Narrative draft

1945-1962

Events:

1945 World War II ends
Science—The Endless Frontier is published, arguing that by default contractors should maintain title to government-funded inventions

1946? Senator Harley Kilgore proposes an "Office of Science and Technical Mobilization" as an alternative to Vannevar Bush's proposed "National Research Foundation"; the OSTM would keep invention rights with the government

1947 The U.S. Attorney General publishes a three-volume report strongly supporting a government title patent policy

1948 Archie Palmer, working with the National Research Council, publishes the first of several reports surveying university patent policies

1958 The Space Act of 1958 gives government title to NASA-sponsored inventions by default but gives NASA authority to waive title

1959 The Senate Committee on Small Business holds hearings on *Patent Policies of Departments and Agencies of the Federal Government*, and, the following year, holds a *Conference on Federal Patent Policies*

1961 The Senate Subcommittee on Patents, Trademarks, and Copyrights holds hearings on *Government Patent Policy*

For at least fifty years, since the U.S. government began to fund scientific research in significant quantity, there has been a debate over what should happen to inventions resulting from such research. There are two basic possibilities, with a host of possible permutations falling between the two poles. One is for the government to keep the rights to such inventions, either patenting them or dedicating them to the public domain through publication. The other is for the inventors to keep the rights, while government maintains the option of requesting a royalty-free non-exclusive license. The first can be abbreviated as a "government title policy"; the second as a "government license policy".

The tension over which approach made for better public policy was evident even during World War II. Most wartime military research gave title to contractors with provisions for a government license (Guston 1999, p. 93). After the war ended, there was a push to reassert a policy of giving title to the government by default. The pull between these two possibilities was evident even at this early date and foreshadowed the arguments that would be replayed for the next several decades. While everyone agreed that the point was to maximize inventions' benefit to the public, there was a lot of disagreement over the best way to do that. One side saw awarding title to inventors as a giveaway of public funds that essentially forced the public to pay twice for the same research. The other thought that government was unlikely to do a good job of developing inventions and that the public would be better served by providing an incentive for inventors to do so.

The two arguments that emerged after the war were epitomized by Vannevar Bush, Director of the wartime Office of Scientific Research and Development on the one hand, and Senator Harley

Kilgore, a New Deal Democrat from West Virginia, on the other.[1] Bush, at the time, was promoting a "National Research Foundation". The National Science Foundation that was eventually established was a much scaled-back version of the original proposal; the National Research Foundation as originally envisioned would have been a single agency controlling all government-sponsored science. Kilgore had an opposing proposal to create an "Office of Science and Technical Mobilization" under somewhat different auspices (Kleinman 1995, ch. 4).

Bush thought patents were an absolutely necessary incentive for the private sector to invest in technology and that assigning patents to government would simply hinder technological development (Kevles 1977; England 1976).[2] Although in *Science—The Endless Frontier*, Bush made the fairly modest argument that the National Research Foundation should have discretion over what kinds of patent arrangements to make (Bush 1945), he was in general a strong believer in a government-license policy, which was in keeping with his general views about the need for autonomy in science.

Kilgore, on the other hand, thought that giving away patent rights would hinder the free flow of scientific information, especially since industry had a motive to restrict, rather than spread, the dissemination of research (Kleinman 1995, p. 77). His initial proposal gave all rights to the government; a later compromise allowed the sponsoring agency to assign rights to the inventor under certain conditions (Kevles 1977, p. 24).

The opposition of these two important figures in science policy set the stage for no single patent policy to be established. Bush was "apparently convinced…that no foundation would be preferable to one wrongly organized" (Geiger 1993, p. 17). He would not compromise with Kilgore and thus the National Research Foundation he envisioned in 1945 was never created. If it had been, it might have been a stronger, more centralized organization that really would have overseen the administration of all science done or sponsored by the federal government. But the National Science Foundation was not established until 1950. As a result, the science research that had sprung up in many different agencies during the war continued to develop on an ad hoc basis. It had time to establish its own constituencies, and by 1950 could no longer be brought under the heading of a single agency. A disorganized, decentralized system of federal science funding became rooted. This in turn led to a disorganized, decentralized system of policies regarding the patenting of government-funded research.

Since no existing law established a uniform patent policy for the various funding agencies, they developed a variety of different policies, whether set internally or by statute. In 1956, when the government began collecting data on federal research spending, the biggest funder by roughly a factor of six was the Department of Defense (DOD), with a budget of $481 million. Very distant seconds were the Atomic Energy Commission (AEC), the Department of Agriculture, and the

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[1] The government-title position can also be seen in the three-volume study published by the Attorney General's office in 1947, which recommended that government should take all rights to patents [double-check this with the study] (U.S. Department of Justice 1947).

[2] See Hart 1998 for a revisionist view on Bush's role.

Department of Health, Education, and Welfare (HEW), home of the National Institute of Health (NIH), each of which spent about $85 million (National Science Foundation 2003, Table A).[3]

Each of these agencies developed its own patent policy through some combination of statute and regulation. The AEC, with its roots in the Manhattan Project, was very concerned with its ability to control research results, and as a result maintained title to almost everything. DOD, on the other hand, despite having an obvious interest in secrecy, generally left invention rights to contractors, subject to a royalty-free license for government. Its reasoning was that inventions resulting from research it funded were not, first and foremost, commercial inventions. They might serve a dual military and commercial purpose, but all DOD needed was a license to use the invention. It was happy to leave the rest to contractors who could then pursue any commercial possibilities (Federal Council 1976, p. 1).

By 1959, NASA had replaced the Department of Agriculture as the fourth-largest research funder. The Space Act of 1958, which founded NASA, made the dissemination of the scientific knowledge it produced an explicit part of its mission. In part because of this, NASA became an important locus of debates about patenting during its formative years. The Space Act of 1958 originally included provisions, modeled on the Atomic Energy Act, under which the government would retain title to patents resulting from NASA-sponsored research. These were withdrawn, however, under pressure from contractors and others. Final language gave the government title by default but gave NASA the authority to waive title (U.S. Congress 1980, p. 22).

DOD, the AEC, and NASA spent most of their research dollars with industry. Though they did fund academic research, it formed a comparatively small fraction of their budgets. Agencies like the young NSF and the rapidly growing NIH, on the other hand, had small overall budgets by comparison but spent the bulk of their money funding research at universities and other nonprofit institutions.[4] Scientists working in industry—at least in industries where patents mattered—had an obvious motivation to pursue patent rights when they thought they would have value. University scientists, on the other hand, tended to know very little about patenting at all, and universities as organizations weren't designed to handle the patent process.

Many universities did pursue patents at least occasionally. The original innovator in patenting was the University of Wisconsin. It created the Wisconsin Alumni Research Foundation (WARF) in 1925, after one of its professors, Harry Steenbock, invented a way to increase the Vitamin D content of foods and donated the patent to the university. Steenbock and university administrators wanted to keep the management of the patent separate from the university as an academic institution, so it created WARF, a separate body, to do so. The patent turned out to be

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[3] In 1951, DOD spent $1.12 billion on research and the AEC spent $158 million. The next two largest funders were Commerce, with $46 million, and the National Advisory Committee on Aeronautics, the precursor to NASA, with $45 million. Health, Education and Welfare, home of the National Institutes of Health, spent only $39 million and the infant National Science Foundation spent a mere $151,000 (National Science Foundation 2003, Table C). The government did not collect data on research spending alone (distinct from development) until 1956.

[4] The government did not systematically collect data breaking down research spending by agency and type of performer (e.g. industry, university, nonprofit, intramural) until 1970. If development is included, however, the top agencies in terms of R&D spending at universities in 1959 were DOD ($124 million), HEW ($110 million), and NSF ($48 million) (NSF 2003, Table B).

extremely profitable and brought Wisconsin many millions of dollars over the years (Wisconsin 2005).

But this model was not widely copied. In fact, the most striking thing about university patent policies in the 1950s was their diversity. Many universities did have formal policies (see Archie Palmer's numerous publications from the 1940s and 50s documenting them), but they had something of an ad hoc character about them. Some universities claimed title to any inventions of their faculty; others did not; yet others' policy was to take title but their practice was to waive it to any faculty member actively interested in pursuing a patent on research. Universities that did patent faculty members' research had different kinds of arrangements for sharing any resulting income with the inventor. Sometimes patenting was allowed in some parts of the university but not others. Harvard, for example, maintained until the mid-1970s a policy under which no inventions by Medical School faculty could be patented, under the justification that it was ethically inappropriate for an academic institution to patent inventions that might save people's lives.

Most universities did not have an administrative infrastructure for pursuing patents and licenses. A very few had research foundations modeled on WARF. Some, like the University of California, had an attorney who acted as patent administrator. Perhaps the most common arrangement was for a university to contract with an outside group that specialized in patent administration to handle the process. The largest such group was Research Corporation, which, over the years, held contracts with Stanford and MIT, among many other universities.

But the total number of patents filed by or on behalf of universities in these years was quite low—in the early 1960s it was on the order of 100 per year—across *all* universities (Mowery and Sampat 2001, p. 798). For the most part patenting and licensing was a very minor activity at research universities, and one that was slightly frowned upon, as well, for two reasons. First was the belief also held by many members of Congress—that what the government pays for, it should own. Second was similar, but more specific to academia—that universities should not be involved in making money off of science.

For all these reasons, patents were rarely pursued on inventions made at universities. NSF and NIH, the big funders of academic science, had patent policies too. In general, they followed the principle that the government would assume rights to inventions by default, but that it would waive those rights, under certain conditions, upon request. The decisions were made on a case-by-case basis and seemed somewhat arbitrary. But in the 1950s it wasn't much of a problem, since few waiver requests were made.[5]

As NSF and NIH grew dramatically during the second half of the 1950s, and as the investment they had made in basic science began to show results, this gradually changed.[6] NIH, in particular, began to see inventions pick up, and problems with its patent policy began to emerge.

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[5] Need better details/citation here.

[6] Data for research spending in the 1950s are a little spotty, but NSF started collecting data on R&D spending at universities in 1955 for each federal agency. NSF itself went from spending $7 million on R&D in universities in 1955 to $60 million in 1960. NIH is not broken out separately from HEW, but HEW's R&D spending on universities went from $27 million in 1955 to $158 million in 1960 (National Science Foundation 2003, Table B).

For one thing, if the government patented an invention, the policy made no provisions for exclusive licenses. In many cases, there were significant costs involved in moving an invention through the development process to the point where it was a saleable product. This was particularly true in the pharmaceutical area, where the clinical trials required by the Food and Drug Administration were expensive. In such situations, an exclusive license (or an actual patent) assured the developer that it had a chance at recouping those costs. If several firms held licenses, no one firm would have an incentive to develop the drug because the other firms could then just copy it without investing in the development process. So in these situations, if NIH owned a patent but could not give an exclusive license to it, the result would be no licensees even though the invention might hold great promise. Paradoxically, if the invention were available to everybody, nobody would use it.

Problems like these became more and more prevalent at NIH during the early 1960s. Finally, in 1963, the agency decided to hire Norman Latker, a young patent attorney working for the Air Force, to come help sort things out.

1963-1969

Events:

1963 President Kennedy publishes a *Memorandum and Statement of Government Patent Policy*, attempting to clarify confusion over policy
The Senate Select Committee on Small Business holds hearings on *Economic Aspects of Government Patent Policy*
Norman Latker becomes Patent Counsel at NIH

1965 The Federal Council for Science and Technology creates a Committee on Government Patent Policy
The Senate Subcommittee on Patents, Trademarks, and Copyrights holds hearings on *Government Patent Policy*
The Federal Council for Science and Technology publishes its first *Annual Report on Government Patent Policy*

1966 Senator John McClellan introduces a bill providing for a patent policy similar to the Kennedy *Memorandum*; it never reaches the floor
Senate Majority Whip Russell Long introduces a bill giving the government patent rights to all federally funded inventions

1968 Harbridge House publishes its four-volume report, *Government Patent Policy Study*
The U.S. General Accounting Office publishes the report, *Problem Areas Affecting Usefulness of Results of Government-Sponsored Research in Medicinal Chemistry*
NIH establishes Institutional Patent Agreements with the University of Wisconsin and other universities to simplify the patent waiver process
Stanford's Office of Technology Licensing is created

1969 NIH becomes the first federal agency to allow exclusive licenses on government-owned patents
Latker becomes Chair of FCST's Ad Hoc Subcommittee on University Patent Policy

In October 1963 the Kennedy administration, in an attempt to untangle and clarify the government's complicated patent policies, published a *Memorandum and Statement of*

Government Patent Policy. While the policies of twelve science-funding programs, including all of the AEC, NSF, and NASA, were governed by statute, the Kennedy memorandum was supposed to provide a flexible but uniform policy for the rest of the agencies (McNett 1966, p. 8). Unfortunately, it failed to do so. It tried to steer a middle course between the government-title and government-license approaches by laying out circumstances in which making government title the default but giving fairly generous discretion to the agencies to waive title as they saw appropriate, establishing a loose set of guidelines about how these decisions should be made.[7]

The very attempt to make the guidelines flexible, however, meant that the statement was worded broadly enough that the agencies could pretty much interpret it as supporting whatever policies they wanted to pursue anyway. Agencies did not necessarily base their patent policies on actual analysis of what was happening to inventions—whether they were being used in any effective way. Instead, slowed down by organizational inertia, they tended to maintain existing practices, regardless of their effectiveness. Furthermore, some agencies had other interests in maintaining the status quo—for example, in protecting the jobs of their patent attorneys, whose work consisted of applying for patents on behalf of the government.

The Kennedy memorandum did have one lasting impact, however. It required that the Federal Council for Science and Technology (FSCT), an interagency group that assisted the administration in setting science policy, establish a committee on government patent policy to improve understanding of the patent process, to assist with the implementation of the memorandum, and to produce annual reports on the state of government patent policy.[8]

The new Committee on Government Patent Policy of the FCST, established in December 1965, was made up of representatives from the various agencies that funded government research and thus encountered the issue of what to do with patentable results of that research. It included both the biggest funders of research as well as agencies that encountered patent issues less frequently (the Department of Commerce, for example). Although members of Congress periodically sponsored bills that would govern patent policy, these did not necessarily reflect the experiences of the federal employees who actually administered patents on research and understood the patent process. The interagency committee provided for the first time a meeting place for those who were directly involved in implementing patent policy in various parts of government.[9] While by no means did they agree with one another about what government patent policy should look like, at least they all knew how the patent system worked.

Norman Latker, the new patent counsel at NIH, would soon be involved in the FCST Committee on Government Patent Policy. But in 1963, his goal was just to sort out the "chaos" that then existed in the invention area at NIH. Section 1-C of the Kennedy memorandum said that government would maintain title to inventions in the health area. There was some leeway in the

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[7] Do I have this backwards? *CHE* article says generally gave rights to the inventor. Look at the final FCST volume's history of patent policy, because it distinguishes when a middle position—which is the one the Kennedy memorandum took, I think—emerged; i.e. a position that things should vary from agency to agency rather than have one default of government title or contractor title.

[8] Is this a fair description of FCST and the requirements of the Kennedy memorandum?

[9] Is this true? The Harbridge House report seemed to suggest that the Kennedy memo itself was a result of several years of interagency discussion—but I don't know if it was in a formal setting.

memorandum, but NIH's default policy at the time was to take title to department-funded inventions and to require they be published. Inventions were dedicated to the public and, if patented, only non-exclusive licenses were granted.[10]

The Department of Health, Education, and Welfare (HEW), which contained NIH, knew that much of the research it funded was never being applied in any way, and that its patent policy was part of the problem, but had no idea what to do about this. When Latker arrived, he quickly made it clear that he believed the department's patent policy was too heavy-handed, and that it should generally waive title to inventors upon request. Medical inventions were one of those areas that usually required a great deal of additional investment before they could reach the market and thus where firms frequently required patent rights or an exclusive license in order to justify such an investment.

Latker had sole discretion over the patenting of the inventions of actual NIH employees. But the inventions of grantees were reviewed by other offices as well, and he quickly found himself coming into conflict with those offices. When universities came to NIH requesting that it waive title to a particular invention, the request would first go to an administrative office that would routinely recommend such requests be denied. Then the request would go to Latker for review. Before long Latker began challenging these denials on the basis that the department had no intention to pursue development of these inventions and thus that the public's interest was not served by the department's refusal to waive title.

This brought him into open conflict with other offices within HEW. Several difficult years ensued, during which Latker kept pushing for more title waivers while others within the department resisted.

Latker's beliefs about what government patent policy should look like were based on his own experiences with the patent process as well as his personal philosophy. But there had been little systematic analysis to this time of the effects of government patent policy. Two studies published in 1968 helped remedy this problem.

The first was a study by the General Accounting Office (GAO) of the effects of patent policy on NIH's medicinal chemistry program. The GAO had become aware of problems that were occurring in that program as a direct result of NIH's patent policy, and it decided to take a look at the program.

The medicinal chemistry program was a relatively small one (costing about $9 million annually at the time[11]) that funded basic research, mostly in universities, that resulted in the production of many chemical compounds with potential pharmaceutical applications. The funded researchers were primarily interested in the properties of the compounds themselves, and not in creating pharmaceuticals. But useful drugs had, in the past, been discovered in all sorts of unlikely places.

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[10] Look at Section 1-C to verify this statement. This and following paragraphs rely on a January 2005 phone interview with Norman Latker (Latker 2005).

[11] Get citation

As a result, it made sense for these compounds to be screened for any therapeutic potential. This was an activity beyond the interest or capability of the academic scientists who created the compounds. Instead, drug companies had traditionally screened the compounds in exchange for the right to develop any that seemed useful.

There is a large gap between a chemical compound of conceivable medical interest and a marketable drug. The first step in bridging that gap involves screening many different potentially useful compounds for pharmaceutical activity, only a handful of which will actually show promise. This step involves only moderate expense. The really costly part of the process is the final step, putting a developed drug through the extensive FDA testing required before making it publicly available.

In 1962, NIH had changed its patent policy so that pharmaceutical companies no longer felt sure they would be able to maintain patent rights to any drugs they might develop as a result of screening these compounds. As a result, they stopped screening them. They didn't want to invest a great deal of money in the development process if they had no means of knowing whether they would be able to sell the final product.[12] Although screening services could have been purchased elsewhere, they weren't—such activity was outside the purview of the chemists creating the compounds, and NIH wasn't doing it either.

This meant that all these promising compounds were never being screened, despite the relatively low cost of such testing. Useful research was never being taken advantage of and, presumably, useful drugs were never being developed.

Conceivably, government could have stepped in and begun screening compounds. But even if it had done so, there was still another barrier. NIH made no provisions for exclusive licenses to government-held patents. A pharmaceutical firm would require an exclusive license in order to have an incentive to pursue the still-large cost of development; otherwise, it would have no way to recoup its investment. Thus the process of transforming the chemical compounds resulting from basic research into actual drugs was effectively halted (General Accounting Office 1968).

These were the basic conclusions of the GAO report. They were in keeping with the observations Latker had made from his position within NIH, though they were based on more formal study than he had undertaken. The GAO recommended that NIH adopt a much more liberal policy of waiving title to patents so that pharmaceutical companies would once again have an incentive to screen such compounds.

The second 1968 study was commissioned by the FCST's Committee on Government Patent Policy. In September 1966 one of the first actions it took was to ask Harbridge House, an independent consulting group, to study the effects of government patent policy. The ensuing four-volume report examined three major questions about government patent policy: whether it was effectively encouraging the utilization of government-funded research, whether it was contributing to business monopolies, and whether it was causing some contractors to refuse to work with the government.

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[12] Is this too strong? Were they still guaranteed a license and it was just that they weren't guaranteed an exclusive license?

The report was able to answer the second question fairly simply: government patent policy seemed to have no effect on business monopoly one way or the other. The answers to the other two questions were more nuanced. It appeared that patents were not being utilized as often when government held title as when it waived title. However, situations differed greatly from industry to industry and even company to company, depending on how important patents were to a particular industry and on firms' experience making use of them.[13]

The third question, whether existing patent policy was causing some contractors to refuse to work with the government, arose from several specific programs that were reported to be having such problems. One of these was NIH's medicinal chemistry program. Harbridge House also did a detailed case study of the medicinal chemistry program, and its resulting analysis took up about a fourth of the total study, despite the program representing under $10 million of annual funding.[14] Its findings were similar to the GAO's, as were its recommendations: that the NIH change its patent policy (Harbridge House 1968).

Studies have a way of causing a good deal of talk and little actual change, and the Harbridge House and GAO reports did not transform government patent policy. But they did have some effect, particularly on NIH. With the additional pressure from outside the agency, the tide was turning in Latker's favor, and there was now less opposition to a more liberal patent policy.

Latker used this shift to create a mechanism to simplify the process of waiving title to patents. At the time, if a university or a scientist wanted to pursue a patent on an invention, the university had to go to NIH and request that the government waive title to that specific invention. The process was bureaucratic and administratively complicated, and pursuing a waiver required the scientist and the university to spend a lot of time and effort. Universities who found themselves applying for such waivers on a regular basis were undergoing the elaborate waiver process repeatedly.

In the 1950s, a mechanism called institutional patent agreements (IPAs) had been created to simplify this process. NIH would create an agreement with a particular institution to waive title on all NIH-sponsored inventions that met certain conditions. Then that institution could avoid the elaborate process of applying for waivers for specific inventions.

The 1950s IPAs had not been designed very well, however, and they had fallen into disuse. Latker now resurrected the idea, creating a new institutional patent agreement that actually did simplify the waiver process and, in 1968(?), set up such agreements with a number of universities with active patent programs, including Wisconsin, (more examples here). As a result, patent waivers at NIH showed a small spike. Over the next few years, as more IPAs were established and as opposition to patent waivers decreased within HEW, Latker's goal of making it easier for inventors to get patents became actual NIH policy. Latker was hopeful that other federal agencies might emulate the IPAs and that this liberalization of government patent policy would spread.

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[13] This is a description from memory; double-check against the report?

[14] Check that dollar amount is accurate

During this time Congress had not completely forgotten about patent policy either. While it was not a major issue—1967 Senate hearings on technology transfer, for instance, made little mention of the role of patents (U.S. Congress 1967)—several bills were introduced that purported to reform government patent policy, and hearings had been held. One bill, sponsored by Senator McClellan, tried to legislate the "flexible" policy of the Kennedy memorandum. Senator Long of Louisiana, was a longstanding defender of the government-title position on the grounds that what the public pays for (i.e., research), the public should own, and he quickly sponsored an opposing bill. Neither bill reached the floor, but Senator Long also made several attempts to attach riders to appropriations bills to accomplish his legislative agenda. Hearings on government patent policy were held during this period by the Senate Select Committee on Small Business in 1963, and the Senate Judiciary Subcommittee on Patents, Trademarks and Copyrights in 1965. But no legislation resulted from any of this.[15]

1970-1976

Events:

1971 President Nixon publishes a new *Memorandum and Statement of Government Patent Policy* intended to give federal agencies somewhat more flexibility in patent administration

Public Citizen, Inc. files suit against the government on the grounds that this is "an unconstitutional disposition of property"

1972 The Commission on Government Procurement publishes a report recommending changes in patent policy

1973 NSF begins using Institutional Patent Agreements

1974 University patent administrators hold a first conference at Case Western Reserve University

By 1970, a somewhat stable situation had been reached. The changes provoked by the Kennedy memorandum were not enormous, but some had occurred. The biggest change was made at NIH: institutional patent agreements had been established with a number of universities and title to patents was being waived to grantees on a regular basis. Most of the other agencies were implementing patent policy in more or less whatever way they had done in the past.

Another change that came out of the Kennedy memorandum was less concrete: the Committee on Government Patent Policy's efforts to study actual data on government patents, including the Harbridge House report, had shifted the conversation about appropriate government patent policy. Evidence was beginning to accumulate that policy based on the dominant and outwardly logical belief that what the government pays for, it should own, was not, in fact, working very well. This shift in public discourse would become clearer in during the coming decade, but it had begun by 1970.

In 1971, the Nixon administration, reacting in part to the recommendations of the FCST's Committee on Government Patent Policy and the Harbridge House report, published a new *Memorandum and Statement of Government Patent Policy*. The Nixon memorandum did not actually differ greatly from the Kennedy memorandum, but it tried to allow the agencies yet a

[15] I need much better info on this—dates, other bills, info on the riders, any other hearings (and their contents)…look at Lexis-Nexus for more details.

little more flexibility on their patent policies.[16] This had one immediate effect: it prompted a lawsuit from Ralph Nader's Public Citizen, joined by eleven members of Congress, to sue the government on the grounds that this was "an unconstitutional disposition of property" (Latker 1977a, p. 2).

By this time, after several difficult years, Norm Latker was having an easier time of things at NIH. The agency had acquiesced to Institutional Patent Agreements after the GAO and Harbridge House reports, and some administrative changes had removed the strongest opposition to waiving title to patents upon the request of inventors. By 1969 Latker had even managed, with help from allies in HEW, to change the department's regulations to permit, on a case-by-case basis, exclusive licensing of its patents. The possibility of an exclusive license meant, for example, that a pharmaceutical company conceivably might have been willing to develop one of those promising chemical compounds even if the government held title to the patent on it. No other agency in the entire government was allowing exclusive licenses at this time.

By 1970 Latker was fairly satisfied with the state of patent administration at HEW. With his energies no longer devoted to political battles within the department, he began to turn more of his attention toward interagency work. The FCST's Committee on Government Patent Policy had a number of subcommittees, and Latker had been chair of the University Patent Policy Ad Hoc Subcommittee since January 1969, and was a member of the Committee on Government Patent Policy as well (Federal Council 1968, p. 26).[17] The dominant view within these committees at the time was that while there might be some flexibility from case to case and agency to agency, in general the government should maintain title to inventions created with taxpayers' money.

Latker, on the other hand, was convinced that the policy should be the reverse: that while there might be specific instances in which it which it would be appropriate for government to hold title to a patent, in the vast majority of cases the inventor (or the institution the inventor worked for) should maintain control of his or her invention. In his view, the medicinal chemistry case was just the tip of the iceberg. Allowing inventors to maintain control of their inventions would result in better use of government-funded research in many different scientific fields and agencies. Latker believed that invention was at the foundation of what made the United States great, and that inventors should be rewarded, both because they deserved to be and because rewarding inventors was what was best for the nation.

Furthermore, he knew that most inventors are passionate about their inventions. A committed inventor both understood his or her invention better than anyone else and was more devoted to getting it into use than anyone else. Because of this personal investment in the invention, keeping control with the inventor was much more likely to result in the invention's development than moving control to a government official with no similar knowledge or personal motivation to see the invention adopted. Latker now devoted his considerable energies to developing support for his position within the FCST and elsewhere.

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[16] This section is sketchy—I need to check what the Nixon memorandum said.

[17] When was he on the Patent Committee?

The publication of the Nixon memorandum also prompted new activity in the legislative branch. Congress was evaluating government procurement policy at the time, and had created a Commission on Government Procurement to create recommendations. One of the areas the Commission was tasked with studying was the disposition of patent rights. Latker served here as well, on the Commission's Task Force on Disposition of Invention Rights. The Commission's final four-volume report contained a significant section on government patent policy, and, once again, the conclusions were that policy should move in the direction, at least, of government taking title to patents less frequently. Again, the study itself had limited direct impact, but it was one more piece of evidence in the pile Latker was accumulating. Another result of Latker's work with the Commission on Government Procurement was that he met Jesse Lasken, a young attorney employed by the Task Force. In the decade to come, Latker would grow to rely on Lasken's support and drafting skills as Latker pursued patent policy reform.

When IPAs were successfully adopted at NIH, Latker initially hoped that this example would encourage other agencies to follow suit. He was disappointed that, by and large, this did not happen. Jesse Lasken, however, had moved from the Commission on Government Procurement to a position in the General Counsel's office at NSF, where he was responsible for reviewing patent rights. He also began working on the FCST subcommittees as a representative for NSF, and he became a strong ally of Latker there.

NSF, like NIH had been ten years earlier, was examining requests for patent waivers one at a time in the early 1970s. One of the things Lasken was hired to do was streamline the process. He was familiar with NIH's IPAs, as were the university patent administrators who came to him with waiver requests. In 1973, Lasken created Institutional Patent Agreements at NSF, modeled on those of NIH with some minor modifications, and signed them with a number of universities.[18]

But no other agency seemed interested in adopting IPAs. (The Navy had a similar mechanism—a list of institutions to which it would routinely waive title upon request—but never actually created IPAs.) This was not just because of philosophical differences among the funding agencies. For one thing, some were operating under statutes that allowed less leeway in disposition of patent rights. Bureaucratic inertia also played a big part. In addition, some of the funding agencies employed a large number of patent attorneys who might be out of a job if the status quo changed too much.

So Latker, with Lasken's help, began to work within the FCST to create regulations that would permit IPAs across all agencies. This process took several years—roughly from the period 1972 to 1976—but eventually the Committee on Government Patent Policy signed off on them and they were published for public comment.[19]

Ralph Nader's Public Citizen had, during these years, made its disapproval of the move toward waiving government patent rights known. When it was just NIH creating Institutional Patent Agreements, Public Citizen didn't take action, but when IPAs threatened to become a standard across all agencies, the organization, in conjunction with eleven members of Congress, filed suit

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[18] Correct date?

[19] Need more detail here; also don't know where Ancker-Johnson and Eden fit into the story.

against the GAO for lacking statutory authority to issue such regulations. The suit was dismissed for lack of standing, but it brought the patent issue to greater attention once again, and made it clearer that it would require legislative action for government to be systematically more generous with disposition of invention rights.[20]

NIH, of course, funded mostly basic research. Because of this, their money went primarily to universities and other nonprofit research organizations (e.g. hospitals). It was these institutions that were participating in IPAs, not corporations.[21] The situation was similar at NSF. So the interest in moving away from a government-title patent policy was coming from the two science agencies that funded universities, not from the agencies that spent most of their funds on R&D contracts with industry.

Interest in patenting at universities had very, very gradually begun to increase, in the late 1960s and early 1970s. There were several forces pushing incrementally in this direction. For one thing, as the scale of research increased dramatically during the 1950s and 60s, there were simply more inventions being made which conceivably might be patented. The exponential growth in funding in the biological sciences by NIH was particularly relevant here. For another, universities were undergoing a financial crisis around 1970—federal science funding had actually dropped in real terms for the first time ever, and potential new sources of money held more interest than they might have in the flush years. Finally, a few individuals who believed universities should be more active in patenting and licensing showed what could be done. For example, Niels Reimers founded Stanford's Office of Technology Licensing in 1968, after seeing that the university's contract with Research Corporation had earned it less than $5,000 in the last ten years. In its first year, the OTL earned $50,000, and revenues increased rapidly for the next several years (Reimers 1995). Other universities paid attention to such examples.

A pivotal event, however, happened in 1974. While a group of five or so universities (Wisconsin, California, Purdue, MIT, and Iowa State[22]) had gotten together informally every other year or so to discuss patent issues during the 1960s and early 1970s, no formal meeting on the topic had ever been held. In October 1974, though, Allen Moore, Director of Research Administration at Case Western Reserve University, organized a conference on technology transfer and universities that drew representatives from over fifty universities, as well as from Research Corporation and other patent-administering organizations. Norm Latker also attended, along with other government officials including Betsy Ancker-Johnson, the Assistant Secretary of Commerce for Science and Technology (*Technology Transfer* 1974).

This three-day "National Conference on the Management of University Technology Resources" was well-attended, and its participants found lots to talk about. Many of them shared frustration about the enormously complicated process of securing title waivers from the government for federally funded research, even with the advent of IPAs. In fact, after hours at the conference some attendees decided that they needed to form an ongoing organization to share information

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[20] I'm confused on dates here—did Public Citizen sue twice?
[21] Any corporations with IPAs?
[22] Check list against Bremer tape.

about the university patenting process. The organization was called the Society of University Patent Administrators (SUPA), and it would later prove to be an effective lobbying group.[23]

The meeting also introduced Norm Latker to Betsy Ancker-Johnson, who had only been in Washington for a year. Ancker-Johnson, a university scientist and inventor, was aware from her own experience of the problems inherent in government patent policy, and she became another important ally of Latker in his efforts to change that policy. Her appointed position gave her a seat on the Federal Council for Science and Technology's Executive Committee, as well as *ex officio* positions on the Committee on Government Patent Policy and its subcommittees.[24]

Norm Latker had already worked with many of the university patent administrators who attended the conference, as patent counsel for NIH, the largest funder of university research. He had set up IPAs with a number of them and tried to facilitate individual patent waivers with others. Because of his position, he was particularly attuned to patent policy as it affected the academic community. He was able to draw on that knowledge and those relationships as he stepped up his interagency work. In 1969 he became chair of the Federal Council's Ad Hoc Subcommittee on University Patent Policy.[25]

The Case Western conference was not the only group Latker was working to sign on to the program of patent policy reform. In fact, he traveled to speak at a number of conferences in the 1970s, sometimes at his own expense, in an effort to convince people of the importance of the issue—not only university administrators and groups interested in university-industry relations, but also pharmaceutical industry and patent law groups (Latker 1973, 1974, 1975, 1977a, 1977b).

The approach was two-pronged at this point. On the one hand, Latker was working within the FCST to create uniform governmental regulations that would simplify patent policy and extend IPAs to the extent possible, given that the patent policies of a number of federal agencies was governed by law. On the other, after the Public Citizen lawsuit it became increasingly clear that permanently changing the situation was going to require legislative action. This is where alliances with political appointees like Betsy Ancker-Johnson and her administrative aide Dave Eden became helpful. But Congress was not actively pursuing the issue of patent policy at this time and it did not return to the legislative agenda until 1977.

1976-1980

Events:

1977 Rep. Thornton introduces a patent policy reform bill that looks much like the FCST legislative recommendations

1978 The Senate Subcommittee on Monopoly and Anticompetitive Activities holds two sets of hearings on *Government Patent Policies*

Senators Bayh and Dole introduce their bill

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[23] Citation?

[24] Need more on Ancker-Johnson's role

[25] It later became a regular subcommittee. Jesse Lasken was a member of this committee as well, I think.

By 1976 the Patent Committee of FCST had both created a new set of regulations that simplified the patenting process to the extent possible and drafted a bill that would have unified patent policy across all agencies, by giving patent title to grantees and contractors while reserving a royalty-free license for government. (Unlike the eventual Bayh-Dole Act, this draft bill would have applied to large corporations as well as small businesses, nonprofits and universities.)[26]

In April 1977 Representative Ray Thornton, D-AR, who did not have close ties to the FCST, introduced a bill that was substantively similar to the one FCST had written. Thornton's bill died in committee, but it was the first effort in several years to seriously change the laws governing patent policy. The implementation of the new FCST regulations, though, concerned those who believed them to be essentially a government giveaway. One of these was Senator Gaylord Nelson, D-WI, who chaired the Senate Subcommittee on Monopoly and Anticompetitive Activities. The following year Senator Nelson convened hearings on the issue, inviting mostly speakers who were against the revised regulations, including Ralph Nader and the Attorney General, whose office had historically opposed giving title to grantees and contractors on anti-monopoly grounds (U.S. Congress 1978a).

By this time patenting was definitely on the rise at universities. In 1977 the number of patents issued to universities was about 350, up from under 100 in 1969 (Mowery and Sampat 2001, p. 798). Universities, under the guise of SUPA, were becoming better-organized around the issue. SUPA was formed as a means for university patent administrators to share their experiences and knowledge, but it quickly became a vehicle for lobbying as well. When Senator Nelson held these hearings, the various IPA holders, now in more regular communication with one another, began to bombard him. Perhaps in part because the president of SUPA (Howard Bremer, patent counsel for WARF) was Nelson's constituent, he eventually set up a follow-up hearing and invited the supporters of the regulations. Here Latker testified, along with Jesse Lasken, and Donald Fredrickson, Director of NIH. Representatives of universities also testified in favor of the changes: Thomas Jones, the Vice President of Research at MIT, testified, as did Howard Bremer (U.S. Congress 1978b).

The second set of hearings did the job: Nelson dropped his opposition to the changes in patent policy. In fact, he eventually became a co-sponsor of Bayh-Dole. But the event further convinced Latker, at least, that regulations would not be enough to change patent policy—that legislation would be necessary for lasting change.

About that same time, a conflict began to arise at HEW that helped bring the whole issue to a head. By the mid-1970s, the waiver process within NIH and HEW was more or less routinized. But in 1976 the Carter administration came in, and with it came new HEW Secretary Joseph Califano.

It began with a seemingly minor issue. A small business contractor with NIH invented a new kind of CAT scanner and petitioned for rights. Because the contractor was a for-profit company rather than one of the universities or nonprofits NIH most commonly funded, the agency gave public notice of the petition rather than giving its customary waiver of title.

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[26] Where does the compromise bill that Lasken talked about fit into here?

As a result of the public notice, seven large firms requested non-exclusive licenses. A group within the agency met to review the requests, and Latker argued in favor of giving title to the small business inventor, on the grounds that there was no guarantee any of the firms pursuing licenses would actually pursue development. The small business inventors, the argument went, would only have a motive to request rights to the invention if they intended to develop it. The large businesses requesting licenses, though, *might* actually be interested in developing it, but they also might just be applying for licenses to eliminate any incentive for the small business to develop the invention—thus protecting their existing products which the new invention would supersede. If they held licenses, they could simply knock off their own versions of the CAT scanner once the small business had invested its money in moving the invention through the development process. The point was not that the small business needed protection, but that the invention needed to be developed, and that granting additional licenses might mean that nobody would develop it.

The agency group was convinced by Latker's argument, and the Surgeon General signed off on the small business's petition. The businesses who had requested licenses, however, were not pleased. At least one of them sent a representative to Califano, who unilaterally reversed the decision, despite the Surgeon General's regulatory authority to have the final say on disposition of inventions.

This issue triggered a review of department patent policy by Califano. The status quo was that Latker reviewed waiver requests and IPAs. If he approved them, he sent them to the Surgeon General to sign off on, which the Surgeon General routinely did. Califano now created a final step in the process whereby the Surgeon General's office would then send them on to someone in the General Counsel's office for final approval.

Now Latker continued to approve waivers and IPAs as usual, and sent them off to the Surgeon General who signed off on them as usual. But when they reached the General Counsel's office, nothing happened. They were neither approved or rejected; they just sat on the desk, going nowhere.

After a few months people started to become aware that the waiver process in the Department had essentially shut down. Change began through two different channels. First, Barry Leshowitz, a staffer in Senator Bob Dole's (R-KS) office, contacted Latker and asked what was going on. Leshowitz no longer remembers how he first heard what was happening, but he had a personal interest in patent policy as an inventor. A professor of psychology at the University of Arizona who had worked on hearing aids, he knew from colleagues a little about the difficulty of pursuing development of government-funded inventions. So he was a natural supporter of Latker (Leshowitz 2005).

At the same time, Ralph Davis, the technology transfer manager at Purdue University and an active member of SUPA, contacted one of his Senators, Birch Bayh (D-IN), and explained that Purdue's inventions were getting stuck in this bureaucratic tar pit at NIH. Bayh was particularly sympathetic to the need for potential pharmaceuticals to be developed quickly because of a personal tragedy—his wife was then dying of breast cancer.

Senator Dole came out publicly excoriating HEW for "stonewalling" patent applications (Broad 1978). The offices of the two Senators began to strategize about a bill along the lines of the FCST recommendations and the Thornton bill that had never gone anywhere. It was decided that a bill that gave rights to inventions across the board—that is, to industry as well as universities and nonprofits—would never succeed, and in fact Bayh was not willing to support such a bill. But Jesse Lasken of NSF suggested they might be able to bring in the small business community. He knew NSF had a small program giving research funding to small business. If small businesses could not maintain rights to inventions made through this program, however, the inventions made through such a program would die right there. So small business had a motive to support such a bill, and some members of Congress might be willing to support giving rights to small businesses even if they saw giving the same rights to big businesses as a government giveaway.

The university community, especially under the guise of SUPA, was of course already supportive of such a bill, and had only grown more so as NIH's generous policy with waivers was being reversed by Califano. At a dinner Lasken and Latker brought together Eric Schellin, patent attorney for the National Small Business Association, and Shelly Steinbach, general counsel for the American Council on Education. Both signed on in support of such a bill and Milt Stewart, head of the Small Business Administration's Small Business Innovation Research Program (SBIR) soon added his considerable clout. With the support of education and small business, a powerful coalition was building (Lasken 2005).

Senators Bayh and Dole, through staffers Joe Allen and Barry Leshowitz, were working out the details of the bill, much of which was drafted by Lasken. The coalition was trying to get the support of members of the Senate Judiciary Committee. An attempt by representatives of MIT to get the support of chair Ted Kennedy (D-MA) was unsuccessful, although Kennedy ultimately became a cosponsor of the bill as well (Stevens 2004; Lasken 2005).[27]

Latker, in the meanwhile, was beginning to hear rumblings within HEW that his position might be in jeopardy if he continued his work with people on the Hill. Eventually, he was fired for his efforts. He appealed the decision, and with the support of Senator Dole and the help of some publicity about his being fired as a whistleblower—as well as his status as a public servant rather than a political appointee—was reinstated several months later (Broad 1979a, 1979b). But the experience was personally very trying for him and he left for a position in the Commerce Department soon after.[28]

In late 1978 Bayh and Dole introduced the bill to the Senate. Unlike previous attempts to move toward a government-license policy, this one did not elicit the same degree of immediate opposition. In part, the political and economic climate had changed. The U.S. economy was in a dismal state, and worries about the ability to compete technologically with Japan were high. This mood—in conjunction with the decision to limit the bill to universities, nonprofits and small business—made the bill seem less like a government giveaway and more like part of the answer to the problem of U.S. technological competitiveness. But the slow work of Latker and others to educate different constituencies about the complexities of patent policy had also made a

[27] Double-check.
[28] Correct?

difference. For the first time, there was no immediate effort to shoot down a bill taking a government-license approach.

At the same time, though, another bill was still in the works. This bill, supported by the Carter administration, took the approach that patent policy should look different from agency to agency—that some agencies should have title policies and other license policies. This compromise position was introduced by Rep. Robert Kastenmeier (D-WI), and until the very end it was not clear which bill would succeed. Ultimately a deal was cut in which Kastenmeier, in part under pressure from Bremer, agreed to replace the text of his bill with the text of Bayh-Dole. As a resulting fluke, the official legislative history of the Bayh-Dole Act reflects the failed Kastenmeier bill rather than the Act as it was passed.

Senator Russell Long, D-LA, who had been opposing such legislation on populist grounds for two decades, was also neutralized through Senatorial courtesy, though he still personally opposed the legislation on principle. The bill was not approaching a final vote until the end of 1979, in a lame-duck session of Congress. Senator Bayh, after a long and distinguished Congressional career, was unexpectedly unseated by a young Dan Quayle. Senator Long agreed to set aside his opposition out of respect for Senator Bayh. The resulting bill was finally passed the Senate by unanimous consent in the last days of the 96th Congress. It also narrowly avoided a pocket veto by President Carter. The Act was signed into law on January 20th, 1980, the culmination of almost two decades of hard work on the part of Latker and his allies (Stevens 2004).

This did not end the effort to change government patent policy. Latker spent the next several years in his Commerce Department position working on the regulations implementing the bill, which he saw as being extremely important to its implementation. The Federal Technology Transfer Act of 1986 further extended its principles. But the 1980 passage of the Bayh-Dole Act was a significant turning point which made, for the first time, the default assumption of government policy that the public would be best served if inventions were kept by the inventor and not by the government.

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3. Group created by mc.
4. Story about the elimination of government barriers to development and marketing of invention
5. Building grass root support at management level.

1. Act of revolution ~~any~~ against their existing government policies.

~~2. Need to organize~~ Congress and the executive
2. Alerted public to the problems created by the existing policies (G.A.O.) report, Commission on Gov't contracts, ~~etc.~~ University sub com. of Fecset.

3. Organized resistance to existing ~~policie~~ through IPA's while eliminating gov't barriers to development and marketing invention.
4. Initiated corrective legislation
5. Changed the direction of basic research forever

6. Created Biotech industry
7. Enlarged collaborative efforts