National Academy of Sciences
Committee on University IP Management

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Council on Governmental Relations

A Word About COGR

- Council on Governmental Relations (COGR)
- Established in 1948; consists of 178 U.S. research universities and affiliated academic medical centers and research institutes.
- Focuses on federal government regulations, policies and practices that affect research conducted at member institutions.
- Seeks to advocate for university research community with federal agencies.
- Staff of 5; several standing committees (Costing, Compliance, Contracts & Intellectual Property).

Bayh-Dole Background

- Bayh-Dole Act of 1980 (P.L. 96-517—35 USC 200-212) provides legal framework for title to and disposition of inventions made under U.S. government-funded research programs.
- Trademark Clarification Act of 1984 (P.L. 98-620) assigned responsibility for implementing regulations to Commerce Department.*
- Implementing Regulations published March, 1987 (37 CFR 401).
- Extended to large business by Presidential Order (2/18/83 Presidential Memorandum and E.O. 12591 (4/10/87).

  * Note: Commerce recently decentralized its Bayh-Dole oversight responsibilities to NIST.

Pre-Bayh-Dole

- No single government-wide policy regarding ownership of inventions made with federal government funding.
- Government typically held title to inventions and made them available via non-exclusive licenses.
- Result: in 1980 govt. held title to 28,000 patents, fewer than 5% of which were licensed for commercial development.

Bayh-Dole Objectives

- Promote commercialization and public availability of federally-funded inventions.
- Provide incentives for universities to work directly with the private sector in commercializing federally-funded inventions.
- Establish uniform government policy on ownership and patenting of inventions made with federal government support.
- Promote leverage of federal funding by private sector to encourage innovations.

Basic Features of Bayh-Dole

- Non-profit organizations (including universities) and small businesses may elect to retain title to inventions developed under federally-funded research programs.
- In return, universities must seek to achieve practical application by promoting the utilization of such inventions by the public.
- Universities must file patents on inventions that they elect to own (and report to government).
- In licensing inventions, preference must be given to small business & products substantially manufactured in U.S.
- Government retains a non-exclusive world-wide license to practice the patent itself.
- Government retains “march-in” rights.

What Has Been the Result?

Economist 12/2/02 edition:

> The (Bayh-Dole Act) “is perhaps the most inspired piece of legislation to be enacted in America over the past half-century… this unlocked all the inventions and discoveries that have been made in laboratories throughout the United States with the help of taxpayers’ money. More than anything, this single policy measure helped to reverse America’s precipitous slide into industrial irrelevance.”

December, 2006 Congressional Resolution (S. 1785)

“The Bayh-Dole Act…has made substantial contributions to the advancement of scientific and technological knowledge, fostered dramatic improvements in public health and safety, strengthened the higher education system in the United States, served as a catalyst for the development of new domestic industries that have created tens of thousands of new jobs for American citizens, strengthened States and local communities across the country, and benefited the economic and trade policies of the United States; and it is appropriate that the Congress reaffirm its commitment to the policies and objectives of the Bayh-Dole Act by acknowledging its contributions and commemorating the silver anniversary of its enactment.”

Measures of Success

- U.S. universities signed almost 5000 new licenses in FY 2006 (1079 in FY ‘91).
- 697 new products introduced into the market in 2006 – 4,350 introduced from FY98 through FY06.
- 553 new startup companies launched in 2006 (5,724 new spinouts from FY80 through FY06).
- 3255 U.S. patents issued to U.S. universities in FY 2006 (approx. 500 in FY 1980).
- Many individual product success stories (see AUTM “Better World” report).
- Other countries now emulating Bayh-Dole-like models.

Invention Revenue (Royalties)

- Bayh-Dole requires that all net revenue from licensing of inventions be used to support research and education.
- Bayh-Dole also requires that revenues be shared with inventors (as an incentive); does not specify specific amount--inventor(s) share is typically 1/3rd of net.
- Relatively few “blockbusters;” 2001 COGR survey of 23 of top 25 HHS-funded institutions (in FY99) showed average university share of royalty income = $9M.
- Most universities do not make money on technology transfer (after subtracting expenses).
- **Bottom line: tech transfer is part of a university’s service mission, and should not be viewed as a revenue producer.**

March-In Rights

- Bayh-Dole specifies (Section 203(a)) 4 conditions under which the government can march in to assure a federally funded invention is made available to the public
- Conditions are:
  - 1) contractor or assignee has not taken effective steps to achieve practical application of the invention;
  - 2) to alleviate health or safety needs;
  - 3) to meet requirements for public use specified by Federal regulations; or
  - 4) breach of U.S. manufacturing requirement.

More on March-in

- Government remedy: compulsory licensing (does not take ownership).
- U.S. government has never exercised its Bayh-Dole march-in rights.
- NIH has received three march-in requests; (in 1997—CellPro; 2004—Norvir/Xalatan); denied all of them.
- 2004 cases involved drug pricing; specifically whether “excessive” prices constitutes lack of practical application or failure to meet health or safety needs; NIH determined that since drug was available in the market there was no violation of Bayh-Dole.
- In effect, march-in is not a remedy for pricing concerns (according both to NIH and the original bill sponsors).

Government Use License

- Bayh-Dole gives the U.S. government a paid-up nonexclusive license to practice or have practiced for or on behalf of the U.S. any invention subject to Bayh-Dole.
- Right extends to government contractors.
- Primary user has been the Department of Defense and defense contractors.
- Note: U.S. law provides (28 USC 1498) that sole remedy for infringement of a U.S. patent by a contractor with government authorization and consent is by suit against the U.S. government.

Note on Other Forms of IP Protection

- Bayh-Dole deals only with patents.
- Use of copyright in university technology transfer activities is increasing but patentable invention disclosures still substantially exceed copyrightable works and other types (i.e. biological materials) of disclosures.
- Materials Transfer Agreements (MTAs) involving proprietary biological materials is another form of IP protection posing complex and increasing challenges.
- “Open source” treatment of software gaining momentum; federal regulations anomalous in treatment of federally funded software.

Challenges to Bayh-Dole

- Historic (pre-Bayh-Dole) view that publicly-funded technology should be freely available to the public and not owned exclusively by anyone retains force.
- Some argue that “platform” technologies should be non-exclusively licensed to encourage greater follow-on innovation and that government should exercise more oversight of university licensing decisions.
- Claim that universities follow a “one size fits all” approach in licensing inventions based on Bayh-Dole even when dealing with industry.

Responses

- Bayh-Dole represented a careful balancing of public and private benefit; need for care in making any changes that would upset this balance.
- Bayh-Dole has provided needed flexibility to help universities develop creative responses to unanticipated new technologies and uses as well as to respond to different industry business models.
- Bayh-Dole often is used as a shorthand for criticisms of university patenting/licensing practices. It also is often used for criticisms of university treatment of IP in non-federal research agreements. NAS Committee should keep these distinctions in mind.
- Contributions of Bayh-Dole not generally known or understood by federal policymakers or the public; more education needed to avoid disruptions.

The Conflict of Interest Issue

- U.S. universities are under increasing pressure to take an active role in local economic development by forming partnerships with industry, but this leads to growth in potential of conflict of interest issues in the performance and reporting of research.
- U.S. universities typically require disclosure of financial interests by investigators and a plan to either manage or eliminate them, or to curtail the research activities if possibility of bias remains.
- These issues are receiving increasing public and Congressional attention and likely to continue.

Federal Guidelines on Commercialization

- Bayh-Dole philosophy is that licensing decisions are best left to award recipients and industry partners to structure an arrangement that meets the needs of both parties.
- There is not much federal guidance on commercialization of federally-assisted inventions.
- NIH has issued some relevant materials.

NIH Guidelines on Developing Sponsored Research Agreements

- Responsibility on recipients to effectively transfer technology to industry for commercial development, consistent with B-D Act, regs, and award terms.
- Recipients should consider experience, capability and commitment of commercial entities to commercialize inventions.
- Sponsored research agreements should not provide exclusive licenses (options to negotiate exclusives are OK).
- Cites need for due diligence and benchmarks in licensing agreements.
- Utilization reporting, U.S. manufacturing, small business preference, non-assignment and need for timely notification of inventions also discussed.

NIH Guidelines on Sharing Biomedical Research Resources

- Sets forth four basic principles for NIH grant and contract recipients.
- 2nd principle is to assure appropriate implementation of Bayh-Dole Act.
- For research tools, if further R&D or investment is not needed to achieve usefulness, discourages exclusive licensing to for-profits.
- Goal is to assure availability to academic research community.

NIH Research Tools Policy—cont.

- Implementation guidelines distinguish research tools from broad enabling inventions and whether resource is readily usable or requires more investment for purposes of developing IP strategy.
- Provides Simple Letter Agreement for transferring unpatented NIH-funded tools.
- If patented or exclusively licensed, option or reach-through rights imposed by patentees or licensees are not appropriate.
- If exclusive license necessary, limit to appropriate field of use.

Other Relevant NIH Policies

- Data Sharing (see http://grants.nih.gov/grants/policy/data_sharing/)
- “Share My Mouse” (see http://www.nih.gov/science/models/mouse/sharing/5.html)
- Genomic Inventions Best Practices (see http://www.ott.nih.gov/policy/lic_gen.html)

Other Federal Agency Guidelines

- Most deal with federally-owned inventions under authority of Stevenson-Wydler and Federal Technology Transfer Acts, e.g. DOE: http://www.directives.doe.gov/cgi-bin/explhcgi?qry1344812016;doe-276
- NSF has published a patent policy at 45 CFR 650; basically follows Commerce clause except for funding agreements covered by international agreements; provides for retention of rights by inventor(s) where awardee elects not to retain rights (or dedication to the public).

OMB Guidance for Grants

- 2 CFR 215.36(b) (OMB Circular A-110) cites Commerce regulations for rights to inventions for grants and agreements with universities and non-profits.
- Standard research grant terms and conditions for FDP agencies (73 *FedReg*4563; 1/25/08) follows above.
- Agency-specific requirements mostly address specific invention reporting requirements.
- Note: i*Edison* is used by most agencies for invention reporting; see https://s-edison.info.nih.gov/iEdison/ .

Questions/Comments

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