Is Patent Protection Industrial Policy? Notes on the Political Economy of University Patenting

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Walter D. Valdivia, "Is Patent Protection Industrial Policy? Notes on the Political Economy of University Patenting," Mercatus Special Study, Mercatus Center at George Mason University, Arlington, VA, February 2022.

ABSTRACT

The Bayh-Dole Act of 1980 allowed universities to take title to inventions resulting from federally funded research. This reform accelerated the preexisting uptick in university patenting resulting in portfolios heavily weighted in pharmaceuticals, chemicals, and biotechnology. That Bayh-Dole had the effect of an R&D subsidy for those sectors authorizes its analysis as an industrial policy. A subsidy creates its own political force that organizes to protect it; an interest group that promulgates a narrative linking the subsidy to the national interest. This paper takes just that perspective and examines the politics of this policy, identifying the Bayh-Dole lobby and their narrative. This policy was not a broad-based patent law reform, rather it was pushed by a handful of policy entrepreneurs and universities working upstream in drug R&D. In addition, the law, as enacted, placed constraints on university patenting and exclusive licensing; such an activity was never considered an unqualified good. Yet, over forty years, the Bayh-Dole coalition grew into a formidable defender of this subsidy claiming widespread benefits without social costs. They present this policy as the nexus between federal R&D funding and national innovation. In light of the history told here, such a narrative becomes suspect of being one-sided.

JEL codes: O38, L5

Keywords: Industrial policy, Bayh-Dole, university patents, patent policy, patent protection.

The uses and effects of patent protection vary by industrial sector. It is well understood that a few economic sectors use patents intensely while other sectors use them sparsely, if at all.[1] This differentiated effect begs the question about whether patent policy works like industrial policy—that is, policy aimed at shoring up specific industries by means of subsidies, tax benefits, rights, licenses, and other advantages. In this paper, I offer a preliminary and limited answer to that question, and my answer is in the affirmative. I tell the story of the Bayh-Dole Act of 1980 and how it worked, in its effect if not in its design, as a subsidy for the pharmaceutical industry. Many of the facts in my story are well known, and for that reason I focus on the evolution of the public debate about Bayh-Dole and how the political coalition that defends this policy seems to have advanced a *parti pris* argument.

Enacted into law at the end of President Jimmy Carter's administration, Bayh-Dole granted universities, not-for-profit organizations, and small businesses the right to retain title to inventions that emerged from federally funded research. An uptick of university patenting had started in the 1960s, and Bayh-Dole worked as a catalyst of that trend. As universities learned to patent—and learned to manage the non-negligible costs of patenting—their licensing portfolios became heavily invested in pharmaceuticals and, in particular, the biotechnologies that ushered in a new generation of drugs. Patent policy may seem a neutral policy instrument with respect to economic sectors. In retrospect, however, Bayh-Dole looks like a large and directed subsidy for the pharmaceutical industry. Once universities were able to take title to government-funded inventions, industry was able to license

1. See R. C. Levin, A. K. Klevorick, R. R. Nelson, and S. G. Winter, "Appropriating the Returns from Industrial R&D," in Special Issue on Microelectronics, *Brookings Papers on Economic Activity* (1987): 783–820, also referred to as the *Yale Survey on Industrial R&D*; and W. M. Cohen, R. R. Nelson, and J. P. Walsh, "Protecting Their Intellectual Assets: Appropriability Conditions and Why US Manufacturing Firms Patent (or Not)" (NBER Working Paper No. 7552, National Bureau of Economic Research, Cambridge, MA, February 2000), which presents results from the *Carnegie Mellon Survey on Industrial Activity*.

those patents on exclusive terms. Starting in the 1990s, pharmaceutical companies were able to cut their costs in preclinical trials research, which is the research part in R&D and derive windfall profits from research originally paid with tax dollars.[2] In other words, Bayh-Dole had the effect of working like a subsidy for pharmaceutical R&D.

Just as important, the patent reforms introduced in the 1980s, including Bayh-Dole, were critical in the consolidation of biotechnology from a myriad of startups into a few market players either owned by or affiliated with pharmaceutical firms. The importance of university patenting for biotechnology and the eventual industrial concentration of that sector are well-established facts.[3] Therefore, I turn my attention to a more subtle piece of evidence of patent policy as industrial policy: A subsidy creates its own interest group to protect the subsidy.[4] There is cultivated artistry in the manufacture of arguments in defense of a subsidy as its beneficiaries invariably link their own interests to the common good while they underplay counterarguments that constrained the subsidy in the first place. Empirical evidence of this dynamic in the political economy of subsidies can be found in lobbying activity as well as the public discourse in support of the subsidy. And Bayh-Dole has both: a coalition to lobby on its behalf and a discourse of innovation that equates unrestricted university patenting to the national interest.

The small coalition that designed and pushed for the Bayh-Dole reform has grown into a well-organized and powerful lobby that is a formidable defender of university patenting. Self-dubbed the Bayh-Dole Coalition, this group projects all the respectability of its members, prominent among them top research universities (also top recipients of federal research funds), the Association of University Technology Managers (AUTM), and the largest biotechnology trade association (BIO). The Bayh-Dole Coalition skillfully connects its own interests to the public good by suggesting that patents are the nexus between universities and national

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2. F. Cohen, "Macro Trends in Pharmaceutical Innovation," *Nature Reviews Drug Discovery* 4 (2005): 78–84.

3. See part III in Alfred Chandler, *Shaping the Industrial Century: The Remarkable Story of the Evolution of the Modern Chemical and Pharmaceutical Industries* (Cambridge, MA: Harvard University Press, 2009). For a more general discussion of patents in biotechnology consolidation, see Peter Lee, "Innovation Consolidation," *UC Davis Law Review* 54 (2020): 967.

4. The seminal pieces buttressing this conclusion include G. S. Becker, "A Theory of Competition among Pressure Groups for Political Influence," *Quarterly Journal of Economics* 98, no. 3 (1983): 371–400; S. Peltzman, "Toward a More General Theory of Regulation," *Journal of Law and Economics* 19, no. 2 (1976): 211–40; R. A. Posner, *Theories of Economic Regulation* (NBER Working Paper No. W0041, National Bureau of Economic Research, Cambridge, MA, 1974); and G. J. Stigler, "The Theory of Economic Regulation," *The Bell Journal of Economics and Management Science* 2, no. 1 (1971): 3–21.

innovation. There is no question that universities are central to innovation, but it is an exaggerated speculation to suggest that patents are the only or even the primary vehicle of university technology transfer. Unpatentable knowledge moves from the campus to the street in several ways: as training of the professional labor force, as faculty consulting with the private and public sectors, as research published in the public domain, and as tacit knowledge imparted to trainees in laboratories and classrooms. Furthermore, only a tiny fraction of university patents is commercialized. Never mind these facts, the Bayh-Dole Coalition insists that the nexus would be broken if patenting would be constrained in the slightest: "Failing to stand by Bayh-Dole will undermine the critical alliances between academic research institutions, federal laboratories, and private sector entrepreneurs that help keep the country prosperous and secure."[5]

The story I am about to tell puts in perspective the balance achieved to enact Bayh-Dole. It is a balance between opposing arguments about the putative effects of university patenting on innovation, competition, and the public interest. Under this light, the discourse of the Bayh-Dole Coalition is suspect of being one-sided.

THE GENESIS OF REFORM

The debate about ownership of "public patents"—that is, patents originated from publicly funded research—dates back to the debate on the institutionalization of US science policy that started when World War II was ending.[6] Two prominent figures, Vannevar Bush, former director of the wartime Office of Scientific R&D

5. Joseph P. Allen, "President Biden: Don't Misuse Bayh-Dole March-in Rights," *Stat News*, September 17, 2021.

6. For the leading accounts of how Bayh-Dole became law as told, respectively, from the legal, political, and economic perspectives, see R. S. Eisenberg, "Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research," *Virginia Law Review* 82, no. 8 (1996): 1663–727; D. H. Guston, *Between Politics and Science: Assuring the Integrity and Productivity of Research* (Cambridge: Cambridge University Press, 2000), esp. chap. 5; D. C. Mowery, R. R. Nelson, B. N. Sampat, and A. A. Ziedonis, *Ivory Tower and Industrial Innovation: University-Industry Technology before and after the Bayh-Dole Act in the United States* (Stanford, CA: Stanford University Press, 2004), esp. chap. 5. For an economic sociology account, see also E. Popp Berman, "Why Did Universities Start Patenting? Institution-Building and the Road to the Bayh-Dole Act," *Social Studies of Science* 38, no. 6 (2008): 835–71. For journalistic chronicles highlighting the formation of the Bayh-Dole Coalition, see D. Greenberg, *Science for Sale: The Perils, Rewards, and Delusions of Campus Capitalism* (Chicago: University of Chicago Press, 2007); J. Washburn, *University Inc.: The Corporate Corruption of Higher Education* (New York: Basic Books, 2005); and A. J. Stevens, "The Enactment of Bayh-Dole," *Journal of Technology Transfer* 29, no. 1 (2004): 93–99. Of the works cited above, Mowery et al. (2004) discuss the impact of this policy on innovation, and Greenberg (2007) and Washburn (2005) focus on the effects of Bayh-Dole on academic science.

and author of the famous report "Science: The Endless Frontier," and Senator Harley Kilgore, clashed on the issue of patents. Bush preferred a clear transfer of rights to inventors regardless of the funding source of the research; Kilgore in turn defended the government's rights to inventions that resulted from federal funding of research.[7] The institutionalization of publicly funded research through agencies such as the National Science Foundation (NSF) was not settled until the early 1950s. The standstill took longer to resolve regarding intellectual property. Only twice in the next 30 years was government patent policy revisited.

In a 1963 presidential memorandum (36 Fed. Reg. 16889), the administration of John F. Kennedy affirmed the government's rights to inventions emanating from research funded by the government at the same time that it allowed federal agencies, under special circumstances, to transfer those rights to research contractors—that is, universities or private laboratories—requiring, however, reasonable terms in that transfer. Eight years later, President Richard Nixon's administration clarified, with its own presidential memorandum (28 Fed. Reg. 90343), that a "single presumption of ownership of patent rights to Government-sponsored inventions" was inadequate government policy, thus emphasizing the discretion of federal agencies in transferring rights that the Kennedy memorandum had expanded. The result was that by the end of the 1970s, there were 26 different patent policies across the federal government.[8]

The then Department of Health, Education, and Welfare (HEW)—renamed in May 1980 as the Department of Health and Human Services (HHS)—was at the center of the Bayh-Dole story. After World War II, universities had allowed pharmaceutical firms to screen chemical compounds developed in research programs funded by the National Institutes of Health (NIH), and depending on each university's policies, the firms were allowed to secure exclusive rights to compounds that were useful (via licensing from the university or licensing themselves). When the practice was denounced in 1962, HEW began to require firms to screen such compounds to commit to not pursue exclusive rights on them. A sequence of events later unfolded, starting with two influential reports that criticized the restrictions imposed by HEW—a 1968 General Accounting Office (GAO) report on patents for medicinal chemistry and the Federal Council for

7. See Guston, *Between Politics and Science;* D. M. Hart, *Forged Consensus: Science, Technology, and Economic Policy in the United States, 1921–1953* (Princeton, NJ: Princeton University Press, 1998); and B. L. R. Smith, *American Science Policy since World War II* (Washington, DC: Brookings Institution, 1990).
8. Eisenberg, "Public Research and Private Development."

Science and Technology (FCST) commissioned report on patents.[9] The main problem, these reports found, was that pharmaceutical companies did not want to undermine their claims to intellectual property from their own laboratories by polluting their discoveries with university compounds for which they could not secure exclusive rights. HEW acted on the report's recommendations and instituted Institutional Patent Agreements (IPAs) in 1968 to grant ownership of discoveries emerging from the agency's research grants to universities that demonstrated technology transfer capabilities. The Department of Defense (DOD) had a similar policy in place already, and the NSF implemented IPAs in 1973. In 1977, HEW's own General Council Office observed that liberal policy on NIH patents could lead to excessive pricing of new treatments. In response, HEW Secretary Joseph Califano moved to withhold 30 patent applications and three IPAs applications. The universities and the NIH then mobilized to reverse this move and found an ally in Senator Robert Dole. In a press conference, Dole criticized HEW for "stonewalling" university patenting. Senator Birch Bayh, already an advocate of university patenting, was then able to partner with Dole to introduce a bill modeled after the IPAs. The legislation was introduced in the Senate on September 13, 1978.

Similar bills had previously attracted supporters and detractors.[10] Representative Ray Thornton (D-Ark) had introduced the previous year a bill to the House Subcommittee on Science, Research, and Technology proposing to transfer rights to all research contractors. The bill died in committee, but the proposal ignited opposition. Senator Gaylord Nelson (D-Wis) held hearings 22 months later and invited vocal detractors of transferring public patents to the private sector. Notably, Admiral Hyman Rickover (who directed the development of the nuclear submarine) and Senator Russell Long (D-La) warned that this bill amounted to a subsidy for industry.[11]

The bill introduced in the 95th Congress had to be reintroduced in the following Congress after the midterm elections as S. 414 on February 9, 1979. The Senate Committee on the Judiciary held hearings on May 16 and June 6 and reported favorably to the Senate on December 12, 1979. The bill was then debated on the floor of the Senate on February 5 and 6, 1980, and passed on April 23. This

9. For a narration of these events, see Mowery et al., *Ivory Tower and Industrial Innovation;* see also Federal Council for Science and Technology, "Effects of Government Policy on Commercial Utilization and Business Competition," in *Government Patent Policy Study, Final Report* (Washington, DC: Harbridge House, 1968).

10. See Elizabeth Popp Berman, *Creating the Market University* (Cambridge: Cambridge University Press, 2012), esp. 107–12.

11. US Senate, "Dear Colleague" Letter, circulated by Sen. Russell Long, February 21, 1980.

was nevertheless not the bill eventually enacted because the House Committee on the Judiciary required the recoupment provision to be dropped—this provision would have had the government share in a portion of the incomes arising from licensing patents. Finally, the mirror bill introduced (with modifications) passed the House on November 17. At this point, the bill had 54 sponsors and enjoyed wide support in Congress; it won the Senate vote 91 to 4 on November 20, 1980.[12] Being late in the year, there was a risk of a pocket veto. In a hurry, congressional advocates reached out for representatives of small businesses and universities to pressure the White House for a last-minute signature.[13] Small business were strategically included in the bill to court the support of members of Congress and the president himself, who had been a vocal supporter of small enterprises. In the end, President Carter signed Bayh-Dole into law on December 12, 1980.

UPSETTING THE POLICY EQUILIBRIUM

This sweeping reversal of the long-standing government patent policy of allowing agency discretion begs the question, What upset the political balance? One reason is the economic environment. The US economy was shaken during the 1970s as the effects of a cyclical recession (1973–1975) were compounded by the oil embargoes of 1973 and 1979. The economic and social turmoil of that period put in question the presumed robustness of the economy. General apprehension verged into histrionics when the surplus of the trade balance went into decline (although the first trade deficit did not occur until 1982). Particularly, visible sectors—such as automobiles, electronics, and textiles—started to lose their competitive edge in international markets, and higher import penetration was suggestive of lassitude in the domestic market as well. The recessive economy and the symbolic loss of strength in the manufacturing sector were perceived as a widespread "competitiveness crisis," even though it was confined to a few economic sectors.[14] The competitiveness crisis became the main characterization of national economic problems, and policymakers who capitalized on this rhetoric were in a better position to advance their policies and programs, casting them as responses to the crisis.[15]

12. E. Popp Berman, "Why Did Universities Start Patenting? Institution-Building and the Road to the Bayh-Dole Act."
13. Stevens, "The Enactment of Bayh-Dole."
14. M. Papadakis, "Did or Does the United States Have a Competitive Crisis?" *Journal of Policy Analysis and Management* 13, no. 1 (1994): 1–20.
15. S. Slaughter and G. Rhoades, "The Emergence of a Competitiveness Research and Development Policy Coalition and the Commercialization of Academic Science and Technology," *Science, Technology, and Human Values* 21, no. 3 (1996): 303–39.

This strategy required an appeal to fresh ideas that buttressed the prescribed reforms, and by the end of the Carter administration, many new ideas focused on small business and entrepreneurship; one of these was Bayh-Dole.

The political balance tilted in favor of reform because a central argument motivating Bayh-Dole had gained great currency in Congress. That argument is that government-funded research was underutilized because, unable to gain title or exclusive license to an invention, firms were discouraged from taking the inherent risks of large developmental investments. The support of this argument relied primarily on one piece of evidence: Only 5 percent of the 28,000 government-owned patents were under a licensing contract.[16] However, legal scholar Rebecca Eisenberg examined those patents in detail and found that two-thirds belonged to the DOD, whose patent policy allowed contractors to take title.[17] What is more, she found that 325 of the 28,000 patents belonged to HEW, and 75 of them were licensed at the time the report was made. The fact that DOD contractors had not taken title suggests that those patents had little commercial value, and that HEWs patents were licensed at a much better rate than 5 percent. Still, the belief that exclusive licenses were considered a sine qua non for product development, as suggested by the FCST report, was cemented in policymakers' minds.

Creating a sense of political urgency and a convincing economic logic were not the only reasons for the legislative agreement achieved by Bayh-Dole. Enactment required skillful policy entrepreneurs who would be able to mobilize an effective if small coalition and push the bill through Congress by anticipating all opposing arguments.[18]

The arguments against reform had been voiced a year earlier when Senator Nelson held the aforementioned hearings to counter the Thornton bill. The objections were (i) that transferring rights to public patents was tantamount to a giveaway to corporations; (ii) that it would condone monopolistic practices, particularly in the health care sector; and (iii) that taxpayers were denied legitimate returns from research investments. In turn, the bill addressed each of these objections with specific provisions. Bayh-Dole, as originally enacted, was for the explicit benefit of small businesses and not-for-profit organizations (universities), and exclusive licenses for large businesses were limited to five years.

16. Federal Council for Science and Technology, "Effects of Government Policy on Commercial Utilization."
17. Eisenberg, "Public Research and Private Development."
18. Washburn, *University Inc.* See also Stevens, "The Enactment of Bayh-Dole"; Berman, "Why Did Universities Start Patenting?"

As mentioned previously, the original bill included a recoupment provision. It also established two mechanisms for government intervention: The first allows federal agencies to limit or cancel rights to a patent but only under "exceptional circumstances"; the second mandates the agency to take up a paid-up, nonexclusive license to use and practice a patent that is not being developed. The fact that the Bayh-Dole introduced those safeguards is clear indication that it emerged as a political compromise between opposing views on the role of university patents.

The policy entrepreneurs that came together to lobby for Bayh-Dole, have over four decades formed a well-organized interest group. The Bayh-Dole Coalition has a name, a website, and an answer for every question raised about university patenting. In a textbook case of industrial policy, the Bayh-Dole subsidy erected its own political interest group to protect and defend the subsidy. This coalition uses the loftiest of languages to make its case, tying its "rights" to the national well-being—in this case, tying university patenting rights to national innovation and US global leadership. But was Bayh-Dole the reason that universities started patenting? And is university patenting critical to US innovation?

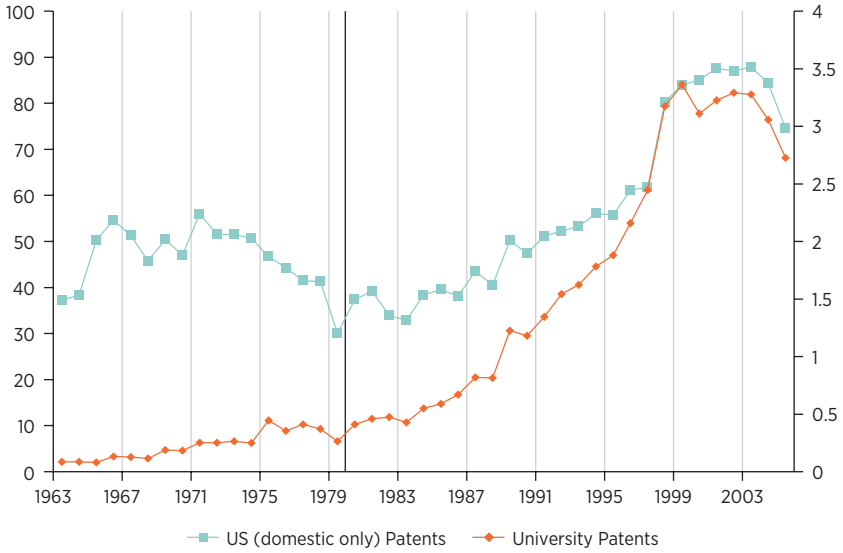
A CATALYST, NOT THE CAUSE

The key argument of the Bayh-Dole Coalition is simple: Federal grants for research are transformed into useful things (i.e., innovation) if and only if inventions from those grants can be patented. The argument suggests itself correct for all sectors of the economy, and that betrays a purposeful ignorance of the well-established fact, in the economics of innovation, that patents play different roles in different industries. Two seminal surveys on industrial innovation—known as the Yale Survey and the Carnegie Mellon Survey—established that only two sectors, chemicals and pharmaceuticals, have historically depended on patents to realize their R&D investments while other sectors benefit from other strategies and do not depend on patents.[19] That is why Bayh-Dole is a duck that walks and talks like industrial policy; in retrospect, it seems designed to favor a specific industry at a key juncture in that sector's history: pharmaceuticals at the birth of commercial biotechnology.

The Bayh-Dole Coalition also defends its subsidy by attributing to Bayh-Dole the heady days of university patenting and, what is more, the claim that university patents are the fountainhead of US innovation. In what follows, I present evidence to question these arguments.

19. See Levin et al., "Appropriating the Returns from Industrial R&D" (the 1987 Yale Survey on Industrial R&D); and Cohen, Nelson, and Walsh, "Protecting Their Intellectual Assets" (the 2000 *Carnegie Mellon Survey on Industrial Activity*).

FIGURE 1. PATENTING ACTIVITY, UNIVERSITIES, AND US SYSTEM



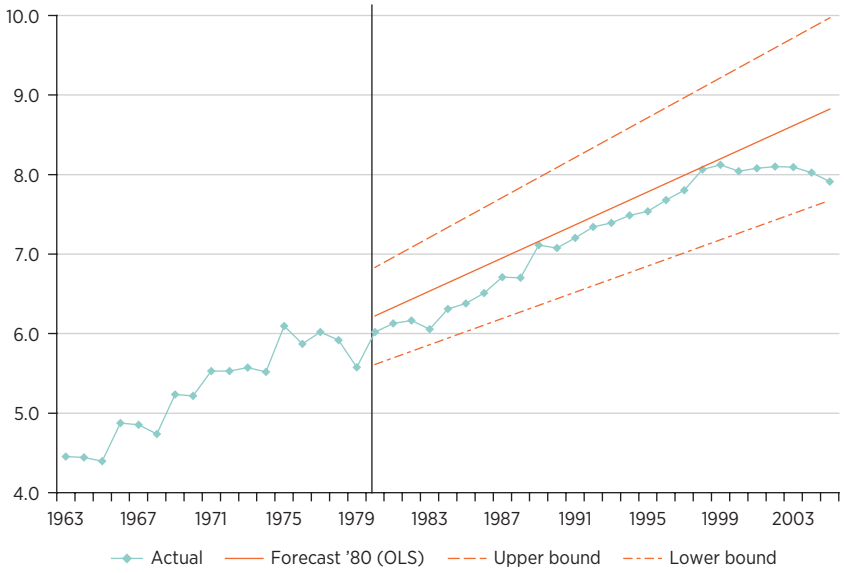
Source: United States Patent and Trademark Office (USPTO), 2009.
Note: Scale is in thousands of patents granted. The vertical line is the year Bayh-Dole was enacted.

Advocates of Bayh-Dole are quick to point to the rapid increase in university patenting following 1980 as proof of the immediate and positive effects of the Bayh-Dole subsidy.[20] By implication, they attribute the growth in patenting to Bayh-Dole. At least two reasons cast doubt on the adequacy of such an attribution. First, by the time Bayh-Dole was enacted, universities were already patenting at increasing rates year after year. For instance, universities were granted 188 patent titles in 1969 and 264 in 1979. In fact, university patenting grew at an exponential rate for at least 17 years before 1980 (figure 1).

Second, before Bayh-Dole, many research universities had already developed the administrative capacity for patenting and licensing. By 1980, nearly 76 percent of the "largest research universities" had signed an invention administration agreement with the Research Corporation, a not-for-profit organization

20. W. H. Schatch, *CR Report for Congress: The Bayh-Dole Act, Selected Issues in Patent Policy and the Commercialization of Technology* (Washington, DC: Congressional Research Service, 2005). See also US General Accounting Office (hereafter GAO), *Patent Policy: Recent Changes in Federal Law Considered Beneficial*, GAO/RCED-87-44, 1987; GAO, *Technology Transfer: Federal Agencies' Patent Licensing Activity*, GAO/RCED-91-80, 1991; GAO, *Technology Transfer: Administration of the Bayh-Dole Act by Research Universities* (Washington DC: General Accounting Office, 1998); AUTM, *AUTM Licensing Survey: Survey Summary* (Norwalk, CT: Association of University Technology Managers, 1996, 1998).

FIGURE 2. FORECAST 1980–2005 OF PATENTING ACTIVITY USING 1963–1979 DATA



Source: USPTO, 2009.
Note: Ordinary least squares (OLS) regression in figure 2 is over time (no lags), with estimated slope statistically significant at $p = 0.01$.

founded in 1912 to be a third-party administrator of university patents.[21] In addition, a few state universities not contracting with the Research Corporation had set up their own offices of technology transfer following the steps of the Wisconsin Alumni Research Foundation (WARF) of the University of Wisconsin, founded in 1924. It should be recalled as well that universities that participated in the HEW's IPA program (and similar programs in other federal agencies) were required to demonstrate technology transfer capabilities.

Considering the rapid growth of university patenting observed from 1963 through 1979, as well as the organizational capacity for patenting prior to 1980, I have projected, using time series analysis, the growth of patenting based on those 17 years of data. The best fit is an exponential curve, and it happens to be, in hindsight, surprisingly accurate 20 years forward (see figure 2). Even before Bayh-Dole, it would not have been unreasonable to expect a long period of exponential growth of university patenting.

21. D. C. Mowery, R. R. Nelson, B. N. Sampat, and A. A. Ziedonis, "Patenting and Licensing University Inventions: Lessons from the History of the Research Corporation," *Industrial and Corporate Change* 10 (2001): 317–55; D. C. Mowery, R. R. Nelson, B. N. Sampat, and A. A. Ziedonis, "University Patents, Patent Policies, and Patent Policy Debates, 1925–1980," *Industrial and Corporate Change* 10 (2001): 781–814.

The foregoing analysis highlights the difference between support and cause: Reforms like Bayh-Dole supported the explosion in patenting but did not cause it. Other reforms to the patent system during the 1980s also shaped the institutional environment to support such a fast growth rate in patenting, but again, they were not the cause, just a catalyst.

The first of these other reforms was the Stevenson-Wydler Act (Pub. L. 96-480), enacted two months before Bayh-Dole. This act created offices of research and technology application (ORTAs) inside federal laboratories. It was later amended and expanded by the Federal Technology Transfer Act of 1986 (Pub. L. 99-502) that introduced economic incentives for federal researchers to seek technology transfer and for federal laboratories to enter into Cooperative Research and Development Agreements (CRADAs) with private parties.[22] The incentives for universities (Bayh-Dole), federal laboratories (Stevenson-Wydler), and CRADAs (Federal Technology Transfer Act) mutually reinforced each other and created a favorable environment for patenting and licensing to industry. The increasing patenting observed through the 1970s (figure 1) stressed and strained the appellate courts that at the time were responsible for hearing appeals in patent infringement cases. To address this problem, in 1982 Congress created the Court of Appeals for the Federal Circuit (CAFC, or Pub. L. 98-462) that centralized patent appeal decisions under a specialized court. The creation of CAFC intended to relieve the regional appellate courts from the flood of patent cases and provide greater consistency across decisions. Greater consistency was in fact achieved. Nevertheless, the decisions of the new court are skewed toward leniency in judging the validity of patents and toward severity in sanctioning patent infringement when taken together and in comparison with the previous decentralized system.[23] Further restrictions related to antitrust legislation were relaxed under the National Cooperative Research Act of 1984 (Pub. L. 98-462) for patents under public-private research joint ventures.[24] Another protection, more specific to the pharmaceutical industry, was packaged in the Hatch-Waxman Act of 1984 (Pub. L. 98-417) that extended patent rights up to five years to compensate pharmaceutical companies for the lengthy approval process of a new drug (on average 7.5 years). Further protection to patenting in the biotechnology and software industries was given by two Supreme Court decisions, respectively: *Diamond v.*

22. Guston, *Between Politics and Science*.
23. M. D. Henry and J. L. Turner, "The Court of Appeals for the Federal Circuit's Impact on Patent Litigation," *Journal of Legal Studies* 35 (2006): 85–117; G. S. Lunney Jr., "Patent Law, the Federal Circuit, and the Supreme Court: A Silent Revolution," *Supreme Court Economic Review* 11 (2003): 1–80.
24. J. T. Scott, "The National Cooperative Research and Production Act," *Issues in Competition Law and Policy (ABA Section of Antitrust Law)* 2 (2008): 1297–317.

Chakrabarty (447 US 303/1980) initiated the patenting of genetically engineered life forms, and *Diamond v. Diehr* (450 US 175/1981) paved the way for the patenting of software.[25]

In summary, the overhaul of patent policy created a favorable environment for patenting, yet it did not cause the growth in patenting activity.[26]

ETIOLOGY OF AN OUTBREAK OF UNIVERSITY PATENTING

What, then, was the cause of the growth of university patenting? Three possible explanations have been put forward. First, starting in the late 1960s, the US government sought greater control of the research agenda and research output of universities.[27] While the total federal research budget did not fall, the focus on some research programs (e.g., Research Applied to National Needs[28] and Nixon's War on Cancer) benefited some universities more than others, increasing pressure for those in the funding periphery to seek sources of income other than federal grants. The economic crisis of the 1970s may have accentuated this problem as state budgets for education shrank and university endowments contracted. Second, new technologies produced entire families of new patentable inventions. One such family of novelties is in the field of biotechnology, which started in the 1970s and flourished into a well-established discipline and industry.[29] Another sector that

25. Following the precedent of *Diamond v. Chakrabarty*, the US Patent and Trademark Office modified its guidelines declaring "non-naturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter" (US Patent and Trademark Office, "Animals–Patentability," *USPTO Official Gazette*, 1077 OG 24, Washington DC: USPTO, 1987). *Diamond v. Diehr* allowed the patenting of a machine controlled by a computer, creating an exception to the theretofore exclusion of mathematical algorithms as patentable subject matter, the scope of which was later expanded by various rulings of the CAFC and ultimately codified in the USPTO 1996 guidelines for computer-related claims (US Patent and Trademark Office, "Examination Guidelines for Computer-Related Inventions," *Fed. Reg.*, 61 no. 40 (1996): 7478–92.

26. Other relevant legislation includes the Orphan Drug Act of 1983 (Pub. L. 97-414), which grants a seven-year exclusive license of government patents related to drugs that target rare diseases (less than 200,000 patients diagnosed), and the US Trade Representative's mandate known as "Special 301," used to monitor and sanction US trade partners that fail to provide adequate intellectual property rights (IPR) protection. For further reference, see Table 1 in Coriat, B. and Orsi, F. "Establishing a new intellectual property rights regime in the United States: Origins, content and problems." *Research Policy*, 31, no. 8–9 (2002): 1491–507.

27. Guston, *Between Politics and Science*, 77–85.

28. The NSF started the Research Applied to National Needs (RANN) program in 1971, expanding the previous short-lived Interdisciplinary Research on Problems Relevant to Our Society (IRPOS) program.

29. H. F. Judson, *The Eighth Day of Creation* (Plainview, NY: Cold Spring Harbor Laboratory Press, 1996); P. Citron and R. M. Nerem, "Bioengineering: 25 Years of Progress—but Still Only a Beginning," *Technology in Society* 26, no. 2–3 (2004): 415–31.

expanded quickly in the 1980s is computer software, both for personal computers and network servers. Looking at patent data, Kortum and Lerner (1998) show that from 1969 and 1991, biotechnology and software patents nearly doubled their weight in the total of patents (from 3 percent to 6 percent for biotechnology and from 4 percent to 7 percent in software).[30] The third explanation for the increase in university patenting is a cultural change in the academic and business worlds about the role of patents. The attitudes of university administrators and even the disposition of some scientists toward patenting have turned from reluctance to euphoria, from setting one's scruples aside and timidly patenting university inventions to actively seeking and promoting patenting.[31] Today, most research universities require their faculty and staff to provide invention disclosures when appropriate and have all personnel sign patent release contracts, and they give great latitude to their offices of technology transfer to maximize licensing profit, including sometimes undertaking aggressive litigation.[32]

In summary, Bayh-Dole was a catalyst rather than the driver of university patenting that started before this policy was enacted. In fact, the drivers of the explosion in university patenting—the coming to maturity of biotechnology, institutional changes in university funding, and changes in venture capital markets—are unrelated to Bayh-Dole. At the same time, it must be recognized that the acceleration of university patenting was supported by important reforms to the patent system that started in 1980 and did create a favorable environment for patenting.[33]

PATENTS ARE A BAD PROXY FOR INNOVATION—EVEN IN BIOTECH

Firms innovate to secure first-mover advantage, but most of them use several strategies other than patenting to protect their R&D investments. Only chemicals and pharmaceuticals use patenting as their top strategy. In addition, the number

30. S. Kortum and J. Lerner, "Stronger protection or technological revolution: what is behind the recent surge in patenting?" *Carnegie-Rochester Conference Series on Public Policy* 48 (1998): 247–304.
31. See Greenberg, *Science for Sale;* D. Bok, *Universities in the Marketplace: The Commercialization of Higher Education* (Princeton, NJ: Princeton University Press, 2003).
32. Greenberg, *Science for Sale*.
33. D. C. Mowery, R. R. Nelson, B. N. Sampat, and A. A. Ziedonis, "The Growth of Patenting and Licensing by US Universities: Assessment of the Effects of the Bayh-Dole Act of 1980," *Research Policy* 30 (2001): 99–119. See also D. C. Mowery and A. A. Ziedonis, "Numbers, Quality, and Entry: How Has the Bayh-Dole Act Affected US University Patenting?" *Innovation Policy and the Economy* 1 (2000): 187–220; D. C. Mowery and A. A. Ziedonis, "Academic Patent Quality and Quantity before and after the Bayh–Dole Act in the United States," *Research Policy* 31 (2002): 399–418; Mowery et al., *Ivory Tower and Industrial Innovation*.

of patents assembled in a final product is a key determinant of the importance of patenting for any specific industrial sector. While a new drug has a low number of patents, a smart phone or an automobile combines thousands of patents in the final product. While the observed patenting could be indicative of greater innovative dynamism in biomedicine, patenting could be impeding innovation in many other industries. And even in biomedicine, the patenting of research tools could be detrimental to scientific research that is incremental and thus heavily dependent on new knowledge entering the public domain. The growth in the number of patents is thus a very ambiguous indicator of innovation that reflects the quantity and not the quality of inventions. There is no definitive causal link between university patenting and innovation.

The Bayh-Dole Coalition is conveniently blind to this ambiguity in the impact of university patents on biotechnology. But it goes beyond, extrapolating its convictions about biotechnology to all economic sectors. Setting aside this overgeneralized characterization of the role of patents on innovation, this interest group also magnifies the importance of university patents on the US innovation system. This is different from asking how important universities are to US innovation, because institutions of higher education enhance and foster innovation through multiple channels, not just patents. As noted earlier, these channels include the training of the workforce, the vast amounts of formal knowledge universities place in the public domain by means of publication, the no less immense amounts of tacit knowledge transmitted to students in research laboratories, and the multiples forms of engagement and knowledge dissemination through the communities engaged with universities. Yet in the Bayh-Dole Coalition discourse, the total impact of universities on innovation is reduced to the impact of university patenting. But the facts do not support this equivalence, as I noted above. The impact that universities have on innovation is large; the impact of university patents on innovation is mixed and comparatively small.

CONCLUSION

The explosion of university patenting, of which Bayh-Dole was a catalyst, is only ambiguously related to innovation in biotechnology and faintly related to innovation in all other sectors. The Bayh-Dole Coalition, ignoring this ambiguity and without differentiating among sectors, claims that without university patenting the US innovation system would be imperiled. It is hard to imagine how universities could cease to contribute to US innovation even if their patenting activity were constrained. At the same time, it is not so hard to imagine that biotechnol-

ogy would have emerged as a viable industry, only under a different industrial and political organization.

The story told in this paper also offers a subtle cautionary tale, because it hints at the unanticipated effects of industrial policy. The government may succeed or fail to boost a given industry, but it never only changes the economics of that sector—it also changes its politics.

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ACKNOWLEDGMENTS

I'd like to thank the participants of the Institute for Humane Studies workshop on industrial policy (July 2021) for their useful comments. Special thanks to Nita Ghei and Elise Amez-Droz for their detailed feedback. All remaining errors are my sole responsibility. Portions of this manuscript were presented in my dissertation, "Equity Concerns in the Evaluation of the Bayh-Dole Act" (Arizona State University, 2011).

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