**NON-DISCLOSURE AGREEMENT**

This agreement is entered into between the parties signed below. The parties desire to disclose to each other information which is proprietary to the disclosing party.

Therefore, the parties agree as follows:

1) The receiving party, for five (5) years after the date of disclosure, shall hold the proprietary information in confidence, and shall not disclose the proprietary information without prior written approval of the disclosing party.

These restrictions on the use or disclosure of the proprietary information shall not apply to any proprietary information:

i) lawfully received free of restriction from another source having the right to furnish such proprietary information; or

ii) after it has become generally available to the public without breach of this agreement; or

iii) which at the time of disclosure to the receiving party was already known free of restriction; or

iv) which the disclosing party agrees in writing is free of such restrictions.

2. The proprietary information shall be subject to the restrictions of paragraph 1 if it is in writing or other tangible form, only if clearly marked as proprietary when disclosed, or if not in tangible form, only if summarized in writing so marked as proprietary and delivered within thirty (30) days of the disclosure. Information, other than proprietary information identified and furnished as provided above, shall not be subjected to the restrictions of paragraph 1.

3. No license under any trademark, patent, copyright, or any other intellectual property right, is either granted or implied by conveying of proprietary information to either party. None of the information which may be disclosed or exchanged by the parties shall constitute any warranty, assurance, guarantee or inducement by any party to the other parties of any kind, and in particular, with respect to the non-infringement of trademarks, patents, copyrights, or any other proprietary rights.

assurance, guarantee or inducement by any party to the other parties of any kind, and in particular, with respect to the non-infringement of trademarks, patents, copyrights, or any other proprietary rights.

4. Neither this agreement nor the disclosure or receipt of proprietary information constitute or imply or promise an intention to make any purchase of products or services by either party.

5. All proprietary information shall remain property of the transmitting party.

6. Each party agrees that it will not, without the prior written consent of the other, transmit the proprietary information received from the other to any country outside the United States.

7. Each party agrees that all of its obligations undertaken herein as a receiving party shall survive and continue after any termination of this agreement.

8. This agreement constitutes the entire understanding between the parties hereto regarding the proprietary information.

In witness whereof, the parties have executed this agreement on the respective dates entered below.

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In witness whereof, the parties have executed this agreement on the respective dates entered below.

Roger Browdy — 3/11/93
Roger Browdy — Date

William Trimmer — 22 March 93
William Trimmer — Date

Robert H. Stroud — 10 Mar. 93
Robert H. Stroud — Date

Robert Sears — 3/10/93
Robert Sears — Date

CONFIDENTIAL DISCLOSURE AGREEMENT

WHEREAS_____

_____ (DISCLOSER) possesses certain proprietary information relating to _____

_____ (SUBJECT MATTER);

WHEREAS _____ (RECIPIENT) is interested in evaluating said information for purpose of_____

_____

for an evaluation period ending _____;

NOW, THEREFORE, it is agreed that:

1. INFORMATION shall mean any information disclosed in confidence, by or on behalf of DISCLOSER, to RECIPIENT, whether such information was generated by DISCLOSER or was disclosed to DISCLOSER by a third party.

2. RECIPIENT warrants that it will maintain INFORMATION in confidence, and will not use INFORMATION for any purpose not contemplated by this Agreement, except as provided by paragraph 3 of this Agreement.

3. RECIPIENT will not be under any obligation set forth herein with respect to any INFORMATION which:

(a) at the time of disclosure is within the public domain, or which thereafter enters the public domain through no fault of RECIPIENT;

(b) is subsequently disclosed to the RECIPIENT by a third party having no obligation of confidentiality with respect to the INFORMATION; or

fault of RECIPIENT;

(b) is subsequently disclosed to the RECIPIENT by a third party having no obligation of confidentiality with respect to the INFORMATION; or

(c) was known to RECIPIENT prior to the time of disclosure under this Agreement, provided:

i) this prior knowledge is evidenced by written records which are contemporaneously dated, signed and witnessed;

ii) RECIPIENT gives written notice to DISCLOSER of this prior knowledge within thirty days of the disclosure of INFORMATION by DISCLOSER;

iii) RECIPIENT permits review of the documents evidencing said prior knowledge by an attorney representing DISCLOSER; and

iv) such prior knowledge was not gained from third parties who obtained it in confidence, directly or indirectly, from DISCLOSER

4. INFORMATION shall be deemed to be disclosed by or on behalf of DISCLOSER if

(a) it is indicated to be proprietary to DISCLOSER or to be disclosed by or on behalf of DISCLOSER;

(b) it is disclosed by any employee, officer or director of DISCLOSER; or

(c) if it relates to SUBJECT MATTER and is disclosed by any employee, officer, director, shareholder, consultant, contractor, attorney or agent of DISCLOSER, or of a company or institution which is a parent, subsidiary, or venture partner of DISCLOSER, or of a company which



company or institution which is a parent, subsidiary, or venture partner of DISCLOSER, or of a company which

2

is a parent or subsidiary of such a company or institution.

5. The term "RECIPIENT" shall include all employees, officers, directors, and attorneys of RECIPIENT. RECIPIENT acknowledges that it is not entitled to disclose INFORMATION to any individual not an employee, officer, director or attorney of RECIPIENT, without the prior written consent of DISCLOSER, and then only on a "need-to-know" basis and only to individuals obligated to hold the INFORMATION in confidence.

This prohibition includes but is not limited to agents and consultants of RECIPIENT; employees, officers, directors, attorneys, agents and consultants of companies or other institutions related to RECIPIENT; and government agencies (except when disclosure is required by law).

6. "Maintain in confidence" means that, as a minimum, RECIPIENT will treat all information disclosed by DISCLOSER as it would its own proprietary information. RECIPIENT will disclose INFORMATION to its own employees, officers, directors and attorneys on a "need-to-know" basis only, and then only to those individuals obligated to hold the INFORMATION in confidence. All such individuals will be informed in advance that such INFORMATION is proprietary to DISCLOSER.

7. RECIPIENT will not make copies of articles representing such INFORMATION except to the extent necessary for the purposes acknowledged above, and such copies will be numbered and tracked by RECIPIENT. All articles representing such INFORMATION will be



such INFORMATION except to the extent necessary for the purposes acknowledged above, and such copies will be numbered and tracked by RECIPIENT. All articles representing such INFORMATION will be

kept in secure locations so that access to such articles is controlled.

8. RECIPIENT will not export INFORMATION or ARTICLES REPRESENTING INFORMATION to another country without the prior written consent of DISCLOSER, or without obtaining such export licenses as are required by law.

9. ARTICLES REPRESENTING INFORMATION shall include any object, device, machine, material, substance, structure, edifice, writing, recording, drawing, sample, specimen, prototype, model, photograph, organism, culture, tissue, organ, antibody, virus, or nucleic acid molecule, or any copy or derivative thereof, which completely or partially describes, depicts, embodies, contains, constitutes, reflects or records INFORMATION, including articles prepared by RECIPIENT based on INFORMATION.

10. INFORMATION shall include information represented by ARTICLES designated as being "confidential" or "proprietary," or words of like import; information initially disclosed without such designation, but later indicated by DISCLOSER to be proprietary information before said information is innocently placed in the public domain by RECIPIENT; or information obtained by RECIPIENT through observations made in DISCLOSER'S facilities. INFORMATION shall include information relating to research, development, patent or trade secret solicitation, licensing or litigation, manufacture, purchasing, accounting, engineering, marketing, merchandising or selling, whether or not used by DISCLOSER. INFORMATION shall include proprietary information



litigation, manufacture, purchasing, accounting, engineering, marketing, merchandising or selling, whether or not used by DISCLOSER. INFORMATION shall include proprietary information

4

disclosed by DISCLOSER to RECIPIENT during the negotiations leading to this Agreement.

11. RECIPIENT will give DISCLOSER 14 days' advance written notice, of its intent to disclose or use (for a purpose not contemplated by this Agreement) unpublished information not designated as proprietary which it has received from DISCLOSER, or one acting on its behalf, whatever the manner of receipt, to give DISCLOSER on opportunity to assert that such information is proprietary.

12. RECIPIENT will give DISCLOSER 60 days' advance written notice, marked to the attention of _____, of its intent to disclose or use (for a purpose not contemplated by this Agreement) INFORMATION which in the opinion of RECIPIENT falls within the exemption of paragraph 2, to give DISCLOSER an opportunity to challenge the applicability of the exemption. The notice will particularize the INFORMATION allegedly covered by paragraph 2 and the basis for the claimed exemption.

13. RECIPIENT, at the end of the evaluation period hereunder, or at any time at the demand of DISCLOSER, shall return all ARTICLES REPRESENTING INFORMATION to DISCLOSER, except that a single copy of documentary ARTICLES may be retained by COUNSEL for RECIPIENT for verification of information received, and then only if DISCLOSER is promptly notified of such retention.

14. The term "disclose" shall include all means of imparting INFORMATION, including disclosure by display or



retention.

14. The term "disclose" shall include all means of imparting INFORMATION, including disclosure by display or

5

transfer of ARTICLES REPRESENTING INFORMATION or oral COMMUNICATION OF INFORMATION.

15. This Agreement shall be construed, interpreted, and applied in accordance with the federal laws of _____ and the state laws of _____.

16. This Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof and any modification of this Agreement shall be in writing and shall be signed by a duly authorized representative of each party. The signatories hereto warrant that they are a duly authorized representative of their respective party.

17. Any controversy or claim arising under or related to this Agreement shall be settled by arbitration in accordance with the Rules of the American Arbitration Association, and judgment upon the award rendered by the Arbitrator(s) may be entered in any Court having jurisdiction thereof.

Executed this _____ day of _____, 19____.

| | |
|---|---|
| By _____ | By _____ |
| Title _____ | Title _____ |
| For _____ | For _____ |
| _____ | _____ |
| _____ | _____ |
| DISCLOSER | RECIPIENT |
| [SEAL] | [SEAL] |



DISCLOSER RECIPIENT

[SEAL] [SEAL]

NOTARIZATION

STATE OF _____

COUNTY OF _____

On this _____ day of _____, 19 ___, before me personally came _____, to me known to be the individual identified as the RECIPIENT named in the preamble of this Confidential Disclosure Agreement who executed this Agreement, or who has acknowledged that he or she has authority to execute this Agreement on behalf of the RECIPIENT (whether a natural or legal entity) and who so executed it.

_____
Notary Public

My commission expires _____.



7

CONFIDENTIAL DISCLOSURE AGREEMENT

WHEREAS_____

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(b) it is disclosed by any employee, officer or director of DISCLOSER; or

(c) if it relates to SUBJECT MATTER and is disclosed by any employee, officer, director, shareholder, consultant, contractor, attorney or agent of DISCLOSER, or of a company or institution which is a parent, subsidiary, or venture partner of DISCLOSER, or of a company which



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This prohibition includes but is not limited to agents and consultants of RECIPIENT; employees, officers, directors, attorneys, agents and consultants of companies or other institutions related to RECIPIENT; and government agencies (except when disclosure is required by law).

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Executed this _____ day of _____, 19____.

| | |
|---|---|
| By _____ | By _____ |
| Title _____ | Title _____ |
| For _____ | For _____ |
| _____ | _____ |
| _____ | _____ |
| DISCLOSER | RECIPIENT |
| [SEAL] | [SEAL] |



DISCLOSER RECIPIENT

[SEAL] [SEAL]

NOTARIZATION

STATE OF _____

COUNTY OF _____

On this _____ day of _____, 19 ___, before me personally came _____, to me known to be the individual identified as the RECIPIENT named in the preamble of this Confidential Disclosure Agreement who executed this Agreement, or who has acknowledged that he or she has authority to execute this Agreement on behalf of the RECIPIENT (whether a natural or legal entity) and who so executed it.

_____
Notary Public

My commission expires _____.



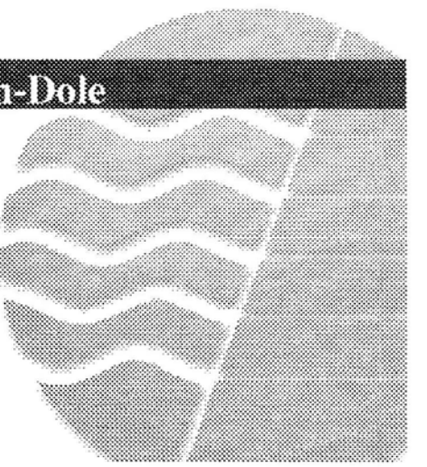
7

Robert C. Byrd National Technology Transfer Center

Joseph P. Allen

# A Quick History of Bayh-Dole

December 5, 2002



# Decentralized v. Centralized Power



Thomas Jefferson



Alexander Hamilton


The ADVENTURES of
BAYH
AND
DOLE

# Starring...

**Forces of Good**



Rocky & Bullwinkle



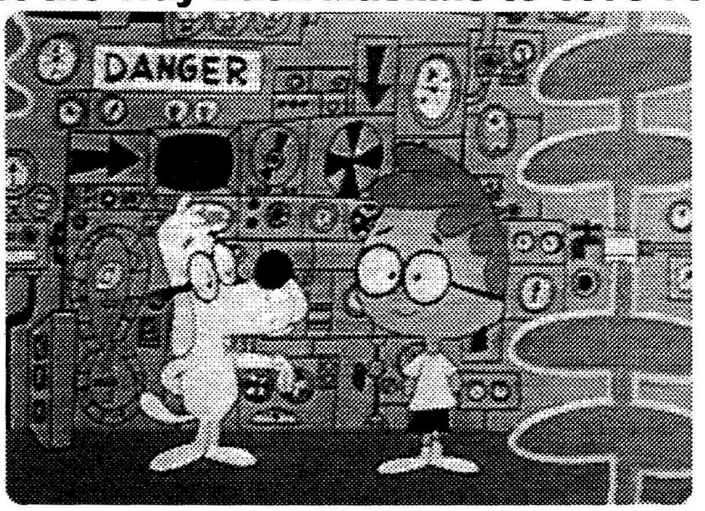
Mr. Peabody & Sherman

**Forces of Evil**



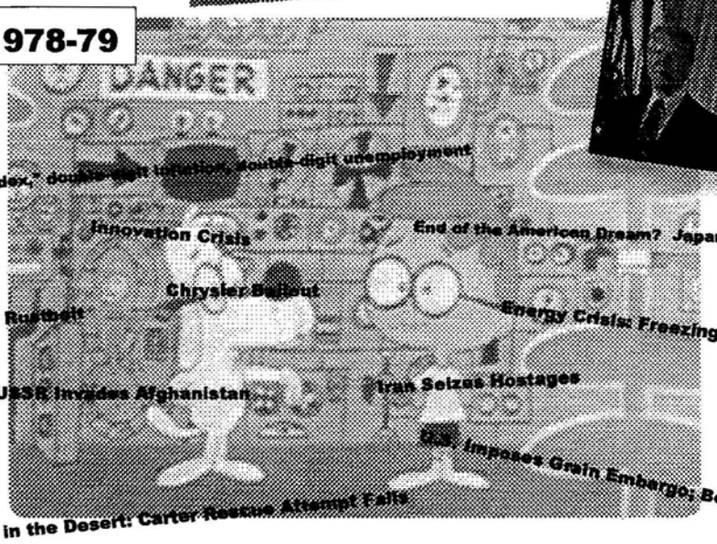
Boris & Natasha

## "Set the Way Back Machine to 1978-79"



# Bayh And Dole

**1978-79**






"Misery Index," double-digit inflation, double-digit unemployment

Innovation Crisis

End of the American Dream? Japan as #1

Chrysler Bailout

Midwest Rustbelt

Energy Crisis: Freezing in the Dark?

USSR Invades Afghanistan

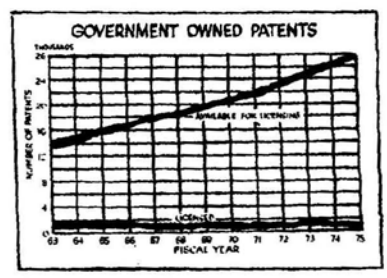
Iran Seizes Hostages

U.S. Imposes Grain Embargo; Boycotts Olympics

Debacle in the Desert: Carter Rescue Attempt Fails



# What's Happening to Our Federal R&D Dollars?




**28,000 government owned inventions; less than 4% licensed**

*We found that hundreds of new compounds developed at university laboratories had not been tested and screened by the pharmaceutical industry because manufacturers were unwilling to undertake the expense without some possibility of obtaining exclusive rights to further development of the product.*

1968 General Accounting Office study of Dept. of Health, Education and Welfare for President Lyndon B. Johnson



# Bayh-Dole First Introduced

*"A wealth of scientific talent at American colleges and universities-- talent responsible for the development of numerous innovative scientific breakthroughs each year-- is going to waste as a result of bureaucratic redtape and illogical government regulations..."*

*"The problem, very simply, is the present policy followed by most government agencies of retaining patent rights to inventions., " Bayh said. He noted: "Government sponsored research is often basic rather than applied research. Therefore, many of the resulting inventions are at a very embryonic stage of development and require substantial expenditures before they actually become a product or applied system of benefit to the public.*

*"It is not government's responsibility-- or indeed, the right of government-- to assume the commercialization function, " Bayh pointed out. "Unless private industry has the protection of some exclusive use under patent or license agreements, they cannot afford the risk of commercialization expenditures. As a result, many new developments resulting from government research are left idle."*

**— Senator Birch Bayh's introductory statement, September 13, 1978**



# A Price is Paid

**Patent Bill Seeks Shift To Bolster Innovation**

*The Bayh-Dole bill is a sort of testimonial to Norman Latker, a hero among university researchers and licensing proponents. Latker was patent counsel at the Department of Health, Education and Welfare until his unceremonious firing in December for what officials say was conduct and judgment not up to the department's professional standards. Latker's fans say he was let go for doing his job too well...*

*He is credited with developing an elaborate arrangement at HEW, called Institutional Patent Agreements, that easily transferred patents out of the government. That was fine with the Republicans in the Nixon and Ford years. But to the Carter people, it appeared that Latker was giving away the store.*

*Senior officials at HEW ordered an extra step to review all of Latker's decisions. As a result, the decisions on pending patent requests were delayed. The universities were miffed. They started complaining to Congress. Latker complained, too.*

*That's when Bayh and Dole stepped in. Dole charged HEW with "pulling the plug" on biomedical research by holding up action on important new drugs and medical devices. HEW responded quickly.* ***It released some patents- - and it also let go of Latker (emphasis added).***

**— The Washington Post, April 8, 1979**



# Let the Game Begin

*Prior to the effective date of the IPA, December 1, 1968, no invention made at the University of Wisconsin with funds from DHEW (Department of Health, Education and Welfare) had been licensed to industry-- one invention not falling under the IPA was licensed after that date. Since December 1, 1968, the Wisconsin Alumni Research Foundation has received a total of 69 invention disclosures under the Institutional Patent Agreements, has filed 79 applications on 55 of these disclosures and has had 55 U.S. patents issued.*

*A total of 20 licenses were issued under one of more of these patents and patent applications, of which 14 are still extant.*

**— Testimony of Howard W. Bremer, WARF**

*In my opinion, government contractors- including small businesses and universities- should not be given title to inventions developed at government expense. That is the gist of my testimony. These inventions are paid for by the public and therefore should be available for any citizen to use or not as he sees fit.*

**— Testimony of Admiral Hyman B. Rickover, "Father of the Nuclear Navy"**

Hearings Before the Senate Judiciary Committee on the University and Small Business Patent Procedures Act (May 16 and June 6, 1970)





# Over the First Hurdle

*The bill is designed to promote the utilization and commercialization of inventions made with government support ... Ultimately, it is believed that these improvements in government patent policy will lead to greater productivity in the United States, provide new jobs for our citizens, create new economic growth, foster increased competition, make government research and development contracting more competitive, and stimulate a greater return on the billions of dollars spent each year by the Government on its research and development programs.*

**— Senate Judiciary Committee Report, December 12, 1979**
*on S. 414, unanimously approved and reported to the Senate*

# No One Said It would Be Easy



*Dear Colleague:*

*When the Senate takes up S. 414, a bill to establish a uniform federal patent policy for small businesses and nonprofit organizations, we intend to offer an amendment extending this policy to all government contractors.*

**— February 5, 1980 to all Senators from Senators Cannon, Stevenson, Packwood and Schmitt**

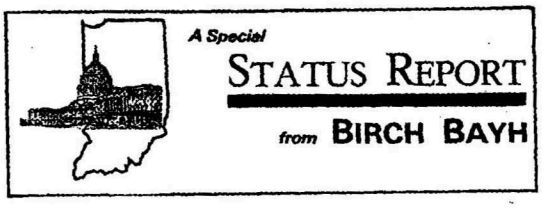
*"This is the worst bill I have seen in my life"*

**— Senator Russell Long to Bayh's staff**



# I Think I Can, I Think I Can, I Think I Can

**Senate Passes Legislation to Stimulate Industrial Productivity and Innovation**




*What sense does it make to spend billions of dollars each year on government-supported research and then prevent new developments from benefiting the American people because of dumb bureaucratic redtape?*

— **News From Birch Bayh,**
*April 23, 1980 reporting on the approval of S. 414 (Bayh-Dole) by the U. S. Senate on a 91-4 vote*

# But the House is Going Another Direction



United States Senate

September 24, 1960

Honorable Birch Bayh
Senate from Indiana
Room 361 ESOB
Washington, D. C. 20510

Dear Birch:

I am deeply concerned by the action of the House Governmental Affairs Committee in reporting H. R. 6933. I am reasonably sure this bill will be considered by the full House on Monday, September 29, and could come to the Senate as early as next week.

As you know, H. R. 6933 expands the scope of the Senate patent policy legislation, S. 434, to allow the giveaway of the benefits of billions of dollars of public financed research to the largest and most dominant corporations in the United States. During consideration of S. 434, the Senate, by a vote of 66 to 34, rejected a similar amendment. You and I stood together in opposition to this anti-competitive and unwarranted proposal. During Senate consideration of S. 434, you repeatedly stated you would vigorously oppose any expansion of that legislation to include big business.

I am adamantly opposed to the House Bill. I urge you to join with me in taking whatever steps are necessary to prevent this monopolistic provision from being included in the final form of any patent policy legislation.

Sincerely yours,

United States Senate

September 26, 1960

The Honorable Russell Long
United States Senator
Washington, DC 20510

Dear Russell:

Thank you for your letter of September 24, 1960 alerting me to your concerns with the big business patent policy provisions of H.R. 6933. I agree with you that the problem of disposing of inventions made under government contract by big businesses is a very complex one that I have taken no position on myself.

The Senate Judiciary Committee in its hearings on S. 434, the University and Small Business Patent Procedures Act, investigated only the problem of universities and small businesses with government patent policy. Your concerns merit a full investigation by the Committee and I will look forward to working with you and your staff in seeking a solution to the problem.

My own strong conviction has been that the present patent policies unfairly discriminate against small businesses and universities who have denied patent rights routinely granted to larger contractors. Because small businesses and universities have such a distinguished record of producing innovative products this particular is more than unfair--it adversely affects American innovation.

Therefore, I will offer an amendment to bring any Senate passed patent policy into conformity with that already passed by the Senate, which as you know is strictly limited to universities and small businesses.

As a former member of the Senate Small Business Committee you have an unusual sensitivity to the problems of innovative small businesses who are seeking to compete against dominant, big businesses. I hope that you will join with me and the other members of the Senate Judiciary Committee in resolving the present small business-university problem.

Sincerely,

Birch Bayh
United States Senator

# Uh, Oh We're Unemployed...

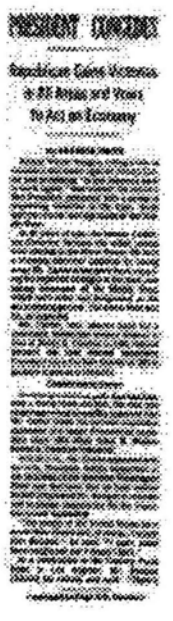


The New York Times

**REAGAN EASILY BEATS CARTER; REPUBLICANS GAIN IN CONGRESS; D'AMATO AND DODD ARE VICTORS**



*Republican Majority Is Possible In Senate, the First in 26 Years*





# Striding, Striding, Behold the Goal!

*Today the House of Representatives approved an amendment to H.R. 6933, the Patent Law Act of 1980....*

*Passage of H.R. 6933 will be seen in coming years as one of the most important first steps taken toward turning around our innovation and productivity problems, and I am proud of having been a part of this endeavor.*

— **News From Birch Bayh,** November 21, 1980



# Come On, Jimmy Sign It!!!

*If any Bill shall not be returned by the President within ten Days (Sundays excepted) after it shall have been presented to him, the Same shall be a Law, in like manner as if he had signed it,* ***unless the Congress by their adjournment prevents its Return, in which case it shall not be a law (emphasis added).***

**— United States Constitution, Article 1, Section 1**





# And on the Last Day, He Acted (You Deserve a Nobel Prize)

**Ninety-Sixth Congress of the United States of America at the Second Session**

***An Act***
*to amend the patent and trademark laws*

---

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That title 35 of the United States Code, entitled 'Patents,' is amended by adding a new chapter 30.*

**— Approved by President Jimmy Carter, December 12, 1980**

# However the Bureaucracy Lives...



**New Patent Law — A battle brews over alleged changes**

*Several legislators and concerned patent experts are saying that the guidelines spelling out how to grant patent rights to small businesses and universities will remove many of the concessions in the law itself.*

**— Chemical Engineering, April 6, 1981**

After a two year battle, the regulations were rescued from an attempted hijacking

# The End



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**From:** <jallen@nttc.edu>
**To:** <user21@browdyneimark.com>
**Date:** Tue, May 13, 2003 11:28 AM
**Subject:** ARTI RAI OUTLINE FOR HHMI CONFERENCE

Here's her outline for the same meeting.

----- Forwarded by Joe Allen/NTTC on 05/13/2003 11:26 AM -----

"Leonard, Joan" <leonardj@hhmi.org>
05/13/2003 10:10 AM

To: "Allen, Joseph P. (E-mail)" <jallen@nttc.edu>, "Brinton, Joyce (E-mail)" <joyce_brinton@harvard.edu>, "Granahan, Patricia (E-mail)" <granahan@wi.mit.edu>
cc: "Rai, Arti K. (E-mail)" <akrai@law.upenn.edu>
Subject: ARTI RAI OUTLINE FOR HHMI CONFERENCE

(See attached file: rai.hhmi.presentation1)

OUTLINE FOR HHMI CONFERENCE
Arti K. Rai
5/28/03

BAYH-DOLE AND THE COMMERCIALIZATION OF SCIENCE

Bayh-Dole: A Brief History

A. Limited Nature of Evidence that FSIs Were Not Being Utilized/Commercialized
B. Political Economy of Bayh-Dole's Passage

Bayh-Dole: Difficulties in Evaluating Success

A. What Are the Appropriate Metrics for Measuring Commercialization?
B. Correlation vs. Causation
    1. Multiple Variables May Have Contributed to Biomedical Progress, 1980-2003 (e.g., Rise of Science, Strengthening of Patent System)
    2. Impossibility of Running Controlled Experiment
C. Tensions Between Short-Term and Long-Term Commercial Progress (the latter being closely tied to unencumbered research)
D. Tensions Between Commercial Progress and University Interests

Safeguards (Bayh-Dole and Beyond)

A. March-in Rights
B. "Exceptional Circumstances" Declarations
C. Government Right to "Practice or Have Practiced" FSIs
D. Possible Strengthening of A,B,C
E. Open Science Norms and Collective Action By Universities

Related Challenges

A. Alternative Research and Commercialization Models (e.g. open source biology)
B. Assessing Patentability Standards, especially Nonobviousness and Patent Breadth

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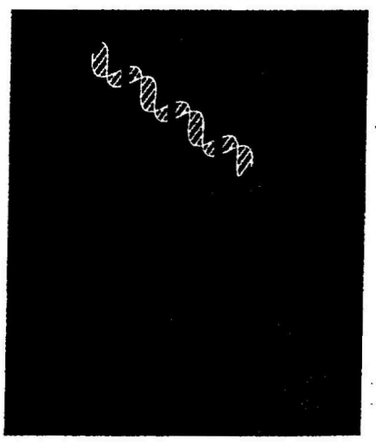
To: Mike Remington
From: Norm Latker
R. call
202-628-
5197

# Razing the Tollbooths

A call for restricting patents on basic biomedical research By GARY STIX



**The Bayh-Dole Act,** a 1980 law intended to prod the commercialization of government-supported research, gave universities a major role in ushering in the new era of biotechnology. The law fulfilled legislators' most ambitious expectations by encouraging the patenting of academic research—and the exclusive licensing of those patents to industry. In 1979 universities received a mere 264 patents—a number that in 2000 rose to 3,764, about half of which went to biomedical discoveries. The 14-fold increase far outpaced the overall growth in patents during that period. A few voices in the intellectual-property community have now charged that Bayh-Dole has gone too far. Patents, they claim, have been granted on the fruits of biomedical research that should remain in the public domain. In recent co-authored articles, Arti K. Rai of the University of Pennsylvania and Rebecca S. Eisenberg of the University of Michigan at Ann Arbor have proposed reform of the law, contending that development of new biopharmaceuticals and related technologies has been hindered by extending patent coverage beyond actual products to basic research findings. DNA sequences, protein structures and disease pathways should, in many cases, serve as a general knowledge base that can be used freely by everyone.

Rai and Eisenberg cite the case of a patent obtained by teams at Harvard University, the Massachusetts Institute of Technology and the Whitehead Institute for Biomedical Research in Cambridge, Mass. It covers methods of treating disease by regulating cell-signaling activity involving nuclear factor kappa B (NF-κB), which controls genes for processes ranging from cell proliferation to inflammation in various maladies. Those institutions and Ariad Pharmaceuticals (also in Cambridge), the exclusive licensee of the patent, are now suing Eli Lilly, claiming that two of its drugs—one for osteoporosis, one for sepsis—infringe the patent. Ariad has contacted more than 50 other companies that are researching or commercializing drugs that work through this pathway, asking them for licensing fees and royalties. The broad-based patent does not protect specific drugs. Instead it has become a tollbooth for commercial drug research and development on the NF-κB pathway. "In this case, as in many others, upstream [precommercial] patents issued to academic institutions serve as a tax on innovation, diluting rather than fortifying incentives for product development," the authors wrote in the winter-spring issue of *Law and Contemporary Problems.* (Their other article on the Bayh-Dole Act appeared in the January-February issue of *American Scientist.*)

Rai and Eisenberg suggest that the law should be altered to make it easier for the government—in particular, the National Institutes of Health—to specify that such upstream research remain public and not be subject to patents. They also recommend facilitating the government's ability to mandate the nonexclusive licensing of a patent at reasonable rates. Both actions are permitted under the current law but have almost never been exercised; the law makes it cumbersome to do so.

Fiddling with Bayh-Dole does bear risks. For instance, an executive-branch agency such as the NIH could be subject to political pressure in barring patents: an administration opposed to using embryos in scientific investigations might order an agency to withhold patents on such research. But university technology-transfer offices, Rai and Eisenberg contend, cannot be entrusted to make decisions about when to forgo patenting, given that a big part of their mission is to bring in licensing revenues. So more leverage is needed to ensure that basic biomedical research remains open to all. SA



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**From:** <jallen@nttc.edu>
**To:** <user21@browdyneimark.com>
**Date:** Tue, May 13, 2003 11:28 AM
**Subject:** My Presentation to Howard Hughes Medical Center

In the attachment below is my presentation to the Howard Hughes Center for May 28. Just got Arti Rai's outline (Razing the Tollbooths) and will send it to you. Would appreciate your thoughts on her points (such as they are).

----- Forwarded by Joe Allen/NTTC on 05/13/2003 11:24 AM -----

"Leonard, Joan" <leonardj@hhmi.org>
05/13/2003 10:06 AM

To: "Brinton, Joyce (E-mail)" <joyce_brinton@harvard.edu>, "Granahan, Patricia (E-mail)" <granahan@wi.mit.edu>, "Rai, Arti K. (E-mail)" <akrai@law.upenn.edu>
cc: "Allen, Joseph P. (E-mail)" <jallen@nttc.edu>
Subject: Hughes.ppt

Dear panelists,

I attach below Joe Allen's Power Point presentation for you information. I will be sending Joyce's and Arti's right behind (sorry, I have not mastered the art of multiple attachments!). I expect that Pat's will be coming along in a couple of days.

Joan

<<Hughes.ppt>>
(See attached file: Hughes.ppt)

(See attached file: Hughes.ppt)

*Robert C. Byrd*
**National Technology Transfer Center**

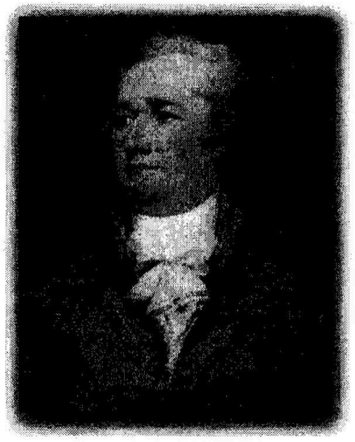
*Partnerships that make commercialization happen!*

# Howard Hughes Medical Institute Conference

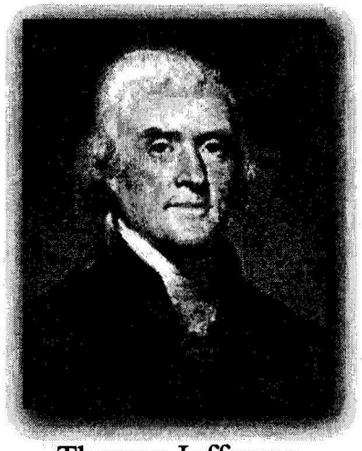
May 28, 2003

*– Joseph P. Allen*
*President*

# Decentralized v. Centralized Power



Alexander Hamilton



Thomas Jefferson

# Bayh-Dole: 1978-79

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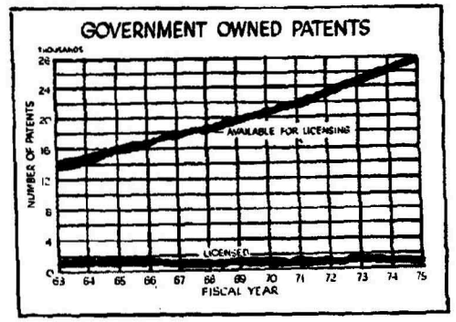
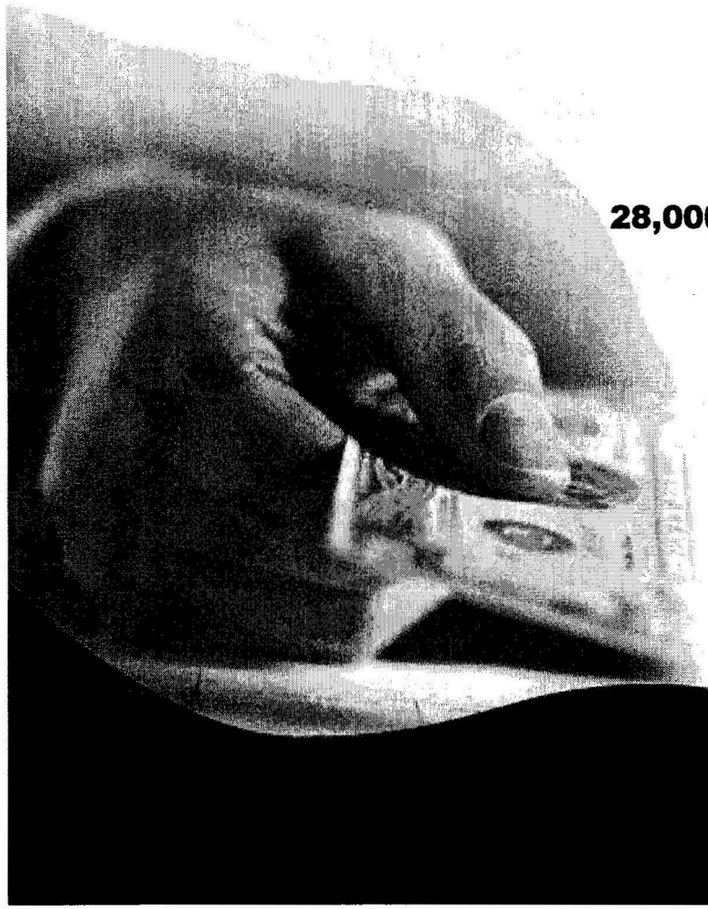
- Innovation Crisis
- Chrysler Bailout
- Midwest Rustbelt
- USSR Invades Afghanistan
- Debacle in the Desert: Carter Rescue Attempt Fails
- End of the American Dream? Japan as #1
- Energy Crisis: Freezing in the Dark?
- Iran Seizes Hostages
- U.S. Imposes Grain Embargo; Boycotts Olympics



# What's happening to our federal R&D dollars?





**28,000 government owned inventions; less than 4% licensed**

We found that hundreds of new compounds developed at university laboratories had not been tested and screened by the pharmaceutical industry because manufacturers were unwilling to undertake the expense without some possibility of obtaining exclusive rights to further development of the product.

**– 1968 General Accounting Office study of Dept. of Health, Education and Welfare for President Lyndon B. Johnson**

*National Technology Transfer Center*

# Bayh-Dole First Introduced

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— **Senator E**

"A wealth of scientific talent at American colleges and universities-- talent responsible for the development of numerous innovative scientific breakthroughs each year-- is going to waste as a result of bureaucratic redtape and illogical government regulations..."

"The problem, very simply, is the present policy followed by most government agencies of retaining patent rights to inventions., " Bayh said. He noted: "Government sponsored research is often basic rather than applied research. Therefore, many of the resulting inventions are at a very embryonic stage of development and require substantial expenditures before they actually become a product or applied system of benefit to the public.

"It is not government's responsibility-- or indeed, the right of government-- to assume the commercialization function, " Bayh pointed out. "Unless private industry has the protection of some exclusive use under patent or license agreements, they cannot afford the risk of commercialization expenditures. As a result, many new developments resulting from government research are left idle."

— **Senator Birch Bayh's introductory statement, *September 13,***



# A Price is Paid

## *Patent Bill Seeks Shift to Bolster Innovation*

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The Bayh-Dole bill is a sort of testimonial to Norman Latker, a hero among university researchers and licensing proponents. Latker was patent counsel at the Department of Health, Education and Welfare until his unceremonious firing in December for what officials say was conduct and judgment not up to the department's professional standards. Latker's fans say he was let go for doing his job too well...

He is credited with developing an elaborate arrangement at HEW, called Institutional Patent Agreements, that easily transferred patents out of the government. That was fine with the Republicans in the Nixon and Ford years. But to the Carter people, it appeared that Latker was giving away the store.

Senior officials at HEW ordered an extra step to review all of Latker's decisions. As a result, the decisions on pending patent requests were delayed. The universities were miffed. They started complaining to Congress. Latker complained, too.

That's when Bayh and Dole stepped in. Dole charged HEW with "pulling the plug" on biomedical research by holding up action on important new drugs and medical devices. HEW responded quickly. It released some patents- - and it also let go of Latker (emphasis added).

— The Washington Post, April 8, 1979

# Let the Game Begin

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Hearings
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Prior to the effective date of the IPA, December 1, 1968, no invention made at the University of Wisconsin with funds from DHEW (Department of Health, Education and Welfare) had been licensed to industry-- one invention not falling under the IPA was licensed after that date. Since December 1, 1968, the Wisconsin Alumni Research Foundation has received a total of 69 invention disclosures under the Institutional Patent Agreements, has filed 79 applications on 55 of these disclosures and has had 55 U.S. patents issued.

A total of 20 licenses were issued under one of more of these patents and patent applications, of which 14 are still extant.

— Testimony of Howard W. Bremer, WARF

In my opinion, government contractors- including small businesses and universities- should not be given title to inventions developed at government expense. That is the gist of my testimony. These inventions are paid for by the public and therefore should be available for any citizen to use or not as he sees fit.

— Testimony of Admiral Hyman B. Rickover, "Father of the Nuclear Navy"

Hearings Before the Senate Judiciary Committee on the University and Small Business Patent Procedures Act (May 16 and June 6, 1970)

# Over the First Hurdle

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The bill is designed to promote the utilization and commercialization of inventions made with government support ... Ultimately, it is believed that these improvements in government patent policy will lead to greater productivity in the United States, provide new jobs for our citizens, create new economic growth, foster increased competition, make government research and development contracting more competitive, and stimulate a greater return on the billions of dollars spent each year by the Government on its research and development programs.

— Senate Judiciary Committee Report, December 12, 1979 *on Bayh-Dole, unanimously approved and reported to the Senate*



# No One Said It Would Be Easy

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Dear Colleague:

When the Senate takes up S. 414, a bill to establish a uniform federal patent policy for small businesses and nonprofit organizations, we intend to offer an amendment extending this policy to all government contractors.

**— February 5, 1980 to all Senators from Senators Cannon, Stevenson, Packwood and Schmitt**

"This i

"This is the worst bill I have seen in my life"

**— Senator Russell Long to Bayh's staff**

# I Think I Can, I Think I Can

*Senate*
*Industr*

## *Senate Passes Legislation to Stimulate Industrial Productivity and Innovation*



*A Special*
STATUS REPORT
*from* **BIRCH BAYH**

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What sense does it make to spend billions of dollars each year on government-supported research and then prevent new developments from benefiting the American people because of dumb bureaucratic redtape?

— **News From Birch Bayh,**
*April 23, 1980 reporting on the approval of S. 414 (Bayh-Dole) by the U. S. Senate on a 91-4 vote*

# But the House is Going Another Direction

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Dear Birch:

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S. 414, the Senate, b
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vigorously oppose a
include big business.

United States Senate
COMMITTEE ON FINANCE
WASHINGTON, D.C. 20510
September 24, 1980

Dear Birch:

As you know, H. R. 6933 expands the scope of the Senate passed patent policy legislation, S. 414, to allow the give-away of the benefits of billions of dollars of public financed research to the largest and most dominant corporations in the United States. During consideration of S. 414, the Senate, by a vote of 60 to 34, rejected a similar amendment. You and I stood together in opposition to this anti-competitive and unwarranted proposal. During Senate consideration of S. 414, you repeatedly stated you would vigorously oppose any expansion of that legislation to include big business.

Sincerely yours,

United States Senate
COMMITTEE ON THE JUDICIARY
SUBCOMMITTEE ON THE CONSTITUTION
WASHINGTON, D.C. 20510

September 26, 1980

Dear Russell:

My own strong conviction has been that the present patent policies unfairly discriminate against small businesses and universities who are denied patent rights routinely granted to larger contractors. Because small businesses and universities have such a distinguished record of producing innovative products this pattern is more than unfair — it adversely affects American innovation.

Therfore, I will offer an amendment to bring any House passed patent policy into conformity with that already passed by the Senate, which as you know is strictly limited to universities and small businesses.

Sincerely,

Birch Bayh
United States Senator

# Uh, Oh, We're Unemployed...

"All the News That's Fit to Print"

The New York Times

LATE CITY EDITION

VOL. CXXX... No. 44,784 NEW YORK, WEDNESDAY, NOVEMBER 5, 1980 35 CENTS

## REAGAN EASILY BEATS CARTER; REPUBLICANS GAIN IN CONGRESS; D'AMATO AND DODD ARE VICTORS



*Republican Majority Is Possible*

*In Senate, the First in 26 Years*

# Striding, Striding, Behold the Goal!

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— **News From Birch Bayh,** November 21, 1980





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**— United States Constitution, Article 1, Section 1**



National Technology Transfer Center

# And on the Last Day, He Acted

*(you deserve the Noble Prize)*

Nine

Ninety-Sixth Congress of the United States of America at the Second Session

***An Act***

*to amend the patent and trademark laws*

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**— Approved by President Jimmy Carter, December 12, 1980**

# However the Bureaucracy Lives...

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## *New Patent Law — A battle brews over alleged changes*

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**— Chemical Engineering, April 6, 1981**

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After a two year battle, the regulations were rescued from an attempted hijacking



# Now, How About Federal Labs?

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The United States can no longer afford the luxury of isolating its government laboratories from university and industry laboratories. Already endowed with the best research institutions in the world, this country is increasingly challenged in its military and economic competitiveness. The national interest demands that the federal laboratories collaborate with universities and industry to ensure continued advances in scientific knowledge and its translation into useful technology. The federal laboratories must be more responsive to national needs.

**— Federal Laboratory Review Panel (chaired by David Packard) report to President Reagan, 1983**

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Senator Dole introduces legislation giving technology transfer authorities to all Government labs as an amendment to Bayh-Dole. Congress approves extending rights to university operated federal labs in 1984. Federal Technology Transfer Act passed in 1986 extending authorities to Government-operated labs, but under the Stevenson-Wydler Act.

# Innovation's Golden Goose

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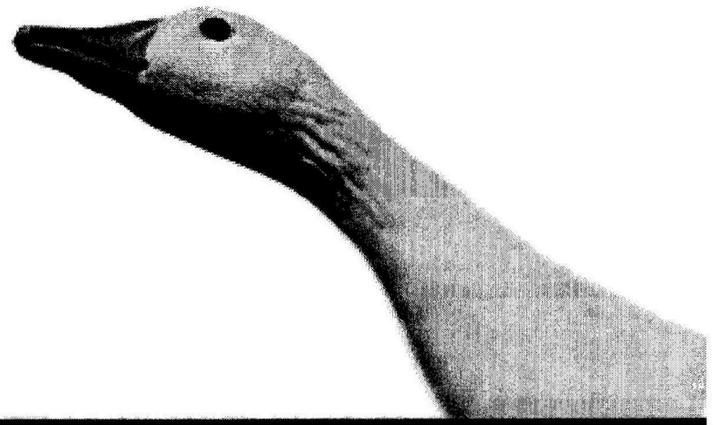
Possibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole act of 1980. Together with amendments in 1984 and augmentation in 1986, this unlocked all inventions and discoveries that had been made in laboratories throughout the United States with the help of taxpayer's money. More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance.

— The Economist Technology Quarterly, December 14, 2002



National Technology Transfer Center