BayhDole25, Inc.

The Bayh-Dole Act at 25

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Introduction

When it comes to the Bayh-Dole Act, there are some for whom no introduction is necessary. In the high-tech corridors surrounding universities and research institutes across the United States, Bayh-Dole has become shorthand for effective public policy for technology transfer. Such a policy has promoted the biotechnology revolution, and enabled the United States to retain global leadership in scientific innovation in other high-technology sectors as well. Yet, if one were to divide the world between those who know about Bayh-Dole and everyone else, the latter would far outnumber the former. Many inside and outside the United States remain unaware of Bayh-Dole's successful track record, and this lack of awareness of Bayh-Dole's importance may undermine the continued vitality of this effective technology transfer policy. Finally, there is a third, albeit small constituency for which no explanation of Bayh-Dole would ever be sufficient. This minority sees Bayh-Dole as a "give-away" of the benefits of publicly funded research to corporations for their private gain.

This paper seeks to provide a comprehensive overview of Bayh-Dole, according to the following structure.

- First, it traces the historical origins of the Bayh-Dole legislation, placing it within a larger context of a series of public policies that enable technological breakthroughs to be successfully transferred to the marketplace. The federal government and many state governments have long traditions of pursuing policies toward universities that promote scientific innovation in the private sector.

- Second, it reviews Bayh-Dole's legislative history, and summarizes the legislation's principal provisions.

- Third, it highlights several significant numbers that quantify the benefits that have accrued from adopting this legislation: patents granted, companies launched, and jobs created. To make these numbers more vivid, this section also discusses some of the more important recent scientific innovations the Bayh-Dole structure has promoted.

- A small, vocal constituency has consistently opposed Bayh-Dole. The fourth section of this paper outlines and assesses some of these criticisms, particularly those that pertain to proposed reforms of Bayh-Dole.

- Finally, Bayh-Dole's success has been best recognized outside the United States, so much so that most OECD members, as well as many developing

countries, have adopted elements of the Bayh-Dole framework. The final section discusses recent trends in both intellectual property protection and technology transfer policies.

Overview

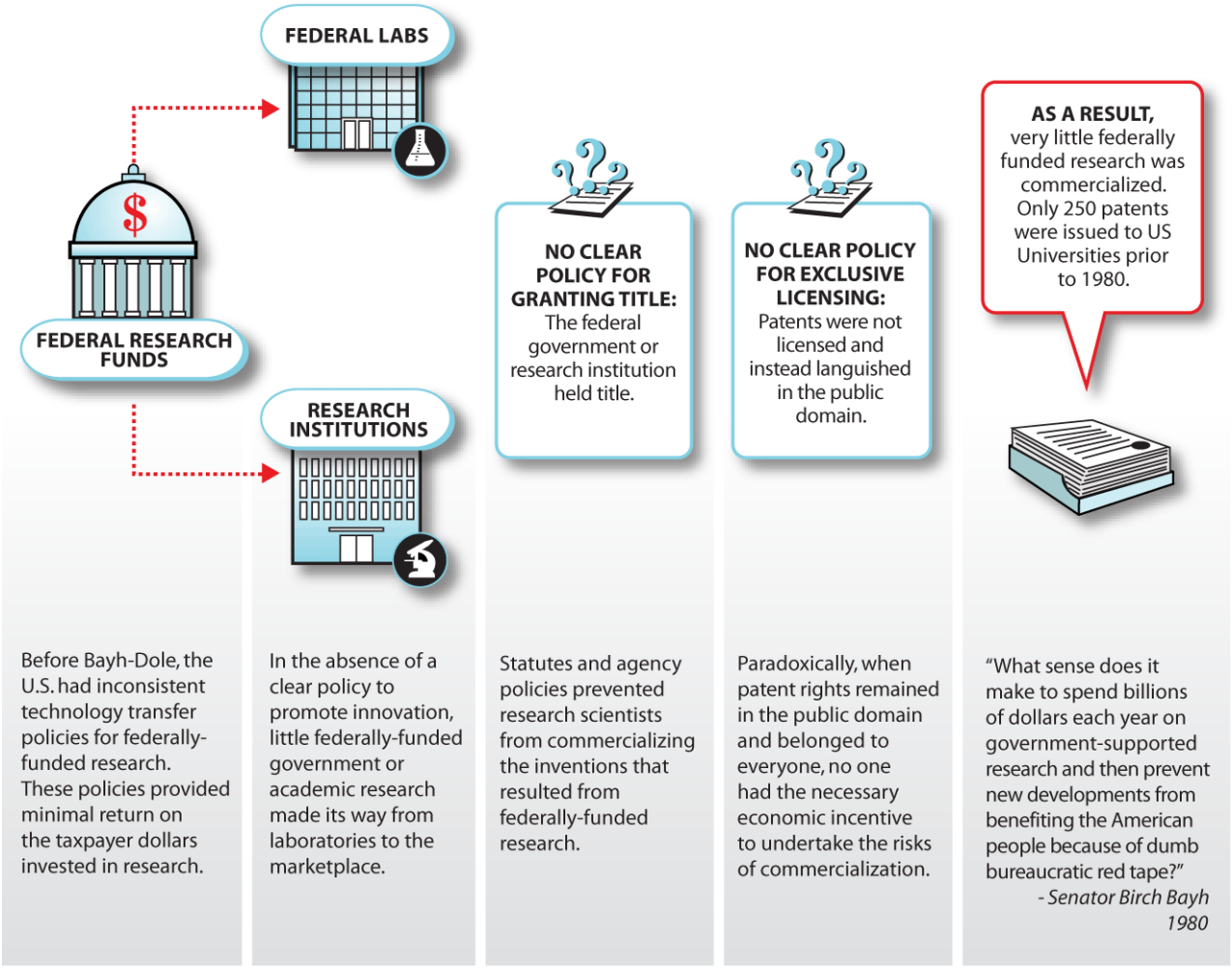
The Bayh-Dole Act of 1980 modernized federal policy toward technology transfer. This bill (and subsequent legislation and executive orders) catalyzed the biotechnology revolution, and made possible breakthroughs in many other leading-edge fields, including electronics, engineering, and environmental technologies. More than any other policy measure, Bayh-Dole addressed the "malaise" famously described by President Jimmy Carter in a July 1979 speech, and reasserted U.S. global technological leadership. The legislation has been described as "[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century".[1] It has helped create thousands of new companies and jobs and promoted life-saving innovations that have improved the quality of life for many if not all Americans. The legislation has also spawned many imitations — some more successful than others — among developed and developing countries alike.

In the post-war period, the U.S. generously funded academic research, with federal expenditures reaching $8 billion in 1980, the year Bayh-Dole was enacted. Before then, no simple mechanism existed to take the fruits of academic research out of university laboratories and bring them to the marketplace. To be sure, many of the largest research universities did engage in successful technology transfer on a limited scale, but the process for so doing was both complex and confusing. The federal government could not agree on a uniform technology transfer policy, so instead, each agency followed its own procedures and requirements for managing the patented innovations that it had financed. The federal government held title to most of the patents that resulted from its funding of university research, and in most cases failed to license them at all. Even when licenses were granted, the legislative and regulatory framework made it difficult to provide exclusive rights to any one licensee. The result was that inventions were placed in the public domain. But with no incentive for any individual or company to take the necessary risk to underwrite product development to commercialize academic scientific breakthroughs, these innovations languished. As Senator Birch Bayh — who co-sponsored the successful bill with Senator Robert Dole would later recognize: "What sense does it make to spend billions of dollars each year on government-supported

[1] "Innovation's Golden Goose," *The Economist*, December 14, 2002, p. 3

research and then prevent new developments from benefiting the American people because of dumb bureaucratic red tape?"[2]

Diagram 1: Commercialization of Federally-Funded Research Before the Bayh Dole Act



[2] News from Senator Birch Bayh, April 23, 1980, on approval of S.414 (Bayh-Dole).

Historical Origins of Bayh-Dole

Property rights framework

The framers of the U.S. Constitution recognized the core importance of private property rights to the economic and political development of the young republic. The Constitution outlines the basic framework for protecting intellectual property; as specified in Article I, Section 8: “The Congress shall have Power… To Promote the Progress of Science and useful arts, by securing for limited Times to Authors and Inventors the exclusive Rights to their respective Writings and Discoveries.” By giving inventors or innovators the sole right to profit from their inventions for a limited time, the framers sought to promote scientific progress. And, as Abraham Lincoln — the only U.S. president to hold a patent — would later eloquently recognize, absent patents “any man might instantly use what another had invented; so that the inventor had no special advantage from his own invention. The patent system changed this; secured to the inventor, for a limited time, the exclusive use of his invention; and thereby added the fuel of interest to the fire of genius, in the discovery and production of new and useful things.”[3]

Since the adoption of the Constitution in 1789, Congress has refined and extended this basic authority in two ways. First, it has enacted various statutes that protect copyrights, patents, and other forms of intellectual property. And second, it has created institutions to administer and settle disputes that arise within this legal framework: the U.S. Patent and Trademark Office examines and issues patents, and registers trademarks for intellectual property, while a specialized later-established part of the judicial system now adjudicates patent claims.

Public financing of higher education

Private property rights, however, are necessary but not sufficient to guarantee effective technological innovation. Throughout U.S. history, both federal and state governments have maintained a high-level commitment to public higher education and academic research. The importance of science and technology in fostering economic development was understood — even if this link was not expressed in precisely those terms. Earlier generations of federal and state leaders developed legislation and policies suited to their times.

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[3] Abraham Lincoln, Second Lecture on Discoveries and Inventions, February 11, 1859, in *Collected Works of Abraham Lincoln*, Vol. 3 (New Brunswick: Rutgers University Press, 1953), p. 363.

Most crucially, public funding of universities and other institutions of higher education has a long pedigree. In the nineteenth century, Congress recognized that America needed a better higher education system. Yet instead of establishing a centralized university of the United States modeled on those that existed in many European countries, Congress provided resources for states to create their own local institutions. The Land Grant Act of 1862 — often referred to as the Morrill Act, after its sponsor, Congressman Justin Smith Morrill of Vermont — allocated to every state that had remained in the Union 30,000 acres of land for each member of its congressional delegation.[4] The land was to be sold to provide an endowment for a state to found a college. The legislation clearly intended to foster state economic development by establishing "Colleges for the Benefit of Agriculture and the Mechanic Arts." Although each college was free to determine the details of its own curriculum, nonetheless Section 4 of the bill specified that for the institutions it launched, the "leading object shall be, without excluding other scientific and classical studies, and including military tactics, to teach such branches of learning as are related to agriculture and the mechanic arts, in such manner as the legislatures of the States shall respectively prescribe, in order to promote the liberal and practical education of the industrial classes in the several pursuits and professions in life."[5]

The Morrill Act led to the founding of more than 70 original land grant institutions; subsequent 1890 legislation extended the system to the 16 southern states. Land grant institutions continue as important components of the successful U.S. system of higher education and include Cornell University, Iowa State University, Kansas State University, the University of Kentucky, Michigan State University, the University of Minnesota, the University of Missouri, Pennsylvania State University, Rutgers University, the University of Vermont, and the University of Wisconsin.

The practice of public funding combined both federal and state elements. Federal support initially launched many of the leading public universities in the U.S. Yet federal resources were limited to those allocated in the Morrill Act. Beyond that, the federal government would not assume a significant role in either financing higher education or in funding academic research (even indirectly) until the twentieth century and instead opted to conduct most of its research activities in dedicated government-run laboratories. Rather, it was left to the states to provide funds to nourish and expand

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[4] Since the Constitution specifies that each state has two senators and at least one member of the House of Representatives, even the smallest states received 90,000 acres of land.

[5] Act of July 2, 1862 (Morrill Act), Public Law 37-108. http://www.ourdocuments.gov/doc.php?flash=true&doc=33

these public universities. For many states, promoting industrial innovation was an important priority, and unsurprisingly, their funding decisions generally concentrated on their particular regional economic needs. As a result, public universities developed curricula that emphasized practical subjects, as well as concentrated on a related research mission. Private colleges and universities also favored a strong and similar practical focus; the lack of a centralized national university system allowed space for the creation of dozens of such private institutions, each of which was free to set its own mission, standards, and curriculum. These institutions depended on private sources of funds, and soon recognized that a policy of emphasizing practical economic needs encouraged donors to make necessary contributions. This strong emphasis on similar practical priorities led state and private universities alike to be the first in the world to pioneer the systematic study of many subjects with immediate commercial applicability, including engineering, applied sciences, business, and finance. Thus, the reputation of America's universities for innovation is not a recent phenomenon, but has strong nineteenth century roots, and results from funding decisions made by states and endowments disbursed by private benefactors.[6]

Universities engage in research

The importance of intellectual property rights in bringing publicly-funded research to market is also not a recent concern. Indeed by 1912, this issue was already on the national agenda. In that year, Frederick Gardner Cottrell, the inventor of the electrostatic precipitator for mitigating air pollution, established Research Corporation, the second foundation established in the U.S. and the first dedicated to promoting science.[7] Cottrell had created his inventions while a researcher at the University of California at Berkeley. While he wished to use revenues from the several patents he held to promote scientific research, Cottrell recognized that merely placing these patents in the public domain would not be sufficient to guarantee their successful commercialization. A manufacturer, he wrote, required "a certain amount of protection before it will invest in machinery or other equipment, to say nothing of the advertising necessary to put the invention on the market". Cottrell recognized that incentives are necessary to bring an innovation successfully to market, "Thus a number of patents given to the public absolutely freely by their inventors have never come upon the market chiefly because 'what is

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[6] See David C. Mowery, Richard R. Nelson, Bhaven N. Sampat, and Arvids A. Ziedonis, *Ivory Tower and Industrial Innovation: University-Industry Technology Transfer Before and After the Bayh-Dole Act* (Stanford: Stanford University Press, 2004), chapter 2.

[7] Research Corporation continues to this day to support academic research. The foundation's website succinctly summarizes its history and mission. See http://www.rescorp.org/history.htm .

everybody's business is nobody's business.'"[8] With the help of Charles Doolittle Walcott, director of the Smithsonian Institution, Cottrell established Research Corporation to manage both his patents, and those of other inventors working in educational or research institutions. Throughout the 1920s and 1930s, many inventors used Research Corporation to manage their patents, and the proceeds of that effective patent management system were recycled into further scientific research, in the form of grants to researchers.

Others independently elected to follow a similar strategy. Consequently, in 1925, the Wisconsin Alumni Research Foundation (WARF) was founded, originally to manage a university discovery that ultimately eliminated the childhood disease of rickets. WARF also recycled research proceeds and channeled them into further academic research: today WARF patents the innovations of University of Wisconsin (Madison) researchers, licenses these patents to companies, and distributes the revenue gained from these licensing deals to fund additional university research. Since its first grant of $1200 in 1928, WARF has distributed more than $750 million to the university, which finances additional research but also pays for other institutional needs.[9]

World War II: role of technological innovation

Policymakers understood that mobilizing America's capacity for technological innovation was vital to winning the World War II, and thus the research mission of both universities and scientists further evolved to address these wartime demands. In June 1940, President Franklin D. Roosevelt established the National Defense Resources Committee (NDRC) "to coordinate, supervise, and conduct scientific research on the problems underlying the development, production, and use of mechanisms and devices of warfare ", and appointed Massachusetts Institute of Technology (MIT) President Karl T. Compton and MIT Dean of Engineering Vannevar Bush to lead it. The Office of Scientific

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[8] Frederick Gardner Cottrell, "The Research Corporation, an Experiment in the Public Administration of Patent Rights," *Journal of Industrial and Engineering Chemistry* 4: 865 (1912) as cited in Mowery, *et al.*, *op. cit.,* p. 59.

[9] The university controls distribution of the funds WARF supplies, in the form "margin of excellence funding" so as to prevent commercial considerations from distorting research priorities. The university allots such funds to early-stage research that would otherwise have difficulty attracting funding. For more information, see WARF's website, http://www.warf.ws/about/index.jsp?cid=26 In 2004, WARF ranked 263rd on a list of the top 300 owners of US patents, with 64. Other US universities, both private and public, also ranked on this list: the University of California (48th on list, with 422 patents), the California Institute of Technology (127th, with 135), the Massachusetts Institute of Technology (131st, with 132), the University of Texas (171st, with 99), Johns Hopkins University (181st, with 94), Stanford University (227th, with 75), the University of Michigan (255th, with 66), and the University of Illinois (283rd, with 58).
http://www.ipo.org/Template.cfm?Section=Top_300_Patent_Owners&CONTENTID=18493&TEMPLATE=/ContentManagement/ContentDisplay.cfm

Research and Development replaced the NDRC in June 1941, and Bush was named to head the new agency.

Two U.S. government-funded projects ultimately gave Allied forces a crucial technological edge. The MIT Radiation Laboratory (RadLab), a division of the NRDC, took Sir Robert Watson-Watt's 1935 radar patent — initially used only in limited meteorological applications — and transformed it into a military innovation essential to winning the war. From its top-secret launch, from scratch, in 1940, the "RadLab" grew by war's end to employ more than 4,000 civilian scientists and engineers in various locations inside and outside the US. Together, they designed more than 100 different radar systems — about half those used in the war — and pioneered other electronics innovations.[10] The other major government-funded initiative, the Manhattan Project, made a more dramatic contribution to the war effort and is much better known. The resources committed to developing the atomic bomb dwarfed those devoted to the RadLab and peaked at more than 130,000 people employed at research facilities in Oak Creek, Tennessee; Los Alamos, New Mexico; and Hanford, Washington.[11] These two programs effectively exploited America's technological superiority, and when combined with other equally important efforts such as Britain's cracking of Germany's Enigma Code, helped win the war.[12]

Science: the endless frontier

Visionary policy-makers were well aware of the role that technological innovation played in winning the war, no one more so than Vannevar Bush. As that conflict wound down, these policymakers turned their attention from winning the war to enjoying the peace. In 1945, following a request from President Roosevelt, Bush presented a report to Congress that was later published as *Science: The Endless Frontier*.[13] In this report, Bush linked government support of basic science to the goal of stimulating the economy;

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[10] http://www.rle.mit.edu/about/about_history.html. Although the RadLab's efforts were formally shuttered on December 31, 1945, its surplus equipment was later deployed in Research Laboratory for Electronics at MIT.

[11] See Richard Rhodes, *The Making of the Atomic Bomb* (New York: Simon & Schuster, 1986). The Axis powers also worked to gain a technological advantage, as Nazi Germany strove to develop its own atomic weapons.

[12] The efforts to break the Enigma Code tapped the talents of Alan Turing and others, who worked at Bletchley Park. Turing's seminal 1936 paper in which he posited his eponymous machine provided the theoretical basis for modern computing; at Bletchley, he developed code-breaking methods and machinery. Ultimately, these theoretical and practical initiatives resulted in 1948 in the first computer. See Alan Hodges, *Alan Turing: The Enigma* (New York: Simon & Schuster, 1983) and Christof Teuscher, *Alan Turing: Life and Legacy of a Great Thinker* (Berlin: Springer-Verlag, 2004).

[13] Vannevar Bush, *Science: The Endless Frontier* (Washington, D.C.: U.S. Government Printing Office, 1945).

the then-recent experience of the Great Depression made this a paramount concern, as many policy-makers were concerned that once the wartime stimulus was removed, the economy might sink back into recession, or worse. Bush failed to see his clear-eyed vision of one uniform, civilian-controlled federal agency to fund all federally supported research (including all military and non-military applications) enacted. Yet Bush's primary goal — promoting basic scientific research through policies including federal government funding — was accepted and soon led to the formation of agencies including the National Institutes of Health (NIH), the National Science Foundation (NSF), and the Office of Naval Research (ONR).[14] More than any other thinker, Bush is responsible for laying the foundation of the modern public/private partnership that continues to be the dominant American model for funding basic scientific research.[15] Sustained government support for science education and research remains a key pillar of Bayh-Dole's success in promoting technology transfer.

These U.S. federal agencies presided over a fundamental evolution in the way the federal government conducted scientific research. Before the war, government research was largely carried out in its own dedicated laboratories. After the war, government-research laboratories continued and indeed expanded, in line with the increased U.S. commitment to defense and military applications. Yet at the same time, modern research universities soon grew to conduct a substantial proportion of federally-financed research. Universities in turn depended on federal funding of their research activities. Whereas in 1935 the federal government only supported just less than a quarter of all academic research and development — or about $575 million (measured in 1935 dollars), by the 1960s, this level of support increased by more than 250% to account for more than 60% of the total spent on academic research and development. By the time Bayh-Dole was enacted, federal support of academic research and development would hover at around 70% of total such spending.[16]

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[14] Speech by Howard W. Bremer, "The First Two Decades of the Bayh-Dole Act as Public Policy," Presentation to National Association of State Universities and Land Grant Colleges, November 11, 2001. http://www.nasulgc.org/cott/bayh-dohl/bremer_speech.htm

[15] See G. Pascal Zachary, *Endless Frontier: Vannevar Bush, Engineer of the American Century* (Cambridge, Massachusetts: MIT Press, 1999). For a thoughtful critique of this model, see Daniel S. Greenberg, *Science, Money, and Politics: Political Triumph and Ethical Erosion* (Chicago: University of Chicago Press, 2001).

[16] Mowery, *et al.*, *op. cit.*, p. 24, table 2.1.

Table 1: Federal Support for Academic R & D, 1960-2000
(millions of 1996 dollars)[17]

Year	Total Academic R&D ($)	Federally- Supported R & D ($)	Federal Share of Total
1960	3,418	2,143	63%
1965	7,333	5,338	73%
1970	9,453	6,668	71%
1975	9,939	6,671	67%
1980	11,575	7,817	68%
1985	14,120	8,828	63%
1990	19,551	11,570	59%
1995	22,827	13,726	60%
2000	27,379	15,932	58%

Technology not transferred to marketplace

Despite Vannevar Bush's vision, and the massive resulting increase in federal support for scientific research, federally-financed technological innovations largely failed to translate into successful, widely available commercial products. Such breakthroughs were stalled in academic institutions, because there was no uniform policy to shepherd technological innovations from the laboratory to the marketplace. The U.S. government lacked a consistent approach to determining who held clear title to federally-financed research innovations resulting from university laboratories, even though as early as 1943, President Roosevelt had recognized the need for a better patent policy for licensing the burgeoning number of innovations that were emanating from government-funded research. Roosevelt's insight led to the creation of the National Patent Policy Commission, which, in 1945, produced a report that triggered further debate on what

[17] This table is a modified version of that found in Mowery, *op. cit.,* Table 2.1, p. 24, which in turn is based on figures drawn from National Science Foundation, *National Patterns of R & D Resources 2001* (Washington, D.C.: U.S. Government Printing Office, 2001).

government patent policy should be.[18] By 1947, when then-Attorney General Thomas Campbell Clark produced his final recommendation, Roosevelt's original imperative had been lost.[19] Instead, Attorney General Clark recommended that the government retain title to patents that emanated from research it had funded (subject only to limited exceptions granted by agency heads).[20]The Department of Defense (DoD) — the leading agency for funding research in the initial postwar period — bucked this recommendation and followed a "title in the contractor policy", which allowed government contractors, including universities, to retain title to an invention. The institution could subsequently license for commercial development in exchange for a royalty fee.[21] But all other agencies fell in line with the Attorney General's report and employed some form of a "title in the government" policy, which required the government to retain title to the patent. If it so chose, the agency could license the inventions, generally free of royalties (or in some cases, with limited exclusivity and subject to some royalties). Agency policies lacked consistency, and were seemingly decided on a somewhat ad hoc basis; this uncertainty discouraged private investment in commercializing innovation.

In the immediate aftermath of the war, America's clear economic dominance allowed it the luxury of an inefficient technology transfer policy. But after an initial post-war boom, the U.S. economy stagnated, and President John F. Kennedy was elected in 1960 in part on a promise to get the economy moving again. As part of its more comprehensive reconsideration of all economic policies — which led to a tax cut to stimulate demand, and a commitment to enter into what later came to be known as the Kennedy Round of trade negotiations — the new administration also was the first in many years to grapple seriously with the hodge-podge patent policy for federally-funded innovations. In 1963, Presidential Science Advisor Jerome Wiesner launched an effort to develop a uniform policy on innovations and patents to apply across all federal agencies. Wiesner's initiative led to a presidential policy statement by President Kennedy in October 1963

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[18] Jennifer A. Henderson and John J. Smith, "Academia, Industry, and the Bayh-Dole Act: An Implied Duty to Commercialize," paper supported in part by a grant from the Center for Integration of Medicine and Innovative Technology, October 2002, p. 2.

[19] The end of the war had led many scientific innovators to return to their university positions, leaving patent policy decisions to be made by lawyers, rather than by scientists familiar with the ins-and-outs of the needs of innovators and universities.

[20] U.S. Department of Justice, *Investigation of Government Patent Practices and Policies: Report to and Recommendations of the Attorney General to the President* (Washington, D.C.: U.S. Government Printing Office, 1947).

[21] It has been suggested that allowing contractors to license patent rights was necessary to convince the best companies to bid for and perform on government contracts.

in which he outlined a program to try to allocate property rights between the government and its contractors — including universities — to serve both the public interest and to encourage the utilization of the inventions. Rather than recommending universal adoption of either a title in the government or a title in the contractor policy, the statement set forth general guidelines for deciding under which conditions each type of policy was most appropriate.[22] Numerous consultations and studies followed, but no major change in federal policies on technology transfer occurred.

President Richard M. Nixon's administration also sought to unify policy, and generally favored granting agencies additional discretion to facilitate transfer of patent rights to the private sector. Several populist members of Congress, led by Senator Russell Long of Louisiana, opposed the Nixon efforts, and instead advocated entrenching the title in the government position. These opponents believed that the government should retain title to innovations resulting from federally-financed research; that government ownership of patents was necessary to ensure widespread dissemination of the knowledge emanating from government-sponsored research; and that government ownership of patents prevented undue concentration of economic power in a small number of large firms.[23] In August 1971, President Nixon issued a Statement of Government Patent Policy, which while it tilted further toward allowing more agency discretion to allow contractors stronger intellectual property rights, failed to resolve inconsistent agency policies. Instead, Nixon's statement concluded that, "A single presumption of ownership of patent rights to government-sponsored inventions either in the government or its contractors is not a satisfactory basis for government patent policy and, that a flexible, government-wide policy serves the public interest."[24]

Unfortunately, in this context, "flexible" may be read as a synonym for confused. A combination of past agency policy decisions, and in some cases, explicit statutory language, meant that each federal agency pursued its own separate patent policy. Yet regardless of which of these two general approaches the federal agency followed, the result was that very little government-funded research was successfully

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[22] 28 Federal Register 10,943 (1963). Even these guidelines were "subject to specific statutes governing the disposition of patent rights of certain government agencies".

[23] [Congressman] Emilio Daddario, "Effects of Government Patent Policy on Research and Development," *Journal of Patent Officers Society* 45 (1963), p. 663, as paraphrased in Edward C. Waterscheid, "The Need for a Uniform Government Patent Policy: the DOE Example, *Harvard Journal of Law and Technology* 3 (Spring 1990), p. 124.

[24] 36 Federal Register 16,886 (1971). The major innovation this statement made was to encourage all federal agencies to grant exclusive licenses for patents for which the agency held title, even absent statutory authority to do so. This provision extended a policy first developed by the Department of Health, Education and Welfare (HEW) to all agencies that still followed a title in the government policy, and is discussed further below.

commercialized. The General Accounting Office (GAO) reported in 1978 that fewer than 5% of approximately 28,000 government-held patents were licensed for commercial use.[25] As Cottrell had recognized when he founded Research Corporation in 1912, with rights belonging to everyone, no one had sufficient incentive to bring innovations to market.[26] One lesson that policymakers have drawn from this example is that it is not enough to offer flexibility. Instead, technology transfer policies require clear direction and authority to promote commercialization of science actively.

Agencies and institutional patent agreements

With the failure of top-down efforts to make federal policy more uniform, advocates of technology transfer turned to relying on the discretion of individual federal agencies to achieve this end. Some agencies themselves took the initiative and negotiated improved technology transfer terms directly with universities, in the form of what became Institutional Patent Agreements (IPAs). The Department of Health Education and Welfare (HEW) was the first to negotiate such an arrangement, in 1969, in part in response to criticism of its existing patent policy and technology licensing procedures. HEW also took other steps to liberalize its technology procedures; the most significant was to be the first agency to claim the right to grant exclusive patent licenses, absent explicit statutory authority.[27] HEW's shift toward easier technology licensing procedures was particularly significant since HEW controlled the NIH's budget, and by this time, NIH funding accounted for nearly half of all federal financing of academic research. Within a few years, about 75 leading universities and research institutions had entered into IPAs. As HEW's chief patent counsel during this period, Norman J. Latker would later explain, the IPAs required that each university designate a contact person to be responsible for technology licensing. Once the IPAs were in place, a slow process began by which

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[25] U.S. Government Accounting Office (GAO) Report to Congressional Committees entitled "Technology Transfer, Administration of the Bayh-Dole Act by Research Universities" dated May 7, 1978, p. 3 as cited in Council on Governmental Relations, "The Bayh Dole Act: A Guide to Law and Implementing Regulations, available at http://www.ucop.edu/ott/bayh.html. Mowery et al. have criticized this widely-cited figure, rightfully pointing out that it may overstate the problem in that it includes defense contracts, and national security considerations would preclude technological innovations that result from such contracts from being licensed. Mowery et al., op cit., pp. 90-91. But such an objection does not change the basic point: once DOD-related patents are removed, the essential point remains — fewer than 10% of the roughly 12,000 unexpired government patents were licensed. This contrasts to a contemporary figure of about 30%.

[26] By the 1970s, the efficacy of Research Corporation in promoting technology licensing had bogged down, in part because this institution had itself become centralized and bureaucratized and its decisions were taken at a level far removed from inventors.

[27] The National Aeronautics and Space Administration (NASA) already granted similar such licenses; it had explicit statutory authority to do so. As previously mentioned, in 1971, the Nixon administration extended the HEW policy to all federal agencies.

universities became strong advocates for improved technology licensing procedures.[28] The National Science Foundation (NSF) followed with its own IPA in 1973.

In the mid-1970s, as part of an effort to extend the IPA policy more widely, Betsy Ancker-Johnson, an experimental physicist then serving as assistant secretary for science and technology at the U.S. Department of Commerce encouraged Latker to convene the University Patent Policy Ad Hoc Committee of the Committee on U.S. Government Patent Policy for the Federal Council on Science and Technology, As chair of that committee, Latker sought to negotiate a uniform, government-wide IPA for universities. Agencies could opt in and use the agreement, unless they believed existing statutes precluded its use (or its terms).[29]The model universal IPA would apply common terms to government dealings with research institutions. In September 1975, the Committee recommended that all executive agencies provide a first option to research institutions to license substantially all patented inventions financed by federal support, provided that the inventing organization had established a technology transfer function (and subject to existing statutory limitations). The committee produced a universal IPA and circulated for public comment its proposals for a federal procurement regulation.

Role of universities

The IPA policy helped trigger university interest in improving technology licensing procedures. These institutions recognized that the *status quo* of allowing each federal agency to continue to set its own individual licensing policy was inefficient and uncertain. But there was as yet no consensus among policymakers on the wisdom of designing a more effective national technology transfer policy more attuned to market forces. Universities therefore stepped up their efforts to press the federal government to change its approach and created the Society of University Patent Administrators (SUPA) in 1974 to promote more effective technology transfer.[30] Although the establishment of SUPA initially led to no immediate changes, concern was increasing, particularly in Congress, that the failure to promote technologically-driven growth was squandering the U.S. economy's full potential. With America's relative economic performance declining,

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[28] Interview with Norman J. Latker, November 30, 2005.

[29] Lawrence Gilbert, "From University to Marketplace," *Les Nouvelles: Journal of the Licensing Executives Society*, December 1977, p. 286.

[30] Ancker-Johnson gave the keynote address at a conference where the decision to create SUPA was made. SUPA has been superseded by the Association of University Technology Managers (AUTM), which continues to promote and monitor technology transfer policies. AUTM's current activities include publication of an influential annual survey of technological innovation at U.S. and Canadian universities. Counterpart organizations have also been created in Australia, and the U.K., among other countries.

ineffective and inefficient technology transfer policy was a luxury the country could no longer afford.

U.S. economy in crisis

The United States entered the 1970s, the decade of American Bicentennial, in a state of economic crisis. Although economists still differ on the precise causes of this crisis, a combination of the oil price shocks (which soon caused lines to appear at the gasoline pump), the deficit spending policies of Democratic and Republican administrations alike to finance both the Vietnam War and new social programs, and a shift in America's relative economic position led, within a few short years, to radical gyrations in economic policy. The U.S. abandoned the gold standard, dismantled the Bretton-Woods system, and temporarily imposed wage and price controls, each to no avail. Desperate political leaders responded with periodic conferences and public hand-wringing — such as Gerald Ford's Whip Inflation Now (WIN) 1974 campaign button program and Jimmy Carter's 1978 White House Conference on Balanced National Growth and Economic Development. But the situation failed to improve. Inflation increased, while growth stagnated — so-called "stagflation" — and a second oil crisis in 1979 - 1980 caused gas lines not only to appear again, but to grow.

International developments spotlighted the American economy's poor performance. Rather than continuing its postwar dominance of export markets, the U.S. instead saw imports of Japanese automobiles, steel and electronics surge, costing jobs and fueling a balance of payments crisis.[31] The U.S. appeared to be losing ground to other economic competitors, such as Germany, and, more ominously, to the then-Soviet Union as well. Difficult as this may be to recall from a contemporary vantage point, the Cold War intensified, with no end in sight, and the centrally-controlled socialist economic model of the Soviet Union loomed as a potent threat to U.S. global pre-eminence.

Technology transfer policy ignored

In this context, it is not surprising that — wrong-headedly, as events were to prove — that technology transfer policy took a back seat to seemingly more pressing problems. Thus it was not until the Carter administration that any concrete change would occur.[32]

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[31] Concern was expressed at the time that America's policy of failing to protect its intellectual property effectively, and instead releasing it into the public domain, allowed its economic competitors to seize that technology, develop products, and as a result of then-prevailing cost advantages, export the resulting products successfully to the U.S. market.

[32] The timing of this success is somewhat ironic, as the Carter administration itself failed to assist — and indeed, in the opinion of some, actively impeded, the efforts to reform technology transfer policy.

Dissatisfaction with the continued lack of a uniform patent transfer policy continued to grow in university circles. Two important developments prompted counter-reactions.[33] First, Senator Gaylord Nelson announced (and subsequently conducted) hearings intended to discredit the effort to create a universal model IPA. And second was the fear that HEW might tighten the requirements for allowing universities to retain title to patents that resulted from agency-financed research, reversing its recent history of actively promoting more effective technology transfer mechanisms.[34] The impetus for this potential change emanated from the highest level of HEW.

HEW Secretary Joseph Califano had initiated an aggressive series of policies designed to reign in health care costs: re-examination of HEW's technology licensing policy was part of this effort. Specifically in August 1977, HEW's Office of the General Council flagged the issue of whether university patent and licensing practices — especially the exclusive licenses that companies believe are necessary to justify investment in an innovation — contributed to higher health care costs. HEW's deliberations highlighted the tension facing policymakers, who must balance the need to reign in costs against that of fostering innovation. Critics then and now have asserted that assigning exclusive patent rights — even for a limited time — amounted to little more than a subsidy to a private company that would then, to use the appropriate economics jargon, capture the monopoly rent that would result if an innovation were successfully commercialized. On the other hand, this same guarantee of exclusivity provides a significant incentive to pursue foster further similar innovation. In the climate of the time, when the benefits of greater innovation were still conceptual while the costs were real, it looked likely that HEW would endorse the cost-cutting strategy, and rescind or at least restrict its relatively liberal licensing strategy.

At this point earlier efforts within HEW to enter into agency specific IPAs now helped sabotage the Nelson and Califano initiatives. As leading U.S. research universities were now already active in patenting and licensing innovations — albeit on a much smaller scale than would follow passage of the Bayh-Dole legislation — these institutions took their concerns over a potential shift in HEW policy to Congress, and soon found sympathetic ears.

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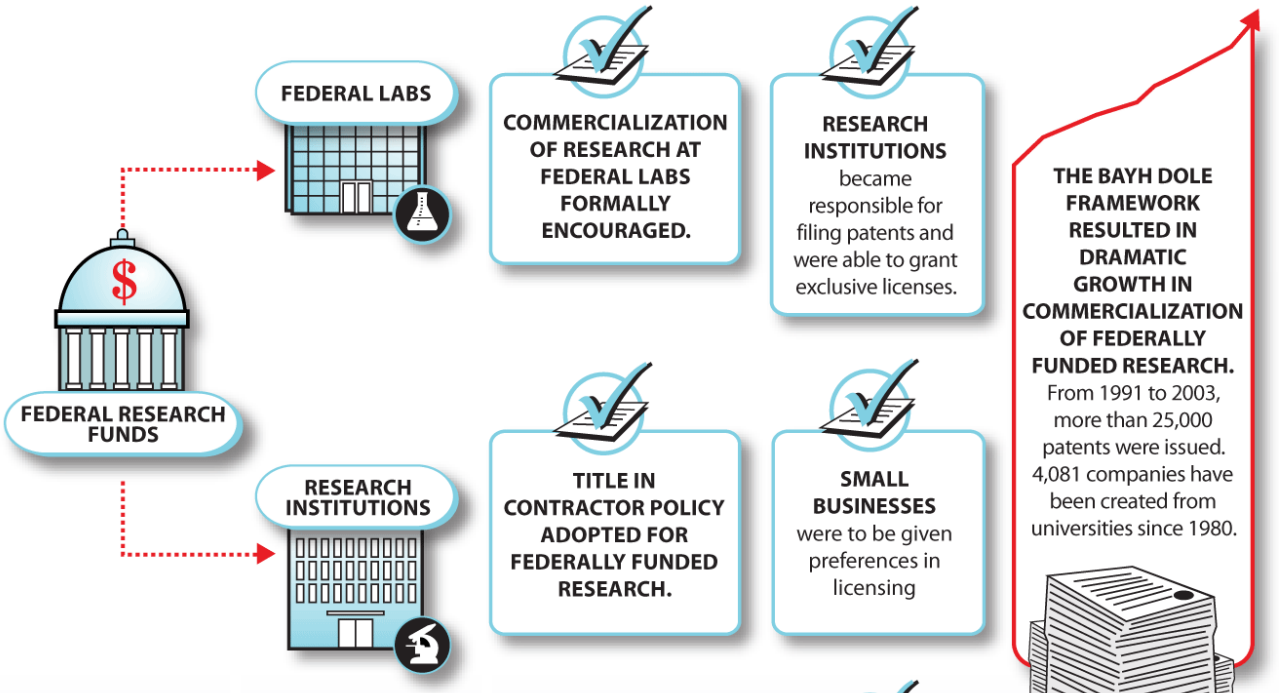
[33] Interview with Norman J. Latker, November 30, 2005.

[34] The Department of Health, Education and Welfare was created in 1953 during President Dwight D. Eisenhower's administration. In 1979, legislation established a separate Department of Education, and on May 4, 1980, HEW became the Department of Health and Human Services (HHS).

Diagram 2: The Bayh-Dole Framework for Technological Transfer



In the 1970s, policymakers and universities began creating a U.S. technology transfer policy that would promote successful commercialization of research, and would gain meaningful benefit from the then-$8 billion annual investment in federal research.

The new policy applied to research conducted in universities and other research institutions, and later was extended to research conducted in federal laboratories.

The Bayh Dole Act produced great benefits for the American economy and society. It relied on three key mechanisms: promoting intellectual property protection for innovators; relying on market forces to guide commercialization of innovation; and maintaining a consistent level of support for higher education and scientific research.

Bayh-Dole: What it Says, Exactly How It Came About

As it had more than one hundred years before when it passed the Morrill Act, Congress again led the way in pursuing a policy innovation. Just as nineteenth-century economic needs had prompted Congress to finance the start-up costs of a system of public land grant institutions, so in the late 1970s widespread concern over declining economic competitiveness now translated into a new approach to technology transfer. “By the late 70s, America had lost its technological advantage,” former Senator Birch Bayh would testify in 2004. Bayh reminded his 21st century audience of six signs that his congressional colleagues recognized signaled such erosion. First, “We had lost our number one competitive position in steel and auto production. In a number of industries we weren't even No. 2.” Second, Bayh tied this decline in competitiveness to reduced capacity to innovate: “The number of patents issued each year had declined steadily since 1971.” Third, this drop in patents could perhaps be traced to reduced investment in research and development which “over the previous 10 years was static.” Fourth, when combined, these factors meant that “American productivity was growing at a much slower rate than that of our free world competitors.” Fifth, although small businesses had compiled “a very impressive record in technological innovation,” they received “a smaller percentage of Federal research and development money.” And finally, “The number of patentable inventions made under federally supported research had been in a steady decline.”[35]

Beginning in 1978, forward-looking members of Congress realized that the U.S. could no longer afford to receive minimal returns on its now considerable annual investment of nearly $8 billion in largely university-based research and development. There was a growing awareness of the need for change, so that federally-funded research could be successfully commercialized. It should not however be forgotten that university concern over the HEW policy was partly responsible for focusing congressional attention on the problem, and indeed, Senator Robert Dole denounced just that policy in September 1978. Soon thereafter, on September 13, Dole and Bayh thereafter introduced the University Small Business and Patent Act into the 95th Congress. Subsequent accounts have generally highlighted the roles played by these senators in passing the legislation; indeed, the resulting legislation is now familiarly known as the Bayh-Dole Act.

[35] See Statement of Senator Birch Bayh to the National Institutes of Health, May 25, 2004. http://ott.od.nih.gov/Meeting/Senator-Birch-Bayh.pdf

But efforts made in the House of Representatives were equally key to securing the new legislation.[36]

The general problem was clear: despite years of debate, the federal government still lacked a uniform technology transfer policy. Instead, each agency followed its own policy, resulting in 26 different sets of agency regulations covering the use of government-funded research by private companies.[37] Indeed, the policies of most agencies were hostile to allowing researchers to retain title to patents. But implementing reform was not a simple process, and it would not be until the following Congress that agreement was achieved on the need for and structure of a new federal technology transfer policy. Congress engaged in extensive hearings, debates and discussions, to reconcile the interests of business, academia and various federal agencies. Nonetheless,once Rep. Robert Kastenmeier introduced a bill into the House in March 1980, final legislation was enacted and agreed relatively quickly. Both House and Senate passed their respective bills in late November, and reconciled them almost immediately. By that date, a solid bipartisan consensus had formed that the federal government should at least try a new approach. The Bayh-Dole Act of 1980 was presented to President Carter on December 1, and he signed it into law as Public Law 96-517 on December 12. The new policy became effective in July of the following year.

The Bayh-Dole Act fundamentally changed U.S. patent policy for federally contracted or funded research, whether conducted by non-profit organizations such as universities, or by small or start-up businesses. Congress set forth multiple objectives for the legislation: to encourage utilization of research; to promote collaboration between commercial and non-profit concerns; and to enhance the commercialization and public availability of the inventions.[38] But many of its provisions were hardly novel, and had a

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[36] As just one example, a sub-committee of the House Science and Technology Committee had launched essential preparatory work that culminated in 1976 in a comprehensive hearing record (and associated exhibits) summarizing the history of government patent policy. See Henderson and Smith, p. 2, and the associated citations.

[37] 20 House Report No 96-1307, 96th Cong. 2d Sess. (1980), p. 1 http://ipmall.info/hosted_resources/lipa/patents/House_Report_96-1307.pdf . See also a more recent Congressional Research Service Report, which highlights the importance of this House Report. Wendy H. Schacht, "The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology," *Congressional Research Service*, June 10, 2005.

[38] 18 U.S.C. § 200. "It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and

long-standing provenance in policy debates that had periodically occurred throughout the postwar period.

First and foremost, the bill adopted a universal policy throughout the federal government of "title in the contractor" for determining who has the rights to patents, subject to certain exemptions, so that contractors, whether they be non-profits (such as universities), or small businesses, have the right to retain title to inventions financed by the federal government in whole or in part.[39] This change was designed to make it easier for universities to engage in technology transfer. No longer would they have to comply with each agency's different rules, nor be subject to shifts in agency patent policy. Second, the bill granted federal contractors the authority to grant exclusive patent licenses. The legislation made explicit that universities were expected to file patent applications on inventions that they owned, and that they were to accord small businesses preference in granting licenses (in part by limiting the time frame for awarding exclusive licenses to large businesses). This emphasis on small businesses deflected criticism that the legislation provided a "give away" of taxpayer financed intellectual property to established corporations that neither needed nor deserved such subsidies.[40]

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labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area." The legislation is codified at 18 U.S.C. §§ 200-212 and is available at http://www4.law.cornell.edu/uscode/html/uscode35/usc_sup_01_35_10_II_20_18.html .

[39] See 18 U.S.C. § 202, which sets forth the legislation's basic approach to disposition of intellectual property rights. The Stevenson-Wydler Act, passed at roughly the same time, pursued a different approach, and centralized technology licensing authority for government laboratories. This approach subsequently proved to be both flawed and ineffective. The legislation was later amended to conform more closely to the Bayh-Dole example in the form of part of the Federal Technology Transfer Act of 1986 (PL 99-502). This amended legislation facilitated the process of transferring technology from federal laboratories. It made scientists responsible for promoting the transfer of technology from their respective laboratories (and evaluated their performance in part based on their success in meeting this objective). In addition, the legislation directed that inventors from federal research laboratories would henceforth receive a minimum of a 15% share of any royalties generated through patenting or licensing, and also established several rules that made it easier to enter into cooperative research agreements; to license any inventions that might therefore result; and to exchange personnel, services, and equipment. Federal employees, whether current or former, could also participate in commercial development (absent conflicts of interest). Finally, the Act established the Federal Laboratory Consortium for Technology Transfer.

[40] Subsequent changes extended these benefits to all businesses. In 1983, President Ronald Reagan distributed an Executive Memorandum that directed federal agencies to allow large businesses to retain title to patents derived by federally funded research; Reagan followed this with an Executive Order in 1987. Additionally, Congress passed the Trademark Clarification Act of 1984 (PL 98-620) which lifted the time restrictions on the exclusive licenses universities could offer to large businesses. Nonetheless, small businesses comprise about 90% of biotechnology start-up companies. See "Patents Save Lives," Speech delivered by Dan Eramian, vice president, communications, of Biotechnology Industry Organization, to the Global Public Policy Institute and Ecole de Science Politique Paris, June 24, 2004. http://www.bio.org/speeches/speeches/20040624.asp . In addition, see the further discussion below.

For products that were to be sold in the U.S., preference in awarding licenses was to go to U.S. manufacturers. The federal government retained a non-exclusive right to use the patent throughout the world.[41]

Importantly, the legislation allowed the government to retain "march-in rights" to the inventions that it financed — essentially allowing a federal agency to pull title back to a patent and grant a license to a responsible new applicant, if the current licensee failed to make the product available to the public on reasonable terms; or if action was necessary to alleviate health or safety needs not reasonably satisfied by the current licensee.[42] This provision was necessary to allay concern that the exclusive patent rights granted would allow private interests to engage in abusive practices. Adding march-in rights made it possible to broker a deal and broaden support for the legislation.

The design of the Bayh-Dole framework incorporated a subtle understanding of what was necessary to stimulate innovation in the late twentieth century and beyond. Some elements of that design were familiar, particularly the understanding that successful innovation depended on a partnership among government, inventors, universities, and private industry. Rather than representing a departure from past trends, the approach merely updated the mechanisms for fostering that partnership, so as to distribute the benefits of scientific innovation more widely. Crucially, each partner was allowed to do what it did best. Government provides funding for university research, much of which is too speculative (and expensive) to be undertaken by the private sector. Scientists decide, on the basis of peer review that relies on their professional expertise, exactly how government research funds should be allocated. The legislation attempted to insulate the scientific process itself from political pressures. Inventors are provided with incentives to motivate them to pursue and persevere in the difficult tasks of conceiving, executing and shepherding a successful idea from innovation to market. And finally, many years of experience showed that universities alone had little understanding of what was necessary to commercialize an innovation successfully. Bayh-Dole created the mechanisms to allow the private sector to step in and fulfill this role, enabling private investors to decide which innovations showed the greatest potential for successful commercialization and then to allocate their capital and resources accordingly.

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[41] 18 U.S.C. § 202 (c)(4).

[42] 18 U.S.C. § 203. To date, the government has yet to assert its march-in rights, although the NIH, the principal federal agency funding medical research, has thus far received three petitions to do so, as discussed further below.

Summary

Congress passed Bayh-Dole at a time of widespread concern over America's relative economic decline. Making it easier to commercialize successful academic research was intended to facilitate technology transfer so as to stimulate economic development. The Bayh-Dole structure made it far easier for universities to own the technology developed in their research facilities, and equally importantly, allowed researchers themselves to profit from successful commercialization of their research. The next section will discuss just how successful Bayh-Dole was in achieving its objective of promoting successful commercialization of federally-financed research, in terms of jobs created, patents licensed and innovations developed.

Results of Bayh-Dole

Congress passed the Bayh-Dole Act so as to make federally-funded research innovations more widely available. How effective has the policy been?

Bayh-Dole: the numbers

Numbers tell part of the story.[43] In the past quarter century, universities have undeniably become much more involved in technology transfer. To be sure, many leading U.S. universities had established technology transfer programs long before the adoption of the Bayh-Dole legislation in December 1980. But since that date, a broad range of institutions have made technology transfer a priority and the percentage of patented innovations licensed for commercial application has climbed from single figures to 30%. The secondary effects of this trend are also significant. Effective licensing generates revenues that may be used to fund more university research. University funding for academic research and development has grown from about 14% of the total in 1980, the year Bayh-Dole was enacted, to 20%, or about $6.5 billion, in 2001. Over this same period, total funding for academic research and development, from all sources, has grown from roughly $6 billion in 1980 to about $33 billion in 2001.[44] More researchers are therefore able to pursue research, and students have been granted more access to

[43] All numbers in this section come from the highly influential annual survey conducted by the Association of University Technical Managers (AUTM). AUTM began conducting that survey and publishing its results in 1991. Although compliance with the AUTM survey is voluntary — only 62% of its members surveyed responded to the latest available survey — 96% of the top 100 research universities did reply. See AUTM, Annual Licensing Survey: FY 2003 (Survey Summary) (Northbrook, Illinois: 2004). http://www.autm.net/surveys/dsp.surveyDetail.cfm?pid=16

[44] All figures are in current dollars. See National Science Board, *Science and Engineering Indicators* 2004 (Washington, D.C. U.S. GPO, 2004), Appendix Table 5.2 http://www.nsf.gov/statistics/seind04/append/c5/at05-02.xls .

faculty researchers, and at some institutions, the opportunity to conduct their own projects (or to assist on faculty endeavors).[45]

What has received the most attention since the passage of Bayh-Dole — and rightfully so — has been the remarkable growth in patenting and licensing activity, as well as in products introduced to the marketplace. In 1980, fewer than 250 patents were issued to U.S. universities each year; only a small percentage of those innovations were ever successfully commercialized. In 2003, by comparison, 3,933 such patents were issued. Between 1991 and 2002, annual invention disclosures increased from 6,087 to 15,510, and patents filed increased from 1,584 to 7,921, to make a cumulative total of 13,280 since the AUTM survey began in 1991.[46] From 1991 to 2003, the number of new licenses and options executed annually increased further from 1,229 to 4,516, taking the cumulative total to 25,979.[47] In addition, in 2003, thirty AUTM members reported introducing 472 new products to the commercial marketplace.

As for companies formed, AUTM noted that 374 university start-up companies were created in 2003 — even though economic conditions made that a difficult year for launching new companies — making a total of 4,081 such companies established since 1980.[48]

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[45] For example, MIT has expanded its pioneering Undergraduate Research Opportunities Program (UROP), which it created in 1969. UROP was inspired by Edwin H. Land, the inventor of instant photography, who emphasized the importance for inventors of "learning by doing". More than half of MIT's undergraduates participate in such projects, either for pay or academic credit. Some students join existing research groups, while others develop their own projects. http://web.mit.edu/urop/basicinfo/index.html.

[46] *Ibid.*, pp. 15-16. It should be noted that this is only a partial figure, as it is limited to the 198 institutions that participated in the AUTM licensing survey. This qualification applies to all figures from that survey. All years cited in this section of the paper relate to the fiscal year used by AUTM.

[47] *Ibid.,* p. 20.

[48] *Ibid.,* pp. 26-28.

Table 2: Start-Ups Formed by U.S. Respondents, 1980-2003[49]

	FY 1980 to 1993	FY 1994	FY 1995	FY 1996	FY 1997	FY 1998	FY 1999	FY 2000	FY 2001	FY 2002	FY 2003	FY 1980 to 2003
Number of Institutions Responding	136	145	157	156	155	157	168	167	167	183	190	
Number of Institutions Reporting One or More	128	75	84	77	86	98	98	116	116	118	120	
Startup Companies Formed	1,013	212	192	202	275	306	294	424	424	401	374	4,081

Numbers alone, of course, do not tell the whole story. More than 70% of the innovations recognized by AUTM emanated from biotechnology, a field that was in its infancy prior to the implementation of Bayh-Dole. Although Bayh-Dole alone may not have created the biotechnology revolution, the incentives it provides for technology transfer remain a critical component for promoting American innovation in this and other fields. Breakthrough biotechnology products resulting from technology transfer include innovations such as an artificial lung surfactant for babies born with respiratory distress system (University of California); a new treatment for Crohn's disease and other inflammatory bowel diseases (Washington University in St. Louis); non-toxic therapies for chagas disease (University of Washington and Yale University); cisplatin and carboplatin cancer therapeutics (Michigan State University); Citracal® calcium supplement (University of Texas Southwestern Medical Center); haemophilus B conjugate vaccine (University of Rochester); and recombinant DNA technology (Stanford University and University of California). Advances have also been made in many other scientific and engineering disciplines, including electronics (nanotechnology, Texas A&M University); computer software (Super Ensemble weather forecasting software, Florida State University); and materials science (inherently conductive polymers, Carnegie Mellon University). [50]

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[49] *Ibid*., p. 28.

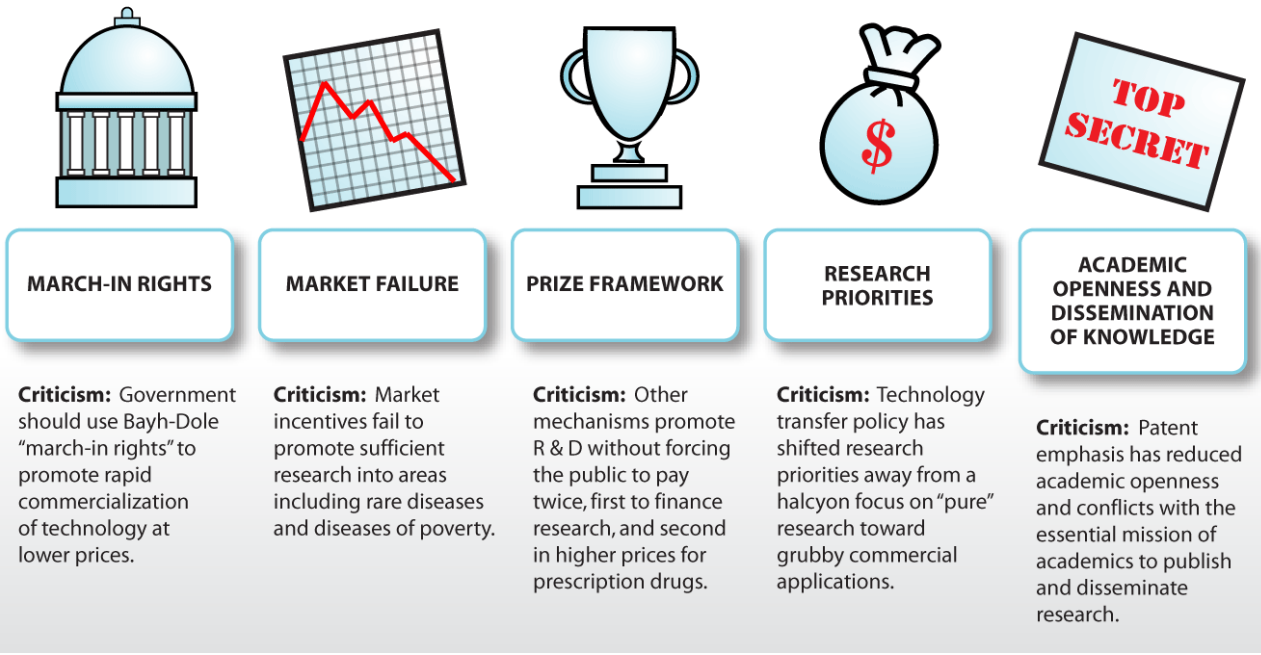
[50] *Ibid.*, pp. 5-11 and http://www.ucop.edu/ott/bayh.html . The innovations sparked by Bayh-Dole have not been limited to matters of life and death. For example, an animal scientist at the University of Wisconsin at Madison (using WARF funds) developed a method to dissolve hairballs in cats; this innovation has been licensed by Nestle Purina for use in hairball-control cat food.

Congress has not ignored Bayh-Dole's legacy. On December 16, 2005, the House of Representatives passed a concurrent resolution commemorating Bayh-Dole's twenty-fifth anniversary, in which it recognized that this legislation: "has made substantial contributions to the advancement of scientific and technological knowledge, fostered dramatic improvements in public health and safety, strengthened the higher education system in the United States, served as a catalyst for the development of new domestic industries that have created tens of thousands of new jobs for American citizens, strengthened States and local communities across the country, and benefitted the economic and trade policies of the United States". Further, in the resolution, Congress "reaffirm[ed] its commitment to the policies and objectives" of this pathbreaking technology transfer policy.[51]

[51] See H. Con Res. 319, http://thomas.loc.gov/cgi-bin/query/D?c109:1:./temp/~c109f9ECCT::

Despite this recognition of Bayh-Dole's achievements, every U.S. government policy has its critics, and Bayh-Dole is no exception.[52] The following section will discuss major criticisms of the Bayh-Dole approach.

Diagram 3: Criticisms of Bayh-Dole



Misinterpreting Bayh-Dole: March-In Rights

The Bayh-Dole Act allows federal agencies to assert "march-in rights" if the holder of the patent fails to make the invention widely available. Under this provision, the federal agency can "march-in", rescind the previous licensing arrangement, and grant a license to a responsible new applicant, if the current licensee failed to make the product available to the public on reasonable terms; or if action is necessary to alleviate health or safety needs not reasonably satisfied by the current licensee. Although to date,

[52] See "Bayhing for Blood or Doling out Cash?", *The Economist*, December 20, 2005.

no federal agency has yet asserted its march-in rights, the NIH has received three petitions requesting it do so. In the first, *In the Case of Cellpro, Inc.*, Cellpro, a private company, petitioned on the basis that Baxter Healthcare and Johns Hopkins University failed in their obligation to take reasonable steps to commercialize patented stem cell technologies. Cellpro asked that Johns Hopkins be compelled to license its patent to the company, so that Cellpro could continue to market its innovation. The NIH rejected this claim in August 1997.[53]

In the second action, *In the Case of Norvir*, Essential Inventions, a consumer advocacy group, petitioned the NIH, with some scattered support from members of Congress.[54] The petitioners asked the NIH to make Norvir, an AIDS drug manufactured by Abbott Laboratories available at a lower price because Abbott had recently increased its price by 400%. The petitioners sought to have the Bayh-Dole march-in rights provision read broadly, as a mechanism to control drug prices.[55] This novel argument prompted (former) Senator Bayh to testify before the NIH and clarify what the intent of Congress had been in enacting the march-in provision: "When Congress was debating our approach fear was expressed that some companies might want to license university technologies to suppress them because they could threaten existing products. Largely to address this fear, we included the march-in provisions that are the subject of today's meeting." In the Norvir petition, Bayh continued, arguments for asserting march-in rights "were being formally presented in an attempt to control drug prices." Bayh emphasized that Congress had not intended for march-in rights to be used in this way and strongly criticized the approach taken in the petition, "The quotations in the petition flagrantly misrepresent the legislative history supporting Bayh-Dole. The petition shows complete lack of understanding of how the legislative process works."[56]

The NIH's decision agreed with Bayh and rejected the claim that march-in rights should be asserted in order to control prices. Instead, the NIH emphasized that such an action might not, after all, lead to lower drug prices "because the market dynamics for all products developed pursuant to licensing rights under the Bayh-Dole Act could be

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[53] See Determination In the Case of Petition of CellPro, Inc., August 1997. http://www.nih.gov/news/pr/aug97/nihb-01.htm

[54] The Essential Inventions petition may be found at http://www.essentialinventions.org/legal/norvir/norvir-29jan04petition.pdf . Further information on the support some members of Congress provided to this effort is available at http://www.essentialinventions.org/drug/ritonavir2.html .

[55] See Susan R. Morrissey, "Marching in On NIH-Funded Drugs," September 14, 2004, *Chemical and Engineering News.* http://pubs.acs.org/cen/news/8237/8237earlygov1.html

[56] Statement of Senator Birch Bayh to the National Institutes of Health, May 25, 2004. http://ott.od.nih.gov/Meeting/Senator-Birch-Bayh.pdf

altered if prices on such products were directed in any way by NIH." The NIH stated it "agrees with the public testimony that suggested that the extraordinary remedy of march-in is not an appropriate means of controlling prices. The issue of drug pricing has global implications and, thus, is appropriately left for Congress to address legislatively."[57] And finally, in a third action, *In the Case of Xalatan,* concerning an anti-glaucoma drug that sold for significantly less in Canada and Europe than the U.S., the NIH again declined to authorize the use of march-in rights as a means for controlling prices. [58]

Market Failure: Effective Policy Responses

Congress has yet to show significant interest in amending the Bayh-Dole's technology transfer framework so as to interfere with market pricing mechanisms for pharmaceuticals. But market incentives alone may provide a necessary, but not sufficient, basis for financing pharmaceutical research. Such incentives often fail, for example, to promote sufficient research into rare diseases because companies fear they will be unable to recoup the extensive costs that must be incurred to research and develop cures. Congress has responded to this problem, not, as some would suggest, by abandoning the market orientation undergirding the successful technology transfer system. Instead, it has adopted policies to address the specific market failure, such as "orphan drug" legislation, which combines various public subsidies — including direct research grants and tax concessions — to finance such research. Another area in which markets fail is in the diseases of poverty (including tropical diseases), since again companies believe they will be unable to recoup their development costs. While the U.S. government has devoted less attention to this problem, multilateral institutions and non-governmental institutions alike have indeed concentrated on designing policies to correct it.

Much of the discussion about such market failure centers on mechanisms to "incentivize" the private sector to innovate in this area.[59] The centrality of market-based

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[57] See *In the Case of NORVIR*, July 29, 2004. http://ott.od.nih.gov/Reports/March-In-Norvir.pdf .

[58] *In the Case of Xalatan*, September 17, 2004, http://ott.od.nih.gov/NewPages/xalatan.pdf . Essential Inventions initiated this petition as well. See http://www.essentialinventions.org/legal/xalatan/xalatan-29jan04petition.pdf .

[59] See, for example, "A Review of IP and Non-IP Incentives for R & D for Diseases of Poverty. What Type of Innovation is Required and How Can We Incentivise the Private Sector to Deliver It?", Final Report for the WHO Commission on Intellectual Property Rights, Innovation and Public Health, submitted 28 April 2005.

See also Precious Matsoso, Martin Auton, Shabir Banoo, Henry Fomundam, Henry Leng, and Sassan Noazin, "How Does the Regulatory Framework Affect Incentives for Research and Development. A Proposal for A Regulatory Framework to Improve Regulatory Capacity and Introduce Incentives for Research and Development in Areas of Public Health Importance," (Geneva: World Health Organization, 2005). http://www.who.int/intellectualproperty/studies/Study5.pdf

incentives to these discussions is, of course, a direct legacy of Bayh-Dole. These discussions are not confined to governments and their multilateral institutions alone; both non-profit and for- profit private companies, as well as NGOs such as the Bill & Melinda Gates Foundation, are also working toward designing solutions that work in conjunction with market forces, rather than in opposition. In one major innovation, in 2000, Dr. Victoria Hale launched a new non-profit pharmaceutical company, the Institute for One World Health, based on the principle that research and product development "decisions could be based on global need rather than financial opportunity." Crucially, the Institute has neither ignored, nor established itself in opposition to, private pharmaceutical and biotechnology companies. To reduce the costs of drugs the Institute has instead promoted partnership and collaboration arrangements with private companies that provide for donations or royalty-free licensing of intellectual property. To the same end, the Institute endeavors to use low-cost research and manufacturing capacity, especially where located in developing countries, when possible. These efforts are now showing results: the Institute will file for regulatory approval in India in early 2006 to use paramomycin, an off-patent antibiotic long approved for use in the U.S., to treat visceral leishmaniasis. The leishmaniasis effort has combined many private and public elements, including foundation funding, assistance from the World Health Organization (WHO) and the U.S. NIH, and alliances with for-profit biotechnology firms such as Celera Genomics.[60] The Institute is also working toward developing new malaria therapies, as well as promoting cures for both diarrhea and chagas disease.

Private, for-profit companies, including Astra-Zeneca, GlaxoSmithKline, Johnson & Johnson, Merck, Novartis, Pfizer, and Sanofi-Aventis, are pursuing other strategies to tackle diseases of poverty. Some have founded specialist centers, while others have created dedicated research programs. Private foundation support, such as from the Gates Foundation and the Chiron Foundation has reinforced several of these efforts; the Gates Foundation has recently provided a grant of more than $100 million to support advanced clinical trials of a malaria vaccine developed by GlaxoSmithKline's vaccines division, and has also targeted several priority diseases and conditions for special assistance, including acute diarrheal illness, HIV/AIDS, and tuberculosis.[61] Additionally,

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[60] http://www.oneworldhealth.org In 2003, the Institute launched the largest phase 3 clinical treatment for leishmaniasis, and treated more than 600 patients; this trial provided the basis for the Indian regulatory application. The Institute also seeks to enter into a collaboration arrangement with a manufacturer, to produce the drug at low-cost and high quality. In addition, the Institute seeks to extend its model treatment program to other countries that have a leishmaniasis problem, including Bangladesh, Brazil, Nepal, and the Sudan.

[61] See http://www.gatesfoundation.org/GlobalHealth/Pri_Diseases/. See also http://www.chiron.com/foundation/focus.html#health_med .

increasing attention is being directed at the role to be played by small companies in developing niche markets for treatments of diseases of poverty, perhaps cross-subsidized by sales in more affluent countries.[62]

Rolling Back Bayh-Dole?

Ironically, just as international organizations and NGOs are focused on improving market incentives to tackle problems caused by market failure, some measures have been tabled in the U.S. to roll-back or restrict Bayh-Dole's market-based framework. Some arguments echo those made in the period leading up to adoption of Bayh-Dole by Senator Russell Long, Senator Gaylord Nelson, Congressman Emilio Daddario, and HEW chief Joseph Califano; they suggest that the public should not have to pay twice for drug development: first in the form of tax expenditures to fund research, and second in higher prices for drugs protected by the temporary benefit provided by exclusive patent rights. Such critics fail to acknowledge the clear and measurable benefits that the Bayh-Dole policy has produced. Moreover, the alternatives they have posed create their own specific difficulties.

Mindful of the context of the Bayh-Dole framework's considerable and measurable benefits, the task here will be to examine some non-market alternatives proposed by critics of that framework. First and foremost among these is the establishment of a prize system for financing medical innovation. In January 2005, Congressman Bernie Sanders introduced just such legislation, which "[p]rohibits any person from having the right to exclusively manufacture, distribute, sell, or use a drug, a biological product, or a manufacturing process for a drug or biological product in interstate commerce, notwithstanding current Federal laws providing otherwise, including laws governing patent rights or exclusive marketing periods." Instead, this measure establishes a fund for medical innovation prizes, which is structured to require its board of trustees "to award prize payments for medical innovations relating to a drug, biological product, or manufacturing process for a drug or biological product."[63]

Under this and other similar prize-based frameworks, a government-controlled commission would be established to reward successful research innovations. Yet such administrative and quasi-judicial bodies are inherently conservative, and tend to undervalue innovations. So, for example, Enrico Fermi received only $300,000 for a

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[62] Andrew Jack, "Neglected Diseases: Small Groups Are a Solution," *The Financial Times*, October 19, 2005, p. 4.

[63] H.R. 417, the Medical Innovation Prize Fund Act of 2005. http://thomas.loc.gov/cgi-bin/query/D?c109:2:./temp/~c109AQbssb::

patent on the reproduction of radioactive isotopes, while liquid fuel rockets yielded only $1 million for Robert Goddard, even though this invention resulted in subsequent federal spending of over $10 billion.[64]

An equally serious problem with such a government-controlled system would be the opportunity it allows to further politicize scientific research. Scientific research decisions — their funding, their outcomes, and their implications — have become one more battleground in the ongoing U.S. cultural war. The best example is the guidelines for stem cell research. The stem cell issue is not merely one of funding, for that problem can be addressed, as California has done, by providing state funds for stem cell research to replace federal research monies. Rather, U.S. law now flatly bans certain areas of stem cell-related inquiry, and this prohibition has led scientists to move their stem cell research outside the U.S. Moreover, the injection of politics into decision-making about scientific research has affected appointments; led unqualified agency staffers to change scientific conclusions; and altered the science curricula taught in schools.[65] As this paper has shown, Bayh-Dole's design minimizes the opportunities for political considerations to distort scientific priorities. Replacing that framework with a government-controlled prize system would allow such considerations greater scope to infect and influence basic pharmaceutical research priorities.

Distorting research priorities

Another line of criticism contends that the Bayh-Dole framework distorts academic priorities by redirecting resources away from basic research to more commercially viable lines of inquiry. Further, it is claimed, the necessity to maintain secrecy until a technology is successfully patented is at odds with the essential values of university openness and efficient and rapid dissemination of knowledge. To the extent that information cannot flow freely, cooperation among academics (as well as outside researchers) is stymied. Each of these criticisms will be addressed in turn.

The assertion that Bayh-Dole has distorted research priorities is generally only supported by anecdotal evidence. History suggests otherwise. U.S. universities have long relied on state, federal and private support, and have often focused on research of practical benefit to a particular state or regional economy or of interest to a specific

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[64] Joseph A. DiMasi and Henry G. Grabowski, "Patents and R & D Incentives: Comments on the Hubbard and Love Trade Framework for Financing Pharmaceutical R & D," June 25, 2004, Department of Economics, Duke University, p. 13.

[65] See Sharon Begley, "U.S. Science Research is in Danger of Losing Place on the Cutting Edge," *The Wall Street Journal*, August 12, 2005, p. B1.

benefactor.[66] Moreover, the federal government's funding priorities have also always favored practical applications. This does not mean U.S. universities ignore basic research. But in reaching the conclusion that the Bayh-Dole framework has shifted research away from a halcyon focus on "pure" research toward more grubby commercial applications, those that hold this view misread the considerable history of just such a prior practical orientation.

Table 3: Federal Funding for Academic R & D by Agency[67]

Agency	1970	1975	1980	1985	1990	1995	2000	2001	2002 (est.)	2003 (est.)
All agencies	4,480	5,376	6,607	7,792	9,456	10,561	14,988	17,043	18,433	19,899
National Institutes of Health	1,686	2,678	3,277	4,069	5,054	5,590	9,439	10,531	11,894	13,633
National Science Foundation	784	1,086	1,215	1,363	1,535	1,768	2,120	2,282	2,415	2,498
Dept. of Defense	606	427	558	799	924	1,068	1,041	1,550	1,414	1,204
National Aeronautics and Space Administration	230	235	261	290	490	599	675	742	736	727
Dept. of Energy	339	290	400	457	557	569	579	635	633	632
Dept. of Agriculture	227	278	383	398	402	440	512	587	571	508
All other agencies	609	383	512	416	495	526	622	717	770	698

Reducing academic openness and impeding the rapid dissemination of knowledge

To turn to the other major objection, some have argued that the need for secrecy has reduced academic openness and conflicts with the essential mission of researchers to publish their conclusions quickly.[68] There are four points to emphasize here.

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[66] See Mowery *et al.*, op. *cit.,* especially chapter 2.

[67] All figures in constant 1996 dollars. National Science Board, *Science and Engineering Indicators* 2004 (Washington, D.C. U.S. GPO, 2004), Appendix Table 5.9, http://www.nsf.gov/statistics/seind04/append/c5/at05-09.xls .

[68] See M.A. Heller and R.S. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research," *Science* 280 (5364) 698-701 (May 1, 1998).

First, Bayh-Dole has engendered a tremendous increase in patent activity but this has largely centered on biomedical and pharmaceutical applications. The explosion of patents in largely reflects NIH's share of federal funding for academic research. But it also stems from a particular characteristic of electronics and computer technology, the other major current fields of technological innovation. Some observers have unfavorably contrasted biotechnology's emphasis on patenting and exclusivity to the prevailing model followed in the computer industry, where the leading companies commonly cross-license their intellectual property, on a reciprocal basis, with their competitors.[69] This criticism misunderstands crucial basic differences between these fields. Most significantly, most electonics innovations are not derived from federally-financed research. Additionally, electronics innovations do not require prior regulatory approval, such as by the by the Food and Drug Administration (FDA), before the innovation may be marketed. That regulatory process is so complex, cumbersome, and costly (albeit indisputably necessary) that companies need the benefit of patent exclusivity in order to recoup their investments. Thus, even if the critical view of Bayh-Dole is accurate, the effect remains confined to the biomedical field.

Second, some studies have found even this concern to be overstated. While a study on genomic patenting found such an effect, it also concluded that the effect constrains rather than cuts off publication completely; declines in impact over time; and is relatively narrow and confined to patented genomic sequences (whereas for non-sequence genomic discoveries, *i.e.* techniques; there is "no statistically significant decline").[70]

Third, the reluctance of some leading scientists to share results existed before Bayh-Dole was enacted. These scientists rushed to publish, rather than patent, but the effect on free and easy dissemination of preliminary research results was similar. Scientific ambition has itself long impeded information flow. James D. Watson's account of cracking the secret code of the DNA molecule describes how he and Francis Crick (with whom he shared the Nobel Prize in Physiology and Medicine in 1962) played cat-and-mouse games with other researchers, including their Cambridge colleague, Rosalind Franklin, as well as Linus Pauling, so as to be the first unequivocally recognized for the discovery. Watson's book captures the excitement of conducting cutting edge science, but also highlights how scientific ambition can lead to questionable

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[69] See Clifton Leaf, "The Law of Unintended Consequences," *Fortune*, September 7, 2005. See also former Senator Birch Bayh's rebuttal of this article. http://www.autm.net/news/dsp.newsDetails.cfm?nid=62 .

[70] Bhaven N. Sampat, "Genomic Patenting By Academic Researchers: Bad for Science?" Study for the Robert Wood Johnson Foundation, December 2004, p. 26. Sampat discusses a variety of policy measures that could correct this problem, if additional research indeed confirms its existence. These include amending Bayh-Dole, changing patent law so that non-commercial researchers cannot be held liable for patent infringement, altering legal criteria for DNA-related patents, and perhaps eliminating genomic patents entirely. Sampat, *op. cit*. p 4.

behavior toward other researchers, as was certainly the case with Watson and Crick with respect to Franklin.[71] To put the point most starkly, Watson and Crick needed no patent incentive in order to shut Franklin out of the progress of their research (and in the opinion of many, deprive her unjustly from sharing in their Nobel Prize).

Finally, critics fail to recognize that the process of filing a patent obligation triggers subsequent publication of the information, whether the filer of a patent wants that information disclosed or not, since U.S. patent law requires the U.S. Patent and Trademark Office to make public patent applications no later than eighteen months after the date of filing.[72] Thus, contrary to what critics assert, the process of filing for a patent actually promotes — rather than retards — timely information flow. A scientist who wishes to withhold research results, for whatever reason, forecloses that option once a patent application is filed.

Summary

Some of the loudest criticisms of the Bayh-Dole framework, such as the assertion that federal agencies should more aggressively assert march-in rights, are based on a fundamental misunderstanding of the intent of Congress in enacting the legislation. There are legitimate criticisms to be made of an exclusively market-based framework, in that it undersupplies drugs and therapies for which there is great medical need but a small potential commercial market. But, many who wish to alleviate suffering in areas such as rare diseases and diseases of poverty have now turned to narrowly targeted policy measures, many of which are being crafted either to increase or replicate market incentives — as the most effective and efficient means for achieving results — rather than discarding the successful market-based system. The alternatives to markets are both inefficient and introduce their own distortions, as they make research priorities highly vulnerable to influence by political, and in some cases, conflicting moral considerations. Finally, the argument that Bayh-Dole has shifted research away from basic research toward commercial applications misreads the history of the largely practical focus of a great deal of prior academic research. It is by no means that clear academic openness has been reduced; ironically, the very structure of the U.S. patent system, requiring automatic publication of a patent application, actually serves to promote rather than impede information flow.

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[71] See, for example, James D. Watson, *The Double Helix: A Personal Account of the Discovery of the Structure of DNA* (New York: Touchstone, 2001).

[72] This disclosure requirement is subject to limited, rarely invoked exceptions the details of which are beyond the scope of this paper.

International Significance

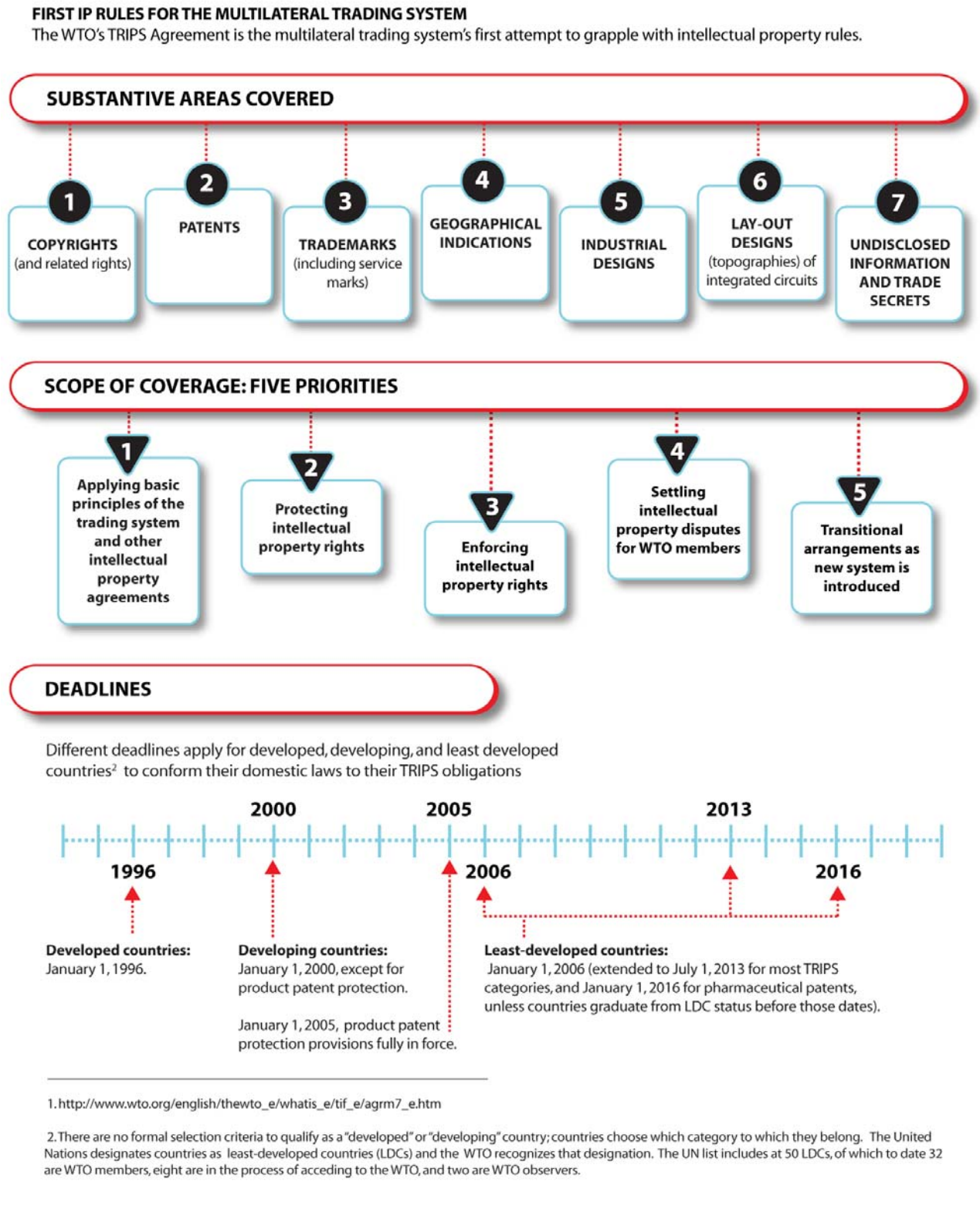
While many Americans seem to take the Bayh-Dole framework for granted, outside America's borders policymakers in other countries seem more aware of its remarkable success.[73] Such recognition is part of a broader awareness of the importance of effective intellectual property protection for fostering technological innovation, and has led to many institutional and statutory reforms.

Intellectual property rights: multilateral approach.

At the international level, changes include establishing new institutions, and expanding the powers granted to existing ones. The most significant innovation has been to create the World Trade Organization (WTO), which came into effect on January 1, 1995, and now numbers about 150 members. The WTO supersedes the General Agreement on Tariffs and Trade (GATT), the members of which launched the Uruguay Round of trade negotiations at Punta del Este, Uruguay, in 1986, and concluded them in 1994. The WTO administers trade agreements, settles trade disputes, serves as a negotiating forum for further trade agreements, monitors trade policies, and provides technical assistance to developing countries. In the realm of intellectual property, the Uruguay Round resulted in an entirely new framework for international treatment of these issues — the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). This agreement also came into effect from January 1, 1995 and establishes minimum standards for intellectual property protection that in large part incorporate existing disciplines under the World Intellectual Property Organization (WIPO) framework with binding dispute settlement procedures.

[73] Michael Remington, "The Bayh-Dole Act at Twenty-Five Years: Looking Back, Taking Stock, Acting for the Future," *Journal of the Association of University Technology Managers* XVII:1 (Summer 2005), p. 15.

Diagram 4: Summary WTO TRIPS Agreement[1]



1. http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm

2. There are no formal selection criteria to qualify as a "developed" or "developing" country; countries choose which category to which they belong. The United Nations designates countries as least-developed countries (LDCs) and the WTO recognizes that designation. The UN list includes at 50 LDCs, of which to date 32 are WTO members, eight are in the process of acceding to the WTO, and two are WTO observers.

Simultaneously, members of WIPO continue to negotiate new treaties and conventions. WIPO's roots stem from two nineteenth-century international treaties, the Paris Convention for the Protection of Industrial Property (1883) and the Berne Convention for the Protection of Literary and Artistic Works (1886).[74] The 1967 WIPO Agreement authorized the establishment of this institution and took effect in 1970. WIPO became a specialized United Nations Agency in 1974, and entered into a cooperation agreement with the WTO in 1996. Currently, 183 countries are members of WIPO.

These international changes have dovetailed with reforms at the national level. In the major industrial countries, patent laws have been harmonized at higher levels of protection for intellectual property. The adoption of TRIPS in 1996 accelerated this process, and led to the inclusion of developing countries.[75] The scope of intellectual property protection has also been expanded into service areas (such as business methods and software) and to include basic research (such as biotechnology). Not only have patent holders been granted broader rights, but the procedures for filing patent claims, and for enforcing patent rights, have been made more efficient. The U.S. has pioneered many changes, but the European Union and Japan have also followed.[76] The result of all the reforms has been an explosion in patent activity, with patent applications increasing from 1.5 million in 1990 to 9.5 million in 2000, according to one estimate.[77]

Promoting technology transfer: the three pillars.

In the past decade, Asian and European countries have adopted policies modeled on Bayh-Dole to promote effective technology transfer. In a March 2004 report, the Organization for Economic Cooperation and Development (OECD) recognized that in the past ten years, many public research organizations (PROs) — defined as universities, national laboratories, and other research organizations receiving significant public research funds— have slowly awakened to the value of the intellectual property they create. At the same time, just as in the U.S. case, other governments have also

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[74] http://www.wipo.int/about-wipo/en/gib.htm#P29_4637

[75] This latter trend will be discussed further below.

[76] See Catalina Martinez and Dominique Guellec, "Overview of Recent Changes and Comparison of Patent Regimes in the United States, Japan, and Europe," in *Patents, Innovation and Economic Performance*, Conference Proceedings August 28-29, 2003 (Paris: OECD, March 2004), pp. 128-129.

[77] Data as cited in Francis Gurry, "A Multilateral View of Change in the Patent System," *Patents, Innovation and Economic Performance*, Conference Proceedings August 28-29, 2003, (Paris: OECD, March 2004), p. 335.

recognized that merely placing the results of such publicly funded research in the public domain fails to translate into significant social and economic benefits. Instead, the report acknowledges, "in…OECD countries and beyond, the Bayh-Dole Act has been widely viewed as a catalyst for increasing the social and economic benefits from public research funding.[78]

With the Bayh-Dole framework widely acknowledged as the most effective to date at promoting technology transfer, it is worth spelling out its essential elements more carefully. This approach is not confined to the terms of Bayh-Dole itself, but instead rests on three pillars:

- recognition of the importance of market forces and market-oriented pricing to economic growth and development;
- strong rule-of-law protection for intellectual property (including patents, data exclusivity, copyrights and trademarks) and
- a durable government commitment to education and financing of scientific research in universities and institutions.

No single pillar is sufficient on its own to facilitate effective technology transfer; yet all are necessary. Indeed, countries that adopt only part of the framework — such as the patent licensing provisions — are unlikely to achieve the benefits of successful industrial innovation that they seek.[79]

Policies in OECD countries

More aggressive management of intellectual property by PROs has raised several questions about the social and economic costs of these policies, and in particular, stimulated inquiry into how they conflict with or complement the traditional PRO mission. The OECD has identified several issues worth examining in this respect, including how much money is raised by licensing; whether more active IP policies impede access to research results; the impact on the cost and efficiency of research; the distortions of research priorities toward more lucrative fields that may arise; and the management of

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[78] *Turning Science Into Business: Patenting and Licensing at Public Research Organizations* (Paris: OECD, March 2004), p. 9. http://www.oecd.org/dataoecd/37/24/30634128.pdf

[79] Mowery, *et. al., op. cit*. conclude that the role of Bayh-Dole alone in promoting the recent explosion in American technological innovation has been exaggerated. See pp. 179-192. But they do not deny the remarkable turnaround in U.S. innovation that has been achieved. The task for future researchers is to study more precisely which public policies have contributed to this renaissance. More systematic attention to the three pillars may provide a starting point for some of this analysis.

inevitable conflicts of interest. Governments find themselves "trying to strike a balance between the research and commercial missions of PROs" as they manage these and other issues. And further, just as in the U.S., many OECD countries have seen a backlash against a more market-oriented approach to licensing PRO research activity.[80] Nonetheless, even though most OECD countries shy away from market incentives in supplying public goods (such as health care), they still understand the advantages that the Bayh-Dole market-based model provides for promoting research. Governments may elect to finance universal health care, but they recognize that the life sciences breakthroughs of the future are best delivered through a market-based framework.

The OECD has begun to collect two types of data, concerning, first, the amount of patenting and licensing activity conducted at PROs; and second, the legal and regulatory frameworks that govern their intellectual property. Some countries, including Australia, Canada, the U.K., and the U.S., already collect substantial data on the public research sector.[81] But for most others, such information is not assembled, even in countries with strong systems of intellectual property protection and technology transfer frameworks in place. Accordingly, the OECD in 2001 initiated the first international survey of such information, which also incorporated case studies of intellectual property management. Only 14 OECD countries were surveyed — Australia, Belgium, Canada, Denmark, Germany, Italy, Japan, Korea, Netherlands, Norway, Spain, Switzerland, the U.S. and Russia.

Many OECD countries, including Australia and the United States, have strong technology transfer frameworks in place; others, such as Canada and the U.K., have recently strengthened already solid existing structures. In general, the OECD notes, throughout its member countries, reconsideration of intellectual property policies concerning publicly financed innovation is occurring, with an eye generally toward promoting ownership of resulting inventions by the institution that conducted the research. Within the European Union (EU), concern has arisen that differences in national IP laws may create barriers to international collaborative research at EU-based PROs. Although this process remains ongoing, several European countries, including Austria, Denmark, Finland, Germany and Norway have either introduced, are considering, or have passed measures that would give title to IP generated by publicly funded research to universities. Some of these countries allow researchers title

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[80] *Turning Science Into Business: Patenting and Licensing at Public Research Organizations* (Paris: OECD, March 2004), p. 10.

[81] Perhaps not coincidentally, these are all countries that also have AUTM-affiliated organizations.

to innovations, but they alone do not have the institutional support necessary to shepherd innovations from laboratory to marketplace.[82]

In general, those OECD countries that chose to make significant changes adopted one of three approaches. Some, including Germany, Japan, and Korea, adopted some form of a Bayh-Dole framework, which award to universities more control over the intellectual property generated by their researchers.[83] Others, such Austria, Denmark, Germany and Norway, abolished "professor's privilege" at universities (thus taking title away from researchers and assigning it to the university, with the researcher to receive a licensing fee). Changing to a framework in which the institution rather than the individual was given title to the invention promoted the stability that private firms look for when they seek to undertake the difficult process of commercialization.[84] A third group, which includes Canada and Ireland, issued "Codes of Best Practice" or "National Intellectual Policy Guidelines."[85]

The OECD notes the "landmark" status of the Bayh-Dole legislation, but also recognizes that its member countries are taking different approaches to technology transfer. Although some change in existing national law or regulation has generally been necessary in order to unlock the value of a publicly-funded innovation, countries will continue to experiment with different approaches. Indeed, some harmonization of these approaches may increasingly be necessary to facilitate cross-border research collaborations — a fact the European Union has already recognized. But at present, countries will likely continue to experiment and tinker with technology transfer policies. The U.S. experience with Bayh-Dole — and its current dominance in creating intellectual property — has set the bar at a high level. But that does not mean that other countries cannot raise the standard even higher.

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[82] It may be all too easy for institutions to understate the difficulties even universities may have in bringing technology successfully to market.

[83] Japan, for example, has passed the Science and Technology Basic Law (1995), the First Science and Technology Basic Plan (passed 1996, to cover 1996-2000), the Law on Promoting Technology Transfer from Universities to Industry (1998), the Abolition of Technopolis Law (1998), the Law on Facilitating the Creation of New Business (1999), the Law to Strengthen Industrial Technology (2000), and the Second Science and Technology Basic Plan (passed 2000, to cover 2001-2005). South Korea also passed Bayh-Dole amendments, and established an Office of Science and Technology Policy along the lines of the U.S. model.

[84] As already noted here, Bayh-Dole itself grants title to an invention to the institution as well; inventors receive an incentive in the form of a percentage of the licensing fee. The Bayh-Dole approach allows inventor, institution, and the industry to share alike in the profits from successful innovation. And the government also reaps a better rate of return on the research funding it provides.

[85] This parallels the approach such countries have also taken in other areas, including corporate governance and accounting, where they have favored a more principles-based schema over the rules-oriented structure that is characteristic of U.S. law and regulation.

Beyond the OECD

Many non-OECD countries have also looked to the Bayh-Dole model. In particular, there is great interest within the (former Communist) Central and East European states in intellectual property in general and in Bayh-Dole in particular. Ten of these countries have joined the EU, and for them, closing the east-west gap is a major priority, as they believe they cannot afford to fall further behind in their relative development compared to EU members of long-standing. Additionally, countries such as Estonia have also targeted — and made great progress in developing — significant information technology sectors.[86] Other non-EU countries, including Brazil, Colombia, and South Africa, have either adopted or are considering significant intellectual property reform legislation.[87]

Developing countries: protecting intellectual property and promoting technology transfer

Throughout the 1980s, most developing countries assiduously resisted the creation of stronger domestic intellectual property protection, as well as the establishment of mechanisms for increasing cross-border enforcement of those rights, arguing that these measures were luxuries they simply could not afford. Yet national policies on appropriate legal frameworks to protect intellectual property rights are not static; they evolve. In fact, as a country develops its domestic capacity for technological innovation, its support for protecting intellectual property rights increases.[88]

The Uruguay Round of trade negotiations brought intellectual property rights for the first time into the multilateral trade framework, overcoming the strong resistance of many developing, countries. The resulting TRIPS Agreement made some concessions to the special needs of developing countries, allowing them some greater flexibility than their developed counterparts, with respect to issues such as looser transition periods. The "Grand Bargain" that these developing countries struck was to acquiesce in adoption of minimal international standards for IP protection — including meaningful

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[86] Mark Landler, "The Baltic Life: Chilly Streets and Hot Technology in Estonia," *The New York Times*, December 13, 2005.

[87] Increased interest on the part of developing countries in promoting intellectual property protection has led consultants such as Public Interest Intellectual Property Advisers, Inc. to specialize in providing advice targeted to their concerns. See http://www.piipa.org/.

[88] So, for example, Japan's position on protecting intellectual property shifted after the World War II, as its companies moved from copying simple technology to developing its own complex technologies. H.G. Grabowski, "Patents, Innovation, and Access to New Pharmaceuticals," *Journal of International Economic Law,* December 2002, pp. 849-860. Notably, Korea has made the same transition. John H. Barton, "Patents and the Transfer of Technology to Developing Countries," *Patents, Innovation and Economic Performance*, Conference Proceedings August 28-29, 2003 (Paris: OECD, March 2004), p. 327.

dispute settlement mechanisms — within the multilateral trading framework in exchange for improved access for their agricultural and goods exports to the markets of developed countries.

The TRIPS commitments undertaken by developing countries have certainly forced changes in their national intellectual property policies, as perhaps best illustrated by India, which passed patent amendments in April of 2005 to meet its WTO TRIPS obligations. Other countries, such as China, had to write meaningful intellectual property protection into their statutes as a condition for joining the WTO.[89] Developing countries have focused their attention on several priorities: access to medicines; biotechnology, biodiversity and traditional knowledge; and technology transfer.[90]

Thus far, it is again India that has made some of the most striking changes. Throughout the 1980s, India had strongly resisted expanding multilateral trading rules to include intellectual property protection. But that policy has now shifted. As a consequence of the success of its information technology sector, India has committed itself to being one of the knowledge economies of the 21st century. In addition, India has a large network of government-funded universities and research laboratories and has spent the equivalent of about $45 billion on scientific research since independence.

The implications for the biomedical and pharmaceuticals areas are equally significant. India is the fourth largest producer of pharmaceutical products and/or active pharmaceutical ingredients, which it sells widely to developing countries as well as to the U.S. Whereas India's amendment of its Patent Act of 1970 was primarily motivated by the need to satisfy its TRIPS obligations, the overall policy change is also part of a more comprehensive shift, in line with India's overall transition to embracing economic policies that accept — and indeed encourage — the forces of globalization.

India's patent reforms will also result in significant re-structuring of the country's highly fragmented pharmaceutical industry, which currently includes more than 11,000 companies. These companies sell 30,000 brands of branded generic drugs. At present, little pharmaceutical research and development occurs in India, but this is changing as India develops its own fledgling biotech industry. Presently discussions are underway to adopt technology transfer legislation modeled on the Bayh-Dole approach so as to

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[89] Effective enforcement is of course another matter entirely.

[90] *Promoting IPR Policy and Enforcement in China: Summary of OECD-China Dialogues on Intellectual Property Rights Policy and Enforcement* (Paris: OECD, 2005), pp. 21-22. For further discussion of developing country concerns over TRIPS issues, particularly with respect to technology transfer, see Keith S. Maskus, *Encouraging Technology Transfer* (Geneva: International Centre for Trade and Sustainable Development and United Nations Conference on Trade and Development, 2004), especially pp. 29-39.

stimulate further economic development.[91] If India does indeed embrace the Bayh-Dole model, it will be interesting to see whether other countries — such as China — elect to follow.[92] Some academic studies suggest that stronger intellectual property protection may increase technology transfer at the international level. Interviews with executives drawn from multinational companies suggest that these decision-makers feel more secure in transferring technology to a subsidiary in a developing country if they believe their firm's investment will be protected by strong, effectively enforced intellectual property rights; this anecdotal evidence is buttressed by more rigorous analysis of firm-level numerical data on intellectual property and technology transfer.[93]

Race to the top?

There are many areas of public policy concerning the developing world — the environment, health and safety, and labor standards spring immediately to mind — where untrammeled economic competition leads countries to abandon protection for their citizens in an effort to attract investment, as well as to increase or merely maintain their relative quota of jobs. Legal scholars call this the "race to the bottom". In the area of technology transfer, however countries— even those on the poorer end of the spectrum— instead may be involved in a race to the top. To compete successfully in a world where deploying innovation depends increasingly on adopting a Bayh-Dole framework (or something similar), at minimum, all three basic pillars must be in place, including a basic market framework, strong and effective support of intellectual property rights, and equally importantly, a commitment to quality education and financial support for academic research. Embracing these three pillars enthusiastically might enable countries one day to abandon the race to the bottom, along with all the squalor and associated human misery.

Conclusion

This paper has aimed to introduce the general reader to the importance of the Bayh-Dole Act of 1980. More than any other policy measure, this legislation spawned the biotechnology revolution and revitalized U.S. industrial innovation. Senators Bayh and Dole introduced their bill to address the failure to transfer technological

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[91] See Narayanan Suresh, "Wanted A Bayh Dole Act for India," *Biospectrum*, July 7, 2005.

[92] Promoting IPR Policy and Enforcement in China: Summary of OECD-China Dialogues on Intellectual Property Rights Policy and Enforcement, *op. cit*.

[93] Lee G. Branstetter, Raymond Fisman and C. Fritz Foley, "Do Stronger Intellectual Property Rights Increase International Technology Transfer? Empirical Evidence from U.S. Firm-Level Data," *National Bureau of Economic Research Working Paper* No. 11516 (August 2005).

breakthroughs from university laboratories to the marketplace. Not only did the legislation fully succeed in promoting such commercial development, but it created new jobs and companies, and alleviated human suffering by introducing new therapies for serious diseases. No successful policy is without its doubters, but perhaps the greatest retort to those critics is the line of countries that has formed to emulate the Bayh-Dole approach. That framework for effective technology transfer is the most successful U.S. public policy export of the past 25 years.