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A "20-20" VIEW OF INVENTION REPORTING TO THE NATIONAL INSTITUTES OF HEALTH

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National Institutes of Health

INVENTION REPORTING TO THE NIH

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A "20-20" VIEW OF NIH EXTRAMURAL INVENTION REPORTING

20 QUESTIONS ABOUT EXTRAMURAL INVENTION REPORTING:

1. WHAT FEDERAL STATUTES AND REGULATIONS COVER PATENT AND INVENTION ISSUES?

The regulations codified at 37 CFR Part 401, "Rights to Inventions made by Nonprofit Organizations and Small Business Firms" apply to all grantees and contractors, including universities and other non-profit entities, and for-profit organizations such as small business firms. The Department of Commerce has been designated the responsible Federal agency for these regulations as they emanated from Public Law 98-620 (November 8, 1984), which amended Public Law 96-517 (December 12, 1980), more commonly known as the Bayh-Dole Act. This law amended Title 35 USC, by adding Chapter 18, Section 200-212.

Other regulations that address these issues are OMB Circular A-124 (February 10, 1982) and a February 18, 1983 Presidential Memorandum on "Government Patent Policy" in 37 CFR 401. The Presidential Memorandum was incorporated into the text of OMB A-124 on March 24, 1984. It was not until 1987 that all of these provisions were finalized in rulemaking and published by the Department of Commerce.

2. WHAT IS THE BAYH-DOLE ACT AND WHY IS IT IMPORTANT?

The Bayh-Dole Act encourages researchers to patent and market their inventions by guaranteeing patent rights. This Act automatically grants first rights to a patent for an invention fully or partially funded by a Federal agency to the awardee organization. To obtain these benefits, however, the inventor and the organization have several reporting requirements that protect the rights of the Government.

This landmark legislation is important because it gives nonprofit organizations and small business firms the right to elect to retain title to inventions. The objectives are to: use the patent system to promote utilization of inventions arising from Federally supported research; encourage maximum participation of small business firms in Federally supported research and development efforts; promote collaboration between commercial and nonprofit organizations; ensure that inventions made by nonprofit organizations and small business firms are used in a manner that promotes free competition and enterprise; promote commercialization and public availability of inventions made in the United States by United States industry and labor; and ensure that the Government obtains sufficient rights in Federally supported inventions to prevent the unreasonable use of inventions.

3. WHAT ARE THE PRINCIPAL FEATURES OF THE BAYH-DOLE ACT, AS IMPLEMENTED BY 37 CFR 401.14, THE "STANDARD PATENT RIGHTS CLAUSES"?

37 CFR 401.14 requires organizations to establish a written agreement with all employees to disclose promptly each subject invention made under a Federally sponsored program and to execute all papers necessary to file patent applications. By its acceptance of an NIH award, a grantee or contractor organization agrees to obtain written agreements from its employees and:

- o Promptly report inventions to the NIH.
- o Elect, in writing, within two years, whether or not to retain title.
- o File a patent application within one year of electing title.
- o Acknowledge Government support in the patent application and send page of application containing Federal support clause.
- o Provide the Government with a royalty free license to the invention; the confirmatory license should be sent to the Office of Policy for Extramural Research Administration (OPERA), NIH.
- o Make reasonable efforts to attract small business licensees.
- o Provide annual reports on the utilization of the invention, including date of first commercial sale or use and gross royalties received.
- o Agree that exclusive licensee will manufacture the invention substantially within the United States, if it is to be used or sold in the U.S.

4. WHY PATENT?

Patent protection gives the owner of the patent the right to exclude others from making, using, offering to sell, selling, or importing into the United States the invention during the lifetime of the patent, thus protecting the incentive for commercial development of the invention. However, it does not give the public the right to use the invention if it is claimed by another's patent. A company will be more willing to make the investment needed to commercialize an invention if it can eliminate or decrease competition. When a patent is licensed and successfully commercialized, it can lead to royalties for the organization and the inventor, economic development for the Nation, and improvements in the public health.

Patent protection is the key component of technology transfer. Of the legal options available, including trademarks, trade names, copyrights, and licensing, patenting is probably the most crucial to commercializing research results.

More than 200 years ago, the Constitutional Convention included in the U.S. Constitution the power "to promote the progress of science and useful arts by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." Almost 90 years later, President Lincoln addressed the importance of patenting, when he said, "the patent system has added the fuel of interest to the fire of genius."

5. DO THE REQUIREMENTS FOR INVENTION REPORTING AND COMPLIANCE WITH BAYH-DOLE VARY FOR DIFFERENT TYPES OF ORGANIZATIONS?

Bayh-Dole legislation, which was also extended to large businesses by the 1983 Presidential Memorandum, applies to all grantees and contractors funded by the U.S. Government. Non-profit organizations are subject to three provisions in addition to those that apply to all organizations:

- o Nonprofit organizations cannot assign rights to an invention to a third party, unless it is an invention management organization, without permission from the Federal funding component;
- o Royalties must be shared with the inventor and the remainder used for scientific research and education; and,
- o Nonprofit organizations must give preference to small businesses when licensing the inventions.

6. WHAT ARE THE RESPONSIBILITIES OF A PRIME AWARDEE VIS-A-VIS FLOWING DOWN BAYH-DOLE REQUIREMENTS TO SUBGRANTEES/SUBCONTRACTORS UNDER FEDERAL AWARDS?

In accordance with 37 CFR Part 401.14g, prime grantees and contractors are required to include the Standard Patent Rights Clause (401.14) in all subcontracts, regardless of tier, for experimental, developmental, or research work to be performed. That clause requires subawardees to report directly to NIH on any inventions developed with Federal funding. It is suggested that the prime awardee include a clause in its written agreement with the subawardee that also requires notification to the prime when an invention is made. This will ensure that prime awardees have accurate information to complete questions concerning inventions on the competing and noncompeting applications and the final invention statement.

7. WHAT IS THE FIRST STEP IN THE INVENTION REPORTING PROCESS AND WHO TAKES THAT FIRST STEP?

The first step, if the inventor believes he/she has an invention/discovery, is to report it promptly to the organization's technology transfer office, the office of sponsored research, or the institutional administrative official responsible for technology issues. The employee/investigator is required to report any invention in accordance with the terms of the employee agreement he/she signed. (Note: Organizations are required, as a condition of Federal funding, to enter into employee agreements with all appropriate staff.)

After the inventor reports the invention in-house, the appropriate office is then responsible for reporting the invention to the Government, as well as providing support to the inventor for fulfilling the administrative requirements for securing a patent and negotiating license agreements if the invention is deemed to have commercial value.

8. WHAT ADDITIONAL STEPS ARE INCLUDED IN THE INVENTION REPORTING PROCESS AND WHEN ARE THEY TO BE TAKEN?

The awardee organization is responsible for the following:

- o Invention disclosure to the NIH, in writing, within 2-months of the inventor's initial report to the organization
- o Election of title to invention -- within 2-years of disclosure to NIH. Sometimes election is made at the time of disclosure of the invention. (For inventions disclosed to the public, notification of the NIH 60-days prior to the statutory bar date, which is usually one year after the date of publication, sale, or public use.)
- o Non-election of title to invention (For inventions not disclosed to the public, notification of the NIH at least 60-days prior to the end of the 2-year period after disclosure.)
- o Patent application -- within one-year of election of title or publication, whichever is earlier, provision to the NIH of the confirmatory license and the page of the patent application that contains the Federal support clause
- o Issued patent -- provision to the NIH of the patent number and issue date at time of issuance of the patent
- o Annual utilization report (See Question 13./Page 5) -- every year subsequent to filing a patent
- o Final invention statement -- prior to closeout of the NIH grant or contract. This form (HHS 568) is to be submitted directly to the awarding component (See Term 9./Page 9)

Unless otherwise specified, the information should be sent to the Office of Policy for Extramural Research Administration (OPERA), NIH.

9. WHAT HAPPENS IF THE ORGANIZATION DECIDES NOT TO ELECT TITLE ON THE INVENTION?

The awardee has two years after it discloses an invention to the NIH to determine if it wants to take title and file a patent application. If the organization does not choose to elect title, it must notify the NIH. Under these circumstances, the NIH has the option to take title. The Government evaluates the invention to determine whether patenting and further development is in the public interest, because of potential commercial interest or health benefit. If the NIH chooses to elect title, the inventor is guaranteed a portion of any royalties.

10. WHAT IF THE NIH ALSO DECIDES NOT TO ELECT TITLE? CAN THE INVENTOR GET TITLE?

Under these circumstances, after NIH consults with the awardee title may be given to the inventor if it is requested. If the inventor takes title, he/she must abide by the Patent Rights Clause.

11. HOW DOES THE GOVERNMENT BENEFIT, IF THE ORGANIZATION ELECTS TO RETAIN TITLE TO AN INVENTION?

The government must be granted a "nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject invention throughout the world" (37 CFR 401.14.6.b; see also "Confirmatory License" in the accompanying terms). The Government does not get a share of the royalties, but the public does benefit if a useful invention is developed, reaches the market, and becomes accessible to those who need it.

12. IS THERE ANY HARM IN AN INVENTOR PUBLICLY DISCLOSING AN INVENTION BEFORE REPORTING IT TO THE TECHNOLOGY TRANSFER OFFICE?

Yes. Inventions should be reported to the awardee organization prior to publication or presentation at any open meeting, since failure to do so may result in loss of the rights to the awardee organization, inventor, and the Federal government in the invention. Most foreign patent rights are immediately lost upon publication or other public disclosure, unless a patent application is already on file. In addition, statutes preclude obtaining United States patent protection after one year from the date of a publication that discloses the invention.

13. WHAT IS THE PURPOSE OF THE ANNUAL INVENTION UTILIZATION REPORT?

An annual Invention Utilization Report is required for all inventions for which a patent application has been filed or that have been licensed, but not patented (e.g., biological material). The utilization reports must provide the status of development, date of first commercial sale or use, and gross royalties received. The NIH cannot require a specific format for this report, but a suggested format for this information is available upon request from OPERA and on the world wide web (http://www.nih.gov). The Invention Utilization Report is used to document the implementation of the Bayh-Dole Act and determine whether or not subject inventions are being appropriately developed. If the organization fails to properly develop an invention, 37 CFR Part 401.6 gives the Government the right to "march in" and, if the invention is deemed important for the public good, develop it (see "March-In Rights" in accompanying list of "20-20" terms).

14. WHY WOULD AN AWARDEE ORGANIZATION NOT PROPERLY REPORT SUBJECT INVENTIONS TO THE GOVERNMENT AND WHAT ARE THE CONSEQUENCES OF FAILING TO COMPLY WITH BAYH-DOLE REPORTING?

Failure to report inventions appropriately is usually caused by "ignorance of the law" or a misunderstanding of the legislation and its implementing regulations. An additional concern that may contribute to a failure to report is based on the incorrect premise that the Government will inappropriately interfere with the commercialization of subject inventions. In fact, the Bayh-Dole Act provides very few restrictions on commercial development. As long as Government funded inventions are reported and commercially viable inventions are being reasonably developed by the organization (which is in everyone's interest), Government involvement is limited to retaining its confirmatory license. On the other hand, failure to comply with the reporting requirements of the Patent Rights Clause can result in loss of the recipient's rights to an invention (37 CFR 401.14(d)) or the use of the Government's right to march-in. In addition, the latest version of the grant application form PHS 398 (rev. 5/95) includes a penalty clause for the improper reporting of an invention or failure to report an invention.

15. WHEN AN AWARDEE LICENSES A COMPANY TO USE AN INVENTION DEVELOPED WITH FEDERAL FUNDS, WHAT INFORMATION OR REQUIREMENTS MUST BE INCLUDED RELATIVE TO THE GOVERNMENT'S RIGHTS IN THE INVENTION?

The financial aspects of the license are between the awardee organization and the licensee. However, the awardee must inform the licensee that the Federal government has a nonexclusive right to make or use the invention for Government purposes. In addition, if the licensee is awarded exclusive rights to the invention, the awardee must inform it that it is obligated to manufacture the invention substantially in the U.S., if it will be sold or used in the U.S.

16. WHO HAS THE RIGHTS TO DATA DEVELOPED UNDER NIH GRANTS?

Under the grant mechanism, recipient institutions have custody of and primary rights to data developed, subject to the Government's right of access.

17. WHAT HAPPENS TO AN INVENTION WHEN THE INVENTOR/PRINCIPAL INVESTIGATOR TRANSFERS TO A NEW INSTITUTION?

The invention belongs to the awardee organization. The Bayh-Dole Act requires that there be employee agreements in place at the awardee organizations that obligate inventors to assign title to Federally-supported inventions to the organization. In return, the inventor receives a portion of any royalties. If the inventor moves to a new organization, the rights to existing patents usually remain with the former organization, although the inventor remains entitled to a share of the royalties. However, depending on the stage of development of the invention, an inventor or the organization, with NIH permission, may negotiate a transfer of rights to the new organization.

18. ARE ROYALTIES FROM PATENTED INVENTIONS CONSIDERED PROGRAM INCOME?

Yes, but they are not considered general program income. Thus, if no specific footnote appears on the Notice of Grant Award pertaining to royalty or other income from patents or inventions, its inclusion as program income for the purposes of the financial status report is not required. However, such income must be reported on the annual utilization report submitted each year by awardee organizations. It is important to note that, according to the Bayh-Dole Act, a portion of royalties must go to the inventor and the balance must be used to support scientific research and education.

19. HOW DO ORGANIZATIONS SATISFY THE FEDERAL LAW THAT REQUIRES AWARDEES TO REPORT INVENTIONS AND PATENTS THAT RESULT FROM NIH FUNDING AGREEMENTS AND WHAT IS NIH DOING TO ENSURE AND FACILITATE COMPLIANCE?

All awardee organizations are to use Form HHS 568 - "Final Invention Statement and Certification" to closeout a grant or contract. The completed Form should be sent directly to the grants or contracts office of the awarding component.

The NIH is in the process of finalizing an on-line information management system based on a client-server database in which common files are established and data is viewed or modified. The system has been named 'Edison' (see "Edison" in accompanying list of "20-20" terms) and includes features that will significantly decrease the amount of work needed for an organization to fulfill the reporting requirements.

NIH may obtain title to inventions that are not properly reported and elected.

20. WHAT IF AN INVENTOR IS UNSURE THAT HE/SHE HAS MADE A SUBJECT INVENTION? WHAT IF THE INVENTOR AND/OR ORGANIZATIONAL OFFICIAL HAVE A QUESTION OF A GENERAL NATURE? WHOM CAN THEY CONTACT FOR ADDITIONAL INFORMATION?

Inventors should be aware that publication prior to filing a patent application will immediately destroy patent rights in most foreign countries. Also, if the awardee organization elects rights, but neglects to file a patent application or tell the Government what action has been taken, a loss of patent rights for the organization, the inventor, and the Government may result. NIH may obtain title if the patent application is not timely filed.

An inventor should work closely with organizational technology transfer personnel. Awardee organizations are encouraged to obtain a copy of 37 CFR 401, which is available through OPERA, NIH, or on the world wide web (http://www.nih.gov/grants and contracts/Edison). Additional assistance can be obtained from the grants management and contracts management offices of the awarding component. For situations beyond the scope of the organizational technology transfer official or the grants or contracts management officers, OPERA, NIH, should be contacted.

WORDS FOR THE WISE:

20 INVENTION REPORTING TERMS WITH WHICH EVERY NIH AWARDEE SHOULD BE FAMILIAR

1. ASSIGNMENT. Transfer of title or ownership in patent rights in the form of a written assignment document. By law, an inventor has initial ownership of an invention. However, awardee organizations are required by the Bayh-Dole Act to have in place employee agreements requiring an inventor to "assign" or give ownership of an invention to the organization upon acceptance of Federal funds.

2. BAYH-DOLE ACT. Enacted on December 12, 1980 The Patent & Trademark Act (Public Law 96-517) created a uniform patent policy among Federal agencies that fund research. Bayh-Dole enables small businesses and non-profit organizations, including universities, to retain title to materials and products they invent under Federal funding. Subsequent amendments created uniform licensing guidelines and expanded the law's purview to include all Federally-funded contractors (Public Law 98-620).

3. CONFIRMATORY LICENSE. Acknowledges right of retention by the U.S. government of a "nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the U.S. the subject invention throughout the world." Such a license is always retained by the U.S. government when the awardee elects title to an invention, regardless of the title holder's licensing strategy. License agreements for Federally-funded technology must include a clause addressing the Government's rights and interests, i.e., "The Licensee acknowledges that the U.S. Government has certain rights in this invention under 37 CFR 401 including a non-exclusive, non-transferable, paid-up license heretofore granted by the Licensor."

4. EDISON. The electronic system for invention reporting to the NIH. The system is based on a client/server database architecture in which a common file is established and data is viewed or modified in real-time. The system allows input and updates of records and includes features in its architecture that will significantly decrease the amount of work presently done by awardee organizations to fulfill invention reporting requirements. The system has been named 'Edison,' in recognition of the prolific American inventor. Grant recipients may request authorization from OPERA, NIH, to use the electronic system for invention reporting.

5. ELECTION OF TITLE. In accordance with 37 CFR 401 - Standard Patent Rights Clauses, the notification of the decision to retain title to an invention. The election must be in writing, or sent electronically, and is due within two years of disclosure of the invention to the NIH.

6. EXTENSION OF TIME. In relation to disclosure, election, and filing, requests for extension of the time needed to evaluate a subject invention or identify a licensee, may, at the discretion of the agency, be granted.

7. FEDERAL SUPPORT CLAUSE. Required language on a patent application and any patent issued for an invention arising from Federally funded activities: "This invention was made with Government support under (identify support) awarded by the PHS. The Government has certain rights in the invention."

8. FILING. The act of submitting a patent application to the Patent Trademark Office or its foreign counterpart. Failure to file within the one-year "grace-period" for public disclosure disqualifies the invention from patent protection in the U.S.

9. FINAL INVENTION STATEMENT AND CERTIFICATION. Form HHS 568, due prior to close-out of a grant/contract which lists all inventions made under the grant or certifies that there were no inventions.

10. FIRST TO FILE. System used internationally for establishing who has the right to patent an invention when more than one party is claiming a single invention. "First-to-Invent" is the system used in the United States.

11. INTELLECTUAL PROPERTY LAW. A widely used term to designate a field of law that encompasses products of the human mind or intellect (e.g., patents, inventions, trademarks, copyrights).

12. INVENTION/SUBJECT INVENTION. An invention is anything made by the "hand of man," that is a new, useful, and unobvious process, machine, manufacture, or composition of matter, or any new and useful improvement thereof. The term "invention" means any invention or discovery that is or may be patentable or otherwise protectable under Title 35 of the U.S. Code. The term "subject invention" means any invention of an awardee conceived or first actually reduced to practice in the performance of work under a Government funding agreement (grant, cooperative agreement, contract).

13. INVENTION DISCLOSURE. A written report to the NIH that includes the title, the name(s) of the inventor, a technical description of the invention, the grant/contract number(s), and date of any public disclosure. Due within two months of inventor's initial report to employer.

14. INVENTION UTILIZATION REPORT. Annual report to NIH regarding status of commercialization of an invention for which a patent application has been filed. These reports are used to record the status of development, date of first commercial sale or use, gross royalties received by the awardee, and compliance with Bayh-Dole legislation. NIH is very lenient in accepting information in any format, provided the basic required information is submitted. A copy of the suggested format is available on the world wide web in Edison (http://www.nih.gov), or from OPERA, NIH. Submission of this information can be done electronically with NIH authorization.

15. LICENSE. The right to develop and practice a patent, invention, trademark, or copyright. A license is a written document granted by the owner of a patent, giving permission to another to make, use or sell articles embodying the invention.

16. MARCH-IN RIGHTS. The government's right to require that the awardee provide nonexclusive, partially exclusive, or exclusive license, under reasonable terms, to responsible applicants, if necessary, because the awardee organization's licensee has not taken (or is not expected to take) effective steps within a reasonable time to achieve practical application of an invention or is necessary to alleviate a health or safety need.

17. PATENT. A grant by the Federal Government to an inventor of the right to exclude others from using, selling, or making an invention during the lifetime of the patent.

18. REDUCTION TO PRACTICE. Actual reduction to practice is the actual construction or working of the invention for its intended purpose. Constructive reduction to practice is the filing of a patent application with the Patent Trademark Office. An invention is a subject invention if it is conceived or first actually reduced to practice in the performance of work under the grant or contract.

19. STANDARD PATENT RIGHTS CLAUSE. Details awardee obligations and responsibilities to the U.S. government with regard to Federally-supported inventions. Full text of the patent rights clause (37 CFR 401.14) can be found in the revised PHS Grants Policy Statement - Appendix 9, or on the world wide web in Edison.

20. TECHNOLOGY TRANSFER. The transfer of research results to the commercial sector or interchange between the private and public sectors.

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