STATEMENT OF
OF
NORMAN J. LATKER
PATENT COUNSEL
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE before the
SUBCOMMITTEE ON SCIENCE, RESEARCH AND TECHNOLOGY
HOUSE OF REPRESENTATIVES
MAY 26, 1977

MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE.

MY NAME IS NORMAN LATKER. I AM PATENT COUNSEL FOR THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE. MY OFFICE IS ASSIGNED TO THE BUSINESS AND ADMINISTRATIVE LAW DIVISION OF THE OFFICE OF GENERAL COUNSEL, WHICH HAS THE INITIAL RESPONSIBILITY FOR MANAGING THE INVENTIVE RESULTS OF THE DEPARTMENT'S RESEARCH AND DEVELOPMENT BUDGET.

I VERY MUCH APPRECIATE YOUR INVITATION TO SPEAK TO THE OPERATION OF GOVERNMENT PATENT POLICY, AS I BELIEVE IT TO BE A FUNDAMENTAL CONCERN TO THE LARGER ISSUES OF:

MAINTAINING A FAVORABLE BALANCE OF PAYMENT AND TRADE FOR OUR RESEARCH INTENSIVE INDUSTRIES,

ENHANCING TECHNOLOGY TRANSFER, AND

QUESTIONS OF INDUSTRIAL CONCENTRATION AND CONSUMER PRICES.

IN MOST PART I HOPE TO UTILIZE THESE MOMENTS AS BEST I CAN TO SUGGEST THE IMPORTANCE OF PATENT PROTECTION IN BRINGING

TECHNOLOGY ARISING FROM GOVERNMENT SPONSORED RESEARCH AT UNIVERSITIES AND NON-PROFIT ORGANIZATIONS TO FRUITION. THIS IS AN AREA OF VITAL INTEREST TO HEW, SINCE THE DEPARTMENT IS THE LARGEST SINGLE SOURCE OF FUNDING FOR SUCH RESEARCH IN THE UNITED STATES, AND THE SUBSTANTIAL PORTION OF ITS RESEARCH BUDGET IS DEVOTED TO THIS CATEGORY OF RESEARCH.

THE MOST OBVIOUS PROBLEM AFFECTING ULTIMATE UTILIZATION OF INNOVATIONS RESULTING FROM DHEW FUNDED RESEARCH AT UNIVERSITIES AND OTHER NON-PROFIT ORGANIZATIONS IS THE FACT THAT THESE ORGANIZATIONS DO NOT ENGAGE IN THE DIRECT DEVELOPMENT AND MANUFACTURE OF COMMERCIAL EMBODIMENTS, AND IT IS INDUSTRY WHICH MUST BRING SUCH INNOVATION TO THE MARKETPLACE.

A FUNDAMENTAL PREMISE OF DHEW PATENT POLICY AND PRACTICE IS THE UNDERSTANDING THAT INHERENT TO THE TRANSFER OF THE INNOVATIVE RESULTS OF THE RESEARCH CONDUCTED IN UNIVERSITY LABORATORIES TO INDUSTRIAL DEVELOPERS IS A DECISION ON THE PART OF THE DEVELOPER THAT THE INTELLECTUAL PROPERTY RIGHTS IN THE INNOVATION BEING OFFERED FOR DEVELOPMENT ARE SUFFICIENT TO PROTECT ITS RISK INVESTMENT. OF COURSE, NOT ALL TRANSFERS OF POTENTIALLY MARKETABLE INNOVATIONS FROM SUCH LABORATORIES REQUIRE AN EXCHANGE OF INTELLECTUAL PROPERTY RIGHTS IN THE INNOVATION, BUT IT IS UNPREDICTABLE IN WHICH TRANSFERS THE

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1/ PROBLEM AREAS AFFECTING USEFULNESS OF RESULTS OF GOVERNMENT SPONSORED RESEARCH IN MEDICINAL CHEMISTRY, AUGUST 12, 1968, GAO REPORT B-164031(2).

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RELATIONSHIP RESULTS WHEN THE PARTICULAR CAPABILITIES OF THE VARIOUS ELEMENTS, FEDERAL AND NON-FEDERAL, CAN BE UTILIZED TO THE FULLEST EXTENT.[5/] IT SEEMS CLEAR THAT THIS COLLABORATIVE RELATIONSHIP CAN ONLY EXIST IF EACH ELEMENT RECOGNIZES TO THE EXTENT FEASIBLE THE FUNDAMENTAL NEEDS OF THE OTHER ELEMENTS.

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1. ESTABLISHMENT OF PATENT MANAGEMENT FOCAL POINT IN THE INNOVATING ORGANIZATION TRAINED TO ELICIT INVENTION REPORTS AND ESTABLISH RIGHTS IN INTELLECTUAL PROPERTY ON A TIMELY BASIS FOR POSSIBLE

5/ TESTIMONY BY DR. JAMES A. SHANNON, DIRECTOR, NATIONAL INSTITUTES OF HEALTH, BEFORE THE SUBCOMMITTEE ON PATENTS, TRADEMARKS, AND COPYRIGHTS OF THE SENATE COMMITTEE ON THE JUDICIARY, AUGUST 17, 1965.

LICENSING OF INDUSTRIAL DEVELOPERS. THIS HAS BEEN ACCOMPLISHED IN THE MAIN BY EXECUTION OF INSTITUTIONAL PATENT AGREEMENTS (IPA) WITH UNIVERSITIES WILLING TO CREATE AND MAINTAIN SUCH A FOCAL POINT. THE IPA PROVIDES AS AN INCENTIVE TO ESTABLISHMENT OF A PATENT FOCAL POINT, A FIRST OPTION TO OWN ALL FUTURE INVENTIONS ARISING FROM DHEW GRANT SUPPORTED RESEARCH. WE PRESENTLY HAVE 70 IPA, AND

2. ASSURANCE THAT THE INNOVATING GROUP HAS THE RIGHT TO CONVEY WHATEVER INTELLECTUAL PROPERTY RIGHTS ARE NECESSARY TO ACCOMPLISH A TRANSFER TO AN INDUSTRIAL DEVELOPER. (THIS IS ACCOMPLISHED IN THE MAIN THROUGH THE IPA HOLDERS' FIRST OPTION TO OWN HEW-FUNDED INVENTIONS AND OUR WAIVER PROGRAM, WHICH PROVIDES FOR OWNERSHIP IN PETITIONING UNIVERSITIES NOT HAVING AN IPA WHO COME FORTH WITH AN ACCEPTABLE DEVELOPMENT PROGRAM FOR AN IDENTIFIED INVENTION.)

DHEW HAS CAREFULLY CIRCUMSCRIBED THE CONDITIONS OF LICENSING WITHIN WHICH A UNIVERSITY PATENT MANAGEMENT FOCAL POINT OR SUCCESSFUL PETITIONER CAN FUNCTION. THESE CONDITIONS HAVE

BECOME WELL KNOWN TO INDUSTRIAL DEVELOPERS AND HAVE BEEN GRADUALLY ACCEPTED IN LICENSING ARRANGEMENTS BY A WIDENING CIRCLE OF SUCH DEVELOPERS. THIS COMPARES TO THE VIRTUAL BOYCOTT REPORTED BY GAO OF DEVELOPMENT OF NIH GENERATED DRUG LEADS BY INDUSTRY DURING THE 1962-1968 PERIOD COVERED BY THEIR REPORT. A MUCH MORE DETAILED DISCUSSION OF THE PHILOSOPHY BEHIND THE DEPARTMENT'S PATENT POLICY WAS MADE IN MY TESTIMONY BEFORE YOUR SUBCOMMITTEE ON DOMESTIC AND INTERNATIONAL SCIENTIFIC PLANNING AND ANALYSIS ON SEPTEMBER 29, 1976.

SINCE 1969 THROUGH THE FALL OF 1974 WE ESTIMATE THAT THE INTELLECTUAL PROPERTY RIGHTS TO 329 INNOVATIONS EITHER INITIALLY GENERATED, ENHANCED OR CORROBORATED IN PERFORMANCE OF DHEW-FUNDED RESEARCH WERE IN THE HANDS OF UNIVERSITIES' PATENT MANAGEMENT OR SUCCESSFUL UNIVERSITY PETITIONERS FOR THE PURPOSE OF SOLICITING FURTHER INDUSTRIAL DEVELOPMENT SUPPORT. WE WERE ADVISED THAT DURING THE 1969-1974 PERIOD THESE UNIVERSITIES HAD NEGOTIATED 44 NON-EXCLUSIVE AND 78 EXCLUSIVE LICENSES UNDER PATENT APPLICATIONS FILED ON THE 329 INNOVATIONS. WE UNDERSTAND THAT THE 122 LICENSES NEGOTIATED HAD GENERATED COMMITMENTS IN THE AREA OF 75 MILLION DOLLARS OF PRIVATE RISK CAPITAL. SINCE 1974 TO THE END OF FISCAL YEAR 1976 THE NUMBER OF INVENTIONS HELD BY UNIVERSITIES HAS SUBSTANTIALLY INCREASED TO 517.

I HAVE ATTACHED TO THESE COMMENTS SOME EXAMPLES OF INVENTIONS LICENSED BY UNIVERSITIES WHICH HAVE REACHED OR ARE NEAR REACHING THE MARKETPLACE SINCE OUR 1974 SURVEY. NOTEWORTHY IS THAT THIS INCOMPLETE LISTING INVOLVES COMMITMENT OF RISK CAPITAL OF APPROXIMATELY 80 MILLION DOLLARS. AS YOU WILL NOTE, THERE ARE A NUMBER OF PHARMACEUTICAL PRODUCTS ON THIS LIST. WE KNEW OF NO COMPARABLE SITUATIONS AT THE TIME OF THE GAO REPORT OF 1968. I WOULD CONJECTURE THAT THIS NUMBER WILL INCREASE IN SUBSEQUENT YEARS DUE TO THE OPPORTUNITY OF THE PHARMACEUTICAL INDUSTRY TO CAPITALIZE ON POSITIVE LEADS FROM THE NON-PROFIT SECTOR WHICH COULD RESULT IN REDUCTION OF THE INDUSTRY'S ESCALATING R & D COSTS BY ELIMINATING A NUMBER OF BLIND LEADS. (THE ULTIMATE SAVING WOULD BE THE DIFFERENCE BETWEEN THE 11.5 AND 24.4 MILLION DOLLARS PER SUCCESSFUL DRUG DEVELOPMENT MENTIONED PREVIOUSLY.) THE RISE IN SUCCESSFUL DEVELOPMENT BY INDUSTRY OF UNIVERSITY GENERATED INVENTIONS IS ALSO CONSIDERED SIGNIFICANT WHEN NOTING THE STEADY DECLINE IN INTRODUCTION OF NEW DRUG ENTITIES IN THE UNITED STATES FROM 65 IN 1959 TO 15 IN 1975.[6/] THIS SLIDE MIGHT ALSO BE ATTRIBUTED TO THE INCREASED COST OF DRUG DEVELOPMENT.

6/ PHARMACEUTICAL TIMES, APRIL 1976 (BASED ON DATA FROM PAUL de HAEN, INC.) AND HENRY G. GRABOWSKI, "DRUG REGULATION AND INNOVATION IN EMPIRICAL EVIDENCE AND POLICY OPTIONS," AMERICAN ENTERPRISE FOR PUBLIC POLICY RESEARCH, WASHINGTON, D. C.

IN THIS CONTEXT IT IS APPARENT THAT THE EXISTENCE OF A LICENSABLE PATENT RIGHT IS PROBABLY A PRIMARY FACTOR IN THE SUCCESSFUL TRANSFER OF A UNIVERSITY INNOVATION TO INDUSTRY AND THE MARKETPLACE, AND FAILURE TO PROTECT SUCH RIGHT MAY FATALLY AFFECT A TRANSFER OF A MAJOR HEALTH INNOVATION. I BELIEVE SOME MEMBERS OF THE COMMITTEE ARE AWARE OF THE SPECULATION THAT PRIVATE DEVELOPMENT AND MARKETING OF PENICILLIN WAS FORECLOSED FOR OVER 11 YEARS DUE TO THE LACK OF A PROPRIETARY POSITION NECESSARY TO THE PROTECTION OF THE LARGE RISK INVESTMENT INVOLVED.[7/] IT WAS ONLY AFTER THE UNITED STATES GOVERNMENT UNDERTOOK THIS RISK UNDER THE PRESSURE OF WORLD WAR II THAT PENICILLIN's CURATIVE POWERS WERE MADE AVAILABLE TO THOSE SUFFERING FROM INFECTION.

IN ADDITION TO INITIAL ADMINISTRATION OF THE IPA AND WAIVER PROGRAM DISCUSSED, THE DHEW PATENT BRANCH ACTS AS THE PATENT MANAGEMENT FOCAL POINT FOR ALL INNOVATIONS TO WHICH THE DEPARTMENT RETAINS TITLE. THE DEPARTMENT'S PATENT PORTFOLIO PRESENTLY CONSISTS OF APPROXIMATELY 400 PATENTS AND PATENT APPLICATIONS, WHICH IN THE MAIN ARE DERIVED FROM DHEW EMPLOYEE INVENTIONS. A LESSER NUMBER ARE ATTRIBUTABLE TO INVENTIONS MADE BY EMPLOYEES OF UNIVERSITIES OR COMMERCIAL CONCERNS FUNDED

7/ DAVID MASTERS, MIRACLE DRUG, THE HISTORY OF PENICILLIN, PUBLISHED BY GYRE & SPOTTI, WOODE, LONDON (1946), PP. 104-105 AND
THE LAW OF CHEMICAL, METALLURGICAL AND PHARMACEUTICAL PATENTS, FORMAN, EDITOR, PUBLISHED BY CENTRAL BOOK CO., NEW YORK (1967).

BY DHEW GRANTS OR CONTRACTS WHICH THEY DID NOT CHOOSE TO MANAGE OR WERE NOT PERMITTED TO MANAGE. SINCE 1969 WE HAVE GRANTED 19 EXCLUSIVE LICENSES AND 90 NON-EXCLUSIVE LICENSES UNDER OUR PATENT PORTFOLIO. UNFORTUNATELY, WE HAVE NO STATISTICS ON THE AMOUNT OF RISK CAPITAL COMMITTED TO DEVELOPING THESE INVENTIONS TO THE MARKETPLACE, THOUGH WE BELIEVE IT TO BE SURELY MEASURED IN MILLIONS OF DOLLARS.

SAMPLING OF UNIVERSITY PATENT LICENSING PROGRAMS

Inventor	University	Invention	Licensee	Approximate Investment
Walser	Johns Hopkins U.	Keto-Acid analogs of Amino Acids for treatment of uremia	Pfrimmer of Germany and Syntex of U.S.A	Millions - Clinical trials in process. Expected to be marketed in 6 mos. in Europe.
Wiktor	Wistar Institute	Rabies Vaccine	Wyeth Laboratories	On the market - millions
Kamen et al	Case Western Res.	Methotrexate Assay during Cancer Chemotherapy	Diamond Shamrock Corp.	Being test-marketed. Production scheduled for late 1977. Millions.
Lillehei/Kaster	U. of Minnesota	Pivoting Disc Heart Valve	Medical, Inc.	Being sold in world-wide market since 1971. Millions.
Blackshear et al	U. of Minnesota	Implantable Infusion Pump (Constant Infusion of Drugs for Treatment of Cancer, Diabetes, Pain, Morphine-addiction, etc.)	Metal Bellows Co.	Undergoing clinical trials $750,000.
DeLuca	U. of Wisconsin	25-Hydroxycholecalciferol for treatment of Osteo-dystrophy with liver dysfunction	Rousel-Uclaf (Hoechst) and	Have applied for equivalen of NDA in France. Approximately $5 million.
			Upjohn	About to apply for an NDA and an NADA. Will spend about $10 million.
DeLuca	U. of Wisconsin	1-Alpha Hydroxycholecalciferol for treatment of Osteo-dystrophy with Kidney Dysfunction	Leo Pharma-ceuticals	Applying for new drug applications in Denmark and Great Britain. May be marketed this year. Approx. $5,000,000.

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DeLuca et al	U. of Wisconsin	1, 25-Dehydroxyergocalciferol for Treatment of Osteodystrophy with Kidney and Liver Dysfunction and Senile Osteodystrophy	Hoffman-LaRoche Inc.	About to apply for NDA. Will spend about $10 million.
Fox	Columbia U.	Silver Sulfadiazine used in Treatment of Burns	Marion Labs., Kansas City, Mo.	Now on market - Approx. $5,000,000
Heidelberger	U. of Wisconsin	Use of F_3TDR for Herpes Infections of the Eye	Burroughs Wellcome Co., Research Triangle Park, N.C.	Approx. $5,000,000 NDA expected by end of 1977.
Fischell	Johns Hopkins U.	Rechargeable Cardiac Pacemaker	Pacesetter Systems Sylmar, California.	On market since Feb. 1975 - Approx. $720,000
Holland	Tulane U.	Method of Reducing Intraocular Pressure in the Human Eyes (Glaucoma Treatment)	Cooper Labs., Bedford Hills, N.Y.	$2,000,000 - Development leading to DNA is in process and on schedule
Pressman	U. of Miami	Application of X-537A in the Cardiovascular System (for stimulation in cardiogenic shock, congestive heart failure, etc.)	Hoffman-LaRoche, Nutley, N.J.	$500,000 to $1,000,000 Clinical evaluations still in progress
Higley	Natl. Institute of Scientific Research	Polycarbonate Dialysis Membranes (kidney dialysis)	C. R. Bard Inc., Murray Hill, N.J.	Over $1,000,000. Market introduction expected imminently.
Talbot/Harrison	Johns Hopkins U.	Ballistocardiograph Apparatus	Royal Medical Corp. Huntsville, Ala.	Approx. $330,000. Now on market.

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Plotkin	Wistar Institute	Rubella Vaccine	1) Wellcome Foundation 2) L'Institut Merieux 3) Swiss Serum and Vaccine Institute and others (Merck, an Italian firm, etc.)	Approx. millions - Now on market.
Schaffner/Mechlinski	Rutgers U.	Derivatives of Polyene Macrolide Antibiotics	E.R. Squibb of U. S. A. and Dumex of Denmark	Millions - Clinical trials progressing favorably
Zweig	Syracuse U.	Apparatus for Measuring and Controlling Cell Population Density in a Liquid Medium	New Brunswick Scientific Co., Inc., of New Jersy	Millions - On the market since 1973
Lovelock	Yale U.	Gas Analysis Method and Device for the Qualitative and Quantitative Analysis of Classes of Organic Vapors	Varian Associates, Palo Alto, Calif.	On the market
Fried	U. of Chicago	Prostoglandins for possible Treatment of Bronchial Asthma, Duodenal Ulcers, Inflammatory Conditions, etc.	Richardson-Merrell, New York, N.Y.	Several millions - In process of development and testing for marketing here and abroad
Leininger/Grotta et al	Battelle Memorial Institute	Preparation of Non-thrombogenic Surfaces and Materials	C. R. Bard, Inc., Billerica, Mass.; Sherwood Medical Industries, St. Louis Mo.; and American Hospital Supply Corp., Irvine, California.	$107,754 - Some products being marketed and others being tested.

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Merrifield	Rockefeller U.	Apparatus for the Automated Synthesis of Peptides	Beckman Instruments, Fullerton, California	Being marketed since 1973.
Smith/Kozoman	Duke U.	Apparatus and Method for Rapid Harvesting of Roller Culture Supernatant Fluid	Bellco Glass, Inc. Vineland, New Jersey	$25,000 - Being marketed since June 9, 1976
Zweng	Stanford U.	Laser Photocoagulator	Coherent Radiation, Palo Alto, Cal.	Approximately $500,000 Standard tool of ophtholmologists
Sweet et al	Stanford U.	Cell Sorter	Becton-Dickinson, Rutherford, New Jersey	Approx. $200,000. Important research tool
Boyd/Macovski	Stanford U.	Computerized Axial Tomography	S.A.I. Cupertino, Cal.	Approx. $300,000. Will be marketed soon.

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1. ESTABLISHMENT OF PATENT MANAGEMENT FOCAL POINT IN THE INNOVATING ORGANIZATION TRAINED TO ELICIT INVENTION REPORTS AND ESTABLISH RIGHTS IN INTELLECTUAL PROPERTY ON A TIMELY BASIS FOR POSSIBLE

5/ TESTIMONY BY DR. JAMES A. SHANNON, DIRECTOR, NATIONAL INSTITUTES OF HEALTH, BEFORE THE SUBCOMMITTEE ON PATENTS, TRADEMARKS, AND COPYRIGHTS OF THE SENATE COMMITTEE ON THE JUDICIARY, AUGUST 17, 1965.

LICENSING OF INDUSTRIAL DEVELOPERS. THIS HAS BEEN ACCOMPLISHED IN THE MAIN BY EXECUTION OF INSTITUTIONAL PATENT AGREEMENTS (IPA) WITH UNIVERSITIES WILLING TO CREATE AND MAINTAIN SUCH A FOCAL POINT. THE IPA PROVIDES AS AN INCENTIVE TO ESTABLISHMENT OF A PATENT FOCAL POINT, A FIRST OPTION TO OWN ALL FUTURE INVENTIONS ARISING FROM DHEW GRANT SUPPORTED RESEARCH. WE PRESENTLY HAVE 70 IPA, AND

2. ASSURANCE THAT THE INNOVATING GROUP HAS THE RIGHT TO CONVEY WHATEVER INTELLECTUAL PROPERTY RIGHTS ARE NECESSARY TO ACCOMPLISH A TRANSFER TO AN INDUSTRIAL DEVELOPER. (THIS IS ACCOMPLISHED IN THE MAIN THROUGH THE IPA HOLDERS' FIRST OPTION TO OWN HEW-FUNDED INVENTIONS AND OUR WAIVER PROGRAM, WHICH PROVIDES FOR OWNERSHIP IN PETITIONING UNIVERSITIES NOT HAVING AN IPA WHO COME FORTH WITH AN ACCEPTABLE DEVELOPMENT PROGRAM FOR AN IDENTIFIED INVENTION.)

DHEW HAS CAREFULLY CIRCUMSCRIBED THE CONDITIONS OF LICENSING WITHIN WHICH A UNIVERSITY PATENT MANAGEMENT FOCAL POINT OR SUCCESSFUL PETITIONER CAN FUNCTION. THESE CONDITIONS HAVE

BECOME WELL KNOWN TO INDUSTRIAL DEVELOPERS AND HAVE BEEN GRADUALLY ACCEPTED IN LICENSING ARRANGEMENTS BY A WIDENING CIRCLE OF SUCH DEVELOPERS. THIS COMPARES TO THE VIRTUAL BOYCOTT REPORTED BY GAO OF DEVELOPMENT OF NIH GENERATED DRUG LEADS BY INDUSTRY DURING THE 1962-1968 PERIOD COVERED BY THEIR REPORT. A MUCH MORE DETAILED DISCUSSION OF THE PHILOSOPHY BEHIND THE DEPARTMENT'S PATENT POLICY WAS MADE IN MY TESTIMONY BEFORE YOUR SUBCOMMITTEE ON DOMESTIC AND INTERNATIONAL SCIENTIFIC PLANNING AND ANALYSIS ON SEPTEMBER 29, 1976.

SINCE 1969 THROUGH THE FALL OF 1974 WE ESTIMATE THAT THE INTELLECTUAL PROPERTY RIGHTS TO 329 INNOVATIONS EITHER INITIALLY GENERATED, ENHANCED OR CORROBORATED IN PERFORMANCE OF DHEW-FUNDED RESEARCH WERE IN THE HANDS OF UNIVERSITIES' PATENT MANAGEMENT OR SUCCESSFUL UNIVERSITY PETITIONERS FOR THE PURPOSE OF SOLICITING FURTHER INDUSTRIAL DEVELOPMENT SUPPORT. WE WERE ADVISED THAT DURING THE 1969-1974 PERIOD THESE UNIVERSITIES HAD NEGOTIATED 44 NON-EXCLUSIVE AND 78 EXCLUSIVE LICENSES UNDER PATENT APPLICATIONS FILED ON THE 329 INNOVATIONS. WE UNDERSTAND THAT THE 122 LICENSES NEGOTIATED HAD GENERATED COMMITMENTS IN THE AREA OF 75 MILLION DOLLARS OF PRIVATE RISK CAPITAL. SINCE 1974 TO THE END OF FISCAL YEAR 1976 THE NUMBER OF INVENTIONS HELD BY UNIVERSITIES HAS SUBSTANTIALLY INCREASED TO 517.

I HAVE ATTACHED TO THESE COMMENTS SOME EXAMPLES OF INVENTIONS LICENSED BY UNIVERSITIES WHICH HAVE REACHED OR ARE NEAR REACHING THE MARKETPLACE SINCE OUR 1974 SURVEY. NOTEWORTHY IS THAT THIS INCOMPLETE LISTING INVOLVES COMMITMENT OF RISK CAPITAL OF APPROXIMATELY 80 MILLION DOLLARS. AS YOU WILL NOTE, THERE ARE A NUMBER OF PHARMACEUTICAL PRODUCTS ON THIS LIST. WE KNEW OF NO COMPARABLE SITUATIONS AT THE TIME OF THE GAO REPORT OF 1968. I WOULD CONJECTURE THAT THIS NUMBER WILL INCREASE IN SUBSEQUENT YEARS DUE TO THE OPPORTUNITY OF THE PHARMACEUTICAL INDUSTRY TO CAPITALIZE ON POSITIVE LEADS FROM THE NON-PROFIT SECTOR WHICH COULD RESULT IN REDUCTION OF THE INDUSTRY'S ESCALATING R & D COSTS BY ELIMINATING A NUMBER OF BLIND LEADS. (THE ULTIMATE SAVING WOULD BE THE DIFFERENCE BETWEEN THE 11.5 AND 24.4 MILLION DOLLARS PER SUCCESSFUL DRUG DEVELOPMENT MENTIONED PREVIOUSLY.) THE RISE IN SUCCESSFUL DEVELOPMENT BY INDUSTRY OF UNIVERSITY GENERATED INVENTIONS IS ALSO CONSIDERED SIGNIFICANT WHEN NOTING THE STEADY DECLINE IN INTRODUCTION OF NEW DRUG ENTITIES IN THE UNITED STATES FROM 65 IN 1959 TO 15 IN 1975.[6/] THIS SLIDE MIGHT ALSO BE ATTRIBUTED TO THE INCREASED COST OF DRUG DEVELOPMENT.

6/ PHARMACEUTICAL TIMES, APRIL 1976 (BASED ON DATA FROM PAUL de HAEN, INC.) AND HENRY G. GRABOWSKI, "DRUG REGULATION AND INNOVATION IN EMPIRICAL EVIDENCE AND POLICY OPTIONS," AMERICAN ENTERPRISE FOR PUBLIC POLICY RESEARCH, WASHINGTON, D. C.

IN THIS CONTEXT IT IS APPARENT THAT THE EXISTENCE OF A LICENSABLE PATENT RIGHT IS PROBABLY A PRIMARY FACTOR IN THE SUCCESSFUL TRANSFER OF A UNIVERSITY INNOVATION TO INDUSTRY AND THE MARKETPLACE, AND FAILURE TO PROTECT SUCH RIGHT MAY FATALLY AFFECT A TRANSFER OF A MAJOR HEALTH INNOVATION. I BELIEVE SOME MEMBERS OF THE COMMITTEE ARE AWARE OF THE SPECULATION THAT PRIVATE DEVELOPMENT AND MARKETING OF PENICILLIN WAS FORECLOSED FOR OVER 11 YEARS DUE TO THE LACK OF A PROPRIETARY POSITION NECESSARY TO THE PROTECTION OF THE LARGE RISK INVESTMENT INVOLVED.[7/] IT WAS ONLY AFTER THE UNITED STATES GOVERNMENT UNDERTOOK THIS RISK UNDER THE PRESSURE OF WORLD WAR II THAT PENICILLIN's CURATIVE POWERS WERE MADE AVAILABLE TO THOSE SUFFERING FROM INFECTION.

IN ADDITION TO INITIAL ADMINISTRATION OF THE IPA AND WAIVER PROGRAM DISCUSSED, THE DHEW PATENT BRANCH ACTS AS THE PATENT MANAGEMENT FOCAL POINT FOR ALL INNOVATIONS TO WHICH THE DEPARTMENT RETAINS TITLE. THE DEPARTMENT'S PATENT PORTFOLIO PRESENTLY CONSISTS OF APPROXIMATELY 400 PATENTS AND PATENT APPLICATIONS, WHICH IN THE MAIN ARE DERIVED FROM DHEW EMPLOYEE INVENTIONS. A LESSER NUMBER ARE ATTRIBUTABLE TO INVENTIONS MADE BY EMPLOYEES OF UNIVERSITIES OR COMMERCIAL CONCERNS FUNDED

7/ DAVID MASTERS, MIRACLE DRUG, THE HISTORY OF PENICILLIN, PUBLISHED BY GYRE & SPOTTI, WOODE, LONDON (1946), PP. 104-105 AND
THE LAW OF CHEMICAL, METALLURGICAL AND PHARMACEUTICAL PATENTS, FORMAN, EDITOR, PUBLISHED BY CENTRAL BOOK CO., NEW YORK (1967).

BY DHEW GRANTS OR CONTRACTS WHICH THEY DID NOT CHOOSE TO MANAGE OR WERE NOT PERMITTED TO MANAGE. SINCE 1969 WE HAVE GRANTED 19 EXCLUSIVE LICENSES AND 90 NON-EXCLUSIVE LICENSES UNDER OUR PATENT PORTFOLIO. UNFORTUNATELY, WE HAVE NO STATISTICS ON THE AMOUNT OF RISK CAPITAL COMMITTED TO DEVELOPING THESE INVENTIONS TO THE MARKETPLACE, THOUGH WE BELIEVE IT TO BE SURELY MEASURED IN MILLIONS OF DOLLARS.

SAMPLING OF UNIVERSITY PATENT LICENSING PROGRAMS

Inventor	University	Invention	Licensee	Approximate Investment
Walser	Johns Hopkins U.	Keto-Acid analogs of Amino Acids for treatment of uremia	Pfrimmer of Germany and Syntex of U.S.A	Millions - Clinical trials in process. Expected to be marketed in 6 mos. in Europe.
Wiktor	Wistar Institute	Rabies Vaccine	Wyeth Laboratories	On the market - millions
Kamen et al	Case Western Res.	Methotrexate Assay during Cancer Chemotherapy	Diamond Shamrock Corp.	Being test-marketed. Production scheduled for late 1977. Millions.
Lillehei/Kaster	U. of Minnesota	Pivoting Disc Heart Valve	Medical, Inc.	Being sold in world-wide market since 1971. Millions.
Blackshear et al	U. of Minnesota	Implantable Infusion Pump (Constant Infusion of Drugs for Treatment of Cancer, Diabetes, Pain, Morphine-addiction, etc.)	Metal Bellows Co.	Undergoing clinical trials $750,000.
DeLuca	U. of Wisconsin	25-Hydroxycholecalciferol for treatment of Osteo-dystrophy with liver dysfunction	Rousel-Uclaf (Hoechst) and	Have applied for equivalen of NDA in France. Approximately $5 million.
			Upjohn	About to apply for an NDA and an NADA. Will spend about $10 million.
DeLuca	U. of Wisconsin	1-Alpha Hydroxycholecalciferol for treatment of Osteo-dystrophy with Kidney Dysfunction	Leo Pharma-ceuticals	Applying for new drug applications in Denmark and Great Britain. May be marketed this year. Approx. $5,000,000.

SAMPLING OF UNIVERSITY PATENT LICENSING PROGRAMS

Inventor	University	Invention	Licensee	Approximate Investment
DeLuca et al	U. of Wisconsin	1, 25-Dehydroxyergocalciferol for Treatment of Osteodystrophy with Kidney and Liver Dysfunction and Senile Osteodystrophy	Hoffman-LaRoche Inc.	About to apply for NDA. Will spend about $10 million.
Fox	Columbia U.	Silver Sulfadiazine used in Treatment of Burns	Marion Labs., Kansas City, Mo.	Now on market - Approx. $5,000,000
Heidelberger	U. of Wisconsin	Use of F_3TDR for Herpes Infections of the Eye	Burroughs Wellcome Co., Research Triangle Park, N.C.	Approx. $5,000,000 NDA expected by end of 1977.
Fischell	Johns Hopkins U.	Rechargeable Cardiac Pacemaker	Pacesetter Systems Sylmar, California.	On market since Feb. 1975 - Approx. $720,000
Holland	Tulane U.	Method of Reducing Intraocular Pressure in the Human Eyes (Glaucoma Treatment)	Cooper Labs., Bedford Hills, N.Y.	$2,000,000 - Development leading to DNA is in process and on schedule
Pressman	U. of Miami	Application of X-537A in the Cardiovascular System (for stimulation in cardiogenic shock, congestive heart failure, etc.)	Hoffman-LaRoche, Nutley, N.J.	$500,000 to $1,000,000 Clinical evaluations still in progress
Higley	Natl. Institute of Scientific Research	Polycarbonate Dialysis Membranes (kidney dialysis)	C. R. Bard Inc., Murray Hill, N.J.	Over $1,000,000. Market introduction expected imminently.
Talbot/Harrison	Johns Hopkins U.	Ballistocardiograph Apparatus	Royal Medical Corp. Huntsville, Ala.	Approx. $330,000. Now on market.

SAMPLING OF UNIVERSITY PATENT LICENSING PROGRAMS

Inventor	University	Invention	Licensee	Approximate Investment
Plotkin	Wistar Institute	Rubella Vaccine	1) Wellcome Foundation 2) L'Institut Merieux 3) Swiss Serum and Vaccine Institute and others (Merck, an Italian firm, etc.)	Approx. millions - Now on market.
Schaffner/Mechlinski	Rutgers U.	Derivatives of Polyene Macrolide Antibiotics	E.R. Squibb of U. S. A. and Dumex of Denmark	Millions - Clinical trials progressing favorably
Zweig	Syracuse U.	Apparatus for Measuring and Controlling Cell Population Density in a Liquid Medium	New Brunswick Scientific Co., Inc., of New Jersy	Millions - On the market since 1973
Lovelock	Yale U.	Gas Analysis Method and Device for the Qualitative and Quantitative Analysis of Classes of Organic Vapors	Varian Associates, Palo Alto, Calif.	On the market
Fried	U. of Chicago	Prostoglandins for possible Treatment of Bronchial Asthma, Duodenal Ulcers, Inflammatory Conditions, etc.	Richardson-Merrell, New York, N.Y.	Several millions - In process of development and testing for marketing here and abroad
Leininger/Grotta et al	Battelle Memorial Institute	Preparation of Non-thrombogenic Surfaces and Materials	C. R. Bard, Inc., Billerica, Mass.; Sherwood Medical Industries, St. Louis Mo.; and American Hospital Supply Corp., Irvine, California.	$107,754 - Some products being marketed and others being tested.

SAMPLING OF UNIVERSITY PATENT LICENSING PROGRAMS

Inventor	University	Invention	Licensee	Approximate Investment
Merrifield	Rockefeller U.	Apparatus for the Automated Synthesis of Peptides	Beckman Instruments, Fullerton, California	Being marketed since 1973.
Smith/Kozoman	Duke U.	Apparatus and Method for Rapid Harvesting of Roller Culture Supernatant Fluid	Bellco Glass, Inc. Vineland, New Jersey	$25,000 - Being marketed since June 9, 1976
Zweng	Stanford U.	Laser Photocoagulator	Coherent Radiation, Palo Alto, Cal.	Approximately $500,000 Standard tool of ophtholmologists
Sweet et al	Stanford U.	Cell Sorter	Becton-Dickinson, Rutherford, New Jersey	Approx. $200,000. Important research tool
Boyd/Macovski	Stanford U.	Computerized Axial Tomography	S.A.I. Cupertino, Cal.	Approx. $300,000. Will be marketed soon.

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TESTIMONY OF

JOSEPH P. ALLEN, VICE PRESIDENT

MARKET AND TECHNOLOGY ASSESSMENT

TO THE

HOUSE SUBCOMMITTEE ON TECHNOLOGY

SEPTEMBER 25, 1997

Thank you for inviting me to testify before you today. I certainly do not need to tell the members of this particular Committee about the importance of linking our unparalleled federal laboratories and universities with American industry. Today's hearing is another significant step toward strengthening these ties which hold great promise for our future economic prosperity. It also underscores the 20 year commitment of this Committee in fostering public/private sector relationships when such ideas seemed outlandish to many.

While we can certainly improve the current public technology management system, we have made enormous strides in the past two decades. Most of us can remember in the 1970's when it was fashionable in some circles to bash U.S. industry and U.S. workers and moan that our best days as a nation were behind us. There were also cries for a Japanese style centrally directed economic policy. Luckily, we chose a more traditional American path--removing barriers to innovation and trusting the genius of the market to respond. We also applied this same philosophy to the perplexing dilemma of how to open up our public sector to commercial partnerships with our private sector. These ideas were first expressed in this very hearing room.

In encouraging R&D partnerships between industry and government, there were no clear models to follow in the 1970's. The journey has turned out to be a step-by-step process. I was fortunate enough to be on the Senate Judiciary Committee staff when the effort began in 1978 to encourage universities and small businesses to commercialize their federally-funded research. This was a highly controversial idea in those days. We certainly realized that by addressing the universities and small businesses we were certainly not solving the entire problem, but former Senator Birch Bayh believed that creating one successful model would ultimately impact the entire federal R&D system. We were delighted when

Senator Bob Dole agreed to become a principal co-sponsor in this effort.

While Senators Bayh and Dole disagreed on many issues, they were in strong agreement that increased international competition no longer allowed us to segregate our public and private sectors from working together to create economic wealth. Luckily this bi-partisan cooperation has continued.

The passage of the Bayh-Dole Act in 1980 was a sea change in U.S. technology policy. The Act removed bureaucratic barriers allowing creators of technologies in universities to work with the developers of products-- our private sector. The legislation relies on providing incentives for success along with a decentralized approach to technology management. This is the traditional American economic policy which has held us in such good stead. Ironically, it is this U.S. model that our economic competitors are studying today.

The Association of University Technology Managers has conducted an important study on the

tremendous economic benefits this law has garnered not just for the universities and companies directly involved in each partnership, but more importantly, for the U.S. economy as a whole.

As we were drafting the original Bayh-Dole bill, I looked at previous legislation in the area. One bill I studied came from this Committee. It was legislation by Rep. Thornton that was headed in the same direction we were. The Thornton bill had a provision that I liked concerning licensing "on the shelf" government inventions. We added your language to Bayh-Dole.

These government licensing provisions are the topic of the hearing we are having today.

The debate over Bayh-Dole was solely focused on the then radical idea that we should allow universities to manage their R&D without micromanagement by government lawyers, so that they could license their inventions to U.S. companies for commercialization.

We believed that the "Thornton" provisions would also demonstrate that while Bayh-Dole was important in itself, it was really the first step in examining the larger question of how to improve the commercialization of billions of dollars of federal R&D. Senator Bayh believed that adding the provisions on licensing government-owned inventions would make it clear to the agencies that we also expected them to be more aggressive in finding partners for their research.

This is what the report of the Senate Judiciary Committee on these sections states as our purpose:

> **S. 414 (*the Senate bill number for Bayh-Dole)* will also allow the agencies to have greater flexibility in finding licensees for the patents that are now in the Government's patent portfolio. Dr. Betsy Ancker-Johnson, Vice President for Environmental Affairs of General Motors and former Assistant Secretary of Commerce for Science and Technology, told the committee that the agencies are now licensing less than 4 percent of the 28,000 patents that the Government now owns to private industry for development. The central problem seems to be that the agencies seek to issue non-exclusive licenses for these patents which are available to all interested parties. Nonexclusive licenses are generally viewed in the business community as no patent protection at all, and the response to such licenses has been lackluster.**
>
> **The University and Small Business Patent Procedures Act (*now called Bayh-Dole)* would allow the agencies to license out these patents nonexclusively, partially exclusively, or exclusively depending upon which avenue seems to be the most effective**

means for achieving commercialization. It eliminates current uncertainty over the authority of many agencies to grant such licenses. The bill would require that all interested parties include in their application for Government licenses a plan for commercialization of the patent and agree to submit periodic reports to the agency on their progress. The bill requires public notice and other procedures before the issuance of exclusive licenses, but is not meant to discourage the granting of such licenses when the plans proposed by prospective exclusive licensees show a greater commitment to commercialization than those proposed by persons seeking non-exclusive licenses. A first preference in such licensing would be given to small businesses in order to encourage increased competition.

It is essentially a waste of public money to have good inventions gathering dust on agencies' shelves because of the unattractiveness of non-exclusive licenses. The presence of "march-in rights" in the licensing program (where the agency could issue additional licenses to competitors if such licensing were required to meet a public need) should be a sufficient safeguard to protect public welfare requirements and prevent any undesirable economic concentration.

S. 414, however, does not actually mandate more extensive Government licensing programs. However, the bill will put agencies in a position to more adequately respond to requests for exclusive licenses, to more effectively utilize the resources now rather unsuccessfully devoted to licensing and technology utilization efforts, and to devise licensing programs that might be effective at relatively low cost to the taxpayer. The successful licensing of government-owned patents represents a very real gain to the agencies since it will not only encourage commercialization of the patents, but will also bring in revenues to the government through licensing fees.

The very idea of encouraging the exclusive licensing of government inventions was a very bold idea in 1979 when the report was filed. During this period there were many who believed that patents were bad because they were "monopolies" and that it was unseemly, if not downright immoral, for the government to be a party to such practices. The continued loss of American jobs in high technology fields brought a more market oriented approach to the fore. Companies simply were not willing to invest the funds and effort to develop new products if they could not defend their investments with adequate intellectual property protection. This is especially true in the development of publicly-funded R&D where the discoveries are usually a long way from commercial development.

President Reagan adopted the Bayh-Dole approach as the centerpiece of his technology management policies. President Reagan asked David Packard for a report in 1983 on why the federal laboratories were not having the same degree of commercial success that universities were beginning to enjoy. The Packard Report pointed out many of the barriers facing the laboratories, one of which was the absence of strong legal authority encouraging such relationships.

In 1984 the next step in the overhaul of the federal technology management system occurred when the Reagan Administration and Congress extended the concepts of Bayh-Dole to university-operated federal laboratories. The 1986 passage of the Federal Technology Transfer Act and its extension to all of the DOE contractor-operated laboratories in 1989 were the next logical steps.

The passage of the National Technology Transfer Act of 1995 under the leadership of Representative Morella was the latest step in this progression. The provision that an industrial partner in a cooperative R&D agreement can be guaranteed an exclusive field of use license for inventions created in a cooperative R&D agreement underscores how seriously Congress takes this issue, and how far we have progressed from the time when, with great caution, we raised the idea of effectively licensing government-funded inventions.

In each evolution, Congress has sought to make the technology transfer process more "industry friendly," realizing, correctly, that without significant time and resources by private companies new products, processes and jobs will not be created for the U.S. economy. Congress has also reminded the public sector technology managers that they are expected to vigorously apply the tools provided them.

While we have progressed a long way in the past 17 years since passage of Bayh-Dole, the provisions for licensing on-the-shelf government inventions remain the same. It is now time to look back on these procedures in light of what we have learned, and improve the system. I believe that this is the next step in our continuum.

The basic problem in the current licensing provisions for government-owned inventions is that they are out of step with the rest of the system.

The current licensing regulations establish a complex system which a company seeking an exclusive license must go through. The creating agency must provide notice in the Federal Register for 90 days that the invention is available for licensing. If someone applies for an exclusive license a 60 day Federal Register notice must be provided giving the name of the company seeking the license. Competitors can seek to block the application by saying that they will accept a non-exclusive license for the invention. This is not the kind of procedure that assures innovative companies that the federal government is a reliable partner.

When Bayh-Dole passed and the Department of Commerce subsequently wrote the

implementing regulations, the idea of the Internet was inconceivable. It is a very rare company that reads the Federal Register looking for technology. Now that virtually every university and federal laboratory has its own web-site, the "public notification" provision is really showing its age. One of the main thrusts of Bayh-Dole was to encourage small companies to develop federally-supported research. The current notification procedures in the Federal Register are certainly not small business friendly.

With electronic notification virtually anyone who is looking for new discoveries can readily find them. This is a much more fair approach than having to comb through the Federal Register. Indeed, companies do not even need computers to find technologies. Entities like the National Technology Transfer Center (NTTC) maintain toll free numbers to assist companies by performing data base searches for them. Posting inventions available for licensing electronically is much more in line with today's world than the current regulations.

While making such a change to the regulations certainly does not require legislation, experience has shown that agencies are very reluctant to make these types of adjustments without "legislative cover." Expediting the current notification process and getting it ready for the 21st Century is a very useful exercise.

The present regulations also make it difficult for government-owned and operated laboratories to bring already existing inventions into CRADA's if such an inclusion would create a more complete technology package. Government-owned, contractor-operated laboratories are allowed to manage their inventions just like universities do. They do not face onerous notification provisions to grant exclusive licenses, and more importantly, they can include already existing inventions in their cooperative R&D agreements under the Federal Technology Transfer Act. Several GOCO technology transfer officials that I spoke with before drafting my testimony believed that the ability to include these inventions greatly strengthened their partnerships.

Companies are taking considerable risks when they agree to develop and commercialize federally-funded technologies. Typically these inventions are a long way from the marketplace. Giving agencies discretion and incentives to consider how already patented discoveries might improve their CRADA's is a positive step. My current position at the NTTC was created to assist the laboratories and universities better assess the commercial worth of their discoveries. We are now beginning work with the NASA and Navy to look at these "on-the-shelf" patents. Having the ability to readily "bundle" related technologies to make them more attractive to industry is an idea we would strongly recommend that our clients consider. This flexibility allows the laboratories to better respond to the realities of the commercial marketplace. I believe that this will prove to be a significant new tool for the laboratories and one that they should be encouraged to aggressively utilize.

The current system with subtle the nuances between what "GOCO's and GOGO's" can do in CRADA's are exactly the kind of bureaucratic jargon that makes industrial executives' eyes roll. I believe that it is helpful to have Congress speak on this subject. The message should be that agencies can include already existing inventions into CRADA's if warranted. Agencies would be expected to use good judgment and would retain needed flexibility on when and when not to use this authority. But such consistency across the federal system is justified if we expect American companies to effectively commercialize technologies from federal laboratories regardless of if they are government or contractor operated. The ability of universities to include existing inventions in their agreements with industry is one of the keys to their phenomenal success rates under Bayh-Dole.

We should seek to make the technology transfer system as understandable to the private sector as possible. A large part of my current job at the NTTC is alerting U.S. industry to the possibilities of working with our federal laboratories and universities. Encouragingly, industry is more open to these partnerships than ever before. When companies convince themselves that they might actually benefit from a partnership with a federal laboratory and then run into a system where one kind of laboratory can manage technology one way and another funded by the same government can't, they are rightly very confused. This desire for greater simplicity in dealing with the federal laboratories led to the passage of the National Technology Transfer and Advancement Act.

Even more importantly, the current restrictions on licensing on-the-shelf technology do not benefit the American taxpayers. It is hard enough to build R&D partnerships. As stated before, any company interested in commercializing publicly-funded R&D is undertaking a real risk. It is not unusual for public technologies to take five-to-seven-years to reach the marketplace. If an agency believes that a company is a good partner and can bring the technology to market, forcing them to wait months and run the gauntlet of public notices

does not benefit anyone. Indeed, it would be a rare company that would want its competitors to know what technologies they are seeking to license. This can be a valuable tool in discerning a company's commercial strategy. This kind of public disclosure underscores many executives' worst fears about working with the government -- it simply does not know or apparently care how the marketplace actually works. It was for similar reasons that this Committee authored the 1995 National Technology Transfer and Advancement Act making clear to industry and agencies the seriousness of moving federally-funded R&D quickly to market.

The core of the Bayh-Dole Act remains solid. The provisions being considered today balance public policy needs with industrial requirements. We can both provide adequate protection of the rights of the public, encourage serious companies to develop existing government inventions, and best of all, make the entire system of developing government technologies more consistent and simple.

The guiding principles of Bayh-Dole in licensing government inventions have held up remarkably well. Agencies must retain ample authority to ensure that a prospective partner company intends to take the technology to market. Agencies need a clear ability to enforce their licenses. The scope of the license should be tailored to the specific plans of the requesting company. Preferences are given to small companies and to those who will manufacture the products in the United States.

In short, I recommend taking a well-thought out incremental approach like the pending bill that simplifies current procedures while retaining important safeguards for the American public. It is gratifying to see that the foundation of Bayh-Dole is still solid. This should not discourage us from shoring it up from time to time.

Thank you very much.

NATIONAL TECHNOLOGY TRANSFER CENTER,

Wheeling Jesuit University/316 Washington Ave./Wheeling, WV 26003

(304) 243-2455 Fax (304) 243-2463

Joseph P. Allen

Biographical Data

Vice President, Market and Technology Assessment National Technology Transfer Center

The NTTC was created by Congress to assist U.S. industry in building commercial partnerships with the massive national laboratory/university R&D system. The Department has just been created in response to requests by the public and private sectors for a more systematic approach for quickly finding and exploiting promising technologies. Services include technology assessments, licensing, automated patent tracking services, and general research portfolio management. Prior to this assignment, Joe headed the Training Department and served as Director of Planning and Development.

Director, Office of Technology Commercialization U.S. Department of Commerce

The office was the principal federal technology management unit of the Department's Technology Administration. Joe was involved in the passage of major laws like the 1986 Federal Technology Transfer Act and the 1989 National Technology Transfer Competitiveness Act which allow U.S. industry to perform joint R&D with federal laboratories. The office also oversaw the implementation of these laws as well as those allowing universities to license their patentable technologies to U.S. industry.

Joe was a negotiator in several international agreements such as the U.S.-Japan Science and Technology Agreement, which were renegotiated to bring them into line with current U.S. technology transfer laws so that publiclyfunded R&D was not inadvertently given away under international scientific agreements.

Professional Staff Member, U.S. Senate Judiciary Committee

Joe staffed the passage of the Bayh-Dole Act of 1980 which reversed 50 years of previous practices making the commercialization of federally-funded technology very difficult. This law is the basis for the present high degree of U.S. university-industry cooperation.

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National Technology Transfer Center

Disclosure of Federal Funding Sources

Funding Sources FY '97 FY '96 FY '95

National Aeronautics and Space $5,997,200 $8,750,000 $7,399,500

Administration (NASA)

National Institute of Justice

(NIJ) $2,661,597 $1,468,627

Ballistic Missile Defense

Organization (BMDO) $1,502,799 $2,467,171 $2,743,500

Entrepreneurial Apprenticeship

Program (ETAP) funded by $596,000

Department of Commerce

(DOC)

Department of Transportation

(DOT) $24,500

Technology for a Sustainable

Future (TSF) $817,044 $1,696,650

Environmental Protection

Agency (EPA) $49,500



A rat race by any other name still involves rats seeking advantage

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DECEMBER 08, 2003

FREE MARKETS 101

Marxicon Economics
by Craig J. Cantoni
Honest Americans Against Legal Theft (HAALT)

Public speaking and writing a newspaper column on public policy issues have introduced me to a new branch of economics: Marxicon economics. It is a bizarre combination of Marxism and free-market capitalism that is embraced by a large number of conservatives.

A case in point:

I recently shared the dais at a meeting of conservatives with British historian David Irving, who has been both praised and vilified for his books on the Second World War and the Holocaust. He spoke about his books, and I spoke about the new Medicare bill.

Both of us had a similar sub-theme: that governments, including democracies, engage in propaganda to further the interests of those in power. My example was Health Savings Accounts, which Republicans are touting as a free-market provision in the new Medicare bill.

To show why it is not a free-market provision, I read excerpts from the 676-page bill, a bill that probably few members of Congress or journalists have read in its entirety. Written in a stultifying bureauclese that will keep judges, lawyers, tax attorneys, accountants, lobbyists, benefits consultants, financial advisors and government bureaucrats fully employed for decades, the bill is replete with wage and price controls, onerous reporting requirements, special considerations for favored political groups, and handouts for large corporations. It is the antithesis of a free market.

Worse, in a propaganda ploy, the bill pretends to be giving taxpayers something when in actually it continues the government's practice of taking much more away than it

gives. For instance, Health Saving Accounts will let Americans save money on a tax-free basis for health care expenses, after paying tributes to accountants, benefit consultants and others to interpret the legislation, which has more red tape than a manufacturer of Christmas ribbons.

But here is the rub: None of this would be necessary if the government did not tax retirement savings at all. The government is not being munificent by allowing us to save a portion of our savings on a tax-free basis through Health Savings Accounts, Medical Savings Accounts, 401(k) plans, SERPs, SIIPs, Flexible Spending Accounts, Rabbi trusts and various other mutations of the tax code. It is being confiscatory by taxing our income and then taxing the investment returns on what we save for retirement out of the balance. Contrary to what most Americans and the ignorant media believe, letting us keep a little of OUR money from the tax collector is not munificence.

Anyway, during the question-and-answer period at the end of Irving's and my remarks, a conservative in the audience asked the kind of question that I have learned to expect from conservative audiences: "Craig, what do you propose that we do about the obscene profits of drug companies?"

Marxicon economics had reared its intellectually inconsistent head and presented me with a speaker's dilemma. Should I disembowel the questioner in public or answer in a way that would not turn the audience against me? I chose the latter course and answered as follows:

"Good question. It's something that I would be happy to debate with you after the meeting, but your question raises the question of how 'obscene' would be defined and who would define it. Also, if we accept that the role of government is to put a limit on drug company profits, then what would stop the government from putting a lid on the profits of any other company or on what you can earn as an individual?"

With that, historian David Irving jumped in with his British perspective, proving that someone can be an expert in one area and the opposite in another. He said that he agreed with the questioner.

I responded to David with a question: "David, what has happened to the British pharmaceutical industry under nationalized health care?" He stammered a non-answer answer.

Of course, what has happened is that the industry has declined because it could no longer attract the capital to invest in research and development and produce lifesaving drugs at a price to provide investors with a satisfactory return on their investment and to compensate them for the risk of losing their money.

It is not unusual to encounter socialism among Europeans. Sadly, it is no longer unusual to encounter a mutant version of socialism, Marxicon, among American conservatives.

* * * * *

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Academia, Industry, and the Bayh-Dole Act: An Implied Duty to Commercialize

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I. Introduction

The Bayh-Dole University and Small Business Patent Procedures Act of 1980[1] (the Bayh-Dole Act) fundamentally altered the ownership paradigm of intellectual property developed with federal research dollars, transferring that ownership from the federal government to grant recipients (grantees) and organizations that are parties to government funding agreements (contractors), in an effort to enhance the public's access to technology developed with federal funds. However, moving innovative technology from the laboratory into the public domain is a complex exercise. In the case of medical technology, those who develop new technologies are ill-trained and ill-equipped to perform this function. Only industry, with its ability to manufacturer and distribute medical products with a high degree of precision and quality control, is able to effectively convert promising ideas into effective, widely available products.

The combination of Bayh-Dole's, 1) stated goal of increased public access to federally-funded research, 2) provision for the transfer of intellectual property to grantees/contractors, and 3) identification of the crucial role of industry in transforming ideas into available products and services, create an implied duty on the part of grant recipients and government contractors to partner with industry to commercialize promising federally-funded research. By its nature, this implied duty transforms the academia-industry relationship from the traditional view of disparate entities into a Congressionally-mandated partnership, intended to advance technology and benefit the public. An analysis of this implied duty and its implications on the complex and often controversial relationship between the academic community and industry are the subject of this paper.

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II. A Brief Legislative History

To fully appreciate the Bayh-Dole Act's revolutionary nature and the dramatic effects brought about by its enactment, it is necessary to examine the government-sponsored research environment that existed prior to the Act's introduction and implementation. An examination of these pre-Act policies illustrates the motivation behind Bayh-Dole, providing a valuable perspective on today's academic medical research environment.

Prior to Bayh-Dole, title to scientific inventions arising from federally-funded research typically vested in the government, reflecting the popular rationale that research funded by the public belonged to the public.[2] Though attractive in a theoretical sense, this rationale stifled the transfer of research from the laboratory to the public domain. To begin, the policy left the federal government with the responsibility to develop and commercialize promising technology, functions that it was ill-equipped to perform. Second, the government practice of granting non-exclusive licenses removed valuable industry incentives to invest. Lastly, adding to these fundamental issues, specific details of patent policy were left to the various agencies funding federal research, leading to significant variation in the policy actually applied in individual cases. Overall, this pre-Bayh-Dole paradigm produced an environment where federally-funded research infrequently led to viable products or services. These effects can be seen in the low technology licensure rate prior to enactment of Bayh-Dole: just prior to the Act's passage, the federal government held title to roughly 28,000 patents, only 5% of which were licensed to industry for commercial development.[3] Concerned that the public was not benefiting from its substantial research investment, Congress began exploring options to stimulate innovation and ensure commercialization of promising technology.

In 1945 the National Patent Planning Commission, created four years earlier by President Roosevelt, issued a report on the role of patents in government sponsored research.[4] The document, 1) recognizing the utility of patent protection in stimulating commercial development, and 2) affirming the belief that government-funded research should remain in the public domain, began a national dialogue regarding the effectiveness of the government's policies toward federally-funded inventions. In contrast, a subsequently issued report by the Attorney General supported the then-existing approach, recommending that title to all government-funded inventions vest in the government, with exceptions only in very limited circumstances.[5] Together, these reports formed the basis of a national debate as to the appropriate policy governing ownership rights.

Those who favored government retention of full title to inventions resulting from federally-supported research formed one side of this debate. These organizations and individuals tended to include small businesses and consumer advocates who feared that big business would gain an unfair advantage over smaller competitors if allowed to retain ownership of patent rights, concentrating too much economic power and possibly creating monopolies, higher prices, and anti-competitive behavior.[6] However, licensing policy advocates saw the issue quite differently. Arguing for grantee/contractor retention of title, this group saw both a stimulus to innovation created by the protections afforded with patent ownership, and investment incentives created from such protections.[7]

In the years succeeding these reports, numerous presidential memoranda, policy statements, and commission reports followed as the federal government sought to establish a mechanism for ensuring public access to federally-funded research results, while at the same time, retaining unrestricted rights to use these innovations as needed for the public good.[8] However, inconsistencies in federal patent policy continued as Congress remained divided on the more desirable overall federal mechanism, leaving untouched the considerable discretion individual federal agencies enjoyed in the policies they imposed on the research they funded.[9]

As major recipients of federal research funding, universities were especially affected by the patent debate and wide variation of funding agency policies. Exacerbating the problem was a report issued to Congress by the Commission on Government Procurement on the issues surrounding patent rights in federally-supported research.[10] This report, proposing an approach whereby title would be granted to contractors subject to the government's right to intervene (quite similar to Bayh-Dole's eventual provisions), explicitly excluded educational and other non-profit organizations due to concerns regarding these institutions' ability to promote inventions "in a manner consistent with the objectives of utilization and maintenance of competition."[11]

However, as the debate on a uniform patent policy continued, the environment changed. In 1979, then President Carter took issue with the Commission's report, publicly advocating full title retention for

universities and small businesses. With regard to large business, Carter proposed permitting exclusive licenses, with the government retaining the right to exercise a non-exclusive license and the right to intervene.[12] Predictably, President Carter's position generated substantial opposition from large business contractors and industry trade groups who lobbied against any restrictions on large business contractors, resulting in a new wave of heightened debate.

Introduced by Senators Birch Bayh and Robert Dole, the Bayh-Dole bill began moving through Congress in 1980. Notably, its provisions were not at all novel, containing many elements similar to previously proposed recommendations and policies. However, with its limited applicability to small businesses and nonprofit organizations, and its exclusion of large business interests, the bill avoided serious opposition from consumer advocates and antitrust lawyers and became law in December, 1980, with an effective date of July 1, 1981.[13]

The Bayh-Dole Act applies to all research performed under a federal funding agreement, whether funded in whole or in part by the government.[14] The Act requires a written agreement between the federal agency and the grantee/contractor which contains the terms upon which federal funding will be provided.[15] Among the sections of the Bayh-Dole Act delineating funding terms are two key provisions, one governing the rights and responsibilities of government grantees/contractors and the other, the rights and responsibilities of the government and government agencies.

Specifically, Bayh-Dole allows contractors to choose to retain title to federally-funded inventions, an option that, if exercised, is accompanied by various responsibilities.[16] For example, non-profit contractors electing title, including academic institutions, are required to file a patent application in the United States and grant the government a non-exclusive, non-transferable, paid-up right to practice the invention in the U.S. and throughout the world.[17] In addition, the Act mandates that contractors take necessary steps to commercialize any discoveries or inventions resulting from federally-funded research, with the right to grant non-exclusive, partially exclusive, or exclusive licenses.[18] The Act also requires contractors to favor U.S. industry for the manufacture of inventions, and small businesses for the granting of exclusive licenses. Contractors must report to the funding agency periodically, share royalties or income generated from inventions with the inventor(s), and apply the balance of income toward additional research or educational endeavors.[19]

In the event the grantee/contractor breaches its agreement with the government, Bayh-Dole includes provisions providing for the government to assume the failed commercialization efforts. These provisions allow the government to "march-in" and assume ownership rights of intellectual property when specific provisions of the Act have not been fulfilled, particularly, failure to take necessary steps to achieve practical application of the subject invention.[20] In addition to this right, the government also has a responsibility under a separate provision to ensure that licensing agreements governing government-owned inventions are granted in accordance with the objectives of the Act, responsibilities very similar to those applicable to grantees/contractors.

The provisions of Bayh-Dole, while addressing the national debate on government patent policy, responded to university and small business frustration with the unpredictable and ever-changing patent policies of the Health, Education and Welfare agency as well as the Department of Defense. In contrast to the previous environment, Bayh-Dole provided clear, predictable grantee/contractor retention of patent rights for non-profit and small business concerns. This shift allowed these individuals and entities to plan technology transfer activities earlier in the development process, ultimately facilitating their success.

In the next few years immediately following enactment of Bayh-Dole, large business contractors continued to operate under the varying agency policies. While occasionally able to gain patent rights to federally-funded inventions under the various agency regulations, they still lacked a predictable uniform policy. In 1983, Bayh-Dole's scope was expanded through a Memorandum to the Heads of Executive Departments and Agencies to include large businesses.[21] In the memorandum, President Reagan directed agencies to treat all inventions resulting from federally-funded research in the manner prescribed under the Bayh-Dole Act, an action which was later endorsed by Congress in a 1984 housekeeping provision.[22] Thus, through Executive Order, President Reagan allowed for the application of a uniform patent policy applicable to all government contractors of federally-supported research.

III. Bayh-Dole's Implied Duty to Commercialize

The Bayh-Dole Act can be seen to impose a duty on the part of all researchers who contract with the government, referred to as grantees or contractors, to pursue the commercialization of government-funded scientific inventions. The duty to commercialize is not explicitly stated within the Act, but is formed through the interplay of two key provisions. The result is a "use it or lose it" policy, whereby government contractors must take steps to reach "practical application" of their inventions and comply with all requirements under the Act, or be subject to the government's right to intervene and assume ownership.

Recognizing an implied duty to commercialize under Bayh-Dole begins with the Act's enumerated objectives, contained in Section 200. Directly implicating utilization of the patent system for the purpose of effectuating its goals, Congress identifies seven objectives which form the basis of its policy promoting commercialization, three of which are of particular importance in outlining a duty to commercialize. The first of these relevant objectives, "to promote the utilization of inventions arising from federally-supported research or development," indicates the intent of Congress to ensure that promising research results are put to productive use.[23] The second objective, "to protect the public against nonuse or unreasonable use of inventions," supports the first objective and further demonstrates Congress's intent to ensure that publicly-funded inventions reach the public. Furthermore, it reflects the government's right to enforce the commercialization provisions of Bayh-Dole.[24] The third key objective, "to promote collaboration between commercial concerns and nonprofit organizations, including universities," explicitly partners academia and industry, providing a pathway for academic interests to comply with the Act's duty and ultimately effectuate the Act's goals.[25]

Section 202, entitled Disposition of Rights, is the first substantive provision embodying Bayh-Dole's implied duty to commercialize, and sets forth the rights and responsibilities of government grantees/contractors.[26] Under Section 202, all grantees/contractors are allowed to "elect to retain title to any subject invention."[27] A subject invention is defined as "any invention...conceived or first actually reduced to practice in the performance of work under a funding agreement...."[28] Thus, contracts, grants, or cooperative agreements between a federal agency and an individual or institution for the "performance of experimental, developmental, or research work" that is funded in whole or in part by the federal government, allows for the option to retain title.[29]

Exercising the option to retain title to a subject invention triggers various requirements and responsibilities, ultimately included in the government's funding agreement with each contractor. A key requirement supporting an implied duty to commercialize is the requirement to file a patent application in the United States. Section 202(c) provides that contractors who elect title to a subject invention "agree to file a patent application prior to any statutory bar date."[30] Furthermore, failure to file a patent application within the statutory timeframe may result in title forfeiture to the federal government and loss of ownership rights.

In addition to the patent-filing requirement, Section 202(c) requires reporting to the funding federal agency. Specifically, contractors must periodically report on the "utilization or efforts at obtaining utilization that are being made by the contractor or his licensees or assignees."[31] Thus, merely filing a patent application in the United States in compliance with Section 202(c) is not enough to satisfy the federal government's goal of ensuring public availability and use of subject inventions. Contractors must also report on efforts to obtain utilization of the invention, with associated consequences for failing to promote utilization, as found in the subsequent section of the Act.

A second key Bayh-Dole provision supporting the implied duty to commercialize sets forth the rights retained by the government. Section 203, entitled March-In Rights, allows federal funding agencies to assume ownership rights to subject inventions, including the right to require the contractor to grant a non-exclusive, partially exclusive, or exclusive license to a responsible applicant.[32] Such actions are permitted when the contractor has failed to take "effective steps to achieve practical application of the subject invention," among three other enumerated circumstances.[33] Under the statute, practical application means "to manufacture...to practice...or to operate...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."[34] Accordingly, when the federal government determines that a contractor has not taken and is not expected to take effective steps to ensure public use of an invention, a federal agency may "march-in" and require the licensing of the invention. Furthermore,

if the contractor refuses to license the technology, an agency may grant the license itself.[35]

Together, the practical effect of Sections 202 and 203 is that contractors to federal funding agreements must actively pursue commercialization, through the development and eventual public availability of inventions to which they have elected to retain title. Incorporated into the requirements and responsibilities attached to title retention are specific retained government rights, applicable should a contractor fail to actively pursue public utilization or commercial development. These provisions effectively establish contractor responsibility to effectuate the Act's objectives, with government intervention as a built-in safeguard to ensure the Act's objectives are carried out.

These provisions of Bayh-Dole are clearly designed to ensure that the ultimate goal of Congress is achieved: federally funded inventions are made available to the public, for the public's benefit. Sections 202 and 203, and the implied duty imposed upon contractors are the main provisions supporting this goal. However, a related provision of the Act also lends support to Congress's principal purpose, and by extension, to the implied duty to commercialize.

Section 209, entitled Restrictions on Licensing of Federally Owned Inventions, imposes on federal agencies duties similar to those imposed on contractors by Section 202, building on the Act's push for successful commercialization.[36] Under its provisions, Federal agencies may only license inventions to those requestors who can provide a concrete plan for invention development and marketing.[37] In addition, federal agencies licensing a federally-owned invention must include provisions detailing "periodic reporting on the utilization or efforts at obtaining utilization," and provide for license termination when the licensee fails to take effective steps to achieve practical application within a reasonable time.[38] These requirements, mirroring those applicable to contractors, are designed to further ensure successful commercialization and public availability of government-funded innovations.

IV. Technology Transfer: Academia's Mechanism for Fulfilling Bayh-Dole's Duty

While Bayh-Dole created an implied duty for government grantees/contractors, including academic medical institutions, to commercialize subject inventions and explicitly encouraged academia-industry collaboration in this pursuit, the Act does not provide specific mechanisms to achieve commercialization and the public access it requires. This effectively leaves the mechanism of accomplishing this duty to the discretion of each grantee or contractor. Academic medical centers, while superb at performing medical research, are not structured to transfer their discoveries into broadly usable technologies through effective commercialization, even where this technology is promising enough to obtain a patent as provided for under Bayh-Dole. For example, even very early clinical trials of a promising new device-based medical technology demand that the product be manufactured to exacting specifications, typically while maintaining sterility. This is very difficult to achieve, even on a very small scale, outside of an industrial setting. Furthermore, if the data from these trials is intended to support eventual marketing approval or clearance for the product, the trials must take place under a U.S. Food and Drug Administration (FDA)-sanctioned Investigational Device Exemption (IDE). In practice, it is extremely difficult and costly for an academic institution to maintain labs that meet FDA requirements to fashion the product, as well as support the significant administrative burden inherent in conducting IDE-covered trials.

The difficulty of pursuing commercialization within the academic medical setting has led centers to turn to industry to move technology from the laboratory to the patient care setting. Technology transfer, effectively moving patented academic discoveries and innovations to the commercial setting, has become the mechanism enabling broader development of research discoveries. Often taking the form of licensure agreements that provide private industry with access to academic research, such transfers are facilitated by the Bayh-Dole patent paradigm: academic patent holders have an incentive to obtain resources via technology transfer agreements and industry gains access to academic technology with patent protection. This arrangement fulfills Bayh-Dole's implied duty to commercialize, with the added benefit of providing an income stream to the academic patent holder that is then required to be reinvested in the academic mission and used to fund further research.[39]

V. In the Wake of Bayh-Dole

A. Technology Transfer Activity Flourishes at Academic Centers

The academic research environment changed dramatically following passage of the Bayh-Dole Act, as evidenced by numerous objective measures. At academic research institutions in particular, technology transfer has become a fundamental part of research activity since the Act's introduction, with an eight-fold increase in the number of universities engaged in transferring academic research to the private sector.[40] The number of patents issued by the United States Patent and Trademark Office to universities alone has skyrocketed, from approximately 250 patents per year prior to the Act to about 1600 by 1993.[41] This trend continues to accelerate, with a recent survey by the Association of University Technology Managers (AUTM) reporting over 3,000 U.S. patents issued to universities in 2000.[42]

Licensing activity, the main vehicle for technology transfer at academic institutions, mirrors the trend seen with patents. In fiscal year 1999, AUTM reported close to 4,000 new licensing agreements executed.[43] The following year saw an 11% rise in agreements to approximately 4,300 in 2000.[44] In addition, new companies and start-ups formed around federally-funded scientific inventions has increased dramatically: about 450 companies were founded in the year 2000 alone, with approximately 2,200 new companies formed since 1980.[45]

With the dramatic increase in patents issued, new companies formed, licensing agreements executed, and incoming royalties and licensing fees to academic institutions, universities have greatly benefited from the Bayh-Dole paradigm. The public has experienced significant benefits as well. Technology transfer activities have resulted in the creation of additional jobs and generated substantial economic activity, adding an estimated $40 billion into the U.S. economy.[46] More importantly, the flow of innovative products resulting from federally-funded research reaching the public has become faster and more efficient, with over 1000 products based on federally-funded academic discoveries reaching the market since its inception.[47] In the case of patient care, Bayh-Dole's impact has translated into a wide variety of medical products to diagnose and treat disease, almost certainly providing patients with beneficial healthcare technology that may not have reached clinical application without Bayh-Dole.[48]

B. Criticism of Academia-Industry Partnerships

While the success of Bayh-Dole in transferring government-supported research to the public is substantial, there are those who are uncomfortable with academia-industry partnerships that have made public access through commercialization possible. Historically, academia's mission has been focused on education and research, with the expectation that research results would be shared throughout the academic community and beyond. Academic medicine operates under the same guiding principles, along with a third mission, patient care. The pursuit of commercialization, as implied under Bayh-Dole, does not exist within the traditional missions of the academic institution, and is seen by some as counter to the basic academic mission.

Though effectively paired together by Bayh-Dole, industry and academia have disparate goals and motivations, and operate in distinct environments (see Table 1). Industry is governed by business ethic, and operates in an environment based on competition and motivated by financial concerns. The primary responsibility of business leaders is to their investors and shareholders, where the ultimate success is increased profits. Academic institutions however, are governed by a professional ethic, with research conducted in a collegial environment motivated by the quest for knowledge for the sake of knowledge. The primary responsibility of academic research, and by logical extension academic researchers, is to society as a whole, not investors.

The inherent tension of the academia-industry relationship, and in particular, the role of patenting, has been the focus of significant analyses and discussion, particularly within the academic community.[49] To some in that community, the purity of the academic mission is a key issue. Through technology transfer activities and collaborative endeavors with private, for-profit industry, motivations underlying academic research have become less clear. Academic centers now have the potential to generate substantial revenue from technology transfer activities. Similarly, individual researchers have the opportunity to profit financially from their work. These economic incentives raise concerning questions as to why research with the potential for financial gain is undertaken and potentially calls into question the results of that research.

Table 1
Fundamental Differences Between
Academic Research Institutions and Industry

	Industry	Academia
Governing Ethic	Business	Professional
Basis	Commerce	Oath
Responsibility to...	Investors	Humankind
Mode of operation	Competition	Collegial
Motivation/Goal	Financial	Knowledge

C. Financial Conflicts of Interest

Compounding the fundamental questions surrounding academia's association with industry are particular problems that have emerged from this relationship, specifically, individual and institutional financial conflicts of interest. Through the pursuit and receipt of patent royalties, licensing agreements, equity holdings, and ownership interests, investigators and academic institutions are presented with financial opportunities with the potential to influence decisions and affect research results. Of particular concern is research involving human subjects, where financial conflicts may jeopardize patient safety. Financial conflicts of interest also threaten to undermine the integrity of academic research and perhaps most importantly, the public's trust of academic research.

VI. Bayh-Dole and Recognizing the Academia-Industry Partnership

The relationship between academia and industry will always be a complex one, combining a culture with a tradition of knowledge for knowledge's sake with an environment that emphasizes increased financial returns. While the tension is real, the cultural differences between the two environments are not an insurmountable barrier to productive collaboration, nor does such collaboration by itself mean that either culture must sacrifice its values. Rather, it is for society to decide how and on what terms academia and industry interact for benefit of all concerned.

The Bayh-Dole Act is just such a societal statement. By transferring ownership of intellectual property developed with federal funds to the grantee or contractor and imposing conditions designed to transfer that research to those who can develop it for broad application, the Act establishes an implied duty to commercialize promising federally-funded research. It recognizes the strength of the academic community in building knowledge, as well as the strength of industry in transforming that knowledge into widely available products. As a practical matter, this implied duty mandates a partnership between academia and industry, providing an effective and definitive answer to those critics who contend that academia and industry should remain arbitrarily separate entities.

Bayh-Dole's implied duty to commercialize, while an important legal and societal statement on the desirability of productive collaboration between academia and industry, is not the only evidence that society encourages this type of interaction. For example, the Association of American Medical Colleges (AAMC) sees the traditional academic medical missions of education, research, and patient care occurring "within the context of service to local, regional, and national communities."[50] This position may be interpreted as establishing community service as a fourth mission of academic medicine, a goal that closely parallels Bayh-Dole's emphasis on realizing the maximum societal benefit from government-funded research. In this light, the AAMC's

community service mission implicitly supports the broadest possible application of new medical technology so as to benefit broader society, something only possible through an active collaboration between the academic medical community and industry.

Associations between individuals and entities entail risks as well as benefits, though it is important to realize that the risk involved in the academia-industry collaboration established by Bayh-Dole is, in effect, a product of the Act's implied duty to commercialize. The inevitable existence of such risks, such as financial conflict-of-interest, should not distract society from the larger benefit derived from academia-industry collaboration, nor should it be allowed to defeat the strong societal statement made by Bayh-Dole. Rather, their existence should serve as a reminder to academia, government and industry to identify and mitigate risks associated with commercialization of academic research, so as to maximize the benefit to society from government-funded research. By doing so, academia and industry will continue to fulfill the vision that is Bayh-Dole, and continue the impressive record of achievement that has provided so much benefit to society.

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[38] *See id.* at § 209.
[39] *See* 35 U.S.C. § 202(c)(7).
[40] *See* The Association of University Technology Managers, *Surveys – Bayh-Dole Act*, available at http://www.autm.net/pubs/survey/fcts.html, last updated November 13, 2000 (accessed Sept. 30, 2002)[hereinafter AUTM Survey]
[41] *See* The Association of University Technology Managers, *Surveys – Common Questions & Answers About Technology Transfer*, available at http://www.autm.net/pubs/survey/qa.html, last updated November 13, 2000 (accessed Sept. 30, 2002)[hereinafter AUTM Q&A]; *see* The AUTM Survey, *supra* note 40.
[42] *See* The Association of University Technology Managers, Licensing Survey: FY 2000, at 1, available at http://www.autm.net/surveys/2000/summarynoe.pdf (accessed September 30, 2002) [hereinafter 2000 AUTM Licensing Survey].
[43] *See* AUTM Q&A, *supra* note 41.
[44] *See* 2000 AUTM Licensing Survey, *supra* note 42 at 1.
[45] *See id.*
[46] *See* AUTM Q&A, *supra* note 41.
[47] *See* Council on Governmental Relations, *The Bayh-Dole Act: A Guide to the Law and Implementing Regulations*, available at http://www.ucop.edu/ott/bayh.html, September 1999 (accessed Sept. 30, 2002) (citing AUTM press release, December 17, 1998).
[48] *See id.*
[49] *See generally* Eisenberg, *supra* note 2; *see generally* Marcia Angell, M.D., *Is Academic Medicine for Sale?*, 342 NEJM 20 (May 18, 2000); *see generally* Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 Nw. U. L. Rev. 77 (1999); *see generally* F. Scott Kieff, *Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science – A Response to Rai and Eisenberg*, 95 Nw. U. L. Rev. 691 (2001).
[50] The Association of American Medical Colleges, Academic Medicine: The Cornerstone of the American Health Care System, available at http://www.aamc.org/hlthcare/start.htm (accessed September 30, 2002).