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

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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

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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

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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.