BIDEN	Ed Williams	5042				
BROOKE	Mike Jones	2742				
BUMPERS	Richard Arnold	4843				
BURDICK	Tom Burgan	2551				
BYRD (VA)	Roger Sintillar	4024				
BYRD (W. VA)	Tom Hart	3954				
CANNON	Bruce Agers	6244				
CASE	Mike Maloof	3224				Co-sponsor
CHAFEE	Cynthia Lerch	4921				
CHILES	Ruth Knight	5274				
CHURCH	Barry Berkoff	6142				
CLARK	Vicky Smith	3254				
CRANSTON	Betty Hight	3553				
CULVER	Paul Harstead	3744				
CURTIS	Jerry Vigoda	4224				
DANFORTH	Chris Brewster	6154				
DeCONCINI	Romano Romani	4521				Co-sponsor
DOLE	Brenda Levenson	6521				sponsor
DOMENICI	George Ramonas	6621				Co-sponsor
DURKIN	Jane Yanulas	3324				
EAGLETON	not sure	5721				
EASTLAND	Frank Barber	5054				
FORD	Dave Leiter	4343				
GARN	Lincoln Oliphant	5444				Co-sponsor
GLENN	Walker Nolan	3353				
GOLDWATER	Terry Emerson	2235				
GRAVEL	Richard Aks	6665				
GRIFFIN	Mark Steinberg	6221				
HANSEN	Will Haley	3424				
HART	Bill Shore	3552				

	Linda Labastian						
HOLLINGS	not sure	6121					
HUDDLESTON	Roger Lamaster	2542					
HUMPHREY	not sure	3244					
INOUYE	not sure	3934					
JACKSON	Joel Merkle	5441					
JAVITS	Carol Corcoran ~~Brian Conboy~~	6542					
JOHNSTON	Cindy Shade	5824					
KENNEDY	Ken Feinberg/Tom Sussman	3543					
LAXALT	Al Regnery	3542					
LEAHY	Sue Braniken	4242					
LONG	Bruce Feingerts	4623					
LUGAR	Bob Kabel	4814					Co-Sponsor?
MAGNUSON	Elizabeth Nash	2621					
MATHIAS	Ralph Oman	4654					Co-Sponsor
MATSUNAGA	Jerry Comcowich	6361					
McCLURE	Blake Hall	2752					
McGOVERN	Alan Stone	2321					Co-Sponsor
McINTYRE	Elizabeth Webb	2841					
MELCHER	Wayne Mehl	2644					
METZENBAUM	Jesse Sidnor	2315					Co-Sponsor
MORGAN	Hans Endorf	3154					
MOYNIHAN	Jim Mors	4451					
MUSKIE	Jim Case	5344					
NELSON	Jerry Sturgis	5323					
NUNN	Gordon Giffin	3521					
PACKWOOD	Ann Reifenberg	5244					
PEARSON	Richard Walker	4744					
PELL	Bradford Penny	4642					
	~~Ken Ackerman~~ Jerry Block	2152					

SCHWEIKER	Doug Ham	4254				
SCOTT	not sure	2023				
SPARKMAN	Eddie Sokol	4124				
STAFFORD	Mike Francis	5141				
STENNIS	Jim Kendall	6253				
STEVENS	Becky Gernhardt	3004				
STEVENSON	John Stewart	2854				
STONE	Tom Moore	3041				
TALMADGE	Randy Knuckles	3643				
THURMOND	~~Eric Hultman~~ Hugh Hadden	5972				Co-sponsor
TOWER	Pam Turner	2934				
TSONGAS	Pat Hoff	6441				
WEICKER	not sure - staffer has name	4041				
WILLIAMS	Paul Skrabot	4744				Co-sponsor
YOUNG	Not sure	2043				
ZORINSKY	Jim Melin	6551				

COMPARATIVE STATISTICS FOR FISCAL YEAR 1975 FOR THE MAJOR R & D AGENCIES OF THE EXECUTIVE BR

	DHEW	ERDA	ARMY	NAVY	AIR FORCE	NASA	INTERIOR	USDA
1. Agency R & D Budget in Millions	2,404	1,907	1,872	3,121	3,346	3,065	305	423
2. Number of Agency Patent Attorneys (including agents) as of Jan. 1977	3	60	70	87	36	32	5	10
3. Total Number of Invention Disclosures Received	260	1,125	998	1,585	1,033	1,138	134	131
4. Invention Disclosures Requiring A Determination of Government Interest and/or Patenting.[B]								
Employee	39	35	619	898	146[C]	259	72	127
Contractor	144	1,090	173[C]	498[C]	426[C]	841	62	4
Total	183	1,125	792	1,396	572	1,100	134	131
5. Number of Invention Reports Processed per Attorney (4 ÷ 2)	61	19	11	16	16	34	27	13
6. Total Patent Applications Filed by Department.	56	277	423	688	188	198	56	146
7. Number of Patent Applications Filed per Patent Attorney (6 ÷ 2)	19	4.6	6	7.9	5.2	6.2	11.2	14.6
8. Percentage of Item 4 Above on Which Patent Applications were filed (6 ÷ 4)	30%	24%	53%	50%	33%	18%	42%	100%
9. Number of Determinations Giving Greater Rights in Identified Inventions	37	8	6	11	10	39[D]	1	0
10. Number of R & D Contracts with Patent Clauses	4,230	204	2,458	2,569	2,277	1,447	505	63
11. Number of R & D Grants with Patent Clauses	14,639	0	5	0	127	422	269	57
12. Exclusive Licenses Granted on Patent and Patent Applications in Department's Patent Portfolio from 1971 through 1976.	19	- [E]	0	0	0	11	0	0

A/ The DHEW Patent staff is currently handling all of the VA's and AID's patent problems in cases related to the Depart

B/ Disclosures in which the contractor has exercised its first option to retain title based on a contract clause provid in this item, which explains the difference in totals between items 2 and 3.

C/ Substantially all of these disclosures represent inventions in which the contractor had a first option to retain tit indicating that these inventions had no substantial commercial potential.

D/ These determinations were handled by the NASA "Inventions and Contributions Board," not by the NASA patent staff.

E/ (-) Fiscal Year 1976 data not available yet, but 0 through Fiscal Year 1975.

Statistics for 1, 3, 4, 6, 9, 10, 11 and 12 derived from Annual Report on Government Patent Policy - Federal Council for

Office, DHHS, c/o NIH, Bethesda, MD 20892, telephone: (301)402-0850. This should be done prior to any publication or presentation of the invention at an open meeting, since failure to report at the appropriate time is a violation of 35 USC 202, and may result in loss of the rights of the applicant institution, inventor, and Federal Government in the invention. All foreign patent rights are immediately lost upon publication or other public disclosure unless a United States patent application is already on file. In addition, statutes preclude obtaining valid United States patent protection after one year from the date of a publication that discloses the invention.

F. ASSURANCES AND CERTIFICATIONS

The assurances listed below may not be applicable to your project, program, or type of applicant organization. Refer to the PHS *Grants Policy Statement* for further clarification about applicability, or contact the awarding agency (See the DRG Grants Information Office Publication List to obtain a copy of Grants Administration Information Sources.) **In signing the application face page, the duly authorized representative of the applicant organization certifies that the applicant organization will comply with the following:**

1. Human Subjects

The DHHS regulations for the protection of human subjects provide a systematic means, based on established, internationally recognized ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the DHHS. The regulations stipulate that an applicant organization, whether domestic or foreign, bears responsibility for safeguarding the rights and welfare of human subjects in DHHS-supported research activities. The regulations require that applicant organizations proposing to involve human subjects in nonexempt research, file a written Assurance of Compliance with the Office for Protection from Research Risks (OPRR), establishing appropriate policies and procedures for the protection of human subjects. These regulations, 45 CFR 46, Protection of Human Subjects, are available from the OPRR, National Institutes of Health, Bethesda, MD 20892, Telephone: (301) 496-7041.

The regulations define "human subject" as "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information." The regulations extend to the use of human organs, tissues, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable state and local law and is not directly regulated by 45 CFR 46.

Research activities in which the only involvement of human subjects will be in one or more of the following six categories are exempt from coverage by the regulations:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special educational instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subjects' responses outside the research could reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior is not exempt under paragraph(2)(b) of this section, if: (a) the human subjects are elected or appointed public officials or candidates

NOT CRISP
W54 GM62114
CRL TECH
G.A.O.
301-496-5643

301-594-5135
NIGMS YVONNE WILLIAMSON
Bldg. 45 Rm. 2AN-32
45000 Rockville Pike
Bethesda, MD 0892

May 4, 1990

Mr. Peter Velde
Suite 310
905 16th St. N.W.
Washington, D.C. 20006

Dear Pete,

Barry Beringer suggested that a position on Senator Dole's staff may be available for someone with my background. I would be interested and am enclosing my C.V. for consideration. As you may recall, virtually all of the legislative initiatives listed in my C.V. were done under the Senator's sponsorship.

I will be out-of-town from May 5-18 and will be available after that time at 951-0375 on 5112 Edgemoor Lane, Bethesda, Maryland 20814.

Thanks,

Norm Latker

1960-1965	
1963	Presidential Memo on Patent Policy
1965	NL and Ronald Wylie: "Utilization of Govt owned Health and Welfare Inventions
1960	Study of subcommittee on Patents, Trademarks and Copyrights "The Patent System: Its Exonomic and Social Basis

1971	
July 20, 1971	NL: Letter to James Whittaker, Snr Pat Cnsl, Radio Corp of America
July 29, 1971	NL: Presentation before Commission on Govt. Procurement
Nov 11, 1971	Report by Task Force #1 Study Group #6 on allocation of rights to inventions

1973	
Apr 2-5, 1973	"Availability of New Technology to Industry from American Universities & Technological Institutes" NL: Presentation before Nat. Congress on (Dvorkovitz), Chicago, IL
May 15, 1973	Science & Govt. Report: NSF Patent Shift To Benefit Universities *

1974	
Feb 4-7, 1974	NL: "Progress Towards A Uniform US Govt. Patent Policy for Universities

Aug 18, 1978	Letter to NL from Senator Bob Dole refereing to Congressional Record, Senate

1979	
March 1, 1979	NL: Address to 2nd Ann TechEx Luncheon, Atlanta GA
Apr 5,6, 1979	Letters from Birch Bayh
April, 1979	Chrysler v. Brown, U.S.S.Ct
May 1979	Bioscience article, Vol 29, 5, "New Patent Policy Bill Gathers Congressional Support" by Robert Henig
3 Aug, 1979	Science article, Vol 205, "Patent Bill Returns Bright Idea to Inventor" by Bill Broad
July 1979	Testimony by Dr Betsy Ancker Johnson on Bayh-Dole

1980	
Feb 28, 1980	Re Bayh-Dole and Carter's Oct 31, 1979 statement on Industrial Innovation
Dec 12, 1980	Carter signs into law Bayh-Dole: Betsy Ancker-Johnson's description

1978	
Jan 5, 1978	NL: DHEW Patent Policy Draft requested by Califano Attachments: A: Federal Security Agency B: General Administration, Patents & Inventions, Ch. 6-10 C: "Exceptional Circumstances under s. 1(a)" D: Memo on Patent Policy to Surgeon General, PHS, Apr 18, 1962 by Kenneth Endicott; E: Memo from James Shannon "Need for change in Dept Patent Policy to Permit effective collaboration with Industry" F: Manual Hiller Memo: "Need for change.... G: Testimony by Janes Shannon H: Report to Congress, Aug 12, 1968, Problem Areas Affecting Usefulness of Results of Govt-sponsored Reearch in Medicinal Chemistry I: Cahp I-901 Department Patent Activities – Purposes; Responsibilities J: Letter from David McBride (U of Rochester) to Califano (Oct 1977) K: Report of the Commission on Federal Paperwork, Apr 29, 1977 L: NL NL: Report of the University Patent Policy Ad Hoc Subcommittee of the executive Subcommittee of the Committee on Govt. Patent Policy, Federal Council For Science & Technology K: Sampling of University Patent Licensing Programs L: Extract from Title 41, Public Contracts, Property Management
Jan 17, 1978	Sherry Arnstein's reactions
Nov 7, 1979	Letter from Califano to Joseph Stetler, Pharmaceutical Manufacturers Assoc.
Feb 6, 1978	NL: Presentation before 3rd Ann Meeting Society Univeristy Patent Administrators, Atlanta GA
Feb 10, 1978	Letter to Joel ? re Califano that NL did not send
Apr 11, 1978	NL: Letter to Newton Cattell, Association of American Universities, re: forcoming Nelson hearings
July 13, 1978	HEW Patent Policy

	& Non-Profit Organizations" Address at Second Annual University/Industry Forum (Dvorkovitz), Chicago, IL
Oct 15, 1974	NL: Presentation at Conference on Technology Transfer – "University Opportunities and Responsibilities" Case Western Reserve University

1975	
Feb 3-7, 1975	NL: "Current Trends in Technology Transfer" 3rd Annual U/Industry Forum Technology Exchange (Dvorkovitz)
July 1975	NL: Report of the University Patent Policy Ad Hoc Subcommittee of the executive Subcommittee of the Committee on Govt. Patent Policy, Federal Council For Science & Technology
Sept 18, 1975	NL: "Current Trends in Govt. Patent Policy" Presentation before New Jersey Patent Bar Association
Nov 5, 1975	Remarks delivered by Dr Betsy Ancker-Johnson, Asst. Sec. of Commerce for Science & Technology, at 17th Ann. Meeting of National Council of University Research Administrators
Nov 19, 1975	NL: "Protection of Intellectual Property under the 4th Exemption of the Freedom of Information Act" Presentation before Academy of Pharmaceutical Sciences, Atlanta, GA

1976	
Jan 8, 1976	NL: "Current Govt. Patent Policy as Applicable to Universities & Nonprofit Organizations" Presentation at American Patent Law Association Meeting, DC
Jan 14, 1976	Letter to Dr Betsy Ancker-Johnson, Chairman, Committee on Govt. Patent Policy, Commerce, from Dr Lowell Harmison, Special Asst. to Assist Sec for Health
May 7, 1976	Preliminary Explanatory Comments Accompanying Draft Legislation: Congressional Record-House, Apr 26th, 1976
Aug 19, 1976	Section-By-Section Analysis: Title I-Federal Intellectual Property Policy
Aug 19, 1976	Statement of Purpose and Need
Sept 29, 1976	NL: Statement before Subcommittee on Domestic & International Scientific Planning and Analysis Committee on Science & Technology House of Representatives
Oct 1, 1976	Statement of Dr Betsy Ancker-Johnson to Subcommittee on Domestic & International Scientific Planning and Analysis Committee on Science & Technology House of Representatives (A-J's testimony on Thornton Bill)
Dec 7-9, 1976	Presentation to Dept of Air Force (written speech)
1979	Letters re IPAs
1976?? FOA	Comments on Impact of Public Disclosure on Proprietary Interests or Patent Rights in Information Contained In Research Protocols....FOA

1977	
Jan 5, 1977	Information Item #47 Comments by NL on paper by James Wallace "Legal Analysis of Public Disclosure Requirements Relevant to Applications for Biomedical Research Grants"

Jan 20, 1977	NL: "Ethical and Economic Issues: University Policies for consulting, Overload Instruction Activities and Intellectual Property" Before the 2nd Annual Academic Planning Conference, U of S. California
Jan 28, 1977	Letter from Phillip Handler, Pres. National Academy of Sciences, to Charles Lowe, National Commission for Protection of Human Subjects in Biomedical & Behavioral Research
Feb 28, 1977	"Two Cultures in the Laboratory" by D Stetten; Reply: Jacobs, Mar 4,1977: 'Thoughts Responsive to "Two Cultures..."'
Mar 16, 1977	Statement by Dr Betsy Ancker-Johnson, before Subcommittee on Health and Environment of House Committee on Interstate & Foreign Commerce
Apr 16, 1977	NL: Cleveland Speech (+ Sampling of University Patent Licensing Programs)
Apr 29, 1977	From: "Report of the Commission on Federal Paperwork"
May 2, 1977	C&EN article: "Drug industry performances continues to slip"
May 26, 1977	NL: statement before the Subcommittee on Science, research & Technology House of Representatives
June 6, 1977	NL: "Current Trends in Govt. Patent Policy" before conference on University Research Management, NY University
July 19, 1977	NL: Letter to Robert Swanson, Pres. Genentech
Aug 19, 1977	NL: Letter to Robert Gellman, Subcommittee on Govt. Information and Individual Rights
Sept 9, 1977	Memo FROM Federal Coordinating Council for Science, Engineering & Technology Committee on Intellectual Property & Information for Members of Subcommittee on Intellectual property: re HR 6249: THORNTON BILL- April 6, 1977
Dec 12, 1977	Federal Patent Policy and HR 8596 (THORNTON)
Dec 22, 1977	Study of Health Technology Management, DHEW ("A")
Nov 22, 1977	Attachments to above ("B"): NL's comment to David Cooper on Study of Health Technology Management, DHEW; hand-written comment by NL; comment from Donald Fredrickson; comments various on the Report; Summary & Decision; paper by Sherry Arnstein of Jan 11, 1977; draft by Barry Leshowitz; misc. "C" previous draft of Report

comments made to titillate the imagination of the listener

"Science to important for Scientists"
"HEW is unmanageable because it has never been managed"

The "Lund Fikar" is the evidence that these comment are not merely idle eyebrow but are the road map to the Sec's total control of science decision making. —

illustrations
a) Verzon firing — replaced by "33 year old "Lund Fikar member"
b) patents — Libassi — William Cartland
c) DNA guideline review chaired by Libassi
d) Fordham — Richmond
e) Califano media exposure ⟵ legionnaire disease; 15 indictments; DES; measles
f) Gori incident —
g) AAAC ~~*~~ —
h) Contracts ⟵
i) Office of Education.
j) Forwarded planning — Health research — ~~[illegible]~~ "5 year plan"
K) ~~[illegible]~~ Health Hazards due to low level radiation — chaired by Libassi. Radiology health

Circulate

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

Patents

OFFICE OF THE
GENERAL COUNSEL

OCT 3 10 43 AM '78

OCT 02 1978

MEMORANDUM

TO : All Assistant General Counsel's

FROM : Deputy General Counsel

SUBJECT: OGC Clearance -- Memoranda to the Secretary

On several occasions the Secretary has received memoranda prepared by an Assistant Secretary or head of a POC or other program person, which states that the Office of the General Counsel has approved the recommendation stated therein or has otherwise expressed an opinion. If any such memoranda come to your attention before they are sent to the Secretary, please be sure that the reference to OGC identifies specifically, by name and title, the most senior attorney that has presented our position or approved the position set forth in the memorandum.

Richard T. Beattie

THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE
WASHINGTON, D.C. 20201

MAY 15 1978

KMA
RCK
NJL

MEMORANDUM FOR THE GENERAL COUNSEL

SUBJECT: Radiation Exposure Inquiry

I have attached the May 9th memorandum from Stuart Eizenstat and Zbigniew Brzezinski which enumerates four aspects of the problem of radiation exposure on which the White House wants HEW to assume leadership in fashioning an action plan for review by June 1.

I want you to lead the HEW task group on this assignment, working closely with Dr. William H. Foege, the Director of CDC, and representatives of other PHS offices who will help shape the technical aspects of the workplan.

You and Dr. Foege should submit a draft plan to me by May 23. It should identify responsibilities and deadlines for each affected agency of the Executive Branch.

After I have reviewed the HEW draft plan, a meeting will be scheduled with the other Federal agencies involved. I would hope this meeting can occur on or before May 26. Please make contact with the other Executive agencies involved (Defense, Energy, and the VA) and work out the details of the inter-agency consultations.

I want to make every effort to meet the June 1st date for submission of a draft plan to the White House.

Joseph A. Califano, Jr.

cc:

Dr. William H. Foege
Director, CDC

THE WHITE HOUSE

WASHINGTON

May 9, 1978

MEMORANDUM FOR

THE SECRETARY OF DEFENSE
THE SECRETARY OF HEALTH, EDUCATION AND WELFARE
THE SECRETARY OF ENERGY
THE ADMINISTRATOR OF VETERANS AFFAIRS

FROM: STUART EIZENSTAT
ZBIGNIEW BRZEZINSKI

SUBJECT: Radiation Exposure Inquiry

The President has approved the development of a coordinated response to the growing agency and Congressional concern about the effects of radiation exposure on participants in nuclear tests and workers in nuclear-related projects.

The Secretary of Health, Education and Welfare should coordinate the formulation of a program including the following:

1. A study or series of studies which would determine the effects of radiation exposure on participants in nuclear tests, including members of the armed forces and civilian personnel, workers at nuclear facilities and projects, and other persons as indicated.

2. A public information program to inform persons who might have been affected and the general public about the steps being taken and the conduct of the studies.

3. A plan for ensuring that persons adversely affected by radiation exposure receive the care and benefits to which they may be or should be entitled.

4. Recommendations on steps which can be taken to reduce the incidence of adverse radiation exposure of this type in the future.

We are aware that the Department of Defense has initiated a study and that the Center for Disease Control has undertaken at least two investigations. Our intent is that these efforts become a coordinated Administration approach to the problem. A proposed plan of action should be prepared for review by June 1, 1978.

PRIORITY

The staff of the National Security Council, the Domestic Policy Staff and the Office of Science and Technology Policy within the Executive Office are available to assist the interagency group.

...diation Probe Is Assigned to HEW

By Walter Pincus
Washington Post Staff Writer

The Department of Health, Education and Welfare has taken charge of the administration's study of the health effects of low-level radiation—a project that may turn out to be the biggest medical research program since the smoking studies of the 1960s.

It could also turn out to be a bureaucratic nightmare, since at least three government departments and another three agencies have institutional or regulatory issues at stake.

The investigation will focus on some 300,000 to 400,000 military and civilian personnel who participated in the government's nuclear weapons testing from the late 1940s through 1964—when atmospheric tests were halted—and several hundred thousand employes of government nuclear facilities.

The scientific community has long disagreed about the long-term cancer-causing effects of low levels of radiation.

Until late last month, the Department of Defense and Energy were the prime agencies directing inquiries into the effects of radiation exposure on participants in 1950s nuclear weapons tests and on workers in atomic facilities and laboratories.

These inquiries were a direct outgrowth of two reports: One that a statistically significant number of GIs who participated in a 1957 nuclear weapons test in Nevada came down with leukemia, a cancer of the blood, the other than an unusual number of former workers at nuclear submarine repair facilities at the Portsmouth, N.H., Naval Shipyard also developed cancer.

Hearings on those situations before a House subcommittee on health and environment last January forced the defense and energy agencies to develop plans to investigate both.

Last month, however, President Carter gave HEW that task and more.

According to a White House memo dated May 9, HEW is to draw up a coordinated governmentwide program that would also:

- Insure "that persons adversely affected by radiation exposure receive the care and benefits to which they may be or should be entitled."
- Inform people "who might have been affected" by low-level radiation and the public about "steps being taken and the conduct of the studies."
- Recommend "steps which can be taken to reduce the incidence of adverse radiation exposure of this type in the future."

The White House staff, according to informed sources, pushed the task on HEW because they did not feel defense and energy were impartial in their approaches.

"Energy looked on it as an energy problem," a Carter aide said recently, "and defense saw it as a defense problem. We wanted it treated as a health problem."

In turning the matter over to HEW, the White House didn't notify two key participants, the Environmental Protection Agency and the Nuclear Regulatory Commission. Both agencies have responsibility for worker and general public radiation standards.

Ironically, when the government reorganization acts of 1970 and 1974 were approved, setting up those agencies, responsibility for establishing governmentwide radiation safety standards was dropped. Today, neither agency has that specific duty.

Those same acts also did away with the Federal Radiation Council, which until the early 1970s coordinated intergovernmental research on radiation.

F. Peter Libassi, general counsel of HEW, now has the task of putting the president's radiation research program back together.

For the past several weeks, Libassi has been getting to know the interested groups both inside and outside government. Watching over his shoulder are environmental and industry groups who look on the radiation study primarily as a vehicle for either attacking or defending nuclear power facilities.

Tentatively, Libassi hopes to give the White House by Sept. 1 an outline of what needs to be accomplished.

There also is a possibility that a new commission will be proposed for continuing supervision of the intergovernmental program.

An early decision is needed on how to handle the claims of veterans for benefits for what they say are service-connected disabilities resulting from radiation absorbed during weapons tests.

The Veterans Administration is beginning to schedule hearings on appeals for these benefits. Since the serious research into the health effects of low-level radiation will require at least three more years, some of these cases may have to be decided before the results are in.

(1)

My Name is Norman Latker
as a private citizen
I am here to speak in defense
of the Bayh-Dole Act as it was
intended to be read and how it
has been practiced for 25 years.
The Act

which has fostered the development of a potent four-way partnership between researchers, their institutions, government and industry. This partnership has become a powerful engine of innovation, generating more practical advances than the rest of the world combined. Nowhere is this more true than in the fields of medical technology and pharmaceuticals.

1.*

The partnership could be viewed as a classic example of a "Nash Equilibrium" which involves a set of strategies, one for each participant such that No. participant has an incentive to unilaterally change its actions. The equilibrium of a change in strategies by any one of the participants would lead that participant to gain less than if it remained with its current strategy.

Should the petitioners succeed in subverting one of the key precepts of Bayh-Dole - that of according broad marketplace prerogatives to the developers of government-funded inventions - this marvelous engine could stall.

the equilibrium will be broken and

The Spirit Of Bayh-Dole

I hope I can provide some perspective on the Bayh-Dole Act, large portions of which I helped to draft back in the 1970s, when I served as Patent Counsel for the Department of Health, Education and Welfare (HEW). I was also an architect of the Act's implementing regulations, to which the authors of the petitions heavily refer.

The authors have woefully misrepresented the spirit and purpose of the legislation, which was intended to enlist the marketplace to develop and distribute government-supported innovations. Judging from the petition, they appear to have been informed primarily by a recent article in the Tulane Law Review, penned by Peter S. Arno & Michael H. Davis, which unfortunately paints a highly distorted picture both of the Act itself and the legislative process leading to its passage.

Before the enactment of Bayh-Dole, an enormous amount of government-sponsored research and innovation went to waste, as there were no clear mechanisms in existence to transfer the resultant inventions to the marketplace.

Although there was spirited opposition to the bill, a powerful bipartisan consensus was built around the basic notion that market forces would do a far better job of [illegible] such inventions to society than government bureaucracies ever could.

Put simply, the drafters of the act wanted to ensure that adequate incentives were in place to facilitate invention and to attract corporate investment into their development and distribution. We understood that inventions resulting from government research are conceptual in nature, and require significant investment by the private sector to bring them into practical application. This is especially the case with regard to life science inventions, the subject of the march-in request.

and unproven medicinal utility.   industry pursuit of a development of a NIH composition of matter with [illegible]

(3) The petitioner estimates that a "modest" $15 million had been invested in the clinical data trials of Ritonavir. But no data is provided regarding the NIH grant funding which resulted in the invention. I presume that the $15 million investment, if correct still, far exceeds that of NIH [illegible] as that is normally the case when

The comparison between the private sector investment vis-a-vis that of the government in specific situations is also not addressed in the Tulane article. On pages 636 - 640, the author's first reject the idea that the life science inventions involved are only conceptual in nature. Thereafter they note that the sum of both the federal and state investment in health related R&D in 1995 exceeded that of the private sector. This fact then becomes the underpinning throughout the article for what the author's maintain is the "public

(4)

equity" in any investment touched in any manner by federal funding. As indicated his definition ~~does not~~ ~~take~~ does not take into consideration the relative contributions of government and industry in a specific drug development situation.

The authors clearly indicate ~~on pg. 634~~ that their game plan in interpreting the Bayh-Dole Act is not its legislative history but how the Act responds to their definitions of "public equity". Thus, on page 634 they state that

"One fundamental thematic question that runs throughout this Article is do American taxpayers who fund a substantial portion of health-related research and development (R+D) receive a fair return on their investment"

(5)

"Their investment" clearly means the "public equity" as defined by the authors.

On p. 663 the authors apply their "public equity" concept to Bayh-Dole.

"The march-in provisions [Bayh-Dole] became the linchpin of the entrepreneurial bargain because Congress wanted to balance the demands of private-industry against the "public equity" that resulted from the massive public investment of funds to produce these patented inventions."

The term "public equity" as defined by the authors has no meaning whatever within the context of the legislative history of the Bayh-Dole Act. Clearly the total public ~~and private~~ investment in health R+D, most

(6) of which does not involve drug research, as compared to that of the private sector has No particular relevancy in determining the appropriate rights of the partners in the equilibrium. It sheds no light on the eventual industry investment necessary to bring an identified invention into an unproven utility to the marketplace.

which the government funds will be more

(7)

In comparison, the Bayh-Dole legislative history notes repeatedly that virtually all of the Federal investment in health related R+D is directed to thousands of basic research grants to explore the

Explains the differences

most likely none of these grants involve creating the bulk of clinical data necessary in the development of a drug for FDA licensure. At most, a minimal portion of this funding may result in identification of a composition of matter which evidences an unproven medicinal utility which would need to be pursued through the FDA with private capital. It is the equities in this situation that are addressed by Bayh-Dole and not a general comparison between all public and private funding of health R+D.

(8) I would note that the 1995 statistics used in the Tulane article to support their "public equity" theory ~~were used in the manner~~ were first used in the same manner by Cong. Sanders of Vt. to support four unsuccessful attempts to amend the HHS appropriation bill to require that any drugs touched in any manner by taxpayer dollars be marketed at a "reasonable price".

Notwithstanding ~~the~~ ~~without request to~~ the industry contribution to the drug

Our answer to the problem was that intellectual property rights should be accorded in full to the innovators, rather than to the government agency that financed their research, and that innovators should be free to leverage their property rights to their advantage in the market place as intended by the patent system. The only conditions to be attached to this freedom were envisioned as follows:

a) Reasonable efforts were required to develop the inventions to practical application;

b) The inventions should be readily available to society;

c) The inventions should not be used in such a way that might threaten public health;

d) If an invention were subject to a federal order of some kind, the developer must comply with that order; and

e) The inventions should be manufactured within the United States.

These conditions were translated into the legal language found in section 203 of the Act, which is reproduced in the subject petitions. The march-in clauses were conceived, as extraordinary measures to be used only when there was overwhelming evidence to show that the public resources invested into an innovation were being wasted or abused. This is clearly not the case with either Retonavir or Latanoprost, both of which have been successfully developed and are readily available to the public at large.

Control Of Drug Prices

What I find most disturbing about the subject petitions is the attempt to transform a fundamental piece of intellectual property law into an administrative mechanism to control drug prices, with no regard for the consequences.

The drafters of Bayh-Dole never envisioned that the law could authorize government funding agencies to compel private entities to divulge internal accounts or pricing information, which is why the Act lacks any functional criteria specifying how this could be done.

Nonetheless, the petition authors hold that the government should issue multiple licenses for the drugs because the companies are charging too much for them, and quite falsely assert that the Act invests funding agencies with the authority to approve the pricing of inventions after they have been developed and distributed in the marketplace by private sector initiatives.

The assertion that funding agencies are vested with the jurisdiction to approve pricing is said to rest on the Act's definition of "practical application" which includes a requirement that the invention be made available to the public on "reasonable terms". The petitioners argue that the latter term ought to be interpreted, in an ordinary context, as including a "reasonable price", and that the funding agency is therefore authorized to assess what a "reasonable" market price might be.

The Scalia Rule

That "reasonable terms" must include the notion of price, they maintain, is evidenced by a number of court decisions supporting that definition. They also cite the Scalia rule:

> [First], find the ordinary meaning of the language in its textual context; and second, using established canons of construction, ask whether there is any clear indication that some permissible meaning other than the ordinary applies. If not - and especially if a good reason for the ordinary meaning appears plain - we apply the ordinary meaning.

Scalia's instruction to refer to the "textual context" of the language is indeed helpful-but not to the argument put forth by the authors of the petition. The march-in conditions and the entire body of the Bayh-Dole Act stress the overriding importance of delivering intellectual property rights to innovators and developers. Property rights are inherently invested with the ability to set prices. The Act also emphasizes the broad dissemination of the benefits of the invention to society.

In context, therefore, "reasonable terms" cannot be interpreted to mean a limitation on the developer's ability to set prices in the marketplace.

which [illegible] of the government

In fact the opposite is true: if the rights-holder were not given the freedom to set prices, it would not be willing to commit resources required to ensure an invention's delivery into the marketplace, thereby obviating the requirement that it be widely available. No commercial concern would invest in the commercial development of any invention knowing that their sales price could be challenged by the government after marketing.

their contribution would be ignorance of cost

As the Tulane article agrees

Again, if the drafters had intended such an interpretation, we would have inserted specific criteria into the law to enable the funding agency to assess exactly what a reasonable price might be. No such criteria are found, precisely because controlling patent rights on the basis of price was antithetical to what the drafters had in mind.

Indeed p. 648 of the article containing that [illegible] is [illegible] such criteria,

"The Act ... does not expressly establish any mechanism whereby the funding agencies can reliably learn whether patentees ... charge no more than a reasonable price for an invention."

The ~~persistence of~~ ~~such~~ critics persist in ~~the~~ face of ~~the~~ ~~[illegible]~~ conviction

After 25 years of successfully meeting its intended purpose beyond even the expectations of its most ardent proponents ~~the B-D continues to be criticized and [illegible] by cottage industry~~ a cottage industry of critics continues to call for its repeal or amendment on the same issues raised, heard and rejected at the time of its passage. ~~The prime basis for their attacks on it for these attacks are their arguments that the~~ ~~[illegible] participants~~

1. The Act has ~~fostered~~ —

It is ~~[illegible]~~

~~But it is exactly these equities that are the primary goal for change pursued~~

But it is exactly these ~~equities~~ rewards that ~~the~~ the critics ~~suggest challenging~~. In their view the return to researchers their institutions and industry ~~are excessive~~ for their efforts is excessive while that to government is ~~[illegible]~~ insufficient.

Rail to alter.

~~Notwithstanding~~ All this, in the face of ~~the~~ Economist conclusion that

In its most malevolent form, the changes deemed necessary would require the Government to selective determine what ~~inventions made with~~ research findings sufficient to characterize an invention under the patent laws could be left to institutional management ~~and~~ licensing to industry for practical application

identified to be excessive.[9] It is the purpose of this article to analyze this assertion and its consequences.

History of March-In Rights

A. 1947 Attorney General Report

March-in rights were discussed in the 1947 Attorney General's Report and Recommendations to the President[10] as part of an appropriate government patent policy which was being developed to accompany the expansion of government research and development program after World War II as recommended by the presidential science adviser, Vannevar Bush.[11] The Attorney General's Report recommended that the Government generally should own inventions made by contractors but in special circumstances, the contractor may be permitted to own provided that "[t]he contractor (or his

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[9] The authors presented similar arguments in an op-ed article in the Washington Post on March 27, 2002 entitled "Paying Twice for the Same Drugs." This was rebutted by Birch Bayh and Robert Dole in another op-ed article in the Washington Post on April 11, 2002 "Our Law Helps Patients Get New Drugs Sooner," that

> "Bayh-Dole did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government .... The [Arno and Davis] article also mischaracterizes the rights retained by the government under Bayh-Dole. The ability of the government to revoke a license granted under the act is not contingent on the pricing of the resulting product or tied to the profitability of a company that has commercialized a product that results in part from government-funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product."

[10] Report and Recommendations of the Attorney General to the President, "Investigation of Government Patent Practices and Policies" (1947). There are three volumes. The report was initiated by a letter dated February 5, 1943 from President Franklin Delano Roosevelt to Attorney General Francis Biddle. President Roosevelt felt there was a need for a uniform Government policy on the ownership of inventions made by Government employees and contractors.

[11] Vannevar Bush, ▒Science: The Endless Frontier,▒ Report to the President on a Program for Postwar Scientific Research (July 1945).

assignee) shall be required to offer nonexclusive licenses at a reasonable royalty to all applicants" if the contractor or assignee does not place the invention in adequate commercial use within a designated period.[12]

B. 1963 and 1971 Presidential Memoranda and Statements

Thereafter, similar provisions attached to contractor ownership of inventions were described in the Presidential Memoranda and Statements of Government Patent Policy by Kennedy (1963)[13] and Nixon (1971)[14]. These were implemented in the Federal Procurement Regulations[15] and various agency procurement regulations.[16]

The Kennedy Memorandum

According to section 1(f) of the Kennedy Memorandum, the government shall have the right to require the granting of a nonexclusive royalty-free license to an applicant if (1) the contractor or grantee who has been permitted to own[17] the invention, its licensee or assignee has not taken effective steps within three years after the patent issues to bring the invention to the point

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[12] Recommendation 2(d), Volume 1 of the Attorney General Report, Chapter Four, pages 76 and 110.

[13] 28 Fed. Reg. 10,943 (Oct. 12, 1963).

[14] 36 Fed. Reg. 16,887 (Aug. 26, 1971).

[15] Section 1-9.107-3(b) of the Federal Procurement Regulations, 38 Fed. Reg. 23782 (Sept. 4, 1973) as revised by 40 Fed. Reg. 19814 (May 7, 1975). The standard patent rights clause is now in 37 CFR 401.14 and 48 CFR 52.227-11.

[16] Compare with a march-in like provision in 9(h) of the Federal Nonnuclear Act of 1974, 42 U.S.C. 5908(h)(6). This section allowed the head of the agency to terminate a waiver of title or grant of an exclusive license if the recipient has not taken effective steps necessary to accomplish substantial utilization of the invention. Section 9 was later repealed by Bayh-Dole.

[17] The Kennedy Memorandum, n.13, refers to principal or exclusive rights and not ownership because of the required Government irrevocable paid-up license for Government purposes throughout the world.

of practical application[18] or (2) has made the invention available for licensing royalty free or on terms that are reasonable in the circumstances or (3) can show why it should be able to retain ownership for a further period of time. As in the Attorney General Report, the fourth paragraph of the Kennedy Memorandum made clear that the reason for march-in rights was to "guard against failure to practice the invention."

The Nixon Memorandum

The march-in rights in section 1(f) of the Nixon Memorandum are very similar[19] to those in the Kennedy Memorandum except that the requirement was expanded to assignees and licensees and the Government could also require the granting of an exclusive license to a responsible applicant on terms that are reasonable under the circumstances if the invention was not being developed.

The authors note that both Presidential Memoranda require that licensing of inventions be on "reasonable terms." There is no requirement in the Memoranda that price of a patented invention be on "reasonable terms."

C. Institutional Patent Agreements

Institutional Patent Agreements (IPAs) were first used by National Institutes of Health (NIH) beginning in 1968 and later by National Science Foundation (NSF) in 1973 to govern the management of inventions made with NIH/NSF support by universities with an approved patent policy. Since many of the provisions[20] in the Bayh-

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[18] As defined in section 4(g) of the Kennedy Memorandum, n.13, "to the point of practical application" means to manufacture in the case of a composition or product, to practice in the case of a process, or to operate in the case of a machine and under such conditions as to establish that the invention is being worked and that its benefits are reasonably available to the public."

[19] The definition of "to the point of practical application" was unchanged.

[20] There are a number of common elements: (1) restriction against assignment of inventions except to a patent management organization, (2) limitation on the term of an exclusive license, which was removed when Bayh-Dole was amended in 1984, (3) requirement that royalty income must be shared with inventors and the remainder used for education and research purposes, (4) requirement that any patent application contain a reference to the federal support which resulted in the invention and (5) a paid-up license to the Government.

Dole Act come from IPAs, Bayh-Dole can be considered a codification of the IPA. Under both these IPAs as in Bayh-Dole, the university had a contractual right to elect ownership to any invention, thereby eliminating the arduous task of justifying ownership after identification of an invention. Each IPA contained all the conditions required by the Presidential Memoranda including march-in rights and the requirement to license on "reasonable terms."

A model IPA containing these conditions was later developed for government-wide use by the University Patent Policy Ad Hoc Subcommittee[21] of the Committee on Government Patent Policy of the Federal Council of Science and Technology after receiving comments from many agencies and universities. Implementation of the model IPA was postponed for 120 days at the request of Senator Gaylord Nelson on March 17, 1978, who held hearings[22] but became effective on July 18, 1978.[23]

Use of March-In Prior to 1980

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[21] Chaired by Norman Latker and included John Raubitschek, then patent counsel for NSF, as a member.

[22] Hearings before the Subcommittee on Monopoly and Anticompetitive Activities of the Senate Select Committee on Small Business, 95th Cong., 2nd sess., 1978, at 4.

[23] Id. at 1014.

Before Bayh-Dole, there was little[24] activity in march-in rights. At most, the focus was on whether a particular invention funded by the Government was being used. During the Nelson hearings, march-in rights were discussed. In particular, Donald R. Dunner, 1st Vice President of the American Patent Law Association, indicated that:

> **"Much has been said about march-in rights. . . . The point has been raised that march-in rights have been available for 10 years, and they have never been used; ergo, they are a failure. We submit that is not the case. There is no evidence to indicate that march-in rights should have been used in a specific situation and were not used. In fact, we submit the high probability is quite the contrary. Where an invention is significant, we submit that the marketplace will take care of the situation. Competitors who want to use a given piece of technology follow a standard routine procedure. They first determine whether there is any patent cover on the development, and then they evaluate the patent cover. If they feel they want to get into the field, they will try to get a license. If they cannot get a license in a Government-owned situation, they will go to the Government agency involved, and they will say, 'I cannot get a license.' They will point to the conditions which the IPA specify as to when march-in rights should be applied; they will provide the information necessary for that evaluation to be made, and we submit in any given situation where march-in should be applied, they will be applied."[25]**

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[24] See Hearings on S. 1215, Subcommittee on Science, Technology and Space of the Committee on Commerce, Science, and Transportation, 96th Cong., 1st sess., 1979 at 366, where Dale Church of the Department of Defense responded to Senator Stevenson's question: "Has the Department exercised march-in rights?" "Only once can I recall there was a case where we exercised march-in rights. It was a case involving two patents held by MIT. There was a complainant who felt as those the patents were not being utilized. As to one of the patents, it was found that MIT was using it and was allowed to exclusive title. In the case of the other, we found that MIT was not efficiently using it, and they did provide for the complainant to use the patent." See also, n.121 of Alstadt, "The 1980 Patent Rights Statute: A Key to Alternate Energy Sources," 43 U. Pitt. L. Rev. 73, 95 (1981) which discusses march-in activity at NIH, NSF and the Air Force and n.245 of Sidebottom, "Intellectual Property in Federal Government Contracts: The Past, The Present and One Possible Future," 33 Pub. Cont. L.J. 63, 95 (2003) which refers to two march-ins by the predecessor to the Department of Energy in 1974.

[25] Hearings, n.22 at 577.

March-in Rights under Bayh-Dole

Under Bayh-Dole, the Government's march-in rights are described in 35 U.S.C. 203, The funding agency may take action if the contractor or grantee or assignee[26] has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application in a field of use.[27] This was clearly intended to follow the precedent established in both Presidential Memoranda and the IPAs. "Practical application" is defined in 35 U.S.C. 201(f) to mean "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."[28] Section 203 not only authorizes the funding agency to require the contractor or grantee, its assignee or exclusive licensee to grant a license to a responsible applicant but itself can grant a license if the ordered party refuses to grant a license.[29]

According to the legislative history[30] of Bayh-Dole, "[t]he Government may 'march-in' if reasonable efforts are not being made to achieve practical application, for alleviation of health and safety needs, and in situations when use of the invention is required by Federal regulations." "'March-in' is intended as a remedy to be invoked by the Government and a private cause of action is not created in competitors or other outside parties,

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[26] It is interesting that § 203 does not mention "licensee" as did the Nixon Memorandum and so does not directly consider the commercialization activities of the contractor's licensee.

[27] There are three other bases for exercising march-in rights. 35 U.S.C. 203(1)(b)-(d). Two relate to health, safety or public use and so are similar to the Nixon Memorandum except that they come into play only if the contractor, grantee, assignee or licensee cannot reasonably alleviate or satisfy such needs. The third basis relates to a breach of the "domestic manufacturing" requirement in 35 U.S.C. 204.

[28] This definition differs from the one in the Kennedy and Nixon Memoranda, which say merely "that its benefits are reasonably accessible to the public."

[29] Licensing by the Government would be unusual since it is not the patent owner. If there were royalties, it is assumed that they would belong to the patentee or exclusive licensee.

[30] S. Rep. 96-480, 96th Cong., 1st Sess., 1979 at 33-34.

although it is expected that in most cases complaints from third-parties will be the basis for the initiation of agency action."

Any decision to exercise march-in is appealable to the Court of Federal Claims within 60 days. The agency's decision is held in abeyance until all appeals are exhausted. A decision not to exercise rights is not reviewable.[31]

The Bayh-Dole regulation in 37 CFR 401.6 sets forth a detailed multi-step process although the agency can terminate the proceedings at any time.[32] The regulation allows an agency to initiate a march-in proceeding "[w]henever it receives information that it believes might warrant the exercise of march-in rights."[33] Since the regulation provides no criteria for the initiation of a proceeding, an agency appears to have unlimited discretion on whether or not to initiate one.[34] However, before initiating a proceeding, the agency is required first to notify the contractor and request its comments.[35]

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[31] Id. at 34.

[32] 37 CFR 401.6(j). Thus, one author has concluded that the procedures have a built-in asymmetry which discourages march-in. See Bar-Shalom et al.,"Patents and Innovation in Cancer Therapeutics: Lessons from CellPro," 80 The Milbank Quarterly 637, 667 (2002) ("The procedures stipulated in Bayh-Dole also have a built-in asymmetry that discourages march-ins. If an agency decides not to march-in, the case is over. If it does decide to march in, the party whose patent is subject to compulsory licensing can contest the decision, which compels the agency to defend its action against a party with a strong financial stake.")

[33] 37 CFR 401.6(b).

[34] Failure to enforce a statute is presumptively discretionary and therefore unreviewable under the Administrative Procedure Act. Heckler v. Chaney, 470 U.S. 821, 837-38 (S.Ct. 1985). However, Arno and Davis, n.7, at 689-90, n.366, suggested that an argument could be made that the detailed requirements in 35 U.S.C. 202 amounts to the kind of guidelines that would render the agencies' actions reviewable.

[35] 37 CFR 401.6(b).

Since 1980, the government has not[36] exercised march-in rights. This might[37] be an indication that march-in is ineffective especially since GAO pointed out that agencies do not seek commercialization reports from contractors and so do not know if inventions are being commercialized.[38] Nevertheless, there have been three petitions to the Department of Health and Human Services (HHS) in recent years.

On March 3, 1997, HHS was asked by CellPro, Inc. to march-in against Johns Hopkins University and its exclusive licensee Baxter Healthcare Corporation on four patents covering an antibody useful for the treatment of cancer (U.S. Patents 4,965,204, 4,714,680, 5,035,994 and 5,130,144). The petition was referred to NIH, which funded the research resulting in the inventions. Dr. Harold Varmus, the Director of NIH, concluded that march-in proceedings were not warranted in a decision dated August 8, 1997[39] because Baxter Healthcare Corporation, an exclusive licensee, had taken steps to make its product available to the public on reasonable terms by obtaining European approval and filing for FDA approval. He also noted that it would be inappropriate for NIH "to provide for CellPro more favorable commercial terms that it can otherwise obtain from the Court or from the patent owners."[40] This matter was

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[36] Several authors have suggested that the Government will never exercise these rights. See Bar-Shalom et al., n.32 and McCabe, "Implications of the CellPro Determination on Inventions Made with Federal Assistance: Will the Government Ever Exercise Its March-in Rights?," 27 Pub. Contr. L.J. 645 (1998). See also Admiral Rickover, no supporter of the Bayh-Dole Act, considered that march-in as a safeguard was "largely cosmetic" because in the rare case of an agency exercising march-in, it would take years of litigation. The University and Small Business Patent Procedures Act Hearings, n.7 at 160.

[37] To the contrary, Mr. Dunner has suggested the lack of any march-in by an agency does not mean it is a failure because there is no evidence of when it should have been used and that the marketplace would take care of the need for march-in with significant inventions. See n.25.

[38] GAO Report ▒Technoloy Transfer: Reporting Requirements for Federally Sponsored Inventions Need Revision▒ (GAO/RCED-99-242), pages 15-16.

[39] http://www.nih.gov/news/pr/aug97/nihb-01.htm.

[40] For a description and analysis of the Cellpro case by two NIH attorneys, see McGarey and Levey, "Patents, Products, and Public Health: An Analysis of the CellPro March-In Petition," 14 Berkeley Tech. L.J. 1095 (1999). There has been some criticism of the Cellpro decision. See Bar-Shalom et al. and McCabe, n.36

complicated by the pending patent infringement suit by Hopkins against CellPro filed in 1994 and included appeals to the Federal Circuit, which ultimately sustained the validity and infringement of the Hopkins' patents.[41]

On January 29, 2004, James Love and Sean Flynn filed two march-in petitions to HHS on behalf of Essential Inventions, Inc. relying on the Arno-Davis "reasonable pricing" theory.[42] Both petitions were referred to NIH which funded the research resulting in the two patented inventions.

One petition related to ritonavir, a drug for the treatment of AIDS sold under the trade name of Norvir and invented by Abbott Laboratories under a $3.5 million grant from the National Institute for Allergy and Infectious Diseases (NIAID) (U.S. Patent 6,232,333). There were other Abbott patents (U.S. Patents 5,541,206, 5,635,523, 5,648,497, 5,674,882, 5,846,987 and 5,886,036) relating to specific formulations or delivery techniques for Norvir, which may not have been invented under the NIAID grant.

The petition appears to have been a reaction to Abbott's increasing the U.S. retail price of Norvir 400% in December 2003 when it shifted from being a primary treatment agent to one used in small doses to boost the effects of other anti-AIDS medicines. Norvir has been a very successful drug with total sales of more than $1 billion since it was introduced although sales fell to $100 million in 2003 from a high of $250 million in 1998.[43]

A public meeting was held at NIH on May 25, 2004 to discuss the petition on the patents owned by Abbott Laboratories on Norvir. Statements were made by Norman Latker, James Love and former Senator Birch Bayh, one of the principle co-sponsors of Bayh-Dole

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and also Mikhail, Hopkins v. CellPro: An Illustration That Patent Licensing of Fundamental Science Is Not Always in the Public Interest," 13 Harvard J.L. Tech. 375 (2000).

[41] Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342 (1998).

[42] See http://www.essentialinventions.org. Both petitions requested that HHS issue non-exclusive licenses on the same non-discriminatory terms but suggested that each patent owner receive a 5% royalty from the generic drug companies.

[43] N.Y. Times, "U.S. Won't Override AIDS Drug Patents" (Aug. 5, 2004).

and a number of other people from universities and the private sector.[44]

In a decision dated July 29, 2004 and released on August 4, 2004,[45] Dr. Elias Zerhouni, the Director of NIH, determined that NIH did "not have information that leads it to believe that the exercise of march-in rights is warranted." NIH found that the record establishes that Abbott has met the standard for achieving practical application by its manufacture, practice and operation of Norvir and the drug's availability and use by patients with HIV/AIDS since 1996 and is being actively marketed by Abbott. With respect to drug pricing, NIH felt "that the extraordinary remedy of march-in is not an appropriate means of controlling prices . . . [which should be] left for Congress to address legislatively." Further, any anti-competitive behavior by Abbott should be addressed by the FTC. Essential Inventions responded on August 4, 2004 disagreeing with NIH's decision: "The plain language of the Bayh-Dole Act says that government-funded inventions should be made 'available to public on reasonable terms.'"[46]

The other petition related to latanoprost, a drug for the treatment for ocular hypertension and glaucoma sold under the trade name of Xalatan and invented by Columbia University under a grant from the National Eye Institute and exclusively licensed to Pharmacia Corporation, now owned by Pfizer (U.S. Patent 4,599,353).[47] Pfizer owns at least three other U.S. patents (5,296,504, 5,422,368 and 6,429,226) relating to Xalatan but none of them were made with federal funds and so are not subject to march-in. According to the petition, Pfizer sells Xalatan in the United States for 2-5 times the price charged in Canada and Europe. The drug is said to cost as much as $65 for a 4-6 week supply although the cost of the active ingredient is less than 1% of the sales price. By 2000, the sales of Xalatan were over $500 million a year. The petition considered this unreasonable in view of the

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[44] Testimony is available on Essential Invention's website, n.42.

[45] http://OTT.od.nih.gov/Reports/March-In-Norvir.pdf.

[46] See n.42.

[47] It is of interest that Arno and Davis mentioned this drug as one where there should have been price controls. See n.8 at 689. An extensive history of this drug is provided by Garth and Stolberg, "Drug Makers Reap Profits on Tax-Backed Research," N.Y. Times, April 23, 2000, at A1. According to this article, when the patent application was filed in 1982, no drug company in the United States was interested in a license because of its unusual approach to treating glaucoma. Id. at A20.

taxpayer support of the research at Columbia University of over $4 million.

In a decision by Dr. Zerhouni dated September 17, 2004,[48] "[a]fter careful analysis of the Bayh-Dole Act and considering all the facts of the case as well as comments received, the National Institutes of Health . . . determined that it will not initiate a march-in proceeding as it does not believe such a proceeding is warranted based on available information and the statutory and regulatory framework." The basis for the decision was that the record "demonstrates that Pfizer has met the standard for achieving practical application of the applicable patents by its manufacture, practice and operation of latanoprost and the drug's availability and use by the public." With respect to the lower prices being charged in Canada and Europe, NIH "believes that the extraordinary remedy of march-in is not an appropriate means for controlling prices." Rather, NIH felt that the lower foreign prices should be "appropriately left for Congress to address legislatively."

"Reasonable Terms" Relate to Licensing

A review of the statute makes it clear that price charged by a licensee for a patented product has no direct relevance. As set forth in 35 U.S.C. 203(a)(1), the agency may initiate a proceeding if it determines that the contractor or assignee[49] has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of an invention made under the contract. In most funding agreements, the contractor will be a university or nonprofit organization. Under the law, the university does not have to achieve practical application, only take "effective steps."

If a university is not engaging in any development of its invention, an agency would need to inquire as to what steps the university is planning on taking to commercialize in a reasonable time. Since this involves future action and an undefined time period,[50] it is not clear how an agency should evaluate this.[51] On the other hand, if the university has licensed a company to make,

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[48] http://OTT.od.nih.gov/Reports/March-in-xalatan.pdf.

[49] Under 35 U.S.C. 202(c)(7), a university is not permitted to assign its invention without the approval of the agency except to a patent management organization.

[50] Under both Presidential Memoranda, the time period was three years from the issue date of the patent.

[51] A mere statement that a patent is available for licensing may not be sufficient.

use and sell the invention, it may be considered as having taken effective steps even if no sales of the invention have yet to occur if the licensee is practicing or using the invention. See the CellPro decision.[52]

The fact that the definition for "practical application" also requires that the benefits of the invention must be "available to the public on reasonable terms" applies only to the licensing by the contractor, which is what a university would normally do.[53] Further, in any license agreement, the price of the licensed product is left up to the discretion of the licensee[54] and if the license were to specify a minimum sales price, this may constitute a violation of the antitrust laws. The typical license has a "due diligence" clause so that if the licensee is not performing adequately the commercialization, the university can terminate the license and seek other licensees.

With Norvir, Abbott Laboratories was the contractor instead of a university and so was responsible for commercialization of that invention. There was no issue of "reasonable terms" as that term only applies if there is licensing as explained above notwithstanding the recent dramatic price increase[55] and the substantial[56] funding of the research by NIH. Further, since Norvir

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[52] See n.39.

[53] We note that NIH handled this a little differently in the CellPro march-in case where NIH concluded that practical application had been achieved because the licensee was manufacturing, practicing and operating the licensed product. See McGarey and Levey, n.40 at 1101. Of course, in view of the substantial sales of Xalatan, the benefits of this invention would have been reasonably available to the public under this approach.

[51] The model IPA contained a requirement that royalties ▒be limited to what is reasonable under the circumstances or within the industry involved.▒ Thus, the focus of reasonable terms was on the licensing by the universities and not the price of the licensed product.

[55] Essential Inventions, Inc. filed a complaint with the Federal Trade Commission on January 29, 2004 alleging that the 400% increase in price for Norvir on December 2003 violated the antitrust laws. The FTC later advised Abbott that it had no plans to investigate this complaint. See N.Y. Times article "U.S. Won't Override AIDS Drug Patents" (August 5, 2004)

[56] Dr. Jeffrey Leiden, president of Abbot, testified at the NIH public meeting on May 25, 2004 that the funding was around $3.5 million. See n.42.

is available to the public from Abbott either directly or through other companies which can purchase it from Abbott, there is no basis to conduct a march-in rights proceeding under 35 U.S.C. 203(1)(a).[57] By manufacturing and selling Norvir, Abbott has taken effective steps to achieve practical application. According to the petition, the sales of Norvir through 2001 is more than $1 billion and may reach $2 billion over the next ten years.

There is No Reasonable Pricing Requirement

Arno and Davis maintain that "[t]he requirement for 'practical application' seems clearly to authorize the federal government to review the prices of drugs developed with public funding under Bay-Dole terms and to mandate march-in when prices exceed a reasonable level."[58] The authors further suggest that under Bayh-Dole, the contractor may have the burden to show that it charged a reasonable price.[59] This could be made part of its development or marketing plan.[60]

As we have mentioned previously, there is very little legislative history on march-in rights and nothing relating to when it is to be used. Similarly, Arno and Davis acknowledge there is no clear legislative history on the meaning of "available to the public on reasonable terms,"[61] but yet they conclude that "there was never any doubt that this meant the control of profits, prices and competitive positions."[62]

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[57] But see 35 U.S.C. 203(1)(b), the march-in for health.

[58] Arno and Davis, n.8 at 651.

[59] Id. at 653.

[60] There is no requirement in Bayh-Dole for contractors to have such a plan although there is one for Federal laboratories in 35 U.S.C. 209. In 2000, Congressman Sanders offered an amendment to HHS appropriations bill H.R. 4577 which would apply the licensing requirements for Federal laboratories to universities. See discussion of Sanders' amendment in Arno and Davis, n.7 at 635 n.12, 666 and 667 n.227. The amendment was not adopted.

[61] Arno and Davis, n.8 at 649.

[62] Id. at 662.

Support for this surprising[63] conclusion is said to be found in unrelated testimony during the Bayh-Dole hearings and other Government patent policy bills which did not become law as supplemented by a number of non-patent regulatory cases to show the phrase "reasonable terms" means "reasonable prices." Even if "reasonable terms" are interpreted to include price, that does not necessarily mean that patented drugs funded by the Government must be sold at reasonable prices.

If Congress meant to add a reasonable pricing requirement, it would have set forth one explicitly in the law or at least described it in the accompanying reports.[64] That a new policy could arise out of silence would truly be remarkable. There was no discussion of the shift from the "practical application" language in the Presidential Memoranda and benefits being reasonably available to the public to benefits being available on reasonable terms in 35 U.S.C. 203.

On the other hand, there was much debate during the Bayh-Dole hearings on whether there should be a recoupment provision to address any windfall profits that a university may make out of research funded by the Government.[65] There was a recoupment provision in S. 414 as passed by the Senate but it did not become law.[66] Further, the limitation on the length of an exclusive license term in Bayh-Dole until 1984 meant that other companies would have access to the patented technology after 5 years from first commercial sale or 8 years from date of license.

Then after convincing themselves they have made their case, the authors criticize Bayh-Dole and the Department of Commerce implementing regulation in 37 CFR Part 401 for leaving the enforcement of reasonable prices up to the agencies.[67] Finally, the authors accuse GAO as committing the "fatal error of confusing

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[63] Compare this with Arno and Davis' opinion of NIH's "unbelievable" complaints that price review is beyond its ability notwithstanding the "countless" cases and "host of" statutes to the contrary. See n.8 at 651-2.

[64] Admiral Rickover in his testimony on Bayh-Dole never suggested a reasonable pricing requirement as a condition for allowing universities to retain title to their inventions made with government funds.

[65] S. Rep. 96-480, n.30 at 25-6.

[66] Section 204 Return of Government Investment.

[67] Arno and Davis, n.8 at 648-49.

march-in rights with simple working requirements."[68] Of course, all this criticism is misplaced since there is no evidence that Congress intended there to be a reasonable pricing requirement in Bayh-Dole.

We submit the interpretation taken by Arno and Davis is inconsistent with the intent of the Bayh-Dole especially since the Act was intended to promote the utilization of federally funded inventions and to minimize the costs of administering the technology transfer policies.[69] As pointed out by Justice Brennan, "a thing may be within the letter of the law but not within the purpose of the law."[70] On the other hand, this would not be the case if agencies were responsible for ensuring reasonable prices for any patented invention, not just a drug, arising out of federal funding. Further, one of the stated objectives of Bayh-Dole is to "protect the public against nonuse or unreasonable[71] use."

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[68] Id. at 676, n.273.

[69] 35 U.S.C. 200.

[70] United Steelworkers of America v. Weber, 443 U.S. 193, 197 (1979), citing Holy Trinity Church v. United States, 143 U.S. 457, 459 (1892) and discussed in Aldisert, "The Brennan Legacy: The Art of Judging," 32 Loyola L.A. L. Rev. 673, 682-83 (1999).

[71] Thus, an agency may march-in for other than non-use of an invention. See S. Rep. 96-480, n.30 at 30 ("The agencies will have the power to exercise march-in rights to insure that no adverse affects result from retention of rights by these contractors.") As Dr. Ancker-Johnson, former Assistant Secretary of Commerce, explained that march-in rights is to correct "should something go wrong" and if there is "any remote possibility of abuse." The University and Small Business Patent Procedures Act, Hearings before the Senate Committee on Judiciary, n.7 at 153-54. Unfortunately, no guidance was given on how to determine what is an abuse and this may refer to the other march-ins in 35 U.S.C. 203(a)(2)-(4). On the other hand, there may be a situation where a contractor is using an invention for itself but not making the benefits of the invention available to the public at all or on reasonable terms, which could include price. This might be a basis for march-in as mentioned by David Halperin on page 6 of his May 2001 paper entitled "The Bayh-Dole Act and March-in Rights," available at http://www.essentialinventions.org/legal/norvir/halperinmarchin2001.pdf although we disagree with the "reasonable pricing" arguments he adopted from Arno and Davis.

35 U.S.C. 200. It does not provide for nor say "unreasonable prices."[72]

In H.R. 6933, a companion bill to S. 414 which resulted in Bayh-Dole, there was a march-in rights provision, section 387, which was similar in part to 35 U.S.C. 203(1)(a). Under 387(a)(1) of the provision, an agency could terminate the contractor's title or exclusive rights or require the contractor to grant licenses if the contractor has not taken and is not expected to take timely and effective action to achieve practical application in one or more fields of use. According to the legislative history,[73] this section was "intended to continue existing practice and the [House Judiciary] Committee intends that agencies continue to use the march-in provisions in a restrained and judicious manner as in the past."

Although H.R. 6933 was ultimately replaced by S. 414, the discussion by the House Judiciary Committee is considered relevant to 35 U.S.C. 203 because of the similarity in language and that it is included in the legislative history of Bayh-Dole. Thus, it does not appear that Congress intended[74] that there be any change in the application of march-in rights by the agencies, which prior to that time focused on the non-utilization or non-working of federally funded patented inventions as is evident from the previous discussion of the history under the Presidential Memoranda and the IPAs.

We recognize that 35 U.S.C. 203 mentions "available on reasonable terms" but one has to understand the context of the term in the statute. As previously mentioned with respect to the history of march-in and the two recent petitions to HHS, that term relates only to licensing. Thus, a university licensing its invention to a drug company which sells the patented product to the public is fulfilling its responsibility under Bayh-Dole of making

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[72] Arno and Davis, n.8 at 683, argued that "unreasonable use" includes unreasonable prices.

[73] House Report No. 96-1307, Part 1, House Judiciary Committee, Sept. 9, 1980, Legislative History of PL 96-517, reprinted in 1980 U.S.C.C.A.N. 6460, 6474.

[74] See Koons Buick Pontiac GMC, Inc. v. Nigh, 125 S.Ct. 460, 468 (2004) where the Supreme Court focused on the lack of Congressional intent to significantly change the meaning of a clause by referring to a Sherlock Holmes story in Church of Scientology of Cal. v. IRS, 484 U.S. 9, 17-18 (1987)("All in all, we think this is a case where common sense suggests, by analogy to Arthur Conan Doyle's 'dog that didn't bark'"). It is remarkable that there is no discussion in the legislative history of Bayh-Dole about a reasonable pricing requirement.

the benefits of the invention available to the public on reasonable terms.

Although we disagree with the interpretation of 35 U.S.C. 203 by Arno and Davis, Congress could decide to amend Bayh-Dole to impose a reasonable pricing requirement. However, we would not recommend such a change because of the difficulty in determining what is "reasonable."[75] Furthermore, that would make any[76] patent license granted by a Government contractor or grantee subject to attack, which would discourage or inhibit the commercialization of Government-funded technology, one of the primary purposes of the Act.[77]

It is of interest that NIH had a reasonable pricing policy several years ago. In October 1991, NIH put a reasonable pricing clause in an exclusive patent license with Bristol-Myers-Squibb for the use of ddI to treat AIDS.[78] Around this time, NIH also had a

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[75] See testimony by Dr. Bernadine Healy on Feb. 24, 1993 that NIH is not equipped, either by its expertise or its legislative mandate, to analyze private sector product pricing decisions. See Arno and Davis, n.8 at 670, n.245, citing Daily Rep. for Executives (BNA), No. 9 (Feb. 25, 1993). Such a determination would be further complicated by when it is done because of the long time and money it takes to get to get a drug to market.

[76] Although 35 U.S.C. 203 applies only to nonprofit organizations and small business firms, it was expanded to large businesses by 35 U.S.C. 210(c).

[77] This could be especially damaging for biotech inventions. See McCabe, n.36 at 645. However, a contrary view is taken by Eberle, "March-In Rights Under the Bayh-Dole Act: Public Access to Federally Funded Research," 3 Marq.Intell.Prop. L.Rev.155 (1999) ("I argue, by contrast, that a march-in under one of the four circumstances enumerated in the Act would not harm technology transfer.").

[78] Hearing before the Subcommittee on Regulation, Business Opportunities, and Energy of House Committee on Small Business, 102nd Cong., 1st sess., 1991 at 9. When then Congressman Wyden asked about objections to this policy at NIH, Dr. Healy, the Director, explained that "we are not interested in price setting, but we are interested in using our leverage." Hearing, id. at 22. She repeated later that NIH should not be involved in price setting. Hearing before Subcommittee on Regulation, Business Opportunities, and Technology of House Committee on Small Business, 103rd Cong., 1st sess., 1993 at 16.

reasonable pricing clause in all its CRADAs.[79] Dr. Harold Varmus, the Director of NIH, withdrew the reasonable pricing requirement in its CRADAs in 1995 after convening panels of scientists and administrators in Government, industry, universities and patient advocacy groups to review this policy.[80] In a recent report to Congress, NIH acknowledges that "[t]he cost of prescription drugs is a legitimate public concern that exists whether or not a drug was developed from a technology arising from federally funded research . . . [but NIH] has neither the mandate nor authority to be the arbiter of drug affordability."[81]

Conclusion

It is our opinion that there is no reasonable price requirement under 35 U.S.C. 203(1)(a)(1) considering the words of this section, the legislative history and the prior history and practice of march-in rights. Rather, this provision is to assure that contractor utilizes or commercializes the funded invention.[82] However, that does not mean that the price charged for a drug invented with Government funding is never a concern to the funding agency. There are other mechanisms to address this concern, including the health march-in of 35 U.S.C. 203(1)(a)(2), the Government license in 35 U.S.C. 202(c)(4) and eminent domain in 28 U.S.C. 1498(a).[83] In addition, NIH asserted co-inventorship in AZT which contributed to reducing the cost for this important AIDS drug

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[79] Arno and Davis suggest that march-in rights apply to CRADAs although they are not funding agreements as defined by Bayh-Dole. See n.8 at 645. However, CRADAs have their own march-in rights provision in 15 U.S.C. 3710a(b)(1)(B) and (C) although it is more limited than 35 U.S.C. 203 and does not refer to "practical application." The only mention of reasonable terms is with respect to a license to be granted by the Government in 3710a(b)(1)B(i). Similarly, there is a march-in like right in the licensing of a Government-owned invention provided in 35 U.S.C. 209(f)(2) and (4) under which the Government may terminate the license.

[80] See C.6 of the NIH Response to the Conference Report Request in the FY 2001 DHHS Appropriation for a Plan to Ensure Taxpayers' Interests are Protected (July 2001), available online at http://www.nih.gov/news/070101wyden.htm.

[81] NIH Report to Congress on "Affordability of Inventions and Products" (July 2004), available at http://ott.od.nih.gov/NewPages/211856ottrept.pdf, pg. 4.

[82] See Alstadt, n.24 at 81.

[83] See McGarey and Levey, n.40 at 1113-15.

sold by Burroughs Wellcome even though the claim of co-ownership was not sustained in court.[84] Finally, discriminatory pricing of drugs, whether or not invented with Government funds, may fall within the responsibility of the Federal Trade Commission.[85]

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[84] See Lacey et al., "Technology Transfer Laws Governing Federally Funded Research and Development," 19 Pepp.L.Rev. 1,2 (1991) and Ackiron, "The Human Genome Initiative and the Impact of Genetic Testing and Screening Technologies: Note and Comment: Patents for Critical Pharmaceuticals: The AZT Case," 17 Am.J.L. and Med. 145 (1991). Dr. Healy explained that the licensing of AZT by NIH was to lower Burroughs-Wellcome's price, which went from $8-10,000 to $2,000. Hearing before the Subcommittee on Regulation, Business Opportunities, and Energy of House Committee on Small Business, 102nd Cong., 1st sess., 1991 at 23.

[85] See NIH decision on the Norvir march-in petition, n.45.

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TELEFAX CONTROL SHEET

SENT TO: Beth Benman

DATE SENT: 3/30/05

SUBJECT: Bayh-Dole

No. of pages (including this cover sheet):

FROM: Norm Latker

Remarks: Attached are two articles of great interest:

1) 1979 Science article on progress toward passage of B-D and discussion of my problems with HEW, and

2) 1984 presentation by Ed Mac Condy (deceased) — The collaborative agreement) developed by Ed were the forerunner of all those thereafter. The presentation is very insightful, accurate and responsive to your interests.

P.S. Did I send you cc: of 2000 presentation at N.I.H.? ~~my~~

Patent Bill Returns Bright Idea to Inventor

And in the process it would help federally funded inventors and their institutions to pick up a little cash

When your innovative idea gets tied up by piles of paperwork and months of delay as Washington dawdles over whether to let you market the thing or not, nasty thoughts about U.S. patent policy are never far off.

Just ask Sydney E. Salmon, a biomedical researcher at the University of Arizona. In 1977, Salmon and another scientist found that by growing human tumor cells in a Petri dish and adding anticancer drugs, they could predict what drug or combination of drugs would best shrink a patient's tumor. The method could also be used to screen the effectiveness of new anticancer drugs.

Salmon wanted to patent the technique. But since the salary of one researcher in the lab was paid by the Department of Health, Education, and Welfare (HEW), all rights reverted to the agency. To make sure the method did not just sit on a government shelf, Salmon on 5 July 1977 asked HEW for the patent rights, and on 29 July published his results in *Science*. An editorial in the *New England Journal of Medicine* soon took note of the technique, and even *Time* ran a story on it. Not long afterwards, drug companies showed up at Salmon's door, wanting to market the method. HEW, however, had not yet ruled on the patent rights, and the companies soon lost interest. It took until March of this year—in all some 20 months—before HEW finally decided to hand over the rights. The drug companies are only now starting again to ask about licensing the patent rights.

"This invention will spare cancer patients from receiving toxic drugs which we can predict would be of no benefit," Salmon recently told a Senate hearing. "Yet this slow process of gaining HEW approval delayed its availability to the public by at least 1 year."

It is an oft-told tale on Capitol Hill these days. A steady stream of inventors has been showing up at hearings to complain about the bureaucratic knots that tie up the transfer of patents derived from federally funded research. Their goal is to boost new legislation, and it seems to be working. Support has been building for a Senate bill that would automatically give patent rights to universities and small businesses. The bill, the University and Small Businesses Patent Procedures Act (S.414), is coauthored by Birch Bayh (D-Ind.), chairman of the Senate Judiciary Committee's subcommittee on the Constitution, and Robert Dole (R-Kan.).

The bill would let any federally funded university or small business make some money off their bright ideas. Say, for instance, that a researcher on a Department of Energy (DOE) grant came up with a cost-efficient way of converting coal into gasoline. Under the bill, the inventing organization could apply for a patent—without waiting for permission from DOE—and then license the idea to a company for up to 8 years. A portion of the money made during commercialization would be returned to the inventing organization with the stipulation that the funds, over and above administrative expenses and a fee to the inventor, be used to support further scientific research.

Not only university researchers are backing the bill. A study by the Department of Commerce has recommended the exclusive licensing of patents derived from federally funded research. The General Accounting Office (GAO) has come out in favor of the Bayh-Dole legislation. And the critics of such legislation, who in the past have railed about the "giveaway of public funds," have grown unusually quiet. The reason seems clear. Industrial innovation has become a buzz word in bureaucratic circles. The White House, for instance, is about to release a study on how to cure the alleged decline in the innovative spirit within U.S. industry. The patent-transfer people have latched onto this issue. It is about time, they say, to cut the red tape that saps the incentive to be inventive.

The way things currently stand, the incentive is indeed small. Years can slip by before a funding agency decides whether or not to return patent rights to an inventor's organization, and, as often as not, the agencies decide to hold on tight. The agencies, moreover, prove to be poor businessmen. Of the 30,000 inventions now in the government's patent portfolio, an estimated 4 percent have been licensed, and even fewer make it to market. One reason is that the government insists on issuing "nonexclusive" licenses—which means that any number of companies can jump in along the road to development and marketing (though few take the chance). Another reason, say many researchers, is that the government doesn't know how to market an invention. The further one goes from the source of the idea, the inventor, the less one knows about how to put it to work.

The government is not all thumbs, however. To help cut through this web, federal agencies over the years have worked out agreements with certain universities that show a knack for peddling their inventions to companies that will produce them. Called Institutional Patent Agreements (IPA), they allow a university to become the owner of a patented invention resulting from federally funded research and to give an exclusive license to a company for up to 5 years. IPA's are few and far between, however. They are in place at only 72 HEW grantee institutions and, out of 1200 institutions that receive National Science Foundation funds, they are in place at about 20. And not many more are expected, since the agencies are conservative in identifying institutions that have what it takes to promote technology transfer.

Critics of such legislation, who in the past have railed about the "giveaway of public funds," have grown unusually quiet.

The Bayh-Dole bill goes beyond the IPA concept in that it makes no distinction between institutions that have a knack for marketing their inventions and those that do not. It says *any* university or small business can manage its own invention better than the government can. The IPA, moreover, is limited to inventions discovered on government grants, not contracts. Not so with Bayh-Dole. Most everyone on any kind of funding is covered, with the exception of big business, and that is mostly for tactical rea-

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sons. "We'd like to extend it to everybody," said one Senate aide, "but if we did, the bill would never have a chance of passing." Such was the situation several years ago when similar patent legislation that applied to all businesses was introduced. Consumer advocates and trustbusters at the time cried giveaway and monopoly, and the bill soon died.

To further mute critics this time around, the Bayh-Dole bill also has a payback clause. This would provide a payment to the federal agency that funded the project, provided the patent proved to be a money-maker. It would give the government 50 percent of all net income above $250,000 received by a university from licensing an invention—not to exceed, however, the amount of government funding in the first place. It sounds straightforward, but some researchers see problems with it. "In arriving at a remuneration formula, is the government support to be determined on the basis of one year? Two years? Ten years?" asked Baruch S. Blumberg, a Nobel laureate who recently testified on behalf of the bill. "Some grants are now in their 20th year. Resolution of this question could become an accounting nightmare."

Despite such problems, which according to Senate aides will be ironed out in conference, the bill has gained considerable congressional support. It has 28 cosponsors that range the political spectrum from Senator George McGovern (D–S.D.) to Senator Strom Thurmond (R–S.C.). Identical legislation (H.R.2414) has been introduced in the House by Peter Rodino (D–N.J.), chairman of the House Judiciary Committee.

The GAO has also given its seal of approval to the bill. "We believe a clear legislative statement of uniform, government-wide patent policy is long overdue," said Elmer B. Staats, Comptroller General, in testimony before Senator Bayh's subcommittee on the Constitution. He noted, moreover, that a recent GAO study showed that HEW and other departments have been moving from what was once a liberal policy on the transfer of patent rights to one that is much more conservative. He said "an easing of the red tape leading to determinations of rights in inventions would bring about an improvement of this record."

In a move that may gain Administration support for the bill, a Commerce Department study has backed the idea of granting exclusive licenses from federally funded research. The recommendations grew out of an Administration domestic policy review on problems with industrial innovation. "If the results of federally sponsored R & D do not reach the consumer in the form of tangible benefits, the government has not completed its job and has not been a good steward of the taxpayer's money," said the advisory subcommittee on patents and information chaired by Robert Benson of Allis-Chalmers Corp. "The right to exclude others conferred by a patent or an exclusive license under a patent may be the only incentive great enough to induce the investment needed for development and marketing of products."

Foes of the legislation are few, but they do exist. One is Admiral Hyman Rickover, the Navy's veteran apostle of nuclear-powered ships. The reason so many government-owned patents are not used, he recently told a Senate hearing, is that the vast majority of them are worthless. "These patents are filed defensively, or as status symbols. Other times an inventor simply misjudges the attractiveness of his ideas. . . . In my opinion, the bill overemphasizes the importance of patents, and, if enacted, would divert attention and resources of the government agencies away from their main functions."

Rickover also criticized as cosmetic a provision in the bill for march-in rights (which let the government take back the patent if it feels a discovery is being marketed too slowly). The government has had march-in rights since 1963, he said, but it has never used them. "To be in a position to exercise these rights a government agency would have to stay involved in the plans and actions of its patent holders and check up on them. If a government agency ever decided to exercise its march-in rights and the patent holder contested the action, no doubt the dispute would be litigated for years."

Though Rickover came down hard against the bill, other traditional foes of such legislation have eased up. The Justice Department, usually hostile to anything that smacks of monopoly, says it is reassessing its position. An aide to Senator Russell Long (D–La.), a veteran backer of government-held patents, has told Bayh's staff that the senator will not "actively oppose" the bill. And Senator Gaylord Nelson (D–Wis.), a longtime foe who asked the Administration to suspend new rules for IPA's last year so he could hold hearings to see if they were a "giveaway" of public funds, is not actively opposing the bill, according to his staffers.

With the opposition not putting up their usual fight, is the bill a sure thing? Not quite, say several Senate aides.

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FDA Bans Speed in Diet Pills

The sale of amphetamines, the much-abused stimulants, will be cut back by 80 percent or more if a decision made by the Food and Drug Administration (FDA) on 16 July is made to stick. The FDA announced that, if no valid objections are filed before 16 August, it will ban the use of amphetamines and methamphetamines as an aid to dieting because they have little beneficial effect and pose a significant risk to public health. The FDA decided that the drugs should be given only to patients with a clear need for them—primarily those suffering from narcolepsy (uncontrollable sleepiness) and childhood hyperactivity.

Other countries took this step years ago, and Canada reports that, since it took action in 1971, the volume of amphetamines used for diet control has declined from 757 kilograms a year to 0.710 kilogram. The corresponding figure for the United States is about 2180 kilograms. The FDA has been trying to accomplish a similar ban for nearly 8 years, but unlike the Canadian government, it has become entangled in lengthy negotiations with U.S. amphetamine makers. No companies in Canada make the drug.

John Griffith of the addiction research center at the National Institute on Drug Abuse has reported that "speed" is not much better than a placebo in diet control. This finding is published in the FDA *Federal Register* notice of 17 July. The notice also summarized the findings of Lester Grinspoon, associate professor of psychiatry at Harvard: "After the 3- to 4-week euphoric high, which may cause diminished food intake and consequent weight loss, amphetamines are no longer effective as anorectics unless the user increases the dose, thus initiating a pattern of abuse." The average weight loss during the first weeks is less than 10 pounds, which is of no help to a clinically obese person, particularly since the effect is short-term. If the prescription is canceled after a few weeks—as good medical practice requires—the patient often suffers a "rebound," eating more than before to compensate for the sudden feeling of deprivation.

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They concede that the biggest hurdle to overcome is the weight of conventional wisdom. It goes something like this. Such a bill would permit the founding of monopolies that can charge high prices for the fruits of tax-aided research. It's a free lunch, say the critics, and it's not fair. One Senate aide who was skeptical of the bill put it this way. "At the stroke of a pen," he said, "you are creating billions of dollars of property that did not exist before, property that is created with taxpayer support. We are not about to jump on the bandwagon. We have an obligation to the public and to other patent holders. We want to make sure this is good public policy before we start touting its wonders."

For more than 30 years, the government has operated on the assumption that the economic rewards from federally funded R & D should be captured by the government, or shared only grudgingly with others, since public funds were used. Hence, the government's collection of 30,000 patents. That policy, however, has not produced an astounding record of economic returns, and the conventional wisdom on public money and private gain may be in the midst of change. The innovation "lag," moreover, is becoming pop drama, as evidenced not only by the Administration's domestic policy review but by media coverage such as the 4 June *Newsweek* cover story on innovation, subtitled "Has America lost its edge?" The winds of opinion are shifting. It may no longer take a leap of logic to see that good public policy might include a modicum of private gain, especially when the alternative is patent portfolios that gather dust on government shelves.

—WILLIAM J. BROAD

Whistle Blower Reinstated at HEW

For more than a decade, Norman J. Latker, while working as patent counsel for HEW, urged the department to give the patents derived from HEW-funded research back to the universities that originally did the work. During this time, HEW patent policy became a model for many federal agencies. Then, last December, Latker was bounced out of government service after denouncing an attempt by his superiors to put a lid on patent transfers. He has now, however, been reinstated.

Latker returned to his post as HEW patent counsel at the end of July. The action was called for by a civil service review board that overturned Latker's firing on procedural grounds. HEW, which hedged for 1 month before commenting on the action of the review board, has decided not to appeal the ruling.

The reinstatement is timely. Support is now building for the Bayh-Dole patent bill, and Latker's return to HEW is seen by many university researchers and patent-transfer fans, to whom Latker is something of a hero, as a shot in the arm for their cause.

Latker is anything but a revolutionary. A 22-year veteran of government service, with 15 of them in HEW's patent office, he is credited with helping develop such mild-mannered innovations as Institutional Patent Agreements (IPA), which aid the flow of patent rights from government to universities. The story of their rise at HEW is simple. In 1968, the Government Accounting Office (GAO) investigated the pharmaceutical programs at the National Institutes of Health (NIH) and found no evidence that drugs developed with NIH support ever reached the public. GAO blamed the lack of technology transfer on HEW's practice of retaining all rights to inventions.

After a departmental shake-up in 1969, Latker helped develop a system whereby HEW automatically gave patent rights to the university where a discovery was made and allowed it to license the patent to a private company, which could then develop and market the product. Such IPA's were issued only to universities with a good track record of technology transfer. Latker, however, also urged the transfer of patent rights to universities without such an IPA, eventually releasing 30 to 40 patents a year on such a case-by-case basis. For some time everything sailed along smoothly. Then in August 1977, Latker was ordered to send all requests for patent waivers up to the HEW general counsel's office. And there they sat. Up until that time, Latker had final say on patent transfers. But no more. The public position of HEW was that all patent matters were "under study," and that no one in the general counsel's office was quite sure just when the review would be finished.

By the fall of 1978, more than 30 requests for individual patents and three requests for IPA's were gathering dust in the general counsel's office. Universities got upset and complained to Congress. So did Latker.

In September 1978, Senator Dole accused HEW of "pulling the plug" on biomedical research. To support the charge, he quoted an internal memorandum from the HEW general counsel's office. "Recent experience with the high cost of proliferating health care technology," it read, "suggests that there may be circumstances in which the Department would wish to restrict or regulate the availability and cost of inventions made with HEW support." HEW Secretary Califano and his advisers had decided to wage war on "runaway medical technology." One way to do so was apparently to deny universities the transfer of patent rights from government-funded research. On 13 September 1978 Dole and Bayh held a press conference and announced a bill that would cut through the backlog. HEW responded quickly. The next day Califano ordered his staff to transfer the patents back to the universities. Within weeks, HEW released 20 of the 30 patents. Soon afterward they also released Latker.

Departmental spokesmen now insist that Latker was not given the boot for blowing the whistle on HEW. Latker was dismissed, they say, because his superior, Richard Beattie said Latker did not meet "professional standards," and because of "specific instances" of misconduct including "forms of lobbying flat out forbidden by the government's codes of conduct."

Latker recently told *Science*, however, that official charges were never brought against him. He was simply fired. But now that the civil service has reinstated him and HEW has decided not to appeal the ruling, Latker says he is simply glad to be back. "It's been a difficult period in my life," he says. "I'm happy to once again have the chance to work with the department."—W.J.B.

SUPA Meeting
February 6, 1984
Washington, D.C.

RESEARCH AGREEMENTS AND THE LONG TERM

by Edward L. MacCordy
Washington University

Collaborating with industry on research programs they sponsor in the university has proved to be an interesting and productive experience for us at Washington University, and we believe for the companies involved. On the whole these research arrangements have involved us in a variety of situations different from our long and continuing experience with government research sponsors. We enjoy the close, cooperative working relationship which has developed with company management, their scientists and even their attorneys. There have been problems but working them out has proved the original intent of both parties, that these be truly collaborative programs. And let's not forget, this is a relatively new experience, one from which we are continuing to learn.

For example, we have two major hybridoma contracts which will expire this year. They have provided us with about $5½ million in research support for three years. The research has been very successful, producing more output than the company labs, production facilities and marketing systems could absorb. Compounding the situation, the product objectives of the companies have changed. Continuation of this line of research into the future is no longer compatible with corporate development plans. So, we have been exploring the alternatives of continuing the program under sponsorship of one or more new companies, or possibly instigating a research and development limited partnership which would provide $12-$15 million in contract support for a five year period.

In another case, our $25 million, five year biomedical research program with Monsanto, the venture has been pleasingly productive as indicated by a constantly increasing presence in our laboratories of their patent attorneys. The other day I was told they anticipate a need for 2½ patent attorneys full time to deal with the research output.

These industrial research contracts essentially represent the integration into a single cooperative venture of activities which previously were separate and independent. These agreements provide (1) support for a broad area of scientific research, (2) a faculty proposal system, (3) a collaborative peer review project selection process, (4) a company monitoring system for early detection and disclosure of inventions (both patentable and not), (5) a process for the immediate filing of patent applications by company attorneys in the university's name, (6) cooperative efforts between our scientists and theirs to transfer the technology to their labs for scale up and commercialization, and (7) an established framework, including basic terms, for licensing any new technology to the company. It's a comprehensive, efficient and productive arrangement for technology creation and transfer which is especially cost effective for the university. But, this approach to technology transfer is not necessarily adaptable to all areas of science and technology nor to all companies, even major ones.

So, today, I would like to deal with industrial sponsorship of university research in the context of a set of technology transfer methods, as only one of the productive methods available in conducting that total transfer process. The agenda of this meeting treats some other elements of a comprehensive technology transfer program. All are useful in the right circumstances, and there are always new concepts on the horizon which will find their proper place in time.

To understand and appreciate where universities are today and especially where they are heading in their technology transfer activities, it is helpful to understand the history of developments in this area.

The early days must have involved a very few mavericks dedicated to bringing research results out of the university lab for public benefit; men who realized that publication in scientific journals, though very desirable for other reasons, none the less represented an ineffective transfer method devoid of incentive for anyone but the university scientist.

In 1912 Professor Cottrell used his patents on the electrostatic precipitator to establish Research Corporation which continues to provide patent management service to educational institutions to this day. I believe one of my neighbors, St. Louis University, used Research Corp. many years ago to obtain and manage a vitamin patent which thereafter provided support to the university's department of Biochemistry for years. Like all of us though, Research Corp. had bad days as well as good in this game of technology roulette. At one time it had assigned to it by MIT the Forester invention on the magnetic core used in computer memory devices. Apparently in the 1950's not desiring to do battle in court with IBM, the invention was reassigned to MIT which went on to settle the case and earn millions on one of the biggest financial winners in university history.

Of course much earlier, in 1925, the unique and famous WARF, the Wisconsin Alumni Research Foundation, was founded with assets of $900 and Professor Steenbock's vitamin D invention. WARF has been fantastically successful with at least two big winners, Vitamin D and Warfrin, and has paid over 100 million dollars to the University of Wisconsin since its founding, an exceptional feat. However, it should be realized that the WARF success story is not one of patent management alone. In those early days the director was not so foolish as to dissipate his major royalty income by investing it

solely in the university's research. No, he played the stock market and built up a critical mass of investments for WARF endowment. To this day WARF possesses a major endowment and is an active venture capital investor in local companies. Although royalty income produces a million dollars or so a year for the university, investment income trebles or quadruples that amount.

There is only one WARF and it has courageously done what few of us, except MIT and in the near future maybe Stanford, would entertain doing, becoming involved in major litigation. Currently it is a co-defendant in an $82 million product liability suit and going back to 1944 it was involved in infringement and invalidation litigation over the vitamin D patent. As an interesting sidelight concerning the practice of field-of-use licensing, since WARF was in the great dairy state of Wisconsin, oleo-margarine manufacturers were denied licenses to this patent. So much for mixing politics and patents.

This brings me to the mid 1960's, to what might be termed the start of the 15 years struggle for ownership by universities of patents derived from government sponsored research. A famous GAO study of that era concerning the use of results from research in medicinal chemistry, reported that industry would no longer cooperate in commercializing new drugs from HEW research and interest by university's scientists in developing new drugs was decreasing. At that time HEW was very resistant to patenting and exclusive licensing of inventions. Instead, the Department preferred to dedicate inventions to the public through the publication process thereby making them freely available to all. In taking this position HEW relied on a 1924 opinion of the Attorney General that agencies could not grant exclusive licenses under government owned patents without specific statutory authority. This question was to reappear in litigation in the mid 70's.

This GAO study resulted in a new and enlightened era at HEW focused on the extensive use of a liberal Institution Patent Agreement, the famous IPA's which technically still exist. Norm Latker, then Patent Counsel for HEW, administered the IPA program in such a manner as to develop a nation-wide interest by universities in patent management. Through his efforts a productive relationship between universities and HEW was developed based on mutual respect and cooperation. In not too many years Norm's extraordinary dedication would come very close to costing him the loss of a lifelong career of outstanding government service.

By the early 70's the number of experienced university patent administrators was still small but there was a sizeable group of us eager to learn and to seek massive riches through licensing for our institutions in the grand style of WARF and MIT. These administrators started getting together in Chicago at the University/Industry forums put on by Dvorkovitz and Associates. At these forums they could present their patent portfolios, if any, to licensing representatives from industry and had an opportunity to learn how companies handled the licensing of new technology. Above all else they made valuable personal contacts in industry whom they could call on for assistance in the future.

Organized and effective communication among university patent administrators, of which this meeting is a continuing part, commenced on October 15-16, 1974 at a special gathering on Technology Transfer organized by Allan Moore at Case Western Reserve University. About 100 university administrators attended along with representatives from government and interested patent management firms including Research Corp, Dvorkovitz, Battelle Development Corp., and Arthur D. Little. Discussions started at that meeting continue to this day on such fundamentals as institutional patent policy, organization of the patent administration function, evaluating disclosures, filing patent

applications, and how to market inventions and draft license agreements. It is notable that Howard Bremer's caution to the attendees, that on average only one out of five hundred disclosures would ultimately produce income, did little to discourage us. Apparently the odds have improved with time. Another momentous event occurred at this meeting. Quietly and without announcement, a few of the attendees met in a back room and founded this SUPA organization.

About this time several major events occurred which would severely impact university technology transfer. Almost unnoticed until years later, at least in the technology transfer field, was the development in 1975 of hybridoma technology by Kohler and Milstein in England. The biotechnology revolution was well under way. For better or worse these English scientists were not as fortunate as Professors Boyer and Cohen. They did not have a Niels Reimers rushing to the British Patent Office to establish their ownership of this new revolutionary technology, not even in their home country.

The year before in 1974, three court cases of overwhelming importance attracted the attention of every university patent administrator. These were the two Public Citizen cases involving the General Services Administration and the case of Washington Research Project vs. HEW Secretary Weinberger. The plaintiffs in all three cases were Mr. Nader's consumer advocate organizations. The first two cases essentially claimed that exclusive licensing by a government agency of a government owned patent was illegal because it involved the disposal of government property without statutory authority. The court ruled in favor of the plaintiffs which could have resulted in the termination of all Institutional Patent Agreements with universities and the voiding of all licenses of inventions derived from government sponsored research. Fortunately the ruling was overturned on appeal but only on a technicality. The Nader forces could have refiled the case and probably would have won. The

The need for Patent legislation was becoming urgent.

The Washington Research Project case involved the issue of whether university research proposals could be withheld from release under the Freedom of Information Act using the "trade secret" exemption, i.e., the 4th exemption. Of course one risk was that if research designs contained in proposals were instantly releasable to the public on request, this might well constitute publication under patent law. The court ruled that research designs submitted in grant applications were not exempt from disclosure since, in the words of the court, "it defies common sense to pretend that university scientists are engaged in trade and commerce." A footnote in the decision saved the day by stating that the possibility of commercial activity was not absolutely precluded simply because no evidence of it had been presented by the Government in Court. Thus was laid the somewhat shaky basis for administrative case by case determination concerning public release that is still in use.

In a brief description I cannot do justice to the struggle for statutory authority which took place over the next few years and which finally resulted in the passage of PL 96-517, the University and Small Business Patent Act. Norm Latker, Howard Bremer, Niels Reimers, Roger Ditzel, Art Smith and many others fought a multi year uphill battle against some of the strongest forces in this town, including powerful Senators and Congressmen, Ralph Nader, Admiral Rickover, and the leading patent counsels of various Government agencies. Victory finally came with the passage of PL96-517 in 1981 and was quickly followed by a final skirmish with patent attorneys from several mission agencies still determined to salvage what power they could during the drafting of implementing regulations, now OMB Circular A-124.

A fresh, invigorating era was dawning for university technology transfer. Everything seemed to be falling into place just at the right time. The Carter Administration's Domestic Policy Review had focused the nation's

attention on lagging innovation and productivity, and had identified what was termed a "gap" in research relations between the country's universities and industry. PL 96-517 blessed exclusive licensing by universities thereby removing industry's long held concern over possible loss of exclusive rights from research they might sponsor in universities. No longer need they fear contamination of their invention rights by closely related government sponsored research, a fact that made universities a much more attractive research resource.

The climate was further enhanced by changes in the tax law designed to encourage industry to undertake more research. Special R&D tax benefits were offered for industrial investment in university research. But beyond that the tax code now encouraged the formation of research and development limited partnerships, a means to stimulate a greater national investment in R&D beyond that being made by government and industry.

Finally, the biotechnology revolution was ushered in by the new technologies of hybridomas and genetic engineering. The 1980 Chakabarty decision by the Supreme Court cleared the way for patenting of the new life forms which would be produced from these revolutionary technologies. Universities would be essential players in the high stakes biotechnology game since their biological scientists were now a scarce, valuable and essential resource. The same phenomena had occurred briefly and on a smaller scale a few years earlier when computer and X-ray technologies were merged to produce the computerized tomographic scanner and computer scientists at several universities found themselves highly valued by X-ray companies. But the biotechnology revolution would bring both opportunities and challenges of a type and scale never before faced by universities.

Niels Reimers would extend his role as a leading innovator in patent management by filing and prosecuting the basic and somewhat controversial Boyer-Cohen patent applications, technology which would quickly earn a couple

of million dollars in licensing fees for Stanford and Cal. Whether he has a tiger by the tail is yet to be seen but most certainly this will be a benchmark example for university patent administrators.

Steve Atkinson would suffer through Harvard's proposal to join with their Professor Patashne and others in the creation of another Genentech ending up two years later with an offer instead to 200 companies to license the Patashne patents, resulting in a somewhat disappointing response from industry.

Agrigenetics would raise $55 million under an RDLP and pose new and different licensing issues for a dozen or so universities who were the recipients of the RDLP's research contracts.

Multi-million dollar research contracts which had appeared earlier between Exxon and MIT, and Monsanto and Harvard would suddenly pop up at Massachusetts General Hospital, Washington University, Rockefeller University University and elsewhere, inviting Congressional and press skepticism about the University's ability to avoid corruption except under government sponsorship.

And all the time with little fanfare the universities continued development of programs to license the technology derived from research sponsored by government and other non-commercial organizations.

It is appropriate now to reflect on what universities should be accomplishing and how this can best be done. Ten years ago at the Case Western Reserve meeting Howard Bremer observed that our purpose was not necessarily to make money for the university but to transfer technology for public benefit. In a 1980 article Niels Reimers reported that with few exceptions a University Licensing Office is economically viable only if one or more "big hit" inventions come along. It should be obvious by now that both patent and research administrators should employ the most cost effective transfer arrangements. Further, they should be concerned with more than just obtaining and licensing patentable inventions for the purpose of enriching their institutions.

Our university laboratories are staffed by over 50,000 innovative, doctorial level scientists and engineers engaged in creative research and development in every field of technology, not just biotechnology. Patent and copyright licensing is of limited effectiveness by itself as a technology transfer method, as is publication in professional journals. Research collaborations with industry add another dimension to technology transfer of significant value in certain situations.

But the opportunities which lie ahead may enhance university technology transfer beyond what we presently can imagine. In the future RDLP's may be used extensively by universities to finance research alliances with the small, capital-poor, but extremely energetic and innovative high tech companies in many fields. Multi-million dollar RDLP's and venture capital pools are being proposed (one talks of a $1 billion dollar fund) to finance appropriate research at a consortium of universities with the intent of transferring patented and unpatented intellectual property to start up companies created, staffed and financed by the general partner or venture capitalist. Could this help us to retain our faculty members if we would take and share equity positions in lieu of royalties? Will such high tech ventures put greater emphasis on the commercial potential of new technology and less on its patent potential.

I am confident that more new ideas will appear soon. Such opportunities are not for the timid or the unimaginative, and take note that they will be accompanied by constant pressure to integrate university research and intellectual property administration, one way or another.

Idle dreaming? Ten years ago at the Case Western Reserve meeting much of what you are discussing in the SUPA program here, today and tomorrow, as well as what is actually happening now in university technology transfer, would have been dismissed as impractical or objectionable, or both.

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TELEFAX CONTROL SHEET

SENT TO: Beth Berman

DATE SENT: 3/28/05

SUBJECT: Bayh-Dole

No. of pages (including this cover sheet):

FROM: Noam LATKER

Remarks: Foun papers we discussed.

D R A F T - 2/28/77
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TWO CULTURES IN THE LABORATORY

The public at-large has shown increasing interest in what goes on in the laboratories dedicated to research and development in our nation, and this is fostered by an increasing attention to these matters in the public press and on television. The public, however, is sometimes confused about what actually transpires, and particularly about the purposes and intents of the people responsible for the action. This confusion, it appears to me, is in part due to the ill-advised use of certain terms, and sometimes it is the scientist himself who is responsible for the confusing usage. It is my purpose in what follows to try to find some useful order in what currently approaches chaos.

There are two quite distinct cultures in this country. One of these is housed largely in the laboratories of our universities and medical schools. The other is the predominant activity of the laboratories of the industrial sector. In the academic environment there is opportunity for science to prosper. "Science" derives from the Latin word for knowledge. It treats [largely] of ideas and stands in contrast to technology, which is emphasized in many industrial laboratories. "Technology" stems from a Greek root meaning art or craft. It deals largely with things--materials, instruments, machines, and sometimes methods. Science and technology are both among the creative activities of the human mind and the human hand. They are extraordinarily valuable activities. They are interdependent and they interdigitate very closely, but they are not the

same. The frequent linkage of the two words by the conjunction "and" does not in any sense imply identity, any more than it does for "bacon and eggs." It is generally relatively easy to tell the bacon from the eggs. It is also relatively easy usually to distinguish the science from the technology. Science progresses through the performance of research, while technology proceeds by the conduct of development. Again, as with bacon and eggs, although research and development (R & D) are often spoken of in one breath and often appear as a single budgetary item, they are not identical. In almost every instance, the person working in the laboratory will know perfectly well whether he is doing research or doing development. It should be noted that the very same person may alternate his activities between research and development. Thus, he may spend the morning developing an instrument or a method in order that he can apply it to a research problem in the afternoon devoted to an understanding of a fundamental mechanism.

The goals of the two activities are also distinct. Research, if successful, leads to discovery; and discovery, in turn, leads to publication. Development, on the other hand, leads to invention; and invention, if deemed meritorious, leads to patents. The rewards of publication are manifold and include ego-gratification, a possibility of academic promotion, and an increase in likelihood of success in the competition for research support. In the rare instance it may also lead to the capture of a prize. Whereas the acquisition of pa··nts may also have many gratifications, the one which clearly predominates is money. These matters are summarized in Table 1.

Whereas these two cultures are distinct and different in their origins and in their purposes, they relate to each other in many ways. The advance of science is critically dependent upon many technological developments, such as the invention of a novel analytical instrument or the development of a useful chemical synthesis. Conversely, the development of technology is critically dependent upon the knowledge which is generated by scientific research. Certainly practically every major technological development in the past can trace its origins back to scientific research which was fundamental to the developmental process.

It should, of course, not be supposed that research is the peculiar domain of academia, and development the exclusive pasture of industry. This line has frequently been crossed and in both directions. The stress, however, is perfectly clear. Whereas publication is the highly respected product--indeed, the currency--of academic research, patents are an important expectation of industrial development.

It is my belief that this dichotomy has proven valuable and is, in general, a good thing. Both channels must proceed if the totality of purposes is to be achieved. A quenching of scientific research could soon lead to the exhaustion of undeveloped knowledge, while a failure of technological development would certainly markedly slow down the progress of science.

Whereas science and scientists may have a slightly tarnished image at this time and in this country, the United States continues to have a love affair with technology. We love our automobiles, our airplanes, our

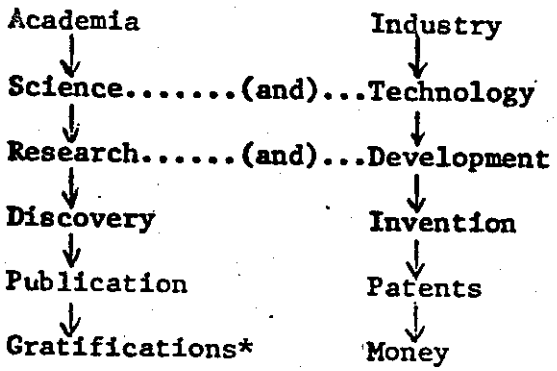
calculators, and our kitchen appliances. It is notable that as our children progress through the school system and are repeatedly exposed to courses in American history, they learn a good deal about Thomas Alva Edison, Samuel F. B. Morse, Alexander Graham Bell, and Eli Whitney. But do they ever hear of Joseph Henry, Josiah Willard Gibbs, A. A. Michelson, or Robert A. Millikan? In most general history courses, science as such receives short shrift despite the enormous contribution which scientific research has made to our present way of life. Recently, technology has come into prominence in such widely used phrases as "technology transfer" and "technology assessment." Curiously, we do not hear much about either the assessment or the transfer of science. Even in the field of medicine, it would appear that it is technology rather than science which must be transferred from the laboratory centers to the physicians in the hustings. This suggests that we are expected to treat our patients with new pills and new procedures but not with new knowledge.

The stress on technology in the absence of an offsetting stress on science is not without hazard. Technology leading to patents is certainly fiscally more immediately rewarding than is scientific research. During the affluent period when scientific research has been very generously supported and academic centers were not in financial distress, scientific research has of course flourished. As academic centers find it increasingly difficult to balance their budgets, as universities and medical schools are forced to cut programs, as Federal and other support of scientific research fails to keep pace with inflation, a new pressure will surely

develop in the academic laboratories. One can imagine that the university officer whose responsibility it is to balance the budget may feel constrained to put pressure upon the scientists who are conducting research in the university laboratories to urge upon them to select product-oriented problems which may lead to remunerative patents. Thus, the financial officer of the university will behave very much as the director of development in an industrial situation must behave. Such pressure could, in fact, upset the present apparently satisfactory balance between the two cultures which we have described. The occasional development of a patentable discovery in the course of a research program has of course occurred and will continue to occur. Notable examples are the oft-quoted discoveries made by scientists at the University of Wisconsin, leading to the establishment and subsequent success of the Wisconsin Alumni Research Foundation. This, however, is quite another matter from the exertion of administrative pressure upon academic scientists to dedicate themselves toward patentable invention. Technological development will always continue to take place in the cellar of the individual inventor, in our great industrial laboratories, and from time to time in academic institutions. Scientific research, however, is so heavily concentrated in these academic institutions that if they should become inhospitable to this activity it would find no other place to go.

Table 1

The Two Cultures



*See text

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3/4/77

THOUGHTS RESPONSIVE TO
"TWO CULTURES IN THE LABORATORY"

I will start off agreeing with the last paragraph of "Two Cultures." Under no circumstances should an academic scientist be subjected to pressure from administrators to select product-oriented problems. We can help avoid such situations by stipulating in institutional patent agreements that the institution's patent office must be removed administratively from the scientist and must have no connection with promotion committees or other committees that deal with a scientist's career.

On the other hand, awareness of the potential of patents on the part of the scientist who is described by Hans as spending a morning in ". . . developing an instrument or method so that he can apply it to a research problem in the afternoon . . ." may be helpful to the university and to him. A notable example occurred here when Sid Udenfriend developed the fluorospectrophotometer. I don't know if the instrument would have been developed by a commercial firm without an exclusive license. I do think that it benefited investigators in that field by having the instrument become available to them.

There are many crossovers between science and technology. As Hans points out, people in academe do both. Also, many of the projects that NIH supports are not basic research, but applied. Indeed, we are currently engaged in an exercise to try to classify "basic" and "applied" by asking

executive secretaries and study section members to put the projects they review into various classes, clinical vs. non-clinical, mechanism-oriented or treatment-oriented. We are trying to classify contractual projects similarly, including development.

Publications and patents are not antithetical. A paper can be submitted to a journal and a patent application can be filed at the same time. There is not much lost by doing both, except a little time. The patent advocates say that the patent is another method of disclosure of the results of research, and they claim that the patent, if properly administered, assures further effort in the development of an invention to practical use.

I am not so much interested in seeing that individual scientists are rewarded for inventions through patents as I am in providing additional funding for their institutions and, even more important, that the products of research are exploited for the benefit of the general public, who after all pay for the support of research.

The advocates of the patent system state that failure to patent inventions results in failure to have useful products or methods developed to the point of application, because investment capital is not available for development when there is no assurance that there will be a return on the investment. Private capital flows where there is some protection of the investment by a patent or a license. Otherwise, when there is no such protection, competitors may come in and exploit the development when it is achieved. This type of situation, it is claimed, results in potentially useful inventions sitting on the shelves.

When asked to give examples of inventions that were not exploited because they were not patented and fell into the public domain, the advocates of patents say that they cannot prove the negative. They would rather give examples of the development that followed the issuance of patents under the Federal patent policy that went into effect in the Kennedy era. A list of patents that led to development is attached. Here again, it is a judgmental appraisal of costs of development and market potential when we try to decide if the work would have been done without a license.

The perception that I have is that antipathy to patents is a phenomenon of the biomedical research community. Certainly chemists and physicists in universities have been alert to patents for years, particularly the chemists. It is a matter of the way the biomedical research culture regards itself. However, I see no harm in making biomedical research investigators aware of the patent route to development.

As I stated at the outset, the principal danger, that investigators may be pressed into an orientation towards patents, can be averted by various means. I am not so sure, either, that the better investigators can be pushed that way. They are the better investigators because of their curiosity and their intuition. When, either as a result of an intuitive approach or a serendipitous observation, they make a discovery that can lead to a beneficial product if it is developed, they can benefit their instituions and society as a whole.

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SENT TO: Beth Berman

DATE SENT: 3/28/05

SUBJECT: Bayh-Dole

No. of pages (including this cover sheet):

FROM: Norm Latker

Remarks: This is a good starting point to the understanding the evolution of B-D. The first nine pgs. of the report which is attached is the logical base from which B-D is built. You need to understand these pages which directly refute current critics of the Act.