American Academics and the Biotechnology Revolution: Commercialization of Breakthroughs under Bayh-Dole

Good afternoon. It is wonderful to be in such illustrious and accomplished company at the Indian Science Congress here in Chandigargh. I would like to thank both Dr. Ananda Chakrabarty for inviting me to participate in today's session, as well as the organizers and hosts of this year's Indian Science Congress, the Panjab University, Chandigargh, the Institute of Microbial Technology, Changigargh, and the Indian Science Congress Association.

The theme for this year's session of the Congress: "Science and society in the Twenty-First Century: Quest for Excellence," is especially significant. As a non-scientist, here on behalf of PhRMA, the Pharmaceutical Research and Manufacturers of America, I view scientific achievement as a critical instrument for the benefit of society and humankind. PhRMA members work to develop scientific

discoveries into new therapies and cures to help patients live longer, better, and more productive lives. While this may appear self-evident, it does not happen by itself. I would like to discuss with you today a collaborative approach that has succeeded in the United States to helping ensure that this transformation actually takes place and that, in fact, society benefits from the potential that science has to offer.

Yes, the American experience is relevant to India. In the scientific and technological sectors, India and the United States have much in common. We both have world-class universities in which the most advanced research is undertaken. India ranks among the world's top ten largest industrializing nations and has the third largest pool of scientific and technical professionals in the world.[1] Traditionally, India's public institutions have actively engaged in and supported R&D. However, only a small percentage of this research

[1] Presentation of Jacques Gorlin, PhD, at the Rajiv Ghandi Institute for Contemporary Studies, New Delhi, India, August 29, 2002. (Dr. Gorlin concludes that: "India's cultural heritage and vast technology base provide unique advantages in the competition for global R&D needed for biotechnology and pharmaceuticals.")

reaches the marketplace in the form of new medicines and improved therapies for patients.

Over 25 years ago, the United States, the United States was faced with a similar challenge. I would like to discuss with you today how the United States responded over two decades ago to that challenge and some more recent developments as we consider the potential in India for a similar biotechnology revolution.

Two Landmarks in 1980

Nearly a quarter of a century ago in the United States, before the IT-revolution that has brought such benefits to India, two important events changed the face of science and its relationship with industry in the U.S. These are the U.S. Supreme Court case of *Diamond vs. Chakrabarty* that established the patentability of new life forms, and the passage in the U.S. Congress of legislation named after two prominent Senators, Birch Bayh and Robert Dole. The

Bayh-Dole Act provided incentives to encourage collaboration and to create new products and services from scientific breakthroughs in the area of biotechnology and beyond. And relying largely on these scientific breakthroughs that take place in universities and research institutes, PhRMA members will spend more than 32 billion dollars this year on development of new, innovative medicines for patients in the U.S. and around the world.

In his key note address at the Indian Government's Interactive Session on the upcoming patent amendments, Dr. Mashelkar cited the benefits of the American Bayh-Dole experience. In his presentation he contrasted the story of Indian science academia with the U.S. Bayh-Dole system as the "Continued Story of Missed Busses." Adoption of a Bayh-Dole system can help bring the benefits of scientific advances to society in the twenty-first century in India as in the U.S.

- **Chakrabarty vs. Diamond (1980)**

The organizer of this panel, Dr. Ananda Chakrabarty invited me to speak here today, but did not know that he would be featured in my talk. He is a mentor to me, as to so many others who look to him as a pioneer in biotechnology. In the mid-1970's Dr. Chakrabarty applied for a patent for a novel, engineered bacterium that was rejected by the patent office as a genetically engineered organism. His application was treated as a test case by the Patent and Trademark Office.

After several years of litigation, the Supreme Court eventually held in favor of Dr. Chakrabarty's invention in 1980, stating that "anything under the sun," including genetically engineered inventions, is eligible for a patent so long as it meets the standard definition of patentability (novelty, non-obviousness and commercially

[2] *Diamond v. Chakrabarty*, 447 U.S. 303, 100 S. Ct. 2204, 65 L.Ed.2d 144 (1980) Even in

applicability).[2] This ruling opened the pathway for biotechnology inventions in the United States.[3] On a personal level, Dr. Chakrabarty has told me how empowering it was for him, as an immigrant to the U.S. and a Non-Resident Indian (NRI) to be able to take his case to the highest court in the U.S., and to win.

The second key enabling development for the biotechnology revolution in the United States was passage of the Bayh-Dole Act in 1980.[4]

- **The Bayh-Dole Act**

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advance of amendment of the Patent Act of 1970 in India, this same thing may now be happening in India where e "recently the Calcutta High Court held, in Dimminaco AG vs. Controller of Patents and Designs that a patent on a microorganism was valid. Dimminaco AG had applied to the Controller for a patent on the process for manufacturing a vaccine for infectious bursitis in poultry. The Controller had rejected the application because it involved a microorganism. In April 2002, Justice Ashok Kumar Ganguly of the High Court set aside the decision of the Controller of Patents and Designs. The Controller then accepted the application." Manisha Shridhar, "Gearing Up for Patents"; Terragreen, issue- 41, 31st July 2003, accessed December 17, 2003 at http://www.teriin.org/terragreen/issue41/essay.htm. The case cited is *Dimminaco AG vs. Controller of Patents and Designs* is A.I.D No.1 of 2001, Calcutta High Court.

[3] "Interestingly, before 1980, only a handful of biotech companies, including Genentech and Cetus/Chiron, were around. After *Diamond v. Chakrabarty,* the biotech industry grew phenomenally. Coincidence? Probably not." Speech: Anything Under the Sun Made by Man, Lila Feisee, Director for Government Relations and Intellectual Property, Biotechnology Industry Organization, Delivered at the Conference- Biotechnology in Northeast Ohio, Current Plans and Visions for the Future, At The Case Western Reserve School of Law, Law-Medicine Center, April 11, 2001, Accessed December 15, 2003 at http://www.bio.org/news/041101.html

[4] P.L. 96-517, the Patent and Trademakr Law Amendments Act, enacted into law in 1980.

In the United States in the 1960's and 1970's, there was a major concern in the United States, that despite increased funding for basic research by the U.S. Government, there was only very limited adoption of new technologies by industry.[5] In 1980, fewer than 5% of the 28,000 patents for which the U.S. held title were developed into commercial products by industry.[6] A large part of the problem was caused by the difficult and time-consuming process for companies interested in obtaining exclusivity rights to government inventions in the U.S.[7] Mainly, U.S. law provided for the grant of non-exclusive rights, but of course this failed to encourage companies to invest in and develop new products. In short, "taxpayers were supporting the

[5] "The Bayh-dole Act:A Guide to the Law and Implementing Regulation," Council on Government Relations (COGR), 1999, accessed at http://www.ucop.edu/ott/bayh.html

[6] Ibid, citing the U.S. Government Accounting Office (GAO) Report to Congressional Committees entitled "Technology Transfer, Administration of the Bayh-dole Act by Research Universities," May 7, 1998.

[7] "[B]y the late 1970s there was a growing dissatisfaction with federal policies on patenting the scientific knowledge resulting from the research. Many government officials, for example, believed that federal laboratories were keeping information away from those who could make use of it. There was also a concern that because the government had retained title to inventions, no one was bothering to advance the research. There was no incentive to do so. Further, with the maze of bureaucracy caused by lack of a uniform policy, made companies reluctant to deal with the government, even if they were interested in the research." Speech: Anything Under the Sun Made by Man, Lila Feisee, Director for Government Relations and Intellectual Property, Biotechnology Industry Organization, Delivered at the Conference- Biotechnology in Northeast Ohio, Current Plans and Visions for the Future, At The Case Western Reserve School of Law, Law-Medicine Center, April 11, 2001, Accessed December 15, 2003 at http://www.bio.org/news/041101.html. See also: "Innovation's golden goose," The Economist, December 12, 2002, noting that "inventions and discoveries made in American universities, teaching hospitals, national laboratories and non-profits institutions sat in warehouses gathering dust."

federal research enterprise, [but] they were not benefiting from useful products or the economic development that would have occurred with the manufacture and sale of those products."[8]

The new policy of Bayh-Dole provided the opportunity for universities and research institutes to become involved in the commercialization process by owning inventions and working with industry to bring products to market. Bayh-Dole also allows for exclusive licensing of inventions, with regulations that ensure that products are developed diligently and for the public good. University-industry partnerships allow researchers to participate in the development of a product or process, speeding up the commercialization process.[9] And income derived by the University goes back to fund additional research.

[8] The Bayh-dole Act:A Guide to the Law and Implementing Regulation," Council on Government Relations (COGR), 1999, accessed November 2003 at http://www.ucop.edu/ott/bayh.html, p. 2. The Economist notes that, "[a]lthough taxpayers were footing the bill for 60% of all academic research, they were getting hardly anything in return." "Innovation's golden goose," The Economist, December 12, 2002.

[9] "Bayh-Dole Act," Cornell Research Foundation, Inc., accessed at http:://wwww.crf.corell.edu/bayh-dole.html

The combined impact of these two nearly simultaneous developments on bringing science to the marketplace was nothing short of amazing. In 1999 alone, the licensing and development of these discoveries added $40 billion to the U.S. economy and supported more than a quarter of a million jobs,[10] the same number employed by the entire IT sector in India. The social benefits of these two developments include the launching of the biotechnology revolution that has brought so much hope of new cures and therapies for diseases in our lifetime. The majority of commercialization of scientific breakthroughs under Bayh-Dole have been in the life-sciences, where products and processes reduce pain and suffereing and save lives.[11] There are thousands of new products on the market due to Bayh-Dole. These include technologies instrumental to the biotechnology industry like recombinant DNA technology, the process for inserting DNA into cells, and new and more effective tests and therapies for cancer and osteoporosis, new vaccines, environmentally sound technologies and even safer guardrails for our

[10] Id.

[11] The Bayh-dole Act:A Guide to the Law and Implementing Regulation," Council on Government Relations (COGR), 1999, accessed at http://www.ucop.edu/ott/bayh.html

highways.[12] And Bayh-Dole generates continuing streams of income for Universities and Research Institutes, leading to increased funding for scientific research.[13] Over two hundred research institutes in the U.S. report more than 37 billion dollars in funding in FY- 2002.[14]

Chakrabarty, Bayh-Dole and the American Biotech Revolution

Lila Feisee of the Biotechnology Industry Organization or BIO has noted the combined synergistic effect of these two critical events:

> With the help of the Supreme Court decision of *Diamond v. Chakrobarty* and the Bayh-Dole Act, the biotech industry sky-rocketed. Today there are over 1,300 biotechnology companies in this country [the U.S.] . . . developing effective new therapies and cures for . . . our most intractable illnesses such as heart disease, all forms of cancer, Alzheimer's, Parkinson's, osteoporosis; almost

[12] Ibid., Op. Cite

[13] "Running royalties on product sales were $1.005 billion," in FY 2002, according to Patricia Harsche Weeks, 2003 – 2004 President of the Association of University Technology Managers (AUTM), and Vice President, Planning and Business Development, Fox Chase Cancer Center, Philadelphia, PA, A Message from the President, AUTM Licensing Survey, FY 2002.

[14] AUTM Licensing Survey, FY 2002, p. 1.

every disease is under assault by biotechnology companies.[15]

But not content to remain a pioneer of the biotech patent, Dr. Chakrabarty now joins the ranks of biotechnology entrepreneurs with the establishment of CDG Therapeutics. In recent months, Dr. Chakrabarty and his colleague Dr. Das Gupta have negotiated exclusive rights to their path-breaking cancer research at the University of Illinois to try to bring new cancer therapies to market through CDG therapeutics. Thus a new chapter begins in the continuing history of biotechnology.

Biotechnology Today and Tomorrow

Let me now turn to the future of biotechnology. As we all know,

[15] Lila Feisee, Director for Government Relations and Intellectual Property, Biotechnology Industry Organization, Delivered at the Conference- Biotechnology in Northeast Ohio, Current Plans and Visions for the Future, At The Case Western Reserve School of Law, Law-Medicine Center, April 11, 2001, Accessed December 15, 2003 at http://www.bio.org/news/041101.html

in the Spring of 2003, the complete sequencing of the human genome became known. This will have a major impact on the way that new diagnostic tools and new medicines are developed. PhRMA member companies and Indian firms alike are using the basic research data of the Human Genome, to understand the associations that exist between genes and diseases. This will translate into new diagnostic options and medicines -- including genetic tests, pharmacogenomics, and gene therapy. We are on the threshold of a new era in medicine. "Today, physicians have at their disposal more than 140 biotech-based medicines and vaccines, in addition to a raft of genetic tests. These medicines have benefited an estimated 325 million people worldwide and are part of the medical mainstream, used both in emergency situations - such as heart attacks and sepsis - and to slow progression of previously intractable chronic diseases, like rheumatoid arthritis and multiple sclerosis."[16]

[16] Carl Feldbaum, President of the Biotech Industry Organization (BIO), "It was 20 years ago today . . .," U.S. Biotechnology Trends, Fall 2002, BioIreland, Dublin, Ireland, November 14, 2002, accessed December 15, 2003 at http://www.bio.org/news/speeches/20021114.asp

We have seen a consistent pipeline of biotechnology products moving towards regulatory approval, with biotechnology therapies for over 200 diseases representing roughly a third of the more than 1,000 medicines in human clinical testing. And this year, the 50th anniversary of the discovery of DNA, the FTA received more submissions for biotechnology drugs than for traditional pharmaceutical medicines.[17]

So far, 95 biotechnology drugs, most developed by PhRMA member companies, have received marketing approval. Another 371 are in the pipeline.[18] Companies today also have already mastered the duplicating of individual body cells, tissues and genes into new biotechnology medicines that are often safer and more effective than older, conventional chemical compounds.

[17] "Biotech reaches a turning point in its evolution," The Financial Times, December 17, 2003.
[18] PhRMA, Pharmaceutical Industry Profile 2003 (Washington D.C.: PhRMA, 2003): 16.

Intellectual Property Elements of Bayh-Dole

When Bayh-Dole was adopted in the United States, of course there was already a long-standing commitment to patent protection, rooted in the U.S. Constitution.[19] And one of the most positive developments in the last two years has been the recognition that India, as a knowledge economy, must protect its intellectual patrimony through strong protection of the intellectual property associated with pharmaceutical and biotechnology inventions. This includes protecting patents, assuring data exclusivity, and creating linkages between health regulatory officials and industrial property offices to provide needed incentives for commercialization of products to benefit patients.

[19] "The Congress shall have the Power . . . to promote the Progress of Science and useful arts, by securing for limited Times to Authors and Inventors the exclusivity Right to their respective Writings and Discoveries." U.S. Constitution, Article I, Section 8.

With the upcoming parliamentary debate of the Third Amendment of India's 1970 patent law, India has an excellent opportunity to gain maximum value from the best and brightest scientific minds trained by Indian universities that currently apply their genius both within India and in Western laboratories.

We have seen that good ideas have no nationality. In this context, India's best minds need the legal infrastructure to bring their ideas into the marketplace, and to bring India into the patent mainstream as the last major market to adopt patent protection for pharmaceutical products.[20]

We need to provide a transparent and predictable commercial

[20] The 34th Annual Report 1999 – 2000 of the Organization of Pharmaceutical Producers of India (OPPI) notes that since the late 1980's, "The following developing countries extensively changed and improved their patent systems: Korea (1987), Czech and Slovak Republics (1990), Mexico, Bulgaria, Indonesia, Chile, Belarus (1991), Romania Taiwan, Russia Ukraine, Thailand (1992), China, Yugoslavia, Philippines, Poland, Slovenia, Macedonia (1993), Andean Pact, Hungary (1994), Brazil (1996) and Jordan (2000). All of them introduced product patents for pharmaceuticals." OPPI 34th Annual Report 1999 – 2000, p. 6.

environment that will encourage greater foreign investment, partnerships, and technology transfer. Recognizing this need, the Government of India has already initiated the process of amending the Patents Act of 1970 to allow product patent protection for pharmaceutical products, which it must enact by January 1, 2005.

India should complete all legislative action needed by 2005 to be fully compliant with its international obligations, including those TRIPS provisions that, to date, it still has not implemented.

Stated simply, India needs to introduce a product patent system that conforms to international standards. Included should be:

- a streamlining of the application process, that is, elimination of pre-grant opposition and

shortening of the application time period.

- introduction of TRIPS due process requirements in the areas of compulsory licensing, with removal of the numerous triggers and low hurdles that eat away at the innovators' rights, and

- elimination of provisions that are clearly inconsistent with minimum international obligations, like patentability standards that go beyond novelty, obviousness and commercial applicability.

But more needs to be done to ensure that India becomes the major biotech hub it deserves to be. India does not yet provide protection for the commercially valuable, confidential clinical dossier

information that is disclosed to regulatory authorities as a condition for obtaining marketing approval. This is known as data protection or data exclusivity. WTO members are obligated to provide this as a TRIPS obligation (TRIPS Article 39.3) from January 1, 2000. Countries with data exclusivity include the U.S. and nearly all other OECD-level economies, Jordan, Singapore, Chile, Morocco, and others.

Within India, there is growing recognition that data exclusivity is a separate and independent form of intellectual property protection from patents that is also critical to innovation and technology transfer in the pharmaceutical and biotech fields. The Government of India should be encouraged to resolve this well ahead of the January 1, 2005 deadline for introduction of product patents.

Data Exclusivity brings multiple benefits, allowing the Ministry

of Health to better track applications for marketing approval, provide transparency on the registration process, safeguard the confidentiality of the data and prevent registration of unauthorized products that rely, directly or indirectly, on the data provided by the innovator or his agent or licensee. We see the possibility for positive spill-over effects that will improve the drug registration process, provide better care for patients, and assist all legitimate drug manufacturers.

Finally, PhRMA members also seek linkage in India. Patent linkage refers to the obligation to delay the approval of marketing applications for generic drugs until after the expiration of patents that cover the drug product or its approved use. It is a way of ensuring that one governmental agency does not undercut the efforts of another agency to provide effective intellectual property protection.

To date, India does not provide any mechanism to ensure linkage. It is critical that there be communication between the Patent Office and the Ministry of Health to ensure that the health regulatory authority does not provide market authorization for unauthorized copies of products subject to patent protection. Governments, not patents offices, are bound by WTO TRIPS Agreement, and it is the responsibility of all relevant Government agencies to ensure that TRIPS obligations on patent protection and data exclusivity are met.

Patent linkage is most important in countries like India that have just adopted or are in the process of adopting product patent protection for pharmaceutical products. Several OECD-level and/or middle-level developing countries do now provide linkage, including Canada, Mexico, Jordan, Chile, China and Singapore.

If the regulatory constraints are minimized and other forms of

regulation streamlined in India, the Indian Biotech industry can easily surpass the Indian IT industry and even the bio-informatics sector through the adoption of legislation similar to Bayh-Dole.

Based on the experience of the United States, both Japan and Taiwan have now passed legislation modeled on Bayh-Dole in recent years, and in the future should also benefit from greater public/private partnerships in research.[21] I have spoken frequently of India's vast reservoir of scientific talent and established global pharmaceutical industry. I believe that once India establishes a strong platform of effective patent and data protection, India will be uniquely positioned to benefit from similar legislation, to bring the benefits of collaborative relationships between research institutions and industry to light, and to speed India's own biotechnology revolution.

[21] Patricia Harsche Weeks, 2003 – 2004 President, AUTM, Remarks on the 23rd Anniversary of the Implementation of Bayh-Dole, December 12, 2003, Washington, DC.

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Policy Innovation:
The Initiation and Formulation of New Science and Technology Policies in the U.S. During the 1980s

A Report to JETRO-New York
and NEDO-Washington

Executive Summary

George R. Heaton, Jr.
Christopher T. Hill
Patrick Windham
with
Tatsujiro Suzuki

March 2000

Policy Innovation ES - 1

1. Introduction

During the 1980s, a proliferation of initiatives broke new ground in U.S. science and technology policy. Many focused on industrial technology policy -- theretofore largely unexplored. Most exemplified a new policy style: partnering among government, business and the academic community. Almost without exception, these policy innovations were informed by a new view of the process of technological innovation, which emphasized the system of influences -- far beyond R&D -- that conditioned its environment.

With the science and technology policy innovations of the 1980s as its subject, this report asks: how are policy innovations generated in the overall

context of American public policy; and how did particular science and technology policy reforms arise and gain acceptance in this era?

Four retrospective case studies anchor the analysis, covering the Bayh-Dole Patent Act, the Federal Technology Transfer Act (FTTA), the Advanced Technology Program (ATP) and public policies affecting the U.S. biotechnology industry. A beginning overview of the American public policy formulation process and general conclusions frame these case studies. The work draws not only on published sources but also on the personal involvement of the authors in the areas chosen for study.

2. The Policy Formulation Process

Though science and technology policy making has much in common with other areas, some important differences exist. Many issues involving science and technology require access to sophisticated and complex knowledge; thus experts play a greater role than usual, which creates some tension with the American polity's strong democratic and populist streaks. In addition, since much of science and technology policy is formulated within the context of broader areas of public policy, the "S&T part" is sometimes treated as marginal or an "after thought."

The character of the U.S. policy generation system derives from Constitutional and conceptual bases. The Constitution's guarantees of the right to petition for the redress of grievances and to speak and assemble freely has led

to a highly developed "civil society." Individuals are accustomed to addressing the government directly, and typically criticize its actions. The wide variety of organizations that influence policy development -- political parties, think tanks, trade associations, labor unions, single-issue advocacy groups, universities and others -- participate on their own initiative and without official chartering. Depending on the issue, these groups cooperate or compete in a pattern of ever-shifting relationships. It is not surprising, therefore, that the American policy generation system is uncomfortable with centralized planning and, with the exception of financial planning, has never developed strong institutions of this type.

Conceptually, policy design bears a number of resemblances to engineering design, drawing on fundamental scientific understanding and past experience, and hypothesizing new approaches that will work within constraints to achieve desired ends. An essential difference, however, is the frequent lack, in public policy, of agreement on goals -- which necessitates compromise. Most policy innovations in America are in fact marginal adaptations of pre-existing ideas, which is consistent with the U.S. aversion to central planning.

Alternative policy designs can come from a variety of sources, including analogies to other circumstances, social theories, prior experiences, the efforts of individual states, or other countries. Certain policy tools are used repeatedly. Policy design by analogy thus emerges as the strongest tendency in the U.S. system. One of the most unique features of the U.S. system is its dependence on states and their leaders as the source of policy experimentation -- "laboratories of democracy."

Each year the U.S. policy making system is presented with thousands of concepts and ideas. Executive agencies are routinely involved in self-evaluation, and frequently propose policy changes. The large network of agency advisory committees offers a fertile source of new ideas. The U.S. Congress has a highly developed range of mechanisms to generate, assess and develop new ideas. The Congress is extremely open to externally generated proposals, from individuals

and organizations. The large professional staff -- both individual staff members and a number of staff agencies -- play a critical role, serving as a repository of expertise and institutional continuity. Members themselves are highly attuned to the wishes and ideas of their constituents, and often make their mark by championing new ideas.

Political parties in the U.S. play a relatively weak role in developing new policy ideas. In contrast to Parliamentary systems, the Members of the U.S. Congress enjoy more independence from their parties, and candidates are expected to bring their own ideas to campaigns. In contrast to political parties, external groups exert a uniquely strong influence in the U.S. These include interest groups, lobbying firms, corporate public policy staffs, thinks tanks, university professors and research institutes, community leaders and ordinary citizens. A climate of "policy entrepreneurship" reigns.

The expression of a policy idea or initiative is the first step in a long evolution. Congressional examination and debate is often prolonged, centered around the jurisdictions of particular committees. The views of the Administration are frequently sought. A "mark up" process considers amendments before a legislative draft solidifies. The process is further intensified by the fact that each House must pass legislative proposals in identical form and the President must approve them.

Although in theory the responsibility of Executive agencies is implementation rather than policy design, the mandates that Congress offers them are typically broad enough to allow for a great deal of policy innovation at

the implementation stage. In this regard, agencies rely heavily on formal "rule-making" processes, whose procedures ensure public input.

From early in its history, the American judiciary has assumed a uniquely pivotal role in policy-making. Access to judicial review of government action is remarkably open, and the courts are by no means reluctant to set aside agencies' programs, on Constitutional, substantive or procedural grounds.

The processes of policy design, evolution, and adoption in the U.S. should not be seen as rational processes in the sense that rationality is understood by a

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policy analyst or an economist. Instead, many institutional and political factors, as well as many different actors and organizations, intervene to help shape what finally becomes law and policy; mere assurance by expert analysts that an alternative would be successful if adopted is no guarantee that it will be adopted. Nevertheless, a number of theories -- each useful, but none sufficient -- provide frameworks for thinking about the American policy process. These include:

- the theory of interest groups, which argues that policies emerge as the result of context among special groups
- the "Iron Triangle" variant on interest group theory, which emphasizes coalitions among federal agencies, regulated industries and Congressional committees
- the public administration model, which urges the development and empowerment of professional public servants
- the rationalist planning model, which though often met with public

- the rationalist planning model, which though often met with public skepticism, nevertheless often surfaces in special commissions and other bodies and is generally urged by the scientific community

- the public choice model, most recently developed to apply the tools of economic analysis to actors in the policy process seeking to "maximize" their own benefits.

Perhaps the most fundamental fact about policy innovation in the U.S. is that it is highly de-centralized. While there are government agencies and commissions so concerned, their work is overshadowed in variety and inventiveness by the extraordinary range of mechanisms devoted to these tasks in America. The diversity of American policy making is a consequence of, or at least consistent with, a package of Constitutional rights that focus on public petition and participation. The multiplicity of voices on important public issues can seem to arise like the calls of a thousand crows, each seeking to outdo the others in volume, intensity, and impact. The enormous marketplace of ideas that is the United States Congress, the policy making bodies of the Executive Branch, and a welter of interest groups and experts can be as confusing as any of the world's great bazaars. The results can be just as satisfying or just as frustrating to those who participate.

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3. The Bayh-Dole Patent Act of 1980

The Bayh-Dole Patent Act is commonly regarded as a major shift in policy: from government to private ownership of the results of publicly financed R&D.

In fact, the idea incorporated in Bayh-Dole had already been tried. During World War II, patent rights were frequently assigned to the government's private contractors, and even at the Act's passage, some agencies had patent policies that favored the private sector in a similar manner. But Bayh-Dole's extension of this approach to small businesses and non-profits, and later, to all businesses, did represent the widespread acceptance of a utilitarian view of intellectual property rights, in which the "sacrifice" of public ownership of knowledge supported by the government was justified by the benefits that private-sector commercialization would yield.

The Bayh-Dole policy innovation is fundamentally about the validity of an idea. In contrast to many other policy debates, Bayh-Dole's did not elicit special interests vying for money or power. While the institutions that would receive patent rights under the Act's procedures stood eventually to profit from them, there was still the need for them to invest their own resources without further subsidy. The private sector -- industry and universities -- was virtually unanimous in favor of the Bayh-Dole approach. So were the major theorists and advocates of technology policy, who argued pragmatically that it would work. Bayh-Dole's proposition also benefited from the increasing acceptance of the need for strong IPR as an incentive to innovation and a weapon in the arsenal of U.S. international competitiveness.

On the other side, ther was no organized oppostion interest group. Those who opposed Bayh-Dole were essentially arguing from the old populist position that the "people" had a "right" to the IPR resulting from expenditure of public monies. Few stood to benefit from this philosophical argument. With the utilitarian position posed as a means to promote U.S. competitiveness, there was little force in the populist argument, as illustrated in the lopsided Congressional votes in favor of Bayh-Dole from both parties.

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The acceptance of Bayh-Dole is also unusual in its absence of strong policy entrepreneurs or advocates. Indeed, its component idea had been debated for more than thirty years, going back to the Bush Report of 1945. Throughout the 1960s and 70s legislative proposals arose from several sources. Many in the private sector had advocated it for some time, and no single individual can really be credited with its origin or advocacy. Even in the Congress, the concept of the legislation was well-formed before Senator Bayh introduced it. The essential process was more one of slow consensus-building than radical policy innovation, and when consensus had matured, it was acted on with little debate.

If one looks at the Bayh-Dole Act in tandem with the Stevenson-Wydler Technology Innovation Act, enacted almost simultaneously, one sees the first full endorsement of several new ideas in U.S. technology policy. First, these statutes testify to the country's realization that something needed to be done to correct the economic malaise that had become apparent in the 1970s. Second, they incorporated a sophisticated view of technological innovation, based on the recognition that it is a process whose encouragement requires a full range of incentives, going far beyond financial support for R&D. Third, they accepted the promotion of technological innovation as an important mission of the Federal government. Both Acts incorporated provisions that cast the Federal government and the private sector as partners in technology development, rather than as arms-length contractors -- or even adversaries -- which had often previously been the case.

Bayh-Dole in particular was based on an empirical proposition largely untested in 1980: that the private sector would commercialize publicly financed technology if it had the legal basis to do so. The stunning acceptance of the Bayh-Dole system since offers verification of this. And the connection between Bayh-Dole's system and the widespread public-private, industry-university ties

that now characterize the American innovation process suggests strongly that it represented a beginning piece of a major paradigm shift in U.S. technology policy and practice.

4. The Federal Technology Transfer Act of 1986

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The Federal Technology Transfer Act of 1986 changed the relationship between U.S. federal laboratories and industry. It provided a new legal framework for most federal laboratories to conduct joint research with companies and with other partners (such as state governments). As an incentive for federal researchers to participate in joint research, the law allowed them to receive part of the royalties (payments) received on inventions they helped to create. In one way, the law was not "revolutionary" -- the Stevenson-Wydler Act, six years earlier, had encouraged federal laboratories to work with industry. But by authorizing a new form of joint research and allowing federal employees to share in royalties, the FTTA was a significant change in U.S. technology policy.

Three points mentioned previously in the general discussion of the U.S. policy process are particularly important in understanding the origins and eventual adoption of the FTTA:

- "Policy entrepreneurs" propose and advocate new policies. Those who are most effective combine an important idea with understanding of how to work within the political process.

- Members of Congress are often interested in new legislative ideas, both to increase their popularity and to achieve policy goals. Thus, Members introduce bills that contain ideas from policy entrepreneurs.

- Since political power is dispersed and decentralized, coalitions are necessary. The chairs of Congressional committees and top Administration officials are particularly important.

The FTTA started as an idea developed by two men, and it became popular because of Congress' concerns in the 1980s with American industrial competitiveness. One of its originators, Norm **Latker**, was a dedicated, blunt-speaking patent attorney who represented Purdue University, in Indiana during the late 1970s. The second, Joe Allen, was an aide to Senator Bayh of Indiana. The team of **Latker** and Allen eventually worked together in the Commerce Department, promoting ways to make federally funded technology from the national laboratories more available the U.S. industry. They worked closely with Congressional staff and members of the technology policy community over a period of years to bring their ideas to fruition.

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Latker and Allen studied past policy closely -- i.e., Stevenson-Wydler -- and saw serious deficiencies, both from a conceptual and a legal point of view. To remedy them, they offered three proposals:

- the extension of Bayh-Dole to government laboratories run by universities

- a new legal arrangement -- a "cooperative research and development agreement (CRADA) -- through which federal laboratories and research partners (usually a company) negotiated resource contributions, the R&D

agenda, IPR ownership, and royalty sharing.

- a monetary incentive -- a portion of technology licensing royalties -- for federal scientists and engineers to work with research partners.

When the FTTA concept was being developed in the 1980s, technology policy issues generally received little attention from White House officials or most members of Congress. This was not bad from the point of view of the policy entrepreneurs since the lack of controversy made their job easier.

In addition, the national political climate was favorable. In 1985-86, the Reagan Administration was looking for initiatives in the competitiveness area -- particularly if they did not "interfere" with the private market and if they cost little or nothing in expenditures. Although the Administration would not formally endorse the FTTA proposal, it did give tacit support.

In the Congress, the FTTA proposal was moved among committees, debated and amended before it passed. One sees throughout this process the important role of individual Members of Congress and particular staff people who had made technology policy the focus of their careers. In October of 1986, a final compromise bill, which enjoyed broad bipartisan support, was passed and signed by President Reagan. Beyond the provisions outlined above, the Act made technology transfer an affirmative mission of all laboratories and personnel, taking this mission into account in performance evaluations.

The post-Congressional implementation process was particularly complex for the FTTA. To begin, the FTTA not well understood by the wide variety of agencies to which it applied. Moreover, since its authority was discretionary

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rather than mandatory, agencies were not required to do anything. Policy entrepreneurs were thus needed to move the program along, which was eventually accomplished through Executive Order and the accumulation of CRADA experience.

The FTTA story emphasizes the following features of the U.S. policy process:

- the role of policy entrepreneurs
- the "learning process" in policy design, which accretes over time
- the absence of "interest group" politics in the technology policy debate of the 1980s
- the consistency of technology policy innovations with the overall political dynamic of the 1980s, particularly concerns about U.S competitiveness.

5. The Advanced Technology Program

The Advanced Technology Program (ATP) supports industrial research and development for the explicit purpose of developing new technologies that have the potential to increase U.S. economic growth. Before its creation in 1988, most U.S. science and technology programs focused on either university basic research or helping the government with well-defined missions such as defense, energy, space, and health. By explicitly focusing on technology for economic growth, the ATP was something new. Its creation was the result of four factors:

- Growing Congressional concern in the 1980s about U.S. technological leadership.
- A new understanding among some analysts of why the U.S. lagged in technology while still leading the world in science, coupled with policy

ideas about how government-industry R&D partnerships might help

- Strong leadership from a senior U.S. Senator and an important Congressman, with support from their staffs and others -- i.e., policy

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entrepreneurs within Congress who authored the program rather than business interests.

- A lucky legislative situation in which this program could be included a large new law that President Reagan wanted.

The legislative language creating the program was made part of the Omnibus Trade and Competitiveness Act of 1988, and Congress provided an initial $10 million in appropriations for the program in late 1989. The Department of Commerce (DOC), which administers the program, made the first awards -- eleven -- in March 1991. Program funding grew steadily for several years, reaching $341 million in federal fiscal year (FY) 1995. In recent years, funding has stabilized at about $200 million per year.

By the early 1980s, the United States had slumped into a deep recession, and academic and journalist voices were arguing for "reindustrialization" -- a responsibility that fell primarily to companies but also raised important questions of public policy. The Reagan Administration, committed to a small role for government except in defense, initially dismissed the need for new policies. Ironically, one of the most thoughtful and influential reports on this subject came from a special commission appointed by President Reagan himself. Chaired by John Young, the chief executive officer of the Hewlett-Packard

Corporation, the President's Commission on Industrial Competitiveness issued a blunt report in January 1985. It said, in part: "Our ability to compete in world markets is eroding. Growth in U.S. productivity lags far behind that of our foreign competitors. Real hourly compensation of our work force is no longer improving."

As many in Congress became interested in competitiveness, they also became more receptive to new policy proposals. Ideas, new and old, appeared, and policy entrepreneurs inside and outside of Congress sought to build support for them. Older-style members often focused specifically on the recession and industrial decline in their home regions. Given the opposition of the Reagan Administration and lack of support from industry leaders, these ideas went nowhere. Younger, "New Democrats" had other proposals. A few members straddled the two generations -- one important example was Senator Ernest

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(Fritz) Hollings of South Carolina, in 1985 the Ranking Democrat on the Senate Commerce Committee. He would later become the author the ATP proposal.

The technology policy ideas then-current can be divided into three groups:

- proposals to make existing Federal R&D more useful to American industry (e.g. Bayh-Dole and FTTA)
- encouragements to more corporate R&D (e.g. tax credits and loosened antitrust regulations)

- direct Federal support to companies for R&D with significant economic potential.

This last idea, the core of the ATP, had already had a long, often unsuccessful history in the U.S., spanning the Hoover (1920s), Nixon and Carter Administrations. Nevertheless, Senator Hollings and Congressman George Brown and the staff surrounding them became convinced of its merits and political viability, especially given the Democrats' new control of the Senate in 1986. Important as well were the increasingly vocal views of the high-technology sector in the U.S. and the increasing reference to Japanese industry and public policy as models worth scrutinizing and emulating.

These forces came together to produce a proposed Technology Competitiveness bill that the Reagan Administration was very much in favor of, and the ATP concept was appended. The final version of the ATP had three main parts:

- a statement of purpose: to assist "United States businesses in creating and applying the generic technology and research results necessary to: (1) commercialize significant new scientific discoveries and technologies rapidly; and (2) refine manufacturing technologies."

- authority for the ATP to aid joint research and development ventures (consortia) by providing a minority share of the cost of such joint ventures for up to five years, provided that emphasis was placed on areas where NIST "has scientific or technological expertise, on solving generic

problems of specific industries, and on making those industries more competitive in world markets."

- NIST contracts and cooperative agreements with individual United States businesses, especially small businesses.

It took about five years for the ATP to define and implement its first set of grants, which were awarded in 1991. This delay can be accounted for not only by the complexity of the mission and its novelty but also by the amount of public involvement solicited for its initial design. In the Clinton years, especially after 1994's Republican political successes, ATP became a magnet for partisan controversy. As this controversy has subsided and experience with the program has grown, so too has its reputation for fairness and effectiveness.

6. Public Policies Toward the Biotechnology Industry

Technology policy in the U.S. is rarely directed at industrial sectors. Indeed, the notion of "targeting" particular technologies at all is a controversial proposition. The idea that the U.S. has had an explicit, definable public policy toward the biotechnology industry would thus be rejected by many observers.

It is nevertheless clear that U.S. public policy has had an extraordinarily important impact -- widely agreed to be positive -- on the development of the biotechnology industry. Certainly during the 1980s, this impact was well-recognized, and it figured significantly in the policy process. In three particular contexts, public policies toward biotechnology were explicitly formulated:

- research funding, particularly from the NIH;
- environmental, health and safety regulation
- intellectual property rights.

More implicitly, the package of public policies and market structures focused on the venture capital industry and university-industry relations emerged during the 1980s as critical to the development of biotechnology. While

these policies in the aggregate had a major positive influence, they were never well coordinated or conceived of as a deliberate sectoral policy.

As early as the Bush Report (1945), U.S. science policy had committed itself to support for health research as one of the main targets of public policy. The vigorous climate for research in biological sciences that ensued during the post-War years, notably in molecular biology, is often cited as the background for Watson and Crick's theorization of the double helix structure of DNA in 1953. In the years after this discovery, the National Institutes of Health (NIH) funding of external research increased dramatically. This occurred across a wide range of disciplines and across many academic and research institutions, thus establishing multiple centers of excellence in relevant fields. The large external research budget, complemented with internal work, led to a widespread network of scientists throughout the U.S. -- and to a significant extent throughout the world -- that connected government, academe, and industry. And the grants system, based on peer-review, established a culture of excellence and competitiveness.

NIH's viral oncology program gave biotechnology research its biggest boost. This arose in the 1960s, when molecular biologists had begun to claim that developments in the understanding of DNA would lead them to discover a cure for cancer. Momentum gathered during the 1970s, when the "war" on cancer led to huge funding increases in this program -- and a wide ambit for the its research scope. Two major differences between the U.S and other countries stand out during this period: the earlier, larger U.S. government financial presence; and

during this period: the earlier, larger U.S. government financial presence, and the connection of government, academe and industry in the research system.

The success of Professors Cohen and Boyer in perfecting "gene-splicing" techniques in 1973 ranks as a transformative moment, in which biotechnology began moving from an enterprise of basic science into a commercial industry. This transformation was not, it should be emphasized, the result of a changed government policy but rather, dramatic inflows of venture capital and large-scale corporate research. Indeed, the public focus on basic research remained constant, with the NIH continuing its dominant role. The very term biotechnology was coined by Wall Street.

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From the mid-1970s through the late 1980s, questions of government regulation of biotechnology -- its form, its severity, and the agencies that would assume jurisdiction -- were among the foremost public policy issues facing the industry. From early regulatory forays that presented the possibility of strict control, to a *de facto* permissiveness that reigned by the end of the 1980s, twin concerns -- the potential dangers of biotechnology, and the economic downside of over-regulation -- gave rise to constant debate in the public policy arena. Several features of this debate stand out. First, it occurred relatively independently from other policy areas, notably, intellectual property and commercial development. Second, the possibility of regulation presented itself on a number of diverse, relatively uncoordinated fronts, both Federally and locally. Third, the decision was ultimately made not to establish a new comprehensive legal/regulatory framework to address biotechnology, thus

leaving oversight within existing laws and institutions. Fourth, the industrial and research communities clearly succeeded in achieving their goal of a relatively supportive regulatory framework, when judged by international standards.

The U.S. intellectual property rights system has functioned as a strong incentive to the development of biotechnology, both as a result of its general features, and through a number of specific decisions and policies pertaining to the industry. These latter events all arose during the 1980s when the industry was in its formative stage.

The general features of the U.S. intellectual property system were characterized during the the 1980s as "the best protection for biotechnology of any system in the world." Later specific IPR actions that helped the industry included:

- the Bayh-Dole Patent Act
- a 1980 Supreme Court case which removed doubt about patenting biotechnology ("life form") products
- validation of "gene splicing" **patents**
- patenting of the "Harvard Mouse"

- the 1988 Process **Patents** Amendments Act, which increased protection against imported biotechnology products

- the 1990 California Supreme Court decision which denied any rig patients whose cells were used as the basis for medical **patents**

- legislation during the 1990s, which extended patent protection to naturally occurring substances produced with biotechnology techniques

The 1980s saw not only the rise of biotechnology, on both the scientific and industrial fronts, but also a number of important transformations of the U.S. economy. These included the rise of "public venture capital," "biomania" on Wall Street, new relationships between industry and academe, and infusions of investment capital from abroad. All of these featues benefited biotechnology as an industry. All were abetted, though not created, by the public policies of the time.

7. Conclusions: Policy Innovation, Process Constancy

This report has focused on both the substance of the major changes in U.S. science and technology policy that arose during the 1980s and the process that produced these policy innovations. In the former regard, it seems clear that the decade saw a significant departure from the substance of past practice: a paradigm shift, in which the U.S. enacted elements of an industrial technology policy and crafted a new, cooperative approach to policy implementation among government, industry and academe. In the latter regard, one primarily sees process constancy: continued use of the traditions and institutions of government, political discourse and citizen input to generate new ideas that were responsive to the needs of the time.

Even in retrospect, it seems remarkable that the U.S. would embark on so many important departures from its traditional science and technology policies -- in intellectual property rights, public funding of research and the missions of government agencies -- during an era such as the 1980s, when government initiatives were seen as suspect by the President and his Administration.

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Certainly the "competitiveness crisis" of the times -- a concern that cut across party lines -- explains a great deal. So too does a change in the intellectual base of science and technology policy: the influence of a matured scholarship which emphasized the overall "system" of innovation. Committed and entrepreneurial individuals in the policy process must also be given a large measure of credit. Lastly, the fact that the new proposals arose largely from the institutions and forms of the traditional science and technology policy process may have had a great deal to do with their acceptance and ultimate workability.

"Technology Transfer: Payoffs or Pitfalls"

Remarks to the
Licensing Executives Society
Workshop #7:
Success Stories and Best Practices in
University Government

February 2003
Salt Lake City, Utah

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

The Economist Technology Quarterly[1]

In the United States, technology transfer is understood not only by government officials, university administrators and faculty, and pharmaceutical and biotechnology companies, but also increasingly by foreign observers who, in a Tocquevillian sense, are more keenly aware (than are Americans) about what is good (and bad) in our society.

As regards technology transfer, Americans are vaguely aware that economic growth depends on our ability to develop and apply new technologies, and that our universities are

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[1] (U.S. Edition) December 14, 2002 at p. 3.

envied around the world. The returns – in terms of the flow of expertise, and the creation of new products and start-up companies – have been impressive. Based on data reported to the Association of University Technology Managers ("AUTM") for the year 2000, and reflected in the AUTM Licensing Survey, we know that certain universities excel at commercializing the inventions of their professors: Stanford University, the University of California system, the University of Wisconsin-Madison (through the Wisconsin Alumni Research Foundation ("WARF")), the University of Washington (Washington Research Foundation), Massachusetts Institute of Technology ("MIT"), the State University of New York Research Foundation, the University of Pennsylvania, the Texas A&M University System, Johns Hopkins University and the University of Michigan. In 2000, universities and non-profits spent a record $29.5 billion on research and development. Sales of goods developed from products that were transferred from university research centers resulted in revenues of a whopping $42 billion, and U.S. universities, research institutes and hospitals recouped almost $1.2 billion in gross income. Much of this income was subsequently made available to fund further research and educational activities.

The benefits of university innovation are palpable and increasingly understood. Dr. James A. Thomson, Associate Professor at the University of Wisconsin, was even featured on the August 20, 2000 cover of *Time* magazine for the wizardry of his stem cell discoveries. In 2000, 347 products – the fruits of university research and technology transfer to the private sector – were made available. Among these, three examples suffice:

- A breakthrough device to increase the comfort and accuracy of mammograms;
- An environmentally-safer alternative to treated wood; and
- A deicing technology for safer air and land transportation.

Finally, in 2000, innovations by universities resulted in 6,375 new U.S. patent applications, a 15% increase from the preceding year; invention disclosures rose to 13,032, a 6% increase.

The federal government is a key part of the technology transfer equation, contributing almost 60% of university research support. In 2000, government sources contributed $18.1 billion, an increase of 8% over the previous year. In response perhaps to the practical limits of federal funding, the growth rate of industry-sponsored research at U.S. universities has also been impressive. Collaborative research has become the norm rather than the exception.

However, aggregate statistics do not provide a detailed road map for an individual university to maximize intellectual assets. In fact, even large research universities are not currently getting rich from intellectual property royalties. Few universities benefit from "blockbuster" patents. Of almost 21,000 licenses active in 2000, less than 1.0% generated income in excess of $1 million.

Arranged marriages between universities and corporations, under the stern eye of the federal government, are not ideal. Universities' fundamental goals are to teach students, to develop new knowledge and to disseminate that knowledge. Corporations' underlying missions are to produce profits and to build value for shareholders. The role of the federal government is to benefit the public and promote the general welfare of the people.

Many university administrators know more about their football team than technology transfer. The Bayh-Dole Act stimulates memories of two fine Senators long departed from public service; however, responding to an essay question about the Act that bears their names would be a hazardous undertaking for university presidents and administrators. Many licensees of university technologies would be equally endangered with a failing grade.

The Bayh-Dole Act

U.S. patent law is a national law (it would make no sense to have different rules in different states) and, like other laws, reflects societal changes. Patents provide inventors the right to exclude others from making, using, selling, offering for sale, or importing a new invention for the life of the patent, which today is twenty years from the date of the filing. A patent, the society's reward for a discovery, is a property right with clear boundaries. It provides a way for a patent holder to secure income from the commercial exploitation of an invention. Parties that are interested in practicing an invention for which they have no ownership may obtain rights by entering into a licensing agreement with the patent holder.

Almost two decades ago, Congress enacted the seminal Patent and Trademark Laws Amendments of 1980 (Public Law 96-517), as later amended in 1984 (commonly known in government and academic circles as the Bayh-Dole Act), to promote patents in the utilization and commercial exploitation of inventions arising under federally-funded research by non-profit organizations, such as universities and small businesses. By creating a uniform patent policy among federal agencies that fund research, Congress linked together the federal government, universities, small businesses and the corporate world. More than any other factor (and there are others), the Bayh-Dole Act contributes to growth of technology transfer.

The Act is balanced in its approach. On one hand, universities may retain title to and market the inventions they create using federal research funds and may collect royalties on the inventions, and, on the other hand, federal agencies are permitted to grant exclusive licenses for federally-owned inventions to provide increased incentives to businesses. As regards the non-profit sector, rights to an invention created in whole or in part with federal funds cannot be assigned without the permission of the government (except that an assignment may be made to

an entity, like a university foundation, that has as its primary function the management of inventions). The Act permits exclusive licenses that may be more financially advantageous than nonexclusive ones (exclusive licenses, however, are frowned upon by many federal agencies). The Act also requires the sharing of royalties generated by the invention with the inventor and the use of the balance of the royalties, after expenses, for support of educational or scientific research activities. In all cases, the federal government retains a royalty-free, non-exclusive license to practice the invention for governmental purposes and also reserves so-called "march-in" rights if a contractor (university or small business) has not taken "effective steps to achieve practical application of the invention," or the invention is "necessary to alleviate health or safety needs which are not reasonably satisfied" by the contractor or licensee. To date, the federal government has never exercised "march-in" rights. The Act additionally provides protections against disclosure by federal agencies of confidential information pertaining to a subject invention while a university (or other contractor) is pursuing a patent.

The benefits of the Bayh-Dole Act are far-reaching. Universities annually receive billions of dollars in direct federal funds. Federal agencies also provide R&D funding to non-profit institutions other than universities (such as research hospitals, independent laboratories and other research-specific institutes). Some of these non-profits are managed by universities. Prior to enactment of Bayh-Dole, universities filed fewer than 250 patents every year (in comparison to the more than 6,300 filed in 2000). Patents granted to universities are increasing annually, and generally fall into key technology areas and involve life-saving advances. As explained by Carl Gulbrandsen (WARF's managing director), "... those patents, since they arise primarily from the results of basic research, can often afford the basis for whole new products or even industries, as in, for example, the biotechnology industry." The certainty of intellectual property title in

universities has promoted a closer relationship with the private sector. At the same time, the Bayh-Dole Act protects fundamental academic freedom to conduct research and reinforces the mission of the academic community to discover and transmit knowledge to the betterment of the public. A university is free not to patent new knowledge that is patentable, and a patent can operate to put an invention in the hands of the public that was responsible for developing it.

The Bayh-Dole Act does not explicitly protect the patent interests of large, for-profit enterprises engaged in government research. Nonetheless, in 1983 President Ronald Reagan issued a memorandum to the heads of executive agencies informing them that, to the extent permitted by law, it would be the policy of the administration to apply the patent policy of the Bayh-Dole Act to any invention made with federal funding and cooperative agreements irrespective of the size of the recipient's business or its non-profit status. In 1987, the President issued Executive Order 12591 which, among other matters, requires executive agencies to promote commercialization in conformity with the 1983 memorandum.

Despite its benefits, the Bayh-Dole Act has a chorus of critics and detractors.

- Drug-price advocate James Love demeans current practices: "the taxpayers pay to invent a promising drug, then give a monopoly to one company and the company's role? To agree to sell it back to us...."
- Well-known columnist Ellen Goodman writes that encouraging faculty members to combine "science and business, nonprofit and profit," is also mixing "altruism and chumphood." She speculates that Dr. Jonas Salk might be considered a chump for giving away his work on the polio vaccine.
- Two intellectual property law professors (Arti Rai and Rebecca Eisenberg) propose that "the time is ripe to fine-tune the Bayh-Dole Act to give funding agencies more

latitude in guiding the patenting and licensing activities of their grantees." In essence, the professors ask for a congressional clarification that patenting and exclusive licensing are not always the best way to go.

- A recent article in the *New Republic* by a Harvard Medical School professor emeritus (Arnold Relman) and senior lecturer (Marcia Angell) opines that "whether the Bayh-Dole Act has been an overall success is questionable."
- Over the past two decades, legislative proposals have been floated in Congress to require that the prices charged for technical advances developed with federal funds are reasonable.

As for any congressional enactment, especially ones that generate policy debates, oversight is necessary (and indeed is required by House and Senate rules). Statutes are never cast in concrete, nor immune from public debate, as has occurred last Congress about whether state universities should be allowed to bring lawsuits for monetary damages in federal court to enforce their patent rights or whether patent administrative formalities for prescription drugs should be tightened to the detriment of pharmaceutical companies and universities. A recent letter to the House Committee on the Judiciary indicates an "urgent" need for increased congressional oversight of compliance with and enforcement of the Bayh-Dole Act. The letter comes from one of the Act's detractors who alleges that the failure to comply with the Act's directions is costing taxpayers billions of dollars every year.

Technology transfer challenges

Today, technology transfer is a very big business. In the face of great complexity and breadth, success has been achieved by some universities. Success, however, has not been

uniform. Places like MIT, the University of California system, Stanford and Wisconsin (all of which had technology transfer programs prior to the Bayh-Dole Act) routinely stimulate inventive activities and harvest millions of dollars in royalties. Others do not. Universities in both camps face crossroad bifurcations with one path leading to a promising business venture but away from a healthy academic environment, and a second path heading towards the intellectual commons with a doomed commercial enterprise. Some carve new paths. In any event, the number of academic technology transfer entrants with little experience in patenting and licensing is growing.

With faculty found increasingly at the busy intersection of business interests and academic obligations, university presidents should inquire about both the upside and downside of the increasingly close ties between academic and private industry. A strategic alliance between Cal-Berkeley and a Swiss pharmaceutical company was pilloried in the press as the "corporatization of the university" without concrete evidence that academic research had been compromised. When perception becomes reality, university officials must react.

Today taxpayer support for basic research must compete with homeland security and national defense in a weak economy. Funds may be diverted from biotechnology and health care to cyberterrorism and germ warfare. Nonetheless, opportunities abound due to the basic research strengths of American universities. So do technology transfer controversies.

The patent law provides a civil battleground for resolution of controversies. Battles are being fought and won (or lost) in at least two significant areas: (1) collaborative research; and (2) experimental use and research.

Collaborative Research. Today, collaborative research among private, public and not-for-profit entities is quantifiably important to the U.S. economy. Despite a clear trend towards

scientific collaboration and the practical necessity for such collaborations, a 1997 decision of the U.S. Court of Appeals for the Federal Circuit threatens to stifle such collaborative activity. This decision is *Oddzon Products, Inc. v. Just Toys, Inc.*, 122 F.3d. 1396 (Fed. Cir. 1997). *Oddzon* interpreted subsection 103(c) of the Patent Act to hold that prior art under subsections 102(f) and (g) could be used to determine the obviousness of an invention where: (1) there was no common ownership or assignment of the invention and information being shared among collaborators; and (2) the information exchanged was not publicly known.

That holding made it clear that information under subsections (f) or (g) could invalidate a patent in the circumstances of joint collaborative research. The *Oddzon* decision creates an ominous threat for the loss of intellectual property rights for inventors who engage in joint research and development projects with scientists not employed by the same entity, be it a university or corporation. Accordingly, while the need for collaborative research in the public interest is apparent, the *Oddzon* decision blows a cold wind on collaborative efforts among universities, the private sector and the government.

The solution is a legislative one. The *Oddzon* court itself invited Congress to review its decision stating that "it is sometimes more important that a close question be settled one way or another than which way it is settled. We settle the issue here (subject of course to any later intervention by Congress ...)." 122 F.3 at 1403.

Congress will soon consider a clarifying amendment to section 103(c) that would result in increasing the flow of information among scientists at different institutions; increasing the collaboration of scientists both within and outside a given institution; promoting collaborations between the university and the private sector; promoting collaborations between government laboratories and the private sector as well as with the university sector; and enhancing the

national pool of knowledge due to the greater unhindered flow of information among scientists and researchers.

To be fair, the proposed amendment should be prospective only. Further, the amendment should not affect any final decision of a court or the U.S. Patent and Trademark Office that is rendered before the date of enactment and, should not affect the right of any party in any case pending prior to the USPTO or a court on the date of enactment to have rights determined on the basis of the substantive law prior to the date of enactment.

Experiment use and research. Another Federal Circuit decision, *Madley v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002), has also created controversy. In *Madley*, the Federal Circuit denied the experimental use exception in the patent law to all academic scientific research, even when that research is manifestly noncommercial. The court held that the exemption is not available to nonprofit universities because scientific research at those universities serves legitimate educational purposes.

A major landmark in this regard was *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984), wherein the Federal Circuit held that the experimental use exemption did not cover one pharmaceutical company's use of another's patented drug for the purpose of performing tests necessary to obtain regulatory approval of its own competing version of td drug. Congress determined that *Roche* had inappropriately narrowed the exemption and overruled it in the Drug Price Competition and Patent Term Restoration Act of 1984 (also known as the Hatch-Waxman Act) (the "Act"). The Hatch-Waxman Act itself represented a congressional compromise (between innovator and generic pharmaceutical companies) to create a level playing field on which the companies operate. The Act added Section 271(e)(1) to Title 35, of the United States Code:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States a patented invention ... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs or veterinary biological products.

Effectively, a "safe harbor" was created that serves to insulate activities "reasonably related to the development and submission of information" to certain governmental agencies necessary to obtain regulatory approval.

Under conventional rules of statutory construction, exceptions or exemptions should be read narrowly. A narrow reading would indicate that section 271(e)(1), although worded broadly, was designed to immunize the bioequivalency testing needed to secure FDA approval of generic drugs (which was the issue raised in *Roche v. Bolar*). Some courts have so held. The Act's legislative history reveals that the "only activity which will be permitted by the bill is a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute. H. Rep. No. 98-857 (Part II), 90th Cong., 2d Sess. (1984).

Courts have departed from a narrow reading, finding that section 271(e)(1) should be read broadly. *See, e.g., Amgen, Inc. v. Hoechst Marion Rousssel, Inc.*, 3 F. Supp. 2d 104 (D. Mass. 1998). A recent case (*Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.* 2001) U.S. Dist. LEXIS 19361 (S.D. N.Y. 2001) held, in essence, that the plain meaning of section 271(e)(1) covers all information required to obtain approval of a drug (in essence, basic research, animal testing, human clinical trials, synthesis of new drug candidates, their initial testing, and a determination of whether drug candidates should be pursued). A party which develops such information but decides not to submit an application for approval is also protected as long as the

development was done to determine whether or not an application for approval would be sought. In effect, new product screenings are covered, and exempt from allegations of patent infringement.

Potentially, patents claiming research tools (such as cell-based assays) and biologics/genomics are implicated, and potentially jeopardized. Given the success of major research institutions for engaging in basic research and also in developing research tools and applications, universities and non-profits should closely monitor developments relating to section 271(e)(1).

The ability of university/non-profit patent holders to protect their patents may be severely compromised by both a broad research exception (*Bristol-Myers*) and a non-existent one (*Madey*). On one hand, a dilution in the strength of patents, especially those related to basic research tools and applications could be harmful to the public interest because investments will not be made in the commercial exploitation of these tools and applications. On the other, the inability to conduct noncommercial research for teaching purposes could chill academic innovations. Ultimately, serious public policy issues may have arisen that warrant the attention of the United States Congress.

A Practical Short-Term Approach

Here are a few practical suggestions for preserving success and avoiding catastrophic failures. At the outset, it should be noted that many lawyers, professors and citizens take the law for granted and feel that they can have little or no impact on the political process. While this feeling in a time of "big" government and campaign finance abuse is understandable, it must be overcome. The law is your vehicle. Please spend as much time on its care as you do your car.

1. Encourage technology managers to monitor overall trends and developments in intellectual property law, both domestically and internationally, and to share those trends with each other. Managers should continue to disseminate to the public their successes (and shortcomings). The annual AUTM Licensing Summary is a step in the right direction; but more can be done.

2. Respect federal laws and regulations. If intellectual property is created as a result of federal funding, regulations make the grantee university (rather than the department or school), or a university foundation, the responsible entity for invention reporting and property administration. Failure to respect regulatory provisions may result in the loss of patent rights. Because the utility of patents varies among industrial sectors (they are more important in the pharmaceutical and chemical industries than they are for semiconductors and aerospace), different university departments (even in the sciences) may have different views. In any event, universities must apply standardized compliance rules across all federally-funded activities.

3. Self-regulation of federally-funded activities must take place. No simple federal agency is responsible for monitoring and managing technology transfer activities government-wide. Each federal agency involved in technology transfer designs its own program and may tailor it to meet the agency's specific mission. The administration of federal technology transfer law is generally decentralized, and technology transfer personnel of recipient entities must recognize that each agency that awards R&D funds is required to ensure that grant recipients comply with the Bayh-Dole Act.

4. Reporting requirements of the Bayh-Dole Act and, by extension, Executive Order 12591 should be respected. On two recent occasions, the Government Accounting Office ("GAO") has found that contractors and grantees were not always complying with reporting

requirements. GAO found that databases for recording the government's interests in inventions were inaccurate, incomplete and inconsistent and, in some instances, some inventions were not recorded at all. To a certain extent, reporting problems were systemic. GAO informed Congress, that it may wish to improve the reporting process. In light of the GAO reports, the law and regulations should be respected.

5. Technology transfer entails partnerships most often through licensing with the private sector and entrepreneurial risk-taking in a very competitive environment. The edge between rightful action and wrongdoing is often razor sharp. Universities must be prepared offensively to enforce rights through litigation and defensively to be sued. The private sector will inevitably be an interested (or aggrieved) party. In any event, careful licensing that reflects the balances in the law and regulations should be pursued.

6. Real and perceived conflicts of interest should be avoided. The desire to maximize financial returns and customer satisfaction, felt especially strongly by large corporations and their shareholders, may occasionally interfere with academic freedom and the core university mission of educating students. Since the enactment of the Bayh-Dole Act, institutional conflicts of interest have grown. On a continuing basis, university administrators should monitor (or assign a monitoring role to a responsible party) to avoid interferences destructive of the public trust.

7. "Best practices" should be established to promote respect for the law, efficient administration, and effective licensing. Organizations like the Licensing Executive Society could play a pivotal role here. So do others like the Association of American Universities, the Council on Government Relations, and the Association of American Medical Colleges.

Conclusion

Science matters, but it does not just happen. Despite arguments that "science is at an end," any scientific endeavor must be incubated, nourished and mentored. Few researchers work alone. The Bayh-Dole Act provides an ideal habitat. Certain things never change: scientific breakthroughs come from the genius of the human mind. Today's reality is that scientific research requires infusions of substantial amounts of cash, and that the academic community operates in a larger ecology inhabited by the federal government, state and local officials, and the private sector. Cultural disparities between the players are significant, but not necessarily adversarial. Reconciliation of the twin goals of developing the intellectual commons as a public good and protecting technology as a property right during a limited time is possible. Licensing plays an instrumental role in achieving this balance.

Like science, laws also do not just happen. They are the product of our constitutional system of governance. Key policy officials are elected periodically by the public, and are accountable to the citizenry. Involve yourself (or your organizations, universities or companies) in that process or do not complain when successful technology transfer is hindered by government intervention, legal changes, or market forces.

Thank you.