthalmic drop used for glaucoma, University of Florida

These examples of successful new technologies demonstrate that a strong national infrastructure to support technology transfer has been established at academic institutions across the nation since passage of the Bayh-Dole Act. In 1980 there were approximately 25-30 universities actively engaged in the patenting and licensing of inventions. It is estimated that there has been close to a ten-fold increase in institutional involvement since then. The AUTM survey reflects the impact of this growth in activity:

- Academic institutions were granted more than 8,000 U.S. patents between 1993 and 1997 for technologies discovered by their researchers.

- Over 2,200 new companies have been formed since 1980 that were based on the licensing of an invention from an academic institution, including over 330 companies formed in FY 1997 alone.

- Approximately $30 billion of economic activity each year, supporting 250,000 jobs can be attributed to the commercialization of new technologies from academic institutions.

- There are more than 1000 products currently on the market that are based on university licensed discoveries.

- Technologies licensed from academia have been instrumental in spawning entirely new industries, improving the productivity and competitiveness of companies, and creating new companies and jobs. [11]

In summary, the Bayh-Dole Act and its subsequent amendments created incentives for the government, universities, and industry to work together in the commercialization of new technologies for the public benefit. The success of this three-way partnership cannot be understated.

Conclusions

On a nation-wide basis, the results support the conclusion that the Bayh-Dole Act has promoted a substantial increase in technology transfer from universities to industry, and ultimately to the public. Certainty of title to inventions made under federal funding is perhaps the most important incentive for commercialization. Implementation of uniform patenting and licensing procedures, however, combined with the ability of universities to grant exclusive licenses, are also significant ingredients for success. This combination of factors led to a tremendous acceleration in the introduction of new products through university technology transfer activities.

Certainty of title to inventions made under Federal funding has one other significant benefit—it protects the right of scientists to continue to use and to build on a specific line of inquiry. This is fundamentally important to research-intensive institutions because of the complex way in which research is typically funded, with multiple funding sources. The retention of title to inventions by the institution is the only way of ensuring that the institution will be able to accept funding from

interested research partners in the future. This is a critically important benefit of the Bayh-Dole Act that is not widely understood.

As Vannevar Bush foresaw, enormous benefits to the U.S. economy have occurred because of federal funding of research. These benefits have been significantly enhanced by the adoption of federal policies encouraging technology transfer. Such policies have led to breathtaking advances in the medical, engineering, chemical, computing and software industries, among others. The licensing of new technologies has led to the creation of new companies, thousands of jobs, cutting-edge educational opportunities and the development of entirely new industries. Accordingly, the Bayh-Dole Act continues to be a national success story, representing the foundation of a successful union among government, universities, and industry.

Web Resources

- http://www.nih.gov/grants/guide/index.htm (search for NIH Bayh-Dole-related policies)
- http://www.access.gpo.gov (GAO and other federal reports)
- http://137.187.120.232/ (Interagency Edison project)

- http://www.autm.net (AUTM home page)
- http://www.cogr.edu/ (COGR home page)

Appendix

Bayh-Dole Act and Related Legislation

The Bayh-Dole Act and subsequent amendments provide the basis for current university technology transfer practices. The federal patent and licensing policy was shaped by four events that occurred between 1980 and 1985.

1. On December 12, 1980, P.L. 96-517, the Bayh-Dole Act was enacted into law. After lengthy and contentious congressional debate, legislation was crafted that created a balance between incentives and controls. Universities applauded the legislation because a uniform federal patent policy was established that clearly stated that universities may elect to retain title to inventions developed under government funding. Industry, particularly the small business community, appreciated an ownership policy that was applied uniformly on a government-wide basis. In addition, industry expected to benefit from the message that universities were encouraged to collaborate with companies to promote the utilization of inventions arising from federal funding, that preference in licensing be given to small business, and that, to the extent possible, licensed products were to be manufactured in the U.S. The federal government, in turn, was assured that universities would file, at university expense, patent applications on inventions they elected to own. In addition, the government retains rights to enforce diligent commercial development of inventions. It also enjoys royalty-free, non-exclusive licenses to practice federally funded inventions throughout the world for government purposes.

2. On February 10, 1982, the Office of Management and Budget issued OMB Circular A-124 to provide guidance to federal agencies regarding implementation of the Bayh-Dole Act. This Circular established standard patent rights clauses for use in federal funding agreements. It also set up standard reporting requirements for universities electing title to inventions.

3. On February 18, 1983, a Presidential Memorandum on "Government Patent Policy" was issued. This Memorandum was issued to satisfy those that recognized the benefits of the legislation and wanted broader coverage. The Presidential Memorandum directed federal agencies to extend the terms and provisions of the Bayh-Dole Act to all government contractors, with a follow-on amendment to the Federal Acquisition Regulations to assure that all federal R&D agencies would implement the Act and the Memorandum.

4. On November 8, 1984, the original Bayh-Dole statute was amended by P.L. 98-620. New language was added to remove term limitations placed on exclusive licenses under the original Act. In addition, the Department of Commerce was designated as the

federal agency responsible for overseeing the implementation of the Bayh-Dole Act and for monitoring the granting of exceptions to the rules.

On March 18, 1987 (52 FR 8552), all of the relevant provisions--the Bayh-Dole Act, the amendment, OMB Circular A-124, and the Presidential Memorandum--were finalized and consolidated in a rulemaking published by the Department of Commerce—appearing at 37 CRF Part 401. These regulations, augmented by the NIH guidelines discussed in this brochure, specify the rights and obligations of all parties involved and constitute the operating manual for technology transfer on a national basis.

Footnotes

[1] U.S. Government Accounting Office (GAO) Report to Congressional Committees entitled "Technology Transfer, Administration of the Bayh-Dole Act by Research Universities" dated May 7, 1998.

[2] The term "university" or "universities" as used in the text applies to all non-profit grantees /contractors.

[3] We gratefully acknowledge the courtesy and cooperation of AUTM in providing these statistics. See also AUTM Licensing Survey FY1991-1995 and subsequent years.

[4] In 1997, federal agencies provided an estimated $14.3 billion or about 60% of total support for research performed at universities. Academic institutions provided $4.5 billion of their own funds. State and local governments and nonprofit organizations each contributed $18.1 billion and industry $1.7 billion. Although the proportion of academic R&D expenditures supplied by industry has been rising fairly steadily, it still only represents a fraction (7%) of total academic R&D support. Science and Engineering Indicators 1998. National Science Board: 4-8 and 4-9.

[5] Presidential Memorandum and Statement of Government Patent Policy, issued October 10, 1963. Published in the Federal Register, Vol. 28, No. 200.

[6] The Secretary of Commerce delegated this authority under 35 USC 206 to the Assistant Secretary for Productivity, Technology and Innovation.

[7] Other circumstances, not clearly elucidated in the regulations, may be invoked by the government. Further detail can be found in 37 CFR Part 401.3; general appeal mechanisms are found in Part 401.4.

[8] March-in rights, including appropriate procedures, are described at 37 CFR Part 401.6.

[9]. Notice for Public Comment, 64 FR 100, 28205-28209.

[10] AUTM Licensing Survey, Fiscal Year 1997.

[11] AUTM press release December 17, 1998.

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A Guide to the Law and Implementing Regulations

COGR

COUNCIL ON GOVERNMENTAL RELATIONS

October 1999

Council on Governmental Relations

This brochure is intended to inform the public about the Patent and Trademark Law Amendment Act of l980, more commonly known as the Bayh-Dole Act, which is the legal framework for transfer of university generated, federally funded inventions to the commercial market place. The brochure provides information about the Act, as well as about its implementing regulations and compliance requirements.

The Council on Governmental Relations is an organization which includes in its membership 145 research intensive universities. This brochure does not claim to be a manual of university technology transfer and licensing activities. Rather, it illustrates the basis for university-industry collaboration and developments since the passage of the Act.

In preparing this brochure, the COGR Committee on Technology Transfer and Research Ethics drew on the assistance of many universities. Their help is gratefully acknowledged. Special appreciation is due to Terence A. Feuerborn, Office of the President, University of California.

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THE BAYH-DOLE ACT
A GUIDE TO THE LAW AND IMPLEMENTING REGULATIONS

INTRODUCTION

The transfer of new technology from university laboratories to the private sector has a long history and has taken many different forms. The current national emphasis on this activity, however, can be dated to the 1980 enactment of P.L. 96-517, the Patent and Trademark Law Amendments Act, more commonly known as the Bayh-Dole Act, and amendments included in P.L. 98-620, enacted into law in 1984.

This brochure reviews the Bayh-Dole legislation, the implementing regulations that have evolved, and the major issues associated with complying with the law and related regulations. It also highlights the significant benefits of the Bayh-Dole Act that have occurred to date.

BACKGROUND

Technology transfer--the transfer of research results from universities to the commercial marketplace for the public benefit--is closely linked to fundamental research activities in universities. Although a handful of U.S. universities were moving science from the laboratory to industrial commercialization as early as the 1920s, academic technology transfer as a formal concept, is said to have originated in a report entitled "Science - The Endless Frontier" that Vannevar Bush wrote for the President in 1945. At that time, the success of the Manhattan Project had demonstrated the importance of university research to the national defense. Vannevar Bush, however, also recognized the value of university research as a vehicle for enhancing the economy by increasing the flow of knowledge to industry through support of basic science. His report became instrumental in providing a substantial and continuing increase in funding of research by the federal government. It stimulated the formation of the National Institutes of Health (NIH), the National Science Foundation (NSF), and the Office of Naval Research (ONR). Due to the success of these and other agencies, the funding of basic research by the federal government is now considered to vital to the national interest.

In the 1960s and 1970s, there was much study and debate surrounding federal patent policies. A major concern was the lack of success by the federal government in

promoting the adoption of new technologies by industry. There was no government-wide policy regarding ownership of inventions made by government contractors and grantees under federal funding. Inconsistencies in policies and practices among the various funding agencies resulted in a very limited flow of government-funded inventions to the private sector. In 1980, the federal government held title to approximately 28,000 patents. Fewer than 5% of these were licensed to industry for development of commercial products.[1]

This problem was due, in part, to restrictions imposed on the licensing of new technologies and reluctance on the part of the agencies to permit ownership of inventions to vest in universities and other grantees.[2] The government would not relinquish ownership of federally funded inventions to the inventing organization except in rare cases after petitions had moved through a lengthy and difficult waiver process. Instead, the government retained title and made these inventions available through non-exclusive licenses to anyone who wanted to practice them.

As a result, companies did not have exclusive rights under government patents to manufacture and sell resulting products. Understandably, companies were reluctant to invest in and develop new products if competitors could also acquire licenses and then manufacture and sell the same products. Accordingly, the government remained unsuccessful in attracting private industry to license government-owned patents. Although taxpayers were supporting the federal research enterprise, they were not benefiting from useful products or the economic development that would have occurred with the manufacture and sale of those products.

In 1980, however, legislators and the administration concluded that the public would benefit from a policy that permitted universities and small businesses to elect ownership of inventions made under federal funding and to become directly involved in the commercialization process. This new policy would also permit exclusive licensing when combined with diligent development and transfer of an invention to the marketplace for the public good. It was understood that stimulation of the U.S. economy would occur through the licensing of new inventions from universities to businesses that would, in turn, manufacture the resulting products in the U.S.

EVOLUTION

With the passage of the Bayh-Dole Act, colleges and universities immediately began to develop and strengthen the internal expertise needed to effectively engage in the patenting and licensing of inventions. In many cases,

institutions that had not been active in this area began to establish entirely new technology transfer offices, building teams with legal, business, and scientific backgrounds. These activities continue to accelerate nationally as the importance of the Bayh-Dole Act becomes fully appreciated. Evidence of this is reflected in the fact that the membership of the Association of University Technology Managers (AUTM) increased from 691 in 1989 to 2,178 in 1999. In 1979, the year before passage of the Bayh-Dole Act, the Association counted only 113 members.[3]

University technology transfer offices perform a wide variety of highly specialized functions related to the patenting and licensing of inventions. In addition, these offices also perform a vital function related to the formation of research partnerships with industry, and in negotiating the exchange of research materials and research tools.

In recent years, the wisdom of the new federal policy has become increasingly apparent. Growing numbers of universities have demonstrated that their newly formed technology transfer programs are effective in licensing inventions made with federal support to commercial partners. As a result, many new technologies have been diligently and successfully introduced into public use.

Another significant result of the Bayh-Dole Act is that it provides a strong incentive for university-industry research collaborations. At the national level, industry support for research and development at universities represents less than 7% of the total funding of university-based research. While small compared to the 60% provided by federal agencies, this private investment in the creativity of universities, including professors, students and staff, drives a form of technology transfer that is increasingly important to industry. The investment by industry rests on a secure footing because it is based on the principles and provisions of the Bayh-Dole Act.[4]

SOME PERSPECTIVE

The principles of the Bayh-Dole Act were the result of years of intense and emotional debate, dealing with fundamental concerns. The record shows that the debate included such issues as whether exclusive licenses would lead to monopolies and higher prices; whether taxpayers would get their fair share; whether foreign industry would benefit unduly; and whether ownership of inventions by a contractor is anti-competitive. Safeguards were hammered out in numerous legislative drafts. It is certain that the Act became much stronger because of the thorough debate that took place prior to its passage.

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Federal agencies have the authority to periodically audit grantees and contractors for compliance with the Bayh-Dole Act. The General Accounting Office (GAO) in turn may also conduct studies to assess how effectively federal agencies are overseeing grantees and contractors in the management of government-funded inventions. 35 U.S.C. Section 202(b)(3) requires the Comptroller General to review the implementation of the Bayh-Dole Act at least once every five years and report its findings to the Judiciary Committees of the House and Senate. In 1991, the GAO focused its review on the licensing of federally owned inventions (GAO/RCED-91-80 issued April 3, 1991). In 1992, the GAO reviewed federal agency mechanisms for controlling inappropriate access to federally funded research results (GAO/RCED-92-104 issued May, 1992). More recently, the GAO reviewed the implementation of the Bayh-Dole Act by research universities (GAO/RCED-98-

126 issued May 7, 1998). In 1999, GAO issued a report on the number and characteristics of inventions licensed by six federal agencies (GAO/RCED-99-173, issued June 1999) and a report on compliance with reporting requirements for federally sponsored inventions (GAO/RCED-99-242, issued August 12, 1999). The GAO reports can be obtained from the Government Printing Office. See Web Resources below.

In order to assist grantees in their efforts to maintain compliance with the Act, some federal agencies have periodically issued guidance to the grantee community. An example is a question and answer document regarding invention reporting, printed in the NIH Guide to Grants and Contracts in l995. (NIH Guide, Vol.24, No.33, September 22, l995).

RESULTS OF THE BAYH-DOLE ACT

University patenting and licensing efforts under the Bayh-Dole Act have fostered the commercialization of many new technological advances that impact the lives of millions of people across the nation. A recent national survey conducted by AUTM[10] reports that 70% of the active licenses of responding institutions are in the life sciences--yielding products and processes that diagnose disease, reduce pain and suffering, and save lives. Most of the inventions involved were the result of federal funding. While it would be impossible to list all such inventions, a few examples of technologies and products originating from federally funded university discoveries include:

- Artificial lung surfactant for use with newborn infants, University of California
- Cisplatin and carboplatin cancer therapeutics, Michigan State University
- Citracal® calcium supplement, University of Texas Southwestern Medical Center
- Haemophilus B conjugate vaccine, University of Rochester
- Metal Alkoxide Process for taxol production, Florida State University
- Neupogen® used in conjunction with chemotherapy, Memorial Sloan Kettering Cancer Institute
- Process for inserting DNA into eucaryotic cells and for producing proteinaceous materials, Columbia University
- Recombinant DNA technology, central to the biotechnology industry, Stanford University and University of California
- TRUSOPT® (dorzolamide) ophthalmic drop used for glaucoma, University of Florida

These examples of successful new technologies demon-

strate that a strong national infrastructure to support technology transfer has been established at academic institutions across the nation since passage of the Bayh-Dole Act. In 1980 there were approximately 25-30 universities actively engaged in the patenting and licensing of inventions. It is estimated that there has been close to a ten-fold increase in institutional involvement since then. The AUTM survey reflects the impact of this growth in activity:

- Academic institutions were granted more than 8,000 U.S. patents between 1993 and 1997 for technologies discovered by their researchers.
- Over 2,200 new companies have been formed since 1980 that were based on the licensing of an invention from an academic institution, including over 330 companies formed in FY 1997 alone.
- Approximately $30 billion of economic activity each year, supporting 250,000 jobs can be attributed to the commercialization of new technologies from academic institutions.
- There are more than 1000 products currently on the market that are based on university licensed discoveries.
- Technologies licensed from academia have been instrumental in spawning entirely new industries, improving the productivity and competitiveness of companies, and creating new companies and jobs.[11]

In summary, the Bayh-Dole Act and its subsequent amendments created incentives for the government, universities, and industry to work together in the commercialization of new technologies for the public benefit. The success of this three-way partnership cannot be understated.

CONCLUSIONS

On a nation-wide basis, the results support the conclusion that the Bayh-Dole Act has promoted a substantial increase in technology transfer from universities to industry, and ultimately to the public. Certainty of title to inventions made under federal funding is perhaps the most important incentive for commercialization. Implementation of uniform patenting and licensing procedures, however, combined with the ability of universities to grant exclusive licenses, are also significant ingredients for success. This combination of factors led to a tremendous acceleration in the introduction of new products through university technology transfer activities.

Certainty of title to inventions made under Federal funding has one other significant benefit—it protects the right of scientists to continue to use and to build on a specific line of inquiry. This is fundamentally important to research-intensive institutions because of the complex way in which research is typically funded, with multiple fund-

ing sources. The retention of title to inventions by the institution is the only way of ensuring that the institution will be able to accept funding from interested research partners in the future. This is a critically important benefit of the Bayh-Dole Act that is not widely understood.

As Vannevar Bush foresaw, enormous benefits to the U.S. economy have occurred because of federal funding of research. These benefits have been significantly enhanced by the adoption of federal policies encouraging technology transfer. Such policies have led to breathtaking advances in the medical, engineering, chemical, computing and software industries, among others. The licensing of new technologies has led to the creation of new companies, thousands of jobs, cutting-edge educational opportunities and the development of entirely new industries. Accordingly, the Bayh-Dole Act continues to be a national success story, representing the foundation of a successful union among government, universities, and industry.

WEB RESOURCES

- http://www.nih.gov/grants/guide/index.htm (search for NIH Bayh-Dole-related policies)
- http://www.access.gpo.gov (GAO and other federal reports)
- http://137.187.120.232/ (Interagency Edison project)
- http://www.autm.net (AUTM home page)
- http://www.cogr.edu (COGR home page)

APPENDIX

Bayh-Dole Act and Related Legislation

The Bayh-Dole Act and subsequent amendments provide the basis for current university technology transfer practices. The federal patent and licensing policy was shaped by four events that occurred between 1980 and 1985.

1. On December 12, 1980, P.L. 96-517, the Bayh-Dole Act was enacted into law. After lengthy and contentious congressional debate, legislation was crafted that created a balance between incentives and controls. Universities applauded the legislation because a uniform federal patent policy was established that clearly stated that universities may elect to retain title to inventions developed under government funding. Industry, particularly the small business community, appreciated an ownership policy that was applied uniformly on a government-wide basis. In addition, industry expected to benefit from the message that universities were encouraged to collaborate with companies to promote

the utilization of inventions arising from federal funding, that preference in licensing be given to small business, and that, to the extent possible, licensed products were to be manufactured in the U.S. The federal government, in turn, was assured that universities would file, at university expense, patent applications on inventions they elected to own. In addition, the government retains rights to enforce diligent commercial development of inventions. It also enjoys royalty-free, nonexclusive licenses to practice federally funded inventions throughout the world for government purposes.

2. On February 10, 1982, the Office of Management and Budget issued OMB Circular A-124 to provide guidance to federal agencies regarding implementation of the Bayh-Dole Act. This Circular established standard patent rights clauses for use in federal funding agreements. It also set up standard reporting requirements for universities electing title to inventions.
3. On February 18, 1983, a Presidential Memorandum on "Government Patent Policy" was issued. This Memorandum was issued to satisfy those that recognized the benefits of the legislation and wanted broader coverage. The Presidential Memorandum directed federal agencies to extend the terms and provisions of the Bayh-Dole Act to all government contractors, with a follow-on amendment to the Federal Acquisition Regulations to assure that all federal R&D agencies would implement the Act and the Memorandum.
4. On November 8, 1984, the original Bayh-Dole statute was amended by P.L. 98-620. New language was added to remove term limitations placed on exclusive licenses under the original Act. In addition, the Department of Commerce was designated as the federal agency responsible for overseeing the implementation of the Bayh-Dole Act and for monitoring the granting of exceptions to the rules.
5. On March 18, 1987 (52 FR 8552), all of the relevant provisions--the Bayh-Dole Act, the amendment, OMB Circular A-124, and the Presidential Memorandum--were finalized and consolidated in a rulemaking published by the Department of Commerce—appearing at 37 CRF Part 401. These regulations, augmented by the NIH guidelines discussed in this brochure, specify the rights and obligations of all parties involved and constitute the operating manual for technology transfer on a national basis.

FOOTNOTES

1. U.S. Government Accounting Office (GAO) Report to Congressional Committees entitled "Technology Transfer, Administration of the Bayh-Dole Act by Research Universities" dated May 7, 1998.
2. The term "university" or "universities" as used in the text applies to all non-profit grantees/contractors.
3. We gratefully acknowledge the courtesy and and cooperation of AUTM in providing these statistics. See also AUTM Licensing Survey FY 1991-1995 and subsequent years.
4. In 1997, federal agencies provided an estimated $14.3 billion or about 60% of total support for research performed at universities. Academic institutions provided $4.5 billion of their funds. State and local governments and non profit organizations each contributed $18.1 billion and industry $1.7 billion. Although the proportion of academic R&D expenditures supplied by industry has been rising fairly steadily, it still only represents a fraction (7%) of total academic R&D support. Science and Engineering Indicators 1998. National Science Board: 4-8 and 4-9.
5. Presidential Memorandum and Statement of Government Patent Policy, issued October 10, 1963. Published in the Federal Register, Vol. 28, No. 200.
6. The Secretary of Commerce delegated this authority under 35 USC 206 to the Assistant Secretary for Productivity, Technology and Innovation.
7. Other circumstances, not clearly elucidated in the regulations, may be invoked by the government. Further detail can be found in 37 CFR Part 401.3; general appeal mechanisms are found in Part 401.4.
8. March-in rights, including appropriate procedures, are described at 37 CFR Part 401.6.
9. Notice for Public Comment, 64 FR 100,28205-28209.
10. AUTM Licensing Survey, Fiscal Year 1997.
11. AUTM press release December 17, 1998.

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POLICY NO: 7001
EFFECTIVE DATE: 03/16/2005

UNMC POLICY FOR ROYALTY AND EQUITY DISTRIBUTION

As per RP-4.4.2 Regents' Patent and Technology Transfer Policy, UNMC is responsible for allocating non-inventor technology transfer proceeds according to its individual campus policy. These non-inventor proceeds consist of two thirds of the royalties and equity received in return for use of University owned intellectual property rights. Furthermore, Regents' Policy no longer requires that a share of proceeds be distributed to the academic/administrative units of inventors. In order to best utilize non-inventor proceeds and to serve the objectives of the Regents' Policy, UNMC shall allocate noninventor proceeds on a case by case basis as determined by the Committee for Proceed Distribution. Those academic/administrative units having a connection to proceeds at issue shall participate to provide the Committee with information addressing their support of the underlying technology.

MEMBERSHIP

Members of the Committee for Proceed Distribution shall be the Vice Chancellor for Business and Finance, the Vice Chancellor for Research, the Vice Chancellor of Academic Affairs, the President of UNeMed, the Patent Administrator and one member at large to be selected annually by a majority vote of the other members. The Committee shall meet at least annually to carry out the function of RP- 4.4.2, Section 5(b).

The Committee's responsibilities shall include:

EXPENSES AND NET PROCEEDS

- Reviewing the legal fees and other technology transfer expenses associated with each source of proceeds. Regents' Policy requires that such expenses be reimbursed before any proceed distributions are made.[1]

- Reviewing general proceed allocations with other organizations and non-inventor proceed allocations between campuses.

DISTRIBUTION OF NET PROCEEDS TO INVENTORS

- Ensuring that with respect to proceeds covered by Regents' Policies, one third of all net proceeds received by the University is distributed to University of Nebraska inventors.[2] In some highly meritorious cases a given inventor may be found to have earned a share of the proceeds that exceeds the general

[1] To meet this requirement 10% of all proceeds received will be set aside for the administration of technology transfer. In addition, patent expenses and other legal and professional expenses will first be reimbursed from gross proceeds.

[2] When a single source of proceeds involves multiple University of Nebraska inventors, inventors should coordinate with the UNMC Intellectual Property Office to file a written agreement delineating the division of proceeds between all inventors. Multiple inventor proceeds received but not adequately covered by an written inventor agreement will be distributed equally between all University of Nebraska inventors.

recommendation of one-third; however in no case will a distribution be made to an inventor that exceeds the recommended one-third until the university has recovered 100 percent of its costs, and an appropriate continuing share has been determined for the university. Such decisions are to be considered highly exceptional and will require the approval of the President upon recommendation of the Chancellor. The President shall report such exceptions to the Board of Regents.

DISTRIBUTION OF NET PROCEEDS TO NON-INVENTORS

- Examining sources of net non-inventor proceeds covered by the Regents' intellectual property policies and determining what proportion, if any, should be distributed to inventors' academic/administrative units. This determination shall be in keeping with each unit's level of support and commitment to technology development. Academic/administrative units found to be without significant contribution to technology development may be excluded from receiving proceeds.

  Deans or Directors of the academic/administrative units employing faculty or other persons responsible for creating intellectual property from which net proceeds are generated shall be given notice of Committee meetings and provided the opportunity to present information representing significant support of UNMC technology development. Ordinary support consisting of only the usual salary, space, and equipment afforded to faculty shall not be considered significant. Information intended to be representative of significant support to technology development shall be substantiated through documentation, interviews with inventors, or other appropriate means. The Committee shall refrain from deciding non-inventor proceed allocations until all interested principals have been given reasonable opportunity to participate.

- Earmarking net proceeds as may be distributed to academic/administrative units to be used for research beneficial to technology development.

- Allocating any net non-inventor proceeds to UNMC accounts for use in furthering translational research or otherwise furthering the objectives of technology and economic development. This includes those net non-inventor proceeds not distributed to academic/administrative units.

- The allocation and/or earmarking of net non-inventor proceeds not to be distributed to any academic/administrative units shall take the form of a recommendation made to the UNMC Research Resources Board or its functional equivalent. The Research Resources Board shall then confirm or redirect the nonunit distribution and report the final recommendation to UNMC's Chancellor before such proceeds are made available.

OTHER RESPONSIBILITIES

- Performing other responsibilities within the scope of RP- 4.4.2, Section 5(b).

University of Nebraska Medical Center

Board of Regents
Bylaw 3.10:
Ownership and Commercialization of Inventions and Discoveries
http://www.nebraska.edu/board/board_bylaws.html

3.10 **Ownership and Commercialization of Inventions and Discoveries. The Board** encourages the commercialization of inventions and discoveries arising from research activities of the University, and when appropriate, the pursuit of patents or other intellectual property protection, as a method of bringing recognition and remuneration to the University's inventors and to the University itself. Every invention or discovery by members of the faculty and staff that results from the performance of duties within the scope of their University employment, or from the use of University personnel, property, facilities, or other resources, except where such use is minimal, shall be solely owned by the University provided that the inventor or inventors shall have a share of no less than one-third (1/3) of the net proceeds received by the University resulting from licensing or sale of University owned intellectual property rights associated with such invention or discovery. Further, and unless otherwise explicitly and specifically agreed to in writing, should by operation of law or otherwise it is determined that the inventor or inventors own any rights in the University's inventions and discoveries beyond that described in this section of these Bylaws, then it shall be a condition of employment at the University of Nebraska that any such rights shall be assigned to the University. The Board shall adopt a formal Patent and Technology Transfer Policy which shall govern the disclosure of inventions and discoveries resulting from performance of duties by faculty or staff within the scope of their employment, or from the use of University personnel, property, facilities, or resources. The President, or any administrative officers designated by the President, shall have authority to act for the University with respect to inventions or discoveries owned by the University as required by this section and the Board's Patent and Technology Transfer Policy.

History: Amended, 64 BRUN 139 (17 Oct. 2003);
Amended, 59 BRUN 210 (10 Dec. 1994);
Amended, 49 BRUN 300 (16 June 1984).

Board of Regents
Policy 4.4.1:
Ownership of Intellectual Property

http://www.nebraska.edu/board/RegentsPolicies.pdf

RP - 90 06/01/2002 - Chapter 4. Rights and Responsibilities of Professional Staff
RP-4.4 Intellectual Property
RP-4.4.1 Ownership of Intellectual Property

Introduction

Central to the University of Nebraska's mission is the creation, preservation, and dissemination of knowledge.

The University of Nebraska is committed to providing an environment that supports the research, teaching, and service activities of its faculty, students, and staff. As a matter of principle and practice, the University encourages all members of the University community to publish their articles, books, and other forms of scholarly communication in order to share openly and fully their findings and knowledge with colleagues and the public. This Policy is intended to promote and encourage excellence and innovation in scholarly research and teaching by identifying and protecting the rights of the University, its faculty, staff, and students.

Patent and copyright ownership and their associated rights are concepts that are defined by federal law. This Policy and the University's patent policies are structured within the context of those federal laws. The University's patent policies have been in operation within the University for many years and are hereby incorporated into this Policy.

The long standing academic tradition that faculty own the copyright to academic, scholarly and educational works resulting from their research, teaching, and writing is the foundation of the copyright policy described in this document. Exceptions to this rule may result from contractual obligations, from employment obligations, from certain uses of University facilities, or by agreement governing access to certain University resources. This Policy is intended to clarify many of these situations.

As used in this Policy, "University" shall refer to the University of Nebraska or one of its campuses and shall include any organization of the University whose primary purpose is to facilitate technology transfer and commercialization of the University's Intellectual Property. "Intellectual Property" shall include, but is not limited to patentable inventions, mask works, tangible research property, trademarks, and copyrightable works, including software.

This Policy is included in the terms of employment of all University employees. Admission as a student at the University constitutes an agreement to abide by the terms of this Policy.

1.0 General Policy Statement

The prompt and open dissemination of the results of research undertaken at the University of Nebraska and the free exchange of information among scholars are essential to the fulfillment of the University's obligations as an institution committed to excellence in research, education, and service. Matters of ownership, distribution, and commercial development nonetheless arise in the context of technology transfer, which is also an important aspect of the University's commitment to public service. The University of Nebraska as a public institution has a responsibility to recognize the State’s contribution of tax support for research and creative activity by devoting an appropriate share of the products of that research to the further benefit of the University as a whole. The University must also recognize the intellectual contribution of Authors and Inventors, the need to provide incentives for enhanced intellectual activity, and the role such incentives play in recruiting and retaining creative individuals at the University.

“Author(s)” and/or “Inventor(s)” are defined herein as faculty, staff, and other persons employed by the University of Nebraska, whether full or part-time; visiting faculty and researchers; and any other persons, including students, who create or discover Intellectual Property using University resources, as those terms are subsequently defined.

2.0 Early Disclosure and Incentives for Creative Effort; Use of the University’s Name

2.1 Early disclosure and incentives to create

This Policy is a framework to provide guidance in understanding the relationship between the University and those persons engaged in creative efforts at the University. In some instances, the result of the creative effort will be the property of the University, while in others some or all of these rights of ownership shall belong to the Author or Inventor. Where ownership rests with the University, the University will seek to recognize and provide incentives for those persons who make significant contributions to the University’s mission.

In some instances it may be difficult to foresee with certainty whether Intellectual Property created in a particular context is the property of the University or the employee. In such instances, the employee is encouraged to disclose in writing the nature of any creative endeavor that has potential commercial applications as soon as possible to the employee’s immediate administrative supervisor. This disclosure will provide an opportunity to discuss incentives, seek any necessary interpretation of this Policy, and secure the University’s support for the creative endeavor.

2.2 Use of University's name

The University has an interest in how its name is used and an interest in protecting the value of that name. Individual Authors or Inventors cannot alone decide whether a project should be associated with the University's name. An employee of the University may identify his or her affiliation with the University, but without prior written approval, may not otherwise suggest the University's participation or endorsement of the conclusions of any study or research. Similarly, the University's name may not be used, without prior written permission, in association with the sale or commercialization of the products of research by University employees. Again, early written disclosure will facilitate agreement between interested parties.

3.0 Ownership of Intellectual Property; General Provisions

3.1 Applicable to all technologies and media

The issue of ownership of Intellectual Property resulting from activities of University employees arises in a number of different contexts involving a variety of creative works. Increasingly, University employees utilize new technologies and media to create new inventions, to improve the educational process, and to enhance the delivery and exchange of information. This Policy is intended to apply to all creative works, except patentable subject matter, regardless of the media in which they are distributed or the nature of their technological manifestation, now known or later developed.

3.2 Patent policies not affected

Notwithstanding anything otherwise stated in this Policy, ownership of patents shall be determined in accordance with University patent policies in Section 3.10 of the Bylaws of the Board of Regents of the University of Nebraska and Regents Policy 3.2.7, or as those patent policies may from time to time be amended.

It is essential, however, that Authors and/or Inventors understand that early publication of their patentable research results without notification to the University can compromise the University's patent rights in the research, and by implication, the Authors' and/or Inventors' royalty interest therein. Therefore, if an Author or Inventor wishes to publish research results which involve patentable subject matter, the Author or Inventor should first submit a patent disclosure to the University patent administrator and also disclose the existence of the pending publication so as to allow for the appropriate filings to preserve the University's patent rights.

3.3 Residual Authors' or Inventors' rights

Notwithstanding the University's ownership of any particular Intellectual Property, the University shall not engage in any activity which unreasonably interferes with an Author’s or Inventor’s ability to continue the creative process. Therefore, except in such instances where the University can show that its interests will be significantly compromised, an Author or Inventor, while still in the employ of the University, shall be permitted to make revisions to and develop new works based upon the original creation. Except to the extent that an Author or Inventor may have a right to receive income based upon royalties or other fees generated from a work, this Policy provides no portability of other rights to University-owned Intellectual Property should the employment relationship between the University and the Author or Inventor terminate. However, in many cases it may prove possible for the University to grant a royalty-free license or an appropriate royalty-bearing license to the Author or Inventor to continue to use the techniques or other aspects of a creative work, even when the Author or Inventor is no longer employed by the University.

Comment

When a faculty member leaves the employment of the University, the University will continue to honor the terms of any agreement it has with the faculty member regarding University-owned Intellectual Property. For example, the University may agree to pay a faculty member a royalty for the development of a University-owned distance learning program. If the faculty member leaves, the University will continue to pay in accordance with the agreement with the faculty member. The faculty member may not, however, take other rights of ownership in the Intellectual Property, unless it is agreed to by separate written license agreement between the faculty member and the University.

3.4 Classification of creative works

The ownership of Intellectual Property created by a University employee is determined by the nature of the activity resulting in the Intellectual Property. Under this Policy, Intellectual Property not governed by Section 3.2 (Patent Policy) is classified as either:

(a) an Independent Work governed by Section 4.0;

(b) a University Supported Work governed by Section 5.0;

(c) an Institutional Work governed by Section 6.0; or

(d) a Contractual Work governed by Section 7.0.

The ownership of Intellectual Property produced by non-employees, including students, arising out of activities associated with the University is governed by Sections 8.0 and 9.0 of this Policy.

Comment

The intent of this section is to categorize all works which may contain Intellectual Property rights into one of the listed categories and to allocate the Intellectual Property rights accordingly. Thus any work must be in only one category. It should be understood that the determination of whether a work is an Independent Work, a University Supported Work, or an Institutional Work depends on the context in which the work is created. Any of these works may be transformed into a Contractual Work by an agreement between the University and the Author or Inventor.

4.0 Independent Works

4.1 Independent Works Defined; Ownership

An Independent Work is a work that is not:

(a) a University Supported Work, pursuant to Section 5.0;

(b) an Institutional Work, pursuant to Section 6.0; or

(c) a Contractual Work, pursuant to Section 7.0.

A University employee as the Author or Inventor of an Independent Work owns the Intellectual Property rights in that work.

Comment

It is the policy of the University of Nebraska that faculty shall own all rights to materials prepared and developed at their own initiative, without the use of any University resources, and not pursuant to an approved agreement. The University does not claim ownership of books, articles and other scholarly publications, or to popular novels, poems, musical compositions, or other works of artistic imagination that are created by the personal effort of faculty, staff and students and which do not make use of University resources.

5.0 University Supported Works

5.1 University Supported Work defined

A University Supported Work is a creative work developed in whole or in part with the customary use of University resources. "University resources" means all tangible resources provided by the University of Nebraska to Authors or Inventors, including salary, office, lab, studio space and equipment; computer hardware, software, and support; secretarial service; research, teaching, and lab assistants; supplies; utilities; funding for research and teaching activities; travel; and other funding or reimbursement.

5.2 Ownership of University Supported Works that do not involve use of substantial University resources

By long-standing tradition and the contemporary need to remain competitive in recruiting and retaining a creative faculty, the faculty own the copyright and other rights associated with Traditional Works of Scholarship. "Traditional Works of Scholarship" are defined as works reflecting research or creativity which, within the University, are considered as evidence of professional advancement or accomplishment. Such works result from scholarly endeavors, and include instructional materials, journal articles, research bulletins, monographs, books, plays, poems, and artistic works, and do not involve substantial use of University resources as described in Section 5.3 of this Policy. Accordingly, except for (1) University Supported Works involving use of substantial University resources, and (2) patents, patentable subject matter, trade secrets and commercially viable discoveries and inventions governed by the patent policies described in Section 3.2 of this Policy, the faculty member shall own the the copyright and have the right to register the same and to receive royalties or other income from a University Supported Work, including books, films, cassettes, CDs, software, works of art, or other material. However, such ownership and rights are subject to the requirements of Section 3.11 of the Bylaws of the Board of Regents of the University of Nebraska prohibiting a faculty member from having a financial interest in or receiving compensation from the sale of educational materials used by students of the University, except royalties on books or other educational material from publishing houses of standing.[3] In addition, the following specific rules apply to University Supported Works for which the faculty member owns the copyright:

(a) Research Materials. Materials such as lab notebooks and research files shall remain the property of the individual responsible for directing the project, except when agreements governing Contractual Works described in Section 7.0 require otherwise. However, should such an individual depart the employ of the University or otherwise terminate responsibility for directing the project, he or she shall provide the University with such copies of the research material as may be reasonable in order that the University may protect its

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3

Section 3.11 of the *Bylaws of the Board of Regents* states:

> No member of the University staff shall have any financial interest in or receive any compensation from the sale of books, pamphlets, other educational material from publishing houses of standing, when copyright has been secured or when otherwise provided by agreement with the University for University-sponsored education materials. Except as to those works that are University-sponsored “made for hire” educational materials, the University shall claim no right of ownership of such copyright or such royalties. It shall be the policy of the University to encourage publication of textbooks, if there is no exploitation of University students resulting therefrom.

rights in any Intellectual Property as well as that of the departing Author's or Inventor's colleagues.

(b) Instructional Materials. "Instructional Materials" are other than Institutional Works, the primary use of which is for the instruction of students. Such works include textbooks, syllabi, lectures, lecture notes, and study guides. Instructional Materials developed by a faculty member in the process of delivering a course of instruction to students shall be the property of the faculty member. However, in the absence of a specific written agreement, and with the exception of books or other educational materials covered by Section 3.11 of the Bylaws of the Board of Regents, no royalty, rent or other consideration shall be paid to a faculty member when Instructional Materials are used at the University. Should the Author of Instructional Materials depart the employ of the University, he or she will provide the University with copies of the Instructional Materials (not including lecture notes) and shall grant the University a nonexclusive, royalty free license thereto, when it is determined by the University that such Instructional Materials are necessary to carry out the educational programs of the University. Recordings of lectures shall be the property of the faculty lecturer, unless the recording is an Institutional Work or a University Supported Work Involving use of substantial University resources.

5.3 Ownership of University Supported Works involving use of substantial University resources

(a) Notwithstanding Section 5.2, in circumstances in which use of substantial University resources is involved in the creation of a work, the University shall own the work, including the right to obtain a copyright and the right to royalties or other income. Circumstances involving use of substantial University resources include:

(1) substantial University financial, staff, or other assistance;

(2) extensive use of special or rare University holdings, such as museum collections;

(3) significant use of voice or image of students or staff in a product (other than the author or inventor), or substantial creative contribution by staff or students to the preparation of a work or product; or

(4) use of the name or insignia of the University or any of its units (other than for purposes of identification of individual faculty members) to identify or to promote the distribution of a work or

product, or other identification or promotion that implies the approval or endorsement by the University or one of its units.

Comment

The references in subparagraph (1) to “substantial University financial staff or other assistance” and in subparagraph (2) to “special or rare University holdings, such as museum collections” mean the use of University funds, facilities, equipment, or other resources significantly in excess of the norm for educational and research purposes in the department or unit in which the creator holds his or her primary appointment. The University does not regard the provision of an employee’s salary, office, usual library resources, usual facilities and equipment, and office staff, or personal computers as constituting “substantial use of University resources” unless such resources were made available specifically to support the development of a work to be owned or acquired by the University or was previously designated by the University as a substantial University resource. The reference in subparagraph to (3) to “substantial creative contribution by staff and students” means providing original ideas or new techniques that are essential to the creation of the product or significantly improve its value. For example, devising a new way to test one of the major hypotheses in a study would normally count as such a contribution, but providing ordinary research assistance or conducting standard data analysis would not.

(b) When the responsible Dean or Director determines that any of the circumstances involving use of substantial University resources described above in subparagraph (a) of this Section 5.3 obtain, the University will accord to the Author a non-exclusive, royalty free license to use the work for non-commercial purposes. Further, and in keeping with the University’s strong desire to promote creative efforts, the University will negotiate in good faith with the Author to determine the extent to which the Author should share in the rights to royalties or other “ownership” rights to such work.

Comment

The allocation of rights for University Supported Works in Section 5.0 is modeled after the policy of Harvard University. It attempts to distinguish between traditional works of scholarship for which faculty members hold the copyright and those works created with substantial University involvement. Where the University is involved to a greater extent than ordinarily prevails, the University should be entitled to share in the economic returns of resulting works and to receive reimbursement for its additional costs. It is recognized that the determination of whether a particular project involved substantial university involvement may not always be clear. In such circumstances it is important that the faculty member make early disclosure to the Dean or Director and that, if an interpretation of this policy is required, the procedures adopted in Section 13.0 be initiated.

6.0 Institutional Works

6.1 Institutional Works defined

An Institutional Work is a work created at the specific instigation of the University and under the specific direction of the University, by a person acting within the scope of his or her University employment. Institutional Works are often referred to in copyright law as worksmade-for-hire. A creative work produced on the initiative of a faculty member pursuant only to the general obligation of faculty members to engage in research or creative activity is not an Institutional Work, but may be a University Supported Work involving use of substantial University resources as described in Section 5.3 of this Policy or a Contractual Work as defined and described in Section 7.0 of this Policy. However, Institutional Works may include creative works generated within a specific project initiated by the University. Institutional Works also include committee minutes, internal memoranda, business files, personnel files and other business records created in the ordinary course of the general administration of the University.

Comment

Institutional Works are works that are created at the initiative of the University. In addition to works related to the general administration of the University, such as committee reports, minutes, and business files, an Institutional Work may include more traditional creative works. For example, the products of a University initiated program in distance learning where an employee or numerous employees are assigned the specific task of creating instructional content would be Institutional Works.

6.2 Ownership of Institutional Works

The University owns all rights to Institutional Works. However, in keeping with the University's strong desire to promote creative efforts, the University may determine that the Author or Inventor should share in the rights to royalties and other rights in Institutional Works discussed in this Policy. The Author or Inventor should engage in early written disclosure to the University of the potential for any valuable Intellectual Property rights associated with Institutional Works in order to facilitate agreement regarding such shared
rights. Failure to do so will be an important factor in assessing whether the Author or Inventor is entitled to share in any financial returns from the work.

7.0 Contractual Works (Sponsored Research)

Ownership of the Intellectual Property rights in creative works developed in the course of or pursuant to a sponsored research program or other contractual arrangement will be determined according to the terms of such program or contract, provided that the program or contract was approved by the University. If the program or contract does not provide for the allocation of Intellectual Property rights, such rights will be determined by the other provisions of this Policy. Notwithstanding other provisions of this policy, the

University may elect to enter into a contract with an individual employee regarding the creation of specific intellectual property.

Comment

University personnel and visitors should contact the office on their campus responsible for sponsored programs for information or assistance regarding drafting or interpretation of research contract terms. The terms of such sponsored research agreements apply not only to inventions made by faculty and staff, but also to those made by students and visitors, whether or not paid by the University, who participate in performing research supported by such agreements. Care should be taken to assure that any contract for sponsored research is approved and signed by a University administrative officer having proper Authority to approve and sign such a contract on behalf of the University.

Patents: Research contracts sponsored by the Federal Government are subject to statutes and regulations under which the University acquires title to inventions conceived or first reduced to practice in the performance of the research. The University's ownership is often subject to a nonexclusive license or grant of other rights to the government and the requirement that the University retain title and take effective steps to develop the practical applications of the invention by licensing and other means.

Contracts with outside research sponsors are negotiated on a case-by-case basis with ownership and other rights to the discovery of any patentable invention determined in the course of the negotiations.

Copyright: Normally, research contracts sponsored by the Federal Government provide the government with specified rights in copyrightable material developed in the performance of the research. These rights may sometimes place title to such material exclusively in the government, but more often consist of a royalty-free license to the government with title vesting in the University.

When a work is created under the terms of a sponsored research agreement, Authors of copyrightable works should be aware that there may be contractual terms relating to the form of the research report, advance notice to the sponsor before publication, and other limitations or obligations.

8.0 Ownership of Works Produced by Non-employees

According to federal law, copyright of commissioned works of non-employees is owned by the Author and not by the commissioning party, unless there is a written agreement to the contrary. All University personnel are cautioned to ensure that independent contractors agree in writing that ownership of commissioned work is assigned to the University, except where special circumstances apply and it is mutually agreed that the Author will retain ownership.

9.0 Ownership of Copyrights in Theses, Dissertations and Other Student Works

The ownership of copyrights in student works is governed as follows:

9.1 Theses, Dissertations and Other Student Works

Students will own the copyrights to their theses, dissertations, and other student works; however, a student must, as a condition to a degree award, grant royalty-free non-exclusive permission to the University to store copies of such works for archival purposes and to reproduce and publicly distribute copies of his or her thesis or dissertation within the University education and research missions; provided however, that should the student identify any legitimate proprietary interest the student may have in the work, or should the University determine that it has an ownership interest in any patentable or otherwise protectable Intellectual Property interest in the work, the University shall then delay any public access to the work for up to one year following the presentation of the work, in order for the student to consult with the University regarding the protection of the proprietary interest. Copyright ownership of theses or dissertations generated by research that is performed in whole or in part by a student with the support of a sponsor or grant shall be determined in accordance with the terms of the sponsored research or grant agreement, or in the absence of such terms, the copyright shall be owned by the University.

9.2 Software, Patentable Subject Matter and Non-Copyright Intellectual Property

Software, patentable subject matter, and other Intellectual Property (other than copyright as described in Section 9.1 and Section 9.3 of the Policy) contained or disclosed in theses, dissertations and other student works shall be subject to and governed by the policies that apply to University employees.

9.3 Student Writings Other Than Theses or Dissertations

Students shall own the copyrights to all student writings not commonly referred to as theses or dissertations and to other creative expressions required in the course of class assignments. The University shall retain the right to keep original examination scripts and to possess a copy or record of other student works for purposes of assigning grades, maintaining archival materials, and record keeping.

Comment

In cases where a dissertation or thesis contains patentable or otherwise protectable subject matter belonging to the University, the students and faculty involved with the project have a duty to disclose the existence of the thesis or dissertation to the University office responsible for patent matters. The students and/or faculty members should also contact the campus Dean for Graduate Studies regarding the shelving of

the thesis or dissertation with the University's Library. The campus Dean can provide for the secured storage of the thesis or dissertation for up to one year so as to preserve the patent or other rights of the University in the subject matter of the thesis or dissertation.

10.0 Intellectual Property Rights for Multiple Creating Parties

Due to the nature of current research practices and multi-media creations, it is common for more than one individual to claim part of the recognition as Author or Inventor for a particular creation. In such instances, participating Authors or Inventors are strongly encouraged to define their respective rights to the creation in a written agreement, signed by all of the contributing parties. Misunderstandings between the contributing parties can be avoided if such agreements are entered into as early as is practicably possible. Should the co-Authors or co-Inventors fail to so agree in writing, it is presumed that any benefits to be shared by them shall be shared equally.

11.0 Ownership of Trade and Service Marks

Ownership of trademarks shall be governed by the provisions of this Policy. Thus, trademarks that are Independent Works will be owned by the Author; trademarks that are Institutional Works will be owned by the University; ownership of trademarks that are University Supported Works will be determined by the provisions of Section 5.0 of this Policy; and ownership of trademarks that are Contractual Works will be determined by the provisions of Section 7.0 of this Policy. Note however, that the University owns many valuable trade and service marks, most of which are registered with the appropriate state or federal agencies. Any trade or service marks derived from or based upon University-owned marks shall belong to the University.

12.0 Assignment of Property Rights by the University

The University may assign to the Author or Inventor any rights of ownership it may acquire pursuant to this Policy.

13.0 Resolution of Ambiguities and Policy Interpretation

Should any issue arise regarding interpretation of this Policy, for example, whether Use of Substantial University resources has occurred or will occur, the issue shall be referred to the Author's or Inventor's Dean, Director, or similarly situated administrator. After reviewing the relevant facts, such administrator shall recommend a resolution to the Vice Chancellor responsible for research, sponsored programs and technology transfer (e.g. Vice Chancellor for Research or Vice Chancellor for Academic Affairs). Any campus may establish a committee of peers to review the facts and circumstances surrounding any particular interpretation of this Policy and make recommendations to the Vice Chancellor. The Chancellor will make the final decision on all interpretations under this Policy, based on the recommendation of the Vice Chancellor. The Chancellor's decision will be final with respect to the University.

14.0 Supplemental Income from Commercial Applications

This Policy on ownership rights in no way alters the ability of an Author or Inventor to receive supplementary income from the University under any separate policy, as a result of the commercial application of Intellectual Property created by the Author or Inventor.

15.0 Review of Policy

This policy will be reviewed periodically and revised as deemed necessary to accommodate new technologies and to incorporate changes warranted by experience with its administration.

Reference: BRUN, Minutes, 63, p. 167 (July 28, 2001).

Board of Regents
Policy 4.4.2:
Patent and Technology Transfer Policy

http://www.nebraska.edu/board/RegentsPolicies.pdf

RP - 90 06/01/2002 - Chapter 4. Rights and Responsibilities of Professional Staff
RP-4.4 Intellectual Property
RP-4.4.2 Patent and Technology Transfer Policy

Section 3.10 of the Bylaws of the Board of Regents provides that it is the policy of the Regents to encourage the commercialization of inventions and discoveries arising from research activities of the University, and when appropriate, the pursuit of patents or other intellectual property protection, as a method of bringing recognition and remuneration to the University 's inventors and to the University itself. This Patent and Technology Transfer Policy is adopted for the purpose of providing general policy regulations to implement Section 3.10 of the Bylaws of the Board of Regents:

1. **Ownership of Inventions Resulting From Performance of Duties of Employment; Prompt Disclosure to University**

   Each invention[1] by a member or members of the faculty or staff of the University resulting from performance of duties within the scope of University employment, or resulting from the use of University personnel, property, facilities, or other University resources, except where such use is minimal,[2] shall be solely owned by the University. Questions concerning whether a use of University resources is minimal shall be resolved in accordance with the process set forth in Section 9 of this Policy. Each such invention and any improvement(s) made thereto while under the employment of the University shall be promptly disclosed in writing to the designated campus patent and technology transfer administrator (the "Administrator"). [3]

   A disclosure of an invention shall be properly made when it is submitted to the campus Administrator in such manner and form as may be determined by the Administrator. Any disclosure of an invention shall contain information in such detail as is deemed necessary by the Administrator to allow for a review of its patentability and commercial potential, and shall detail the specific utility or application of the invention.

2. **The Campus Administrator**

The Chancellor of each campus and/or the Chancellor's designee shall designate a campus patent and technology transfer administrator who shall be responsible for the administration of all campus patent and technology transfer activities, and who will provide a central source of information and help in handling the different aspects of patents and technology transfer.

3. Patent and Technology Transfer Advisory Committee

The Administrator in consultation with the Chancellor and/or the Chancellor's designee shall establish an advisory committee on technology transfer (the "Committee"). The Committee will be available to assist the Administrator in the review of disclosures of inventions, and provide advice and peer group scientific review on issues relating to (i) intellectual property development and licensing or other technology transfer issues, and (ii) other related assistance as requested.

4. Review of Invention Disclosures; Acceptance for Technology Transfer by University or Transfer to Inventor

The Administrator, the Committee, and/or the Administrator's designees (one or more of which are referred to herein as the "Reviewers") shall aim to evaluate all disclosures of inventions on behalf of the University within six (6) months from the date the disclosure is formally submitted to the Administrator. The disclosure shall be evaluated by the Reviewers for the ability to obtain effective intellectual property protection on the invention, and the potential of the invention to stimulate business interest and contribute to economic development. Upon the conclusion of the Reviewers' evaluation of an invention, the Administrator shall communicate to the inventor(s) any intent on behalf of the University to pursue protection of the invention. The University shall proceed, in its sole discretion, to seek appropriate intellectual property protection on the invention, and/or market the invention to interested parties. The terms of any license or agreements related to an invention, and the manner in which they may be enforced, litigated or settled shall be at the sole discretion of the University.

The inventor or inventors of a disclosed invention shall assist the University and any counsel retained by the University in the preparation, filing and prosecution of any patent applications based on inventions disclosed to the University, and shall sign any and all necessary documents, including assignments, declarations, oaths and affidavits related thereto.

At any time during the technology transfer process, the University may, for any reason which in its sole discretion it determines is in the best interests of the University, assign title to the invention to the inventor(s). In such cases, however, the University may retain a non-exclusive, paid-up, royalty-free license to the invention, if it so desires.

Although the University may assign title to an invention to the inventor(s), any improvement or modification to or separate invention derived from or based on such invention that results from the use of University personnel, property or facilities, except where such use is minimal, shall be owned by the University subject to this Policy. The inventor(s) shall promptly disclose such improvement, modification or separate invention to the Administrator in the same manner as is described in Section 1 of this Policy.

Should an inventor leave the University and wish to continue research on an invention which the inventor has disclosed to the University, the University shall provide an appropriate royalty-free, non-commercial, research only license to allow the inventor to continue his or her research.

5. Division of Net Royalties and Proceeds

With respect to any invention subject to this Policy, the University shall first be reimbursed for any and all expenses incurred by it that are associated with evaluation of the technology, obtaining of patent or other intellectual property protection, and licensing or other technology transfer activity, including legal expenses related thereto.[4] In the event of any infringement action or other legal action involving technology disclosed under this Policy, the University shall also be reimbursed for any and all expenses borne by the University associated with such action. After such expenses are reimbursed, royalties and other proceeds from licenses or other technology transfer activities related to an invention, o r patent or other intellectual property protection based thereon, shall be distributed as follows:

(a) One-third to the inventor or inventors; and

(b) Two-thirds in accordance with a separate distribution policy to be established and implemented by each University campus, such policy to take effect following approval by the Board of Regents upon recommendation of the relevant campus' Chancellor.

6. Distribution of Equity to Inventors

In the event that the University receives equity or an option to acquire equity in exchange for any license or other intellectual property, the share of such equity due to the inventor(s) shall be based up on the distribution of royalties and proceeds provided in Section 5 of this Policy. Such equity will be distributed directly to the inventor(s) once such equity is transferable. The University shall make every effort to distribute such equity in a timely manner, but the University shall not be responsible for changes in value which might occur before receipt of equity by an inventor.

In the event the University or an affiliated entity of the University receives equity or an option to acquire equity in exchange for something other than a license or other intellectual property right (e.g. performance of a service or clinical trial), the equity interest shall not be subject to distribution under Sections 5 or 6 of this Policy.

7. Division of Inventor's Share Among Co-Inventors

Should there be more than one inventor per license or other source of royalties and other proceeds under Sections 5(a) and 6 of this Policy, the inventors' shares shall be divided and distributed among themselves in accordance with an agreement to be signed by the inventors and filed with the Administrator. Should the inventors fail to sign such an agreement governing distribution among themselves, then the proceeds shall be distributed equally among the sum of inventors per license or other source of royalties.

8. Conflicts of Interest

Conflicts of interest are more likely to present themselves to inventors, University personnel and the University as an entity in the context of intellectual property licenses or other contracts related to technology transfer activities. As such it is of utmost importance that in addition to any compliance required under this Policy, that all involved in technology transfer also comply with any conflict of interest policies as required by law, Section 3.8 of the Bylaws of the Board of Regents or Regents Policy 3.2.8, as those requirements may exist or as they may be amended in the future.

9. Resolution of Issues Concerning Administration or Interpretation of this Policy

Should any issue arise regarding administration or interpretation of this Policy or Section 3.10 of the Bylaws of the Board of Regents, the issue shall be referred to the campus vice chancellor responsible for research, sponsored programs and/or technology transfer activities (e.g. Vice Chancellor for Research or Vice Chancellor for Academic Affairs) . The campus patent and technology transfer advisory committee may review the facts and circumstances surrounding any such issue and make recommendations to the Vice Chancellor. The Vice Chancellor shall then make a report and recommendation for resolution of the issue to the Chancellor, who will make the final decision on all issues concerning administration or interpretation of this Policy or Section 3.10 of the Bylaws of the Board of Regents. The Chancellor's decision will be final with respect to the University.

10. Survival of Policy

The provisions of this Policy and Section 3.10 of the Bylaws of the Board of Regents shall survive the death or termination of employment of any inventor of intellectual property owned by the University. The provisions of this Policy shall inure to the benefit of and be binding upon the heirs and assigns of (1) any inventor of intellectual property owned by the University, and (2) all others who agree to be bound by it.

11. Campus Patent and Technology Transfer Policies and Procedures

The Chancellor of each campus, or the Chancellor's designee, is authorized to adopt and implement more detailed campus patent and technology transfer policies and procedures that are consistent with and supplemental to Section 3.10 of the Bylaws of the Board of Regents and this Policy.

Reference: BRUN, Minutes, 43, p. 39 (May 18, 1979).
BRUN, Minutes, 56, p. 149 (September 6, 1991).
BRUN, Minutes, 64, p. 139 (October 17, 2003).

[1]For purposes of this policy, the term "invention" shall mean patentable inventions or discoveries, computer software, trade secrets and all other intellectual property not addressed under Regents Policy 4.4.1.

[2] The determination as to whether any use of University personnel, property or facilities is or was "minimal" under this policy shall be made based on the following considerations:

a) Whether the invention was conceived of or reduced to practice pursuant to an employee or faculty member's job duties;

b) Whether any funding for the work leading to the conception or reduction to practice of the invention was provided by or facilitated through the University;
c) Whether any University facilities were utilized in the conception or reduction to practice of the invention, and if so, the extent of such use; and
d) Whether any University students or staff were utilized in or contributed to the conception or reduction to practice of the invention.

[3]The Bayh-Dole Act of 1980, 35 U.S.C . §§ 200-212, allows Universities and other non-profit organizations to retain title to federally-funded inventions and requires that strict reporting requirements be met. It is therefore critical that inventors provide a prompt and thorough disclosure to the University so that the University can properly evaluate the disclosure and elect to either retain or de cline title to such inventions in a timely manner.

[4] The University shall make every effort to recover all or part of these expenses from any licensee of University-owned intellectual property upon the execution of the license agreement.

Program. The decision of the Vice President for Business and Finance shall be final, and shall not be subject to further appeal or review.

RP-3.2.8 Conflict of Interest

1. Introduction

University relations with industry, government agencies, individuals, and other enterprises outside the University constitute a complex network of interactions. These interactions have directed attention to potential conflicts of values and interests between these entities and academia. As a result, there has been much attention nationwide to such potential conflicts.

Conflict of Interest is addressed in Section 3.8 of the *Bylaws of the Board of Regents* as follows:

Conflict of Interest. No employee of the University shall engage in any activity that in any way conflicts with duties and responsibilities at the University of Nebraska nor shall any employee hire or supervise a member of his or her immediate family without expressed written consent of the Board.

The objective of this University of Nebraska policy is to further elucidate this bylaw. If members of the University community are to be important participants in the economic development arena, and in providing service to industry, a set of policy statements must be provided with as much flexibility as possible. It is neither possible nor advisable to establish rigid rules governing these relations. Nevertheless, the University, while striving to promote research internally and to transfer technology externally, must safeguard against the use of public funds for private gain, conflicts of interest, conflicts of commitment, or interference with University duties in situations involving faculty, staff, students, or the institution itself. The University must also prevent violation of the tenets of fundamental fairness.

Nebraska statutes relating to conflict of interest apply to all employees of the University and include the following provisions in § 49-14,101 of the Revised Statutes of Nebraska:

... No ... public employee shall use that person's office or any confidential information received through the holding of a public office to obtain financial gain, other than compensation provided by law, for himself or herself, a member of his or her immediate family or a business with which the individual is associated ..." and no "public employee shall use personnel, resources, property, or funds under that individual's official care and control, other than in accordance with prescribed constitutional, statutory, and regulatory procedures, or use such items, other than compensation provided by law, for personal financial gain ...

In addition, many of the funding agencies, especially those operating under the National Science Foundation and the Department of Health and Human Services, require that the University establish safeguards to prevent employees or consultants from using their positions for purposes which are motivated by (or even give appearance of) a drive for private financial gain either for themselves or family members.

What follows is a set of policy statements--some broad, some narrow--for University faculty, staff, students, administrators, industrial sponsors, and other organizations.

Responsibility for assurance of compliance with this policy rests with the Chancellor of each campus and with the President for personnel associated with Central Administration.

2. Personnel Affected by Conflict of Interest Policy

In many instances throughout this policy the term "faculty" is used, primarily because faculty are most often involved in educational, research, and service activities. However, it must be

emphasized that these policies also apply to all other University employees including students, support personnel (staff - B and C lines), and administrators, whether these are full-time or part-time employees. The University seeks to identify situations which might lead to a conflict of interest by requiring that, in certain circumstances that are defined later, employees who propose a relationship with an industrial sponsor or other organization complete a *Disclosure of Interest Form* which has the specific intent of requiring an employee to disclose possible financial interest or other interest in the outcome of the project. The intent of this process is to identify situations which may lead to or be perceived as a conflict of interest. The policy statements which follow are not intended to resolve real conflicts of interest. This is left for resolution by affected personnel and the appropriate administrators.

3. Individuals and Organizations Affected by Conflict of Interest Policy

Likewise, this policy is intended to apply to the University's relations with all kinds and forms of government agencies, individuals, and private enterprises in general: entities big and small, start-up or established and ongoing, independent and/or portions of larger entities; whether proprietorships, partnerships of any variety, corporations, or other forms of business organization; regardless of where they are located geographically; whether entirely separate from the University; companies involving University employees, spun off from the University; companies involving University employees, spun off from faculty research; or University-affiliated companies.

4. Appropriateness of Research

Research is basic to the University's teaching and service missions. Good teaching and learning depend upon research. Likewise, through its research, teaching, and service activities, the University's resources can best be brought to bear on public issues requiring objective, systematic study. Research forms an inherent part of departmental and collegiate missions, and brings recognition to the University and its faculty. All forms of research, which are within departmental and collegiate missions, and which maintain the high quality characteristic of the University, are appropriate to the University's open environment. Similarly, University teaching and service activities have potential for commercial use and development.

Industry-supported research is a legitimate academic endeavor. On a nationwide basis, research universities are actively seeking to strengthen their relations with industry. Government and industry alike support basic, applied, and proprietary research. Since research ranges over a broad spectrum, distinctions between these categories are often arbitrary; all can educate students in the scientific method. Industrial support should complement ongoing faculty research initiatives as well as provide additional opportunities for graduate education. Because industry has pioneered many new scientific areas, collaboration with industry can challenge faculty, enrich graduate and undergraduate education, and open options for students' future employment.

Although the University wishes to foster University-industry partnerships, the University wishes to avoid any potential problems that may arise as a result of industrial sponsors directing research to meet their short-term needs and objectives. Prospects of financial gain could influence faculty and the University to choose the more commercial imminent, product-oriented research problems, rather than those fulfilling the University's objectives of educating students and advancing and applying more basic knowledge. Such problems could affect the quality and breadth of University research, teaching, and service missions, bias student education, cause favoritism, and undermine professor-student relationships.

On federally-sponsored projects, academia attempts to prevent such problems by the established external peer review system of evaluating research proposals. In addition, on each campus the appropriate University department chair(s) or director(s), the appropriate dean(s), and vice chancellor(s) all make appropriate review of external funding proposals. Although an established peer review system is not typically utilized by industrial sponsors, a considerable number of University-industry relations are initiated by faculty proposals which oftentimes complement

federal projects. Such industry-related research should be encouraged. Nevertheless, to make certain that research and service activities conducted for industrial sponsors are appropriate to the University's mission, the University's customary internal review of industry-sponsored projects must be especially thorough.

5. Policy Statement I: Review of Appropriateness of Proposed Research Project

As part of its research, education, and public service missions, the University encourages interactions between faculty and industry and other external agencies that enable faculty and other University personnel to pursue projects within their fields of interest and in keeping with their departmental and collegiate missions, or, if appropriate, the interdisciplinary missions of centers and institutes.

a. Faculty and other University employees have the freedom to undertake research, educational, or public service projects and to seek sponsorship of their liking, but must not be unduly influenced to accept external projects or sponsorship not of their own choosing.

b. Since the integrity and institutional commitment of principal investigators, departmental chairs or directors, and deans ultimately safeguard the quality and relevance of all research, educational, and service activities, all three, and the appropriate vice chancellor or his or her designee must promptly review all proposals to industrial concerns and other equivalent external agencies.

In rare circumstances, the appropriate administrator may nominate a single individual who shall be individually responsible for the review of all aspects of proprietary service and sponsored projects in certain defined areas.

Proposals under $5,000 will continue to receive the traditional campus review but are usually exempt from considerations under the Conflict of Interest Policy. However, any University employee with a personal financial interest of any sort resulting from or associated with the proposed agreement must complete the *Disclosure of Interest Form.* As a result, it may be necessary to require the approval of the appropriate administrator.

c. Internal review of such agreements must ensure that all industrial contracts and grants, or other forms of relationships, conform to departmental, center, institute, and collegiate missions; maintain the breadth and quality of research, teaching, and service creditable to the University; and are executed by the duly authorized administrative officer(s).

d. Questions regarding the appropriateness of industrial contracts and grants, or other forms of relationships, that cannot be resolved at the departmental, center, institute, or collegiate level must be reviewed and resolved by the appropriate vice chancellor or chancellor. Each campus has the option of establishing a faculty committee to make recommendations to the vice chancellor or chancellor for his or her final disposition.

6. Openness of Research and Publication of Results

The traditions of free exchange of ideas and prompt dissemination of knowledge are fundamental to the University's mission and should govern all research, teaching, and service activities conducted by University personnel. The University is committed to an open teaching and research environment, which ensures free faculty and student exchange of ideas, thereby contributing to the advancement of knowledge in all disciplines. As far as possible, the acceptance of support external to the University should not create situations which curtail open discussion of the research among colleagues and students.

Industry or federal agencies, on the other hand, may require a period of confidentiality for proprietary information provided to project participants for patent purposes or to protect trade secret information and may seek prior review of publications resulting from its sponsorship. It is acceptable to protect such proprietary information or trade secrets. The decisions to patent and to file the patent application or to keep the information a trade secret must be made as expeditiously as possible to avoid undue delays in publication.

7. Policy Statement II: Openness of Research and Publication of Results

   a. Research conducted by faculty under industry or other commercial sponsorship must, as far as possible, maintain the University's open teaching, research, and service environment.

   b. The administration must review any new, proposed, or ongoing faculty-industry interactions which might compromise the University's open teaching and research environment. Those in the line of reviewing University-industry relationships--the appropriate department chair(s) or director(s), dean(s), and the appropriate vice chancellor, or, in rare circumstances, the individual designated to perform the complete administrative review as described in Section 1--shall investigate and seek to resolve all potential problems. Concerns regarding violation of the Conflict of Interest policy shall be brought to the attention of the appropriate campus vice chancellor or chancellor, Provost, or President for resolution.

   c. Faculty must have the right to disseminate their research results, indeed are obligated to do so. The University discourages individual faculty from agreeing to forego this basic right. However, the University and faculty may accept reasonable delays in submission of new findings for publication or other release of information to enable sponsors or the University to obtain proprietary or patent protection, for example. In special circumstances to be determined by the University, a researcher may waive his or her right to disseminate the results of his or her research and elect to enter an agreement to maintain the confidentiality of proprietary research for specified periods of time.

   d. Faculty must normally provide written notification to support personnel and students involved in industry-sponsored projects, describing all contract and grant terms affecting them, including the possibility of delays in publication caused by the need of the sponsor to review manuscripts or any other obligations of confidentiality. Graduate students must not be assigned to thesis research topics which might be affected by confidential agreements. The appropriate administrator may authorize exceptions for personnel involved in short-term service-related projects.

8. Outside Employment: Avoidance of Conflicts of Commitment

   The University not only permits but expressly encourages faculty to pursue outside professional activities including interactions with industry, with or without compensation, which will enrich a faculty member's academic contributions to the University. Consulting can expose faculty to research problems and perspectives which may enrich faculty teaching, research, extension, and service backgrounds. However, faculty and administration must be sensitive that such interactions could cause conflicts and must ensure that University employees do not make unnecessary or inappropriate commitments of their time or expertise which can adversely affect the University and its mission. A conflict of commitment must be avoided when it could jeopardize the faculty's and the University's integrity which is essential to maintaining the public's trust.

   The assumption that faculty will devote their time and effort to the University's mission in proportion to their appointments--that full-time appointment connotes full-time commitment of time, effort, and expertise to the University--is inherent in University employment. Outside consulting activities, often acceptable in themselves, can interfere with a faculty member's

paramount obligations to the University by placing significant, competing demands upon the time and energy of the faculty member with the potential for the neglect of instructional and research obligations. In some circumstances, the faculty member's proposed outside activities may directly conflict with the objective of assignments within the University.

The University, through an outside employment policy enacted by the Board of Regents, seeks to minimize the potential for faculty conflict of commitment by several mechanisms. The time that may be devoted to outside activity is normally limited to two working days per month; greater time commitments require specific approval of the Board of Regents. (For practical reasons, faculty are given considerable freedom in the scheduling of any outside activities.) In addition, the University must examine the application of an employee's expertise to proposed educational, industrial, or other consulting activities to assure that there is no conflict of commitment or other conflict of interest. Hence, the University requires prior disclosure of proposed consulting, extramural teaching, or other activities to the department chair and the subsequent approval of the college dean and campus administration. Such disclosure may be made by completing the *Disclosure of Interest Form* and may require the provision of additional documentation to the chair, dean, or other administrator.

In certain other circumstances, the specific approval of the Board of Regents may be required. The relevant policy of the Board of Regents is set forth in Section 3.4.5 of the *Bylaws of Board of Regents.*

9. Policy Statement III: Disclosures of Outside Commitment

a. Outside Employment and Consulting Relationships. As University-industry relationships increase with a growing desire for consultantships and other professional activities outside the University, University staff members must continue to observe the University policy on outside employment embodied in Section 3.4.5 of the *Bylaws of the Board of Regents.* In addition, University employees must observe the Board of Regents policy on conflict of interest stated in Section 3.8 of the *Bylaws of the Board of Regents*.

b. Outside Professional Activities Requiring Regental Approval. The *Application for Permission to Engage in Professional Activity Outside the University Form* is to be used by members of the professional staff for the purpose of requesting requisite approval pursuant to Section 3.4.5 of the *Bylaws of the Board of Regents* to engage in professional activity outside of the University.

Section 3.4.5 of the *Bylaws* specifically encourages University staff members to engage in professional activities outside the University as a means of broadening their experience and keeping them abreast of the latest developments in their specialized field. It is implicit in this Regental policy that the University, as an educational and research institution, will benefit and better serve the people of the state as a result of outside professional activities by its professional staff.

The purpose of the *Application for Permission to Engage in Professional Activity Outside the University Form* is to provide documentation of the requisite approval under Section 3.4.5 and to provide an established procedure for review and approval of outside professional activity.

Department chairpersons, department heads, deans, and directors have primary responsibility to review the specific nature of each proposed outside professional activity within their respective areas of administrative responsibility and to deny approval to any such activity which would interfere with the normal University duties of the staff member involved or which would represent a conflict of interest or a conflict of commitment.

It is impossible to anticipate all questions which may arise in connection with the application of Section 3.4.5 of the *Bylaws* to the varied outside professional activities of staff members. However, several general guidelines are set out below to assist in the administration of this policy:

1) Section 3.4.5 of the *Bylaws* applies only to members of the professional staff, that is, A-line and B-line personnel.

2) Section 3.4.5(a) of the *Bylaws* requires Regental approval of outside professional activities where the staff member will accept retainer fees or other remuneration on a permanent or yearly basis as a professional consultant. The key consideration in determining whether there will be acceptance of a retainer fee or remuneration on a permanent yearly basis is the nature of the professional business relationship between the staff member and his or her client or patient. If this business relationship is one where the staff member is obligated at the beginning of the professional relationship with a client or patient to provide professional services over a period of one year or longer, then approval by the Board of Regents is required.

3) Section 3.4.5(b) of the *Bylaws* requires Regental approval of outside professional activity requiring more than an average of two days per month during the period of the staff member's full-time employment. The Board of Regents has interpreted this language to mean two days per month during the assigned work week. It is often very difficult to identify an assigned work week, particularly for faculty. They often perform their regular or routine University duties during evening hours and on weekends. For this reason, Regental approval will only be required when a staff member's outside professional activities will prevent the performance of his or her assigned duties at the University more than an average of two days per month during the period of full-time employment. Thus, if outside professional activities are to be performed only during a time when the staff member would not otherwise be performing such duties, then Regental approval under the two days per month provisions of Section 3.4.5(b) of the *Bylaws* would not be required, regardless of the length of time to be devoted to the outside activity.

4) Section 3.4.5(c) of the *Bylaws* requires Regental approval of outside professional activity involving the charging of fees for work performed in University buildings with University equipment and materials. It is not practical to prescribe guidelines under subparagraph (c) which will cover the many and varied outside professional activities of staff members. Specific policies with regard to the charging of fees for work performed in University buildings with University equipment and materials should be developed by each chancellor.

5) Section 3.4.5(d) of the *Bylaws* requires Regental approval of outside professional activities where remuneration is received for services provided to departments or agencies of state government. This subsection applies only to the departments or agencies of the government of the State of Nebraska. It does not apply to services provided to departments or agencies of the governments to other states. Also, it does not apply to services provided to political subdivisions within the State of Nebraska, such as municipalities, counties, school districts, public power districts, irrigation districts, natural resource districts, etc.

6) Section 3.4.5 of the *Bylaws* does not require individual approval of each separate client or patient relationship for professionals such as accountants, engineers, architects, lawyers, psychologists, therapists, etc. It is sufficient that the nature of the outside professional activity be generally described so that appropriate

evaluation may be conducted regarding potential interference with University duties, conflict of interest, and conflict of commitment. So long as none of the circumstances requiring Regental approval under subparagraphs (a), (b), (c), and (d) of Section 3.4.5 of the *Bylaws* exist, no further information need be provided by the staff member, and the professional activity may be approved by the chancellor upon the recommendation of the appropriate dean or director.

7) Activities for a professional organization with which a staff member is associated do not constitute the type of professional activity coming within the scope of Section 3.4.5 of the *Bylaws* unless a professional service is provided to the organization for which the staff member is paid a professional fee which is commensurate with the actual value of the professional service provided.

The foregoing should not be construed to relieve any staff member of complying with applicable policies or regulations of the department, college, division, campus, or University with regard to time one is allowed away from regular University duties.

c. Declaration of Interest

University employees proposing outside employment or a consulting relationship are required to complete a confidential *Disclosure of Interest Form.*

10. Other Activities Requiring Disclosures of Economic Interest or Commercial Involvement

With increasing University interactions with outside organizations, the University must ensure that other less obvious potential conflicts are identified and, if necessary, addressed in a formal process. Accordingly, the University requires that faculty identify and report, to the appropriate administrator, the potential for real or perceived conflicts which can result from their relations with industry, or other organizations, so that problems may be avoided. For example, the University must avoid situations where the possibilities for personal gain for the University employee or his or her immediate family may be judged to be so significant that it is unreasonable to expect the employee to exercise the objectivity necessary to the University's public trust. In addition, employees are required to report their involvement with commercial or educational enterprises where the name of the University may be used for commercial gain.

To assist in identifying such potential conflicts of interest, each member of the faculty or University staff proposing any arrangement with an industrial sponsor or proposing to have financial interest in an outside organization must complete a *Disclosure of Interest Form* which seeks to identify situations likely to lead either to a conflict of interest or conflict of commitment or the appearance of such conflict. It must be emphasized that while such disclosures are necessary, they will not and should not, ipso facto, prevent such arrangements. Personal discretion or administrative adjustments can often be used to resolve most potential conflicts. For example, reducing the percentage of a faculty appointment, or granting a leave of absence, to reflect the faculty member's respective commitments to the University and to the outside entity may be appropriate and help to resolve the conflict.

11. Policy Statement IV: Disclosures of Interest

a. Situations Requiring Disclosure of Economic or Commercial Interest. When accepting support from industrial sponsors, faculty and other University personnel, whether full-time or part-time, must disclose all directly or indirectly related commercial connections with and financial interests in such sponsors. In addition, in situations where a faculty member's immediate family has such commercial connections and financial interests, disclosure must also be made. Further, disclosure of economic interest in any company which competes with the industrial sponsor must also be provided.

In the following specific situations, University employees are required to declare their economic or commercial interest, since there is significant possibility of conflict of interest:

1) If a University employee and/or a member of his or her immediate family (defined as the spouse of an individual, a natural or adopted child of an individual, a parent of an individual or his or her spouse, or a person claimed by an individual or his or her spouse as a dependent for federal income tax purposes) in the aggregate own or have options to purchase the lesser of either 5 percent or more or $2,000 or more of voting stock in a company which sponsors a research project of the employee, then the University employee is required to declare the equity interest in full.

2) If a University employee or a member of his or her immediate family, as defined in Section 11.a.1), in the aggregate own the lesser of 5 percent or more or $2,000 or more of the voting stock, is an officer in a company which competes with the sponsor of a research project in which the employee is involved.

3) If a University employee or a member of his or her immediate family, as defined in Section 11.a.1), holds a position as an operational officer in a company with which the employee has a University research project.

4) If a University employee or a member of his or her immediate family, as defined in Section 11.a.1), holds a full-time or part-time position or has financial interest in a company which is the recipient of funds from a government agency or other sponsor.

5) If a University employee has involvement with commercial or educational enterprises where the name of the University may be used to further the commercial development of a product or service.

6) If a University employee or his or her immediate family, as defined in Section 11.a.1), receives a loan, honorarium, gift, in-kind contribution, or other consideration of value from a sponsor or a sponsor employee.

7) If the sponsor or agency supporting research is the Department of Health and Human Services, the National Science Foundation, other Federal units or a not-for-profit private agency, it is necessary to declare any significant financial interest with any other agency, company, corporation, or other entity that might influence or be perceived to influence the conduct of research. Such significant financial interest is defined to be anything of monetary value, including but not limited to, salary or other payment for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options, and other ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights). A significant financial interest in business enterprises or entities exists when the value of such interests exceeds $2,000 per annum, or if salary, fees, or other continuing payments represents more than a 5 percent ownership interest for any one enterprise or entity when aggregated for the investigator and the investigator's spouse and dependent children.

   Investments in mutual funds in which the extent of investment in a particular industry is unknown are excluded from the requirement to declare financial interest.

b. Memberships on Boards of Directors. Faculty or other University personnel memberships on boards of directors associated with the sponsor of any project proposal must be

declared since the individual may be in a position to direct funds and direct the use of other University personnel, including research students and assistants, into areas of research that result in conflict of interest.

c. Part-time Employees and Faculty on Leave of Absence. The Conflict of Interest policy applies to part-time employees and faculty or other employees who are on leave of absence. The possibility of conflict of interest or conflict of commitment is especially likely if the employee is also a part-time employee of the sponsor of the project.

d. Process for Disclosure of Interest. Disclosure of economic or commercial interest is made by completing the *Disclosure of Interest Form.* All new, renewal, or continuation sponsored project proposals in excess of $5,000 prepared for submission to a sponsor must also have a completed *Disclosure of Interest Form.* Information provided in this form will be considered confidential.

e. Resolution of Conflicts. Wherever possible, the appropriate departmental chair(s) or director(s), dean(s), and the appropriate vice chancellor(s) must review and resolve any faculty conflicts of interest or conflicts of commitment. In some circumstances, the involvement of the chancellor, Provost, or President may be required to resolve the conflict.

12. Conflicts of Interest Involving Faculty Commercialization of University Technology

University projects have resulted in the creation of new Nebraska businesses which have transferred research results into products and services and which have contributed to the State's economy. Certain research discoveries lend themselves to commercialization by starting new ventures through the University or through faculty rather than the traditional licensing to existing companies. Moreover, this means of commercializing discoveries may be the best, or in some instances the only, means to transfer such new technology. The University recognizes this as an acceptable method of commercializing discoveries when it is in the best interests of the University, the State, and the inventor and is the most effective means to transfer such technology.

In establishing new companies to commercialize University technology, the University may accept equity positions or combinations of equity and future royalties in return for licensing the technology. This is an acceptable University activity and is an integral part of the technology transfer program. However, in such situations, reasonable limits on the University's involvement with respect to administrative time and the amount of equity taken must be observed. This will enable the University to be aware of and take steps to prevent potential conflicts of interest which may arise, involving, among other things, favoritism in future dealings with the same company, discrimination against its competitors, or the use of public funds for private gain. Accordingly, University direction of the company must be limited in time, and the amount of equity taken must be less than controlling.

Conflict situations also apply to any profit- or nonprofit-affiliated private entities established by the University or one of its employees. Therefore, in the University's relations with all such entities, the Conflict of Interest policy must be followed.

Ownership of equity in a company may entitle the University to membership on the company's board of directors. Such memberships are positive from the University's perspective since board members can look after the University's interest in company management. However, increased possibilities for conflicts of interest are inherent in such membership. In addition, ownership of equity in a company established by a University employee may also create situations which may lead to conflicts of interest. Thus, University employees, who hold ownership or equity or receive company royalties, or board members or company officers, who are University administrators involved in internal decisions regarding personnel, budgeting, contract negotiations, and the like,

may be in a position to direct University projects to benefit the company causing problems of favoritism, discrimination, and improper use of public funds for private gain. In addition, board members or company officers are exposed to internal confidential matters of their companies, and their company obligation may, therefore, conflict with their obligations to the University. Although accepting membership on a company's board of directors may be appropriate, the University must be provided with sufficient information to determine whether conflicts may arise as a result of the membership on the board.

Where University technology is transferred in return for an equity position, or royalties, or projects are to be performed in exchange for an equity position, the affected University employees must be fully apprised of such proposals, and a suitable arrangement that reflects the Regents Patent Policy must be concluded, both with the faculty and with the industry sponsor. The arrangement should provide for the faculty inventor to share in any consideration received by the University in accordance with established practices.

In recent years, because of federal tax law changes, for-profit entities have been formed specifically to fund research and development, such as research and development limited partnerships. Such entities solicit investors from members of the public. There is the possibility that prospective investors may be induced to invest by what appears to be University involvement in the funding entity or by unrealistic expectations of the outcome of the projects. In either event, the name of the University could be unfairly traded upon. Therefore, care must be taken that the investor solicitation is consistent with the potential outcome of the research and the policy on the use of the University's name.

13. Policy Statement V: Conflicts of Interest Involving the University

a. Where appropriate, the University may accept equity in a company as complete or partial payment for transferring University technology to the company for commercialization. Only the Board of Regents may approve acceptance of equity in a company upon the recommendation of the cognizant chancellor, the Provost, and the President.

b. The University may designate individual(s) to hold membership on the board of directors of a company in which the University holds equity.

c. University faculty, administrators, or other members of the University community holding any such board of directors membership shall oppose or absent themselves, as appropriate, from any funding decisions or other decisions relating to the University which:

1) violates or is contrary to any law or University policy or procedure in regard to grants or contracts;

2) would constitute a conflict of interest with such person's University office of employment, or

3) involves improper use of University (public) funds.

d. When external entities raise funds for University projects through any form of investment offerings, University personnel must scrupulously avoid the endorsement of any such offering or any statement of potential research results. The University's prior written consent must be obtained to use its name in connection with advertising or promotion of any investment offering.

e. The past history of funding of University research or other projects by any company or firm shall not have any bearing on purchasing decisions made by the University of Nebraska.

14. Commitments of University Equipment and Facilities

Company access to specialized University equipment, facilities, and personnel, acquired to further the teaching, research, and public service missions, may form the basis of University-industry relationships much as faculty seek access to complementary industrial facilities. Industry's use of University facilities and personnel, whether for research or for routine testing on a fee-for-service basis, is mutually advantageous. Access to sophisticated or unique University facilities for research or product development benefits companies of every size. The University benefits from full utilization of its facilities, resulting revenues, and increased opportunities to educate students. Since facilities are limited and are dedicated to all University missions, however, uses furthering these missions shall have priority. Depending upon availability, use by external sponsors is appropriate.

15. Policy Statement VI: Commitments of University Equipment and Facilities

When allowing industry to utilize University facilities directly for commercial purposes, the University shall make certain that industry indemnifies the University for all liabilities arising from such use; that industry pays an appropriate fee determined by the institution; and that such use does not interfere with University research, education, or public service programs.

16. Transfer of Rights in Discoveries

The Regents' patent policy extends to all patentable inventions and discoveries made at the University. Transfer of rights in and commercialization of such inventions and discoveries, whether by license, assignment, or sale, can further the mission of the University by making the discoveries available to the general public, by bringing recognition to the University and faculty, and by providing funds to the University which strengthen its research, teaching, and service roles. Such transfer of technology is encouraged.

Industry typically treats the products of its research in a very confidential manner. On occasion, industry expects project participants to maintain the same degree of confidentiality with sponsored projects. It is important to note that openness, freedom of discussion, and freedom to publish go to the very core of the University. Nonetheless, there are certain legitimate needs for confidentiality on the part of industry that must be met by project participants. Data received from an industry sponsor and marked "confidential" may be kept in a confidential status for a stated period of time. Also, it is prudent to recognize the need to maintain the confidential status of the results of the project for a period of time sufficient to determine patentability and filing of patent applications or as agreed upon in an agreement between the sponsor and the University. When appropriate, the University may enter into confidential agreements to protect proprietary information, where this is deemed necessary, either through direct agreement with an industrial sponsor or through an agreement between the sponsor and an individual employee.

17. Policy Statement VII: Transfer of Rights in Discoveries

a. Each campus of the University has a process for the evaluation and disposition of inventions and discoveries created by University employees. Following appropriate evaluation but prior to making a patent application, the invention or discovery is brought to the attention of the Board of Regents in writing. The Board may accept the invention or discovery and pursue a patent application or return the invention to the inventor, in accordance with Section 3.10 of the *Bylaws of the Board of Regents*. It should also be noted that Regental Policy RP-3.2.7, "Patent and Technology Transfer Policy", mandates that one-third of royalties be paid to the faculty inventor(s) of a patent.

b. Faculty, or other principal investigators on industry-sponsored research, must ensure that all individuals who assist in their research projects are fully informed in writing of the

ownership and disposition of inventions and requirements of confidentiality regarding research results and other confidential information provided by the sponsors of associated projects.

18. Appeal of Administrative Decisions

Each campus shall assure that an appeal mechanism is in place to allow faculty and others to appeal any administrative decision relating to the Conflict of Interest policy.

19. Disclosure of Interest Form

A facsimile of the *Disclosure of Interest Form* appears on the next page.

Reference: BRUN, Minutes, 58, pp. 11-12, (February 13, 1993).
BRUN, Minutes, 60, p. 20, (March 24, 1995).