The IPA and Wisconsin's 1969 Patent Policy

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Published at Research Enterprise May 15-28, 2017

The 1969 Wisconsin Patent Policy

Tucked into Congressional testimony in 1978 on expanding the Institutional Patent Agreement program is the 1969 University of Wisconsin patent policy. This policy is notable for a number of reasons. First, because it is an actual policy statement on patents, where for a long time Wisconsin refrained from having a formal patent policy. If the university had no interest in the patents of its personnel, why should it have a policy about it? After all, the university has no ownership interest in the cars or houses of its personnel, and has no need of a formal policy to disclaim that interest, or to try to find strangely curious situations in which it might end up with an ownership interest anyway. So why patents?

The 1969 Wisconsin patent policy is interesting for a second reason. The Wisconsin Alumni Research Foundation's Howard Bremer was one of the primary players behind the efforts to make the IPA program government-wide. That effort failed but in its place came an even rougher beast called Bayh-Dole. In 1968, Norman Latker at the NIH had revived the IPA program, following on the Harbridge House report regarding federal government patenting activity and policies. The next year, in 1969, Wisconsin's new patent policy includes an account of how the IPA program affects university researchers and inventors.

The new patent policy opens with a typical preamble--creativity is important, inventions happen. The university asserts a say in how inventions are managed:

> In an institution such as the University of Wisconsin, where creativity is a major ingredient of research, new products, devices, processes and compositions are often found. It is our purpose here to state for University faculty and staff what their responsibilities, privileges and options are when they have made an invention or discovery.

The policy repeats the traditional Wisconsin expectation: inventors own all rights in their inventions unless there's a contract otherwise.

> **Historically, The University of Wisconsin has never claimed that it has proprietary rights in any invention generated at the University. In the absence of contractual provisions obligating the transfer of all or some proprietary rights in such an invention to a third party, the inventor at The University of Wisconsin has been free to dispose of his rights in the manner of his own choosing.**

It is the rise of extramural research contracts that creates a need to monitor inventions, which may be deliverables in these contracts. And more particularly, it is the rise of extramural research contracts with the university itself rather than with faculty personally that creates the need for institutional intervention--when the university handles the contract and the money, the university rather than the faculty investigator becomes responsible for compliance.

The presence of a contract for research rather than a donation agreement is also worth noting. If research support comes in the way of a donation, then there are no deliverables to the sponsor, though there might be conditions on the use of the donation (and that might include a requirement, say, to make any inventions freely available--essentially, forbidding any inventor using the donated funds to claim a personal ownership interest in any invention and as well forbidding the university to claim such an interest). Something about contracting with research sponsors leads toward the idea of delivery of invention rights--whether title or a license--as if research sponsorship is a form of procurement.

But federal contracting has created problems, or so the policy asserts. Some federal agencies require assignment of patent rights while others require only a non-exclusive license. Such requirements are entirely consistent with research agreements from all sources, not just federal agencies. Some sponsors--companies, foundations, state governments--require assignment of inventions and others ask only for a non-exclusive license and some don't care at all. This is the usual situation. That some federal agencies vary in just this same way is entirely without interest for research management, except for one thing--because federal agencies are all parts of the federal government, it is easier to mix funding from different agencies through informal collaboration or even joint funding. If different agencies have put different invention management requirements in their funding, then there may be conflicting requirements. In one agreement, inventors might own inventions outright; in another, the government asserts a royalty-free license; in yet another, the government requires assignment of all inventions.

Even here, however, there's not really a problem. If the government asserts in one funding agreement assignment of title, then that requirement spreads to all other federal work that's mixed in with that obligation. There's typically no requirement from the federal government that money from one agency must be mixed with money from another agency, so whatever mixing happens as a choice by university researchers and administrators. The fund mixing problems become more intense if federal money is mixed with industry or foundation money, if the

sponsors have incompatible requirements. For instance, if a company sponsor expects a non-exclusive license and the federal agency sponsor demands assignment, then the university is caught in a double license (not really, at the time, since the government's default was to grant non-exclusive licenses, so the company would be fine in this case, but the contracting wouldn't show that). Or worse, the company expects assignment and the federal government wants a non-exclusive license (or assignment). That condition is not so readily navigated.

But this sort of problem goes on all the time in extramural university research anyway--for instance when two companies support research at a university. Sure, the research might be different laboratories, but people at universities talk to each other, wander into and out of labs, drink coffee together. Such interactions are one of the strengths of university research, that folks aren't working in enforced silos. Thus, mixing of funding with conflicting requirements must be managed, whether for inventions or for mileage reimbursements.

There are various measures administrators might take. They can refuse to accept research terms that require assignment of inventions. They can make any invention obligations conditional on no mixing of funding (and so they might require "you will get assignment of any inventions, subject to the rights of the federal government in those inventions, which may mean you get nothing at all, but you don't have any control over it, so play nice and hope we don't mix funds to screw you out of whatever you hoped to get"). Well, they would use more abstract lawyerly language, but with roughly this meaning. One practice, if used consistently, mitigates mixing requirements--and that is to allow only a non-exclusive license to inventions upfront in a funding agreement. Non-exclusive commitments are generally compatible with each other and are compatible with funding that carries no obligations (such as donations), as long as the non-exclusive commitment does not involve a "first right" to a non-exclusive license.

If one isn't shaping the funding agreement to avoid mixing conflicts, then one has to shape research practice. Funding agreements that require assignment have to be isolated from other research work that carries conflicting obligations. One simply cannot mix--not formally, as in sharing personnel, laboratory space, supplies, and objectives--and not informally, as in having a chat over coffee about research problems and discoveries. One has to silo research that carries incompatible terms. That might mean requiring all personnel on the incompatible project to sign non-disclosure agreements, to secure the laboratory space, and allow access only to personnel employed under the grant--no volunteers, no students, no visitors loping through. Such things can be done--the government requires such practices for defense classified research. But many universities resist performing such work for the government, and when they do, they isolate the work in secure buildings.

Often, university administrators are not able to do either--they don't resist entirely research agreements that require assignment and they don't manage research practices with such assignment-based funding floating around the university. They rely, instead, on the thought that there are only a few of these assignment-required research agreements and so there's little likelihood that there will be mixed inventions. Such thinking might be true if there are only a few extramural research agreements a year, and even fewer reports of inventions. However, if extramural research overtakes donation and departmental research programs, and inventions become routinely reported, then this thinking turns into restless administrative sleep, and restless administrative sleep breeds the desire for formal policy to defend, at least, administrators from blame if something goes terribly wrong.

It's the decision to mix--or rather an administrative decision not to manage mixing--that creates the invention management problem. It is, in its way, another Pigpen problem created by administration but ascribed to those dratted non-uniform federal agencies who have not figured out that arbitrary is better than flexible.

The Wisconsin patent policy asserts that the "University," and not faculty investigators, is responsible for compliance with contract provisions--and thus also with contract provisions having to do with inventions:

> In every case, the University, as the recipient of the grant or contract, has the primary responsibility for complying with the agencies' contractual provisions. Consequently, it has become necessary for the University to scrutinize with care the funding which has assisted the making of the invention to be sure that all of the obligations attaching to the contract or grant have been met.

While this policy statement appears obvious, the statement is doing much more. The university could, for instance, delegate compliance for the invention portion of research agreements to investigators. That, in effect, is what Bayh-Dole's standard patent rights clause requires universities to do with its (f)(2) written agreement requirement. But the Wisconsin policy here insists that university administrators, not faculty investigators, must have the "primary responsibility" (and hence the primary authority) for determining how to manage inventions in order to comply with sponsor requirements. This is a subtle shift, you say. And it is. But to assert responsibility is to assert authority, and to have authority to decide whether a given invention is within or outside the requirements of a given sponsored research contract then can be used to decide whether inventors have an obligation to assign their inventions *to the university*.

Given that the long-standing Wisconsin patent policy is that inventors decide whether to assign their inventions to the university (or to WARF), this change in policy is huge, even if it is presented subtly.

Under Wisconsin research policy, investigators also negotiated the IP terms of their research agreements. That is, since the university did not have an interest in IP of its personnel, it also had no basis to dictate to its personnel what the IP terms of any research contract must be. The university did not assert that it must own all inventions, for instance. It might, perhaps, veto funding that carried conditions that ran against academic mores, such as precluding publication or preventing the participation by non-US nationals. Thus, in this bit of policy, the university asserts that it must comply with the IP requirements of research agreements, even if chosen and negotiated by university faculty investigators.

The challenge with federal funding agreements, however, is that they are not in general negotiable. The federal agency announces a funding program and with it announces the contracting requirements. Take it or leave it. But it's not actually that simple for inventions. There are two areas of flexibility. The first is that a funding agreement may reserve options for the federal agency--so, in the case of inventions, the agency may release its claims on an invention or might not. It's up to the federal agency what it will do. There's nothing particularly hard about such an option, other than if one really wants to do the patent work oneself, and a federal agency futzes around about whether to give up the government's option to own the invention and prevent it.

The second area of flexibility involves waiver of compliance requirements. Yes, there may be a non-negotiable clause in a federal funding agreement, but the federal agency does not necessarily have to enforce the provision, especially if the university doesn't require enforcement. Thus, a federal agency can simply ignore what it otherwise might require and let the university go off and do whatever it will, short perhaps of embarrassing the federal agency into action. If the university has an institutional conflict of interest with regard to the clause--enforced, the university does not get ownership of inventions, say, but unenforced, the university does--then the university's refusal to insist on federal compliance with clauses favoring the federal government ends up serving an institutional self-interest at the expense of the relationship inventors would otherwise have with the federal government.

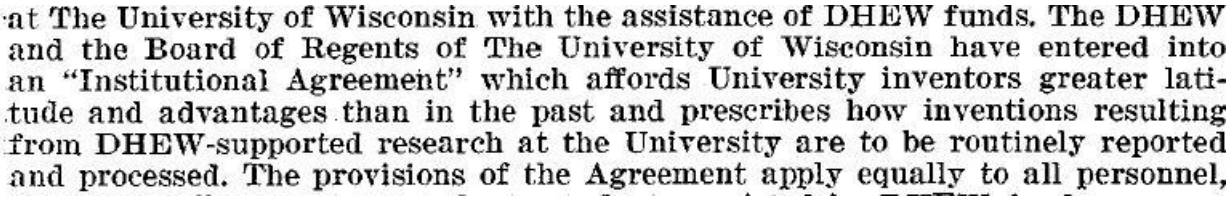
In that relationship with the federal government, inventors might be allowed to retain title to their inventions, might be allowed to publish their inventions openly without patents (and without having to assign patent rights to their university), and even if the federal government obtained assignment, the inventors could expect everyone, including themselves, to have access without charge to their inventions for private use and development. If the inventors were required to assign to their university, so that their inventions became grist in a "commercialization" program, then they may well not have access to their inventions, nor might anyone else if no one is willing to pay the price the university patent licensing operation asks for a license.

One can see how anyone with a love for an single, stone-set administrative process might chaff at the idea that there might be flexibility within a funding agreement. Administrators like the "terms" part of a sponsored research contract and don't care for the sponsor's "conditions" part. All those "In the event thats" pile up and cause restless administrative sleep that leads to more administrative policy. Thus, "uncertainty of title" became one of the mantras of university administrators who focused on the idea that patents were a way to make money for the university while selling the public on the idea that patents were a necessary precondition to beneficial products or any benefit from university research at all, really.

In the new 1969 Wisconsin patent policy, we encounter a corporate agent and the passive voice: "it has become necessary for *the University* to scrutinize with care the funding which has assisted the making of the invention to be sue that all the obligations attaching to the contract or grant *have been met*." The University, of course, cannot scrutinize anything. Someone has to act for the University to do the scrutinizing. Who should that be? Administrators? Faculty investigators? Patent brokers looking for more work? The policy doesn't out and say "administrators" but that's the clear implication, as will be made apparent in the policy soon enough.

The IPA in Wisconsin's Policy

The Wisconsin policy now turns to a discussion of the IPA program, announcing that the university now has an IPA master agreement with the Department of Health, Education and Welfare (HEW). Signing on to the IPA program, then, forms the reason for Wisconsin to have a patent policy. Why? Well, for one thing, the IPA program requires a review of a university's patent policies and practices before a university can be signed up. So Wisconsin rather has to have something to show, if it wants to participate in the IPA program.


at The University of Wisconsin with the assistance of DHEW funds. The DHEW and the Board of Regents of The University of Wisconsin have entered into an "Institutional Agreement" which affords University inventors greater latitude and advantages than in the past and prescribes how inventions resulting from DHEW-supported research at the University are to be routinely reported and processed. The provisions of the Agreement apply equally to all personnel,

This IPA appears to have been the first master agreement negotiated after Norman Latker revived the IPA program at the NIH. We will get to what the policy means when it describes the IPA program as giving inventors "greater latitude."

Inventions are to be "processed" rather than "claimed by the University and assigned to WARF for commercialization." In this context, "processed" is more abstract than what happens to, say, sausage meat. Bremer at WARF and Latker at the NIH negotiated an IPA deal that allows Wisconsin to require assignment of inventions from its inventors, and then assign the right to

receive assignment to WARF, where Bremer worked. Thus, the policy describes a pipeline of inventions made with federal funds going to WARF for management, via the university IPA. This is the first "modern" private pipeline of federally funded inventions to a patent broker. (There were other IPA agreements with nonprofits and universities in the 1950s, but the program had been suspended and no new institutions had been added for some time).

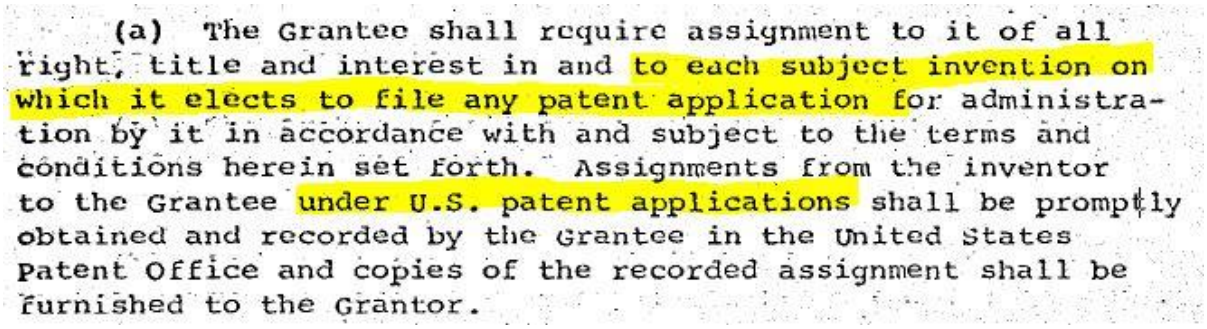
The Wisconsin IPA and patent policy statement are, essentially, ground zero for what will be claimed as a key feature of Bayh-Dole. The NIH IPA program would expand to some fifty organizations, add the NSF, attempt to expand government wide, get blocked, then get shut down by HEW, only to then arise again more powerful than one could possibly imagine as Bayh-Dole.

According to Wisconsin policy, under the IPA, an inventor has a choice--assign to the government or assign to WARF.

> Under the terms of the Agreement, all members of the University staff and faculty or graduate students whose work is supported wholly or partially by DHEW funds will execute a Patent Agreement (Form UW–P–1, Appendix A, pages 9–10). All such personnel whose inventions emanate from research under grants made by the DHEW may, after having complied with the University's established reporting procedure, choose either of two options:
>
> Option 1. He may submit the invention to WARF which will thoroughly examine the invention and will, when it considers such action is warranted in the public interest, accept assignment of the invention, prepare and file patent applications, and thereafter exercise its best judgment to bring the invention quickly and effectively into public use. In keeping with its traditional policies, WARF will pay the inventor annually 15% of the net royalties earned by his invention.
>
> Option 2. He may assign the invention to the Federal government to dispose of as it sees fit.
>
> Although the inventor may, if he chooses, recommend that the invention not be patented, and normally such recommendation will prevail, the final decision will be made by the government.

The policy here presents a faulty set of options--both because an inventor may not have to assign to the federal government and because the inventor ought not to have to choose only WARF, but for university administrators compelling that choice. The IPA does not require this set of choices--these choices are allowed "under the terms" of the IPA but are *not required* by the IPA. It is university administrators that have decided to designate WARF as the only invention management organization that inventors may work with. Inventors might have chosen instead Research Corporation--but the new Wisconsin patent policy precludes such options.

The IPA requires the university to require assignment for only those inventions that the university has chosen to file patent applications on:



(a) The Grantee shall require assignment to it of all right, title and interest in and to each subject invention on which it elects to file any patent application for administration by it in accordance with and subject to the terms and conditions herein set forth. Assignments from the inventor to the Grantee under U.S. patent applications shall be promptly obtained and recorded by the Grantee in the United States Patent Office and copies of the recorded assignment shall be furnished to the Grantor.

The Wisconsin policy navigates this requirement by indicating that the inventor "may submit" inventions to WARF for consideration. What's left out is the idea that an inventor might let WARF look at an invention, WARF might decide it wants it, but the inventor might decide that WARF's terms or its marketing ideas are all wrong and instead refuses to assign to WARF. That is, the policy makes it appear that inventors have no room to negotiate with WARF how they want WARF to deal with their inventions. It's a WARF-take-all policy.

In the IPA, the assignment that is expected is one directed to the actual patent application, in which the invention will be exactly specified. This is an important point. The IPA requires the university to make the commitment to file a patent application, prepare that application, and then obtain the inventor's assignment of rights "under" that patent application. The sequence is not "obtain assignment of invention" and then "futz around with whether to file a patent application." The IPA requirement is narrow and directed to a specific sequence. This sequence will be tossed when it shows up in Bayh-Dole. The Wisconsin restatement of the IPA makes it appear that inventors must assign before they know whether WARF will file a patent application. This will be the practice that gets instantiated in Bayh-Dole. It is details like this in which we can see the slippage from institutional compliance with regard to inventions in research agreements to institutional conflict of interest in seeking ownership before making any commitments.

There's more, of course. If the university's general policy is *not* to require assignment of inventions as a condition of employment or use of resources or involvement in research, then the university really cannot make the choice to file any patent application until an inventor has agreed to permit the university to do so. All the university can do under its policy is indicate to an inventor that it will file a patent application if the inventor assigns the invention to the university (or in this case to WARF). Thus, the inventor's *first* option is to deal with the federal government, as if there were no IPA. There is nothing in the IPA that requires the inventor to assign any invention *to the federal government*. The obligation to assign to the government shows up in (if it does) in the federal funding agreement (and that, in turn, may be a set of regulations that stipulate what the federal contract is). Under the terms of the Kennedy executive branch patent policy, the decision about inventor assignment was a matter of the funding agreement, and within that, the decision about whether to allow an inventor to publish, or to take assignment and

"dedicate" the invention or to file a patent application and license non-exclusively (and likely royalty free) is again a matter of agency discretion, depending on its regulations.

The Wisconsin policy makes it appear that the IPA requires inventors to assign to the government if they do not assign to WARF. But that's just not the case. But one might expect such misrepresentations if the university has a conflict of interest and wants to create a pipeline of inventions to WARF to be licensed for the university's profit. Or, given that it appears that Bremer was behind the drafting of the university's patent policy, it might be expected that WARF had an interest in routing all inventions made with federal support to WARF for management, and not allowing the government to take control, and certainly not allowing inventors to take their inventions (with government approval) to other invention management agents, such as Research Corporation.

According to the policy, if inventions go to WARF, then WARF will be a worker bee to "exercise its best judgment to bring the invention quickly and effectively into public use" and the inventor will get 15% of net royalties. Otherwise, the invention goes to the federal government, which apparently does nothing at all with it.

The Wisconsin patent policy, of course, omits that HEW is required by executive branch patent policy to act in the public interest with all such inventions, and that HEW standing policy is to release inventions by dedicating them to the public or licensing them non-exclusively:

> Government-owned patents shall be made available and the technological advances covered thereby brought into being in the shortest possible time through dedication or licensing and shall be listed in official government publications or otherwise.

The language regarding WARF is remarkably similar to the Kennedy executive branch policy. One might think that an inventor could willing choose government invention management--especially if the goal was broad public access and not a patent monopoly with an income teaser. It is also not made obvious by Wisconsin's policy that the IPA itself requires a default of non-exclusive licensing, perhaps royalty-free, and that exclusive licenses are only to be sought when non-exclusive licensing has failed or is not "feasible" and even then only for limited periods of time.

The effect of the IPA is to make it appear (to the federal government and the public, in the event that the public were at all interested) that WARF is carrying out HEW's obligations under executive branch patent policy, but doing things potentially better because WARF is closer to inventors, has greater capability to manage patents, and is more motivated (profit incentive, but profits to go to university research) to find licensees. But the IPA also contains a pathway (for patent brokers, university administrators, and willing inventors) by which patent monopolies can

be secured and licensed exclusively to companies. While the IPA does not highlight this pathway, patent brokers did and continue to do so, although the pathway now is established by Bayh-Dole, not the IPA program.

The IPA is drafted to create a substantial apparatus to hide this pathway, or to rationalize it, to make it appear "in the public interest." Thus, we find extra language about non-exclusively licensing and how that licensing approach might fail or not appear "feasible" and thus there might, infrequently, be the need for exclusive licensing, but with various protections such as justifications, limited terms, reasonable terms, and government intervention if things aren't working out to the government's satisfaction. But even all this apparatus is just bloat if the government doesn't follow through and enforce these requirements on exclusive licensing. And, apparently, the NIH never did get around to doing much enforcing at all.

Despite the IPA apparatus, the WARF agenda for the IPA was decidedly not to do with inventions what HEW was required to do, but rather to do the HEW one better. When the IPA program was reviewed a decade later, folks found that the universities had done almost all their licensing exclusively. There never would be a robust IPA program of non-exclusive licensing based on access to federally funded inventions, even though high-profile licensing programs involving inventions not made with federal funds had featured non-exclusive licensing, including WARF's own programs for irradiated milk (to end-run restrictions on milk additives--just zap the milk to create vitamin-D) and warfarin (rat poison becomes medical therapeutic).

Exploiting the IPA in Wisconsin Patent Practice

We now get to the Wisconsin rationale for disclosing all inventions:

> Disposition of all inventions generated at the University which are not covered by the Institutional Agreement will, as in the past, be subject to review by the Dean of the College in which the invention originated. Business Office of the University and the Central Administration to determine if any obligation exists in connection with and as the result of the funding of the research leading to the invention.

The "university"--administrators--review all invention reports for compliance with funding agreement obligations. It is easy to see how this requirement might now morph into a review for *university* interest in these inventions rather than contractual compliance with the requirements of research sponsors. By agreeing to the IPA program, university administrators have introduced institutional conflict of interest into their patent policy. Previously, the university had no interest in inventions. Compliance with research funding agreements was just a matter of compliance. The university had nothing in the game but compliance. But now with federal funding, the agreement negotiated by university administrators with the federal government requires the

university to make inventors assign their inventions to the university or to the university's designated patent broker, WARF--whenever WARF decides that a subject invention is worth patenting.

Under the IPA, WARF decides what is worth patenting; WARF decides to patent; WARF can compel Wisconsin inventors to assign their inventions. The IPA does not require WARF to decide what to patent, or when. But the IPA creates the obligation for inventors to assign whenever WARF, as Wisconsin's "designee," wants a patent. In essence, Wisconsin administrators change the patent practice without appearing to change patent policy. They make it appear that the federal agreement--the IPA--requires the change. But it doesn't. Under the IPA, Wisconsin could still have left the decision whether to patent to inventors, in which case, if the inventors wanted "certainty of title," they would select an invention management agent, Wisconsin administrators would designate that agent, and the inventors would assign title to that agent, in exchange for whatever services and financial considerations offered by that agent, along with the obligations specified in the IPA. If inventors did not want to assign to an agent, but still wanted to deal in with a patent, then they would have to work it out with the federal government.

In effect, the IPA encourages inventors to use an invention management agent--either the university or one or more agents designated by the university. This, even, might sound good. But there's one more thing: the IPA makes it more difficult for an inventor to deal directly with companies. If an inventor wants to license to one or more companies and not work through an agent that owns the patent, then it's up to the federal government whether to require assignment of the invention to the government or let the inventor manage the invention. Why? What's the rationale for pushing the assignment of inventions to management agents? Why could not an inventor simply hire an agent to do the work all without giving up ownership of the invention to the agent? There's a whole discussion there--but the key point is that there's no good reason why the federal government should create a contracting mechanism under which inventors must assign their inventions to private management agents, whether universities or their affiliated foundations, *whenever the private agent decides.*

There does not appear to be anything in Wisconsin university research or patent policy that gave the university the right to negotiate an IPA with the government--outside of any specific research proposal--that stipulates that the university must require inventors to assign inventions to the university. And in doing the deal, university administrators set up WARF as the favored external agent to do any patent work--all but ensuring that Research Corporation, say, would not get any work from Wisconsin inventors supported by federal funds.

Here, then, is how the slip to institutional conflict of interest works. In normal circumstances, the university's review of whether any given invention is within a sponsor's claims to a license or

assignment would be objective--is there documentary evidence that the invention was made with sponsor support? Is the invention among the specified deliverables of the grant? Did grant funds go to make or develop the invention?

The university has an interest in expanding the scope of the IPA claim on inventions made with federal support. Anything that appears within scope, the university gets if anyone in the university wants it (or anyone designated by the university wants it). If there were no IPA, then the university's "scrupulous" attention to compliance would be indifferent to the invention ownership outcome, but for the satisfaction of each research sponsor that it obtained the deliverables that it had bargained for. But with the IPA, the university now reviewed inventions for its own deliverables--or deliverables via WARF's efforts to transform patents into money. This, then, is the second ground zero represented by the Wisconsin policy--using federal funding as the premise to review inventions for the host institution's own ownership and financial interest. Wisconsin is not the first university to claim some interest in faculty inventions--it was actually among the last to do so. But it was the first--as far as I can tell--to connect its ownership claim to federally sponsored research. And it used the first IPA in the revived NIH program to do that.

The review for ownership, according to Wisconsin policy, involves both the dean ("relation of the reported discovery or invention to the purpose of any grant or contract that may be involved") and the business office ("review of the financing of the scientific investigation leading to the discovery or invention"). Once these groups have completed their review, then the "Central Administration" will "determine if an obligation to a grantor does exist." This apparatus is all very strange for research contracts in general. A contract, well drafted, will make clear the scope of any deliverables, especially important ones in the form of patentable inventions. Such contracts do not require reviews by deans and business officers and senior university officials. Indeed, it is difficult to imagine deans and business officers and university vice presidents having much capability at all to review the technical details of an invention, its circumstances of development, the statement of work (one or more), and the contractual requirements of a funding agreement (one or more). This would appear to be work for a contracts attorney with a working knowledge of the technology involved in making the invention.

In most cases, a principal investigator will know immediately whether an invention or discovery is within scope of a well drafted research agreement--is this invention something that was proposed, as the solution to a problem, say, or that might arise as a result of an investigation? Did the research propose to build or demonstrate or test something new that might have utility for the grantor? Why would a principal investigator hold out on a sponsor of research? Would such "holding out" constitute research misconduct? If so, how could university administrators properly review the situation to ensure compliance if "holding out" on a sponsor meant that the

university might be in line for profits from patent licensing via an invention management agent? The review of inventions by deans and business officers only works if the university has no interest in the outcome but for compliance.

Of course, with federal funding, this entire calculus is switched around. If the government receives inventions to ensure that the patent system is used to make inventions (and rights to inventions) broadly available to all, then "holding out" on the government amounts to finding a way to prevent the government from making inventions broadly available (without charge, without playing favorites, without upsetting the competition for additional research and development funding). An inventor might "hold out" and claim an invention, then, against the interests of a federal agency because the inventor wants to use the patent system in some other way--to prevent all use, or to make money from any use, or--perhaps--to make the invention broadly available, but using some special method that's different than the government's methods and so does for the government more and faster and better than what the government hopes to accomplish using its methods.

The IPA then switches the calculus of this last --perhaps-- into the primary position. The government, so the IPA proposes, wants private invention management agents to step in and take assignment of inventions made with federal support from inventors and use the patent system better than might the federal government to do this --perhaps-- thing, to make inventions broadly available using special private methods better than the government's own methods. In this view, if an inventor "holds out," the inventor is now "holding out" against *the assumed better use of the patent system entrusted by the federal government by federal contract operating outside the actual funding agreement to private invention management agents.*

Seeking Private Risk Capital

A university administration adopting this rationale, then, argues that aggressively asserting an interest in patenting most anything is an expression of the university's commitment to assist the federal government in making inventions broadly available. The university's methods are better than the government's methods (and hence the continued repeating even now of the "28,000 government patents" nonsense and the unquestioned thought that Bayh-Dole has been wildly successful--these are the moralizing bedtime stories to help them to restful sleep despite their deeds). The university's financial interest is thus aligned with invention ownership. The patent system is to be used to "call forth risk capital" to develop federally supported inventions faster and better than could the government dedicating inventions to the public. The public, so this idea goes, will get a shinier, better invention faster and at lower cost, if private risk capital comes forward to do the work on the public's behalf. Once the new product has been made, then the

sources of the risk capital have an opportunity to recover their expenditures in the public interest, and make a "reasonable royalty" as an "incentive" to provide the risk capital in the first place.

There are two forms, then, of risk capital that come into play. The first form is that of "commercialization"--the activities by which an invention is turned into a product fit for use, with public benefits. Much attention has been paid to the costs of such efforts--almost any university-side discussion of inventions and patents involved a gesture to how much more it cost to develop products than to do the research that made inventions.

There are, of course, huge disconnects. It does not even take research to make inventions--inventions get made all sorts of ways, not only in sponsored research settings involving proposed projects. Epiphanies, accidents, messing around, designing, following goofball predictions, creating works of art or music. And inventions that get made do not have to first become commercial products in order to be widely used with public benefits. Many methods, for instance, merely have to become known to be available for practice by others.

Commercialization, if it ever needs to happen, need not happen first but might rather come later, after use is well established and new users prefer to have much of the work pre-done for them. And even if commercialization might happen in parallel with other uses (such as research uses, or custom uses internal to capable organizations--not offering anything for sale), there's nothing at all that requires that patents should be used to support this commercialization by blocking all other uses.

These disconnects, however, come into play. To induce private risk capital to develop inventions for public use and benefit, recover expenditures, and have a reasonable return, one might use the patent system to provide a degree of exclusivity--not against all research uses or even all DIY uses, but so that sources of risk capital can recover their investments when they do step forward when no one is willing or able to develop an invention in an open environment. Even then, their commitment is to bring something into existence for the public, recover a reasonable return, and then step away from the monopoly and allow "free competition and enterprise." That's the social theory, anyway. It's rather of the form that we would now call "social ventures"--efforts to create something of public value without the requirement that the effort should also maximize profits for the owners or shareholders of the venture. Other than the problems such an idea presents for the public investment corporation, it would appear that such social ventures, even with for-profit profiles, are entirely possible and not outlandish fiction.

Indeed, the idea that university-affiliated patent agents might do a better job than the federal government in just this thing is the fundamental premise of the IPA program. It's the reason for the public covenant that runs with patents on subject inventions--that the patent system is to be

used in particular ways, and not in other ways that are otherwise legal but not appropriate to the purpose (such as suppressing all use or licensing exclusively simply to maximize profit at public expense). It's the reason for all the apparatus for reporting on invention use, for limiting exclusivity, for march-in procedures.

The second source of private risk capital does not get much attention: the cost of reviewing invention reports and filing patent applications. This is the "risk capital" expended by invention management agents. This is also the "risk capital" that sets the institutional conflict of interest in motion. If a university (or its designated agent) decides to file a patent application, then it will expend money on that effort--these days, the cost can be upwards of $15,000 (though the work can often be done for about half that cost, if done attentively). This "risk capital" then must be "recovered" from patent licensing. The expenditure of money on patenting is the primary argument against royalty-free licensing. If university patents were licensed royalty-free, then the expenditure to obtain the patent monopoly would be "wasted." The patent and licensing would merely *be in the public interest*--publishing the invention in the patent literature to promote the progress of the useful arts, and making the claimed invention available to all that would use it.

Thus, the point of spending money on patenting is to make money back on the licensing. In that effort, one can recover the patenting expenditures as a share of income from each license or one can bill the licensees for the patenting expenditures in addition to any earned royalty from the use of the licensed invention. University patent licensing practice is almost entirely built around billing for patenting costs. And in doing so, university patent brokers set up the rationale for exclusive licenses. An exclusive licensee, if put in the position as if the patent had been issued directly to the licensee, should be willing to pay as well the full cost of obtaining the patent. Such exclusive licenses--granting all substantial rights in an invention--are in deed assignments. If an exclusive license agreement provides for the "reimbursement" of all of a university's patenting expenditures, then the exclusive license is in essence a sale of the patent--all substantial rights are granted to the licensee and the licensee pays the legal bill as if the licensee had filed the patent application itself.

In this way, university patent administrators talk themselves into the idea that their best hope for recovering their patenting costs is to get a company to pay for those costs. Back in 1990 or so, when I started in university technology transfer, the old way was slipping away. In the old way, a university sent out a description of the invention in a "non-confidential summary" before filing any patent application. If one (or, rarely more) companies wanted a patent to be filed and were willing to pay the costs, then--and only then--did the university file the patent application. That is, universities (the ones that did not have a big-hit patent license that had given them a reserve budget to spend on new patent work--that is, nearly all of them) didn't make a decision whether to file a patent application until they had a company willing to take a license. Again, all this led

toward exclusive licensing, because the university sought recovery of patenting costs up front, rather than from earned royalties, which would come later--often many years later. Even though 15 non-exclusive licenses for $1,000 each would cover patent costs, university patent administrators were (and mostly are) unwilling to file a patent application thinking that there might be 15 companies willing to acquire a simple non-exclusive license. They'd rather have one exclusive licensee.

If one adopts the idea that patent-induced "risk capital" for commercialization is essential to the public use of university research findings, then it's easy to see how a university patent administrator might move from exclusive license for patent reimbursement to exclusive license as the best way to gain a "return" on the "investment" in obtaining the patent and by extension the "investment" in the research that led to the invention. Thus, rather than seek to keep the costs of commercialized inventions low for broad public access and benefit, university patent administrators have gone the other way and argued that the purpose of a patent monopoly is to generate maximum value in any way that's legal (that is, in any way to which no one with power objects), and therefore the purpose of the licensing agreement is to preserve the monopoly power of a patent while requiring that the university licensor share in the "upside" of maximum pricing preserved for the licensee in the exclusive license.

Public interest, rather than being aligned with broad access to the invention (for research use, for DIY use, for competitive uses) and with low costs--costs below what the market would otherwise bear, costs below what a monopoly position might command--instead was aligned with a share of the maximum that a licensee might make. What's good for the monopolist is good for the university, and what's good for the university is good for the public. In this way, the moral compass of university administrators was made to point, reliably, always at the university's own navel. The apparatus of the IPA program, and later Bayh-Dole, had the apparent role of keeping the moral compass of university patent brokers pointed toward something other than institutional self-interest. But that apparatus was designed to fail in both the IPA program and in Bayh-Dole--and to that extent, Bayh-Dole has achieved the purposes designed into it.

It is something to find these implications in practice designed into the new 1969 Wisconsin patent policy. But it's clear that the Wisconsin policy, by combining the requirements of the IPA program with a review of all inventions by administrators lays the foundations for making it appear that to comply with federal regulations, inventors must assign their inventions to the university (or to WARF) whenever administrators decide they must--even while the IPA program (and later, Bayh-Dole) does not require administrators to take ownership of any invention made with federal support.

Once university administrators get the idea that they are making a decision about ownership in the interests of the university rather than in the interest of compliance with a bargain between inventors and research sponsors, then it's an easy step to argue that patents should be managed for their maximum financial value, and thus licensed exclusively, and thus licensed for their monopoly value rather than for the public benefit that might arise from access to the underlying invention. "Commercialization" becomes the term used to mean "denying public access in favor of receiving payments from a company that derives value from a monopoly position." Most university commercialization deals don't result in commercial products. Of those that do result in commercial products, it's an open question whether those products are made available on "reasonable" terms. But "reasonable" is a technical detail in the IPA/Bayh-Dole apparatus that few university patent administrators worry over--and no federal agencies appear ready to step in to enforce or counter by using their government license to practice and have practiced (quite apart from march-in procedures).

But there's not a compelling argument that university administrators must review all inventions to determine whether any given invention must be owned by the university or the sponsor. That issue can be addressed in the reporting requirements between the university investigators and sponsors, and by making the investigators parties to the funding agreement so that the sponsors and the university understand that the obligation to report inventions is with the investigators. It's just that Wisconsin did not choose to develop its policy in this direction.

In a research procurement environment, a research sponsor seeks deliverables that have utility--application to the areas of the sponsor's interests. Any research agreement written with any competence will specify what the sponsor desires by way of reports and what the sponsor recognizes as deliverables within those reports. There's no need for deans and business officers and university vice presidents to scrutinize invention reports--just send the reports to the sponsors and see what the sponsor says. The university's review, in an environment without institutional conflict of interest, is to determine that its investigators are reporting fully and not holding back inventions from the sponsor and patenting them on the sly. But sly patenting is something that will come out when the patent issues. And the university's review may enter into it if a sponsor claims an interest in inventions that the university investigators argue was not within the scope of the sponsored research agreement, not a deliverable, not bargained for. In each of these two cases, the university retains a concern for compliance with the terms of the research contract--but the outcome has to do only with institutional compliance, not with the outright ownership by the university of inventions that figure in the determination.

The IPA, then, allowed university administrators to conflate an interest in compliance with their own interest in university (or WARF) ownership of inventions that may result from that compliance. This conflation comes about because the IPA makes it appear that the university

obtains *the federal agency's* interest in compliance with the federal funding agreement. The university, as far as patent rights goes, appears to act "on behalf of" or "in the place of" or "as an agent of" the federal government for purposes of patent rights. The university, in this view, is assigned a portion of the federal contract, the part pertaining to inventions, and so, in some way, *becomes the interested sponsor of the research in place of the federal government*, as if, for inventions, the inventors worked for the university and not for the federal government, even while the federal government supplies the money for the work--both direct and indirect costs of the university gets covered and faculty, to participate in the research, are released from their official university duties (so that the university has even less claim on their work that it would have otherwise, as a matter of employment or right to direct the work or expectation of benefit from the work or contribution of university resources for which equitable ownership of inventions might be indicated--none of this).

Public Covenant in Patents on Subject Inventions

One might see how, if university administrators believe that they have become, for invention purposes, the federal sponsor of the research, that they could also come to believe later that the Bayh-Dole Act vested ownership of inventions with the university as if the university were the sponsor of research and the federal funding agreement redirected any federal interest in inventions to the university. If the federal government asserted ownership of inventions through funding agreements (and regulations that form those funding agreements), then when the invention portion of the funding agreement is transferred to the university, so must also the ownership claim. The university can assert equitable title in inventions it never funded, simply because the government had funded them and transferred control to the university.

At least, that's one way of reading the IPA program (and, later, Bayh-Dole). Things start with the Kennedy patent policy "presumption of title" with the government as a basis for federal contracting. Federal contracts are created by a combination of laws, regulations, and written agreements. The university then gets to stand in for the federal government for anything concerning inventions. Thus, the university gets the benefit of the federal "presumption" as a matter of assignment of the invention portion of the federal contract. When a university "elects to retain title" (in this manner of thinking), the university is "technically" "electing to accept being nominated by the federal agency to substitute for the federal government in the federal government's claims to inventions made with federal support." Under the IPA program, this thinking might have almost worked. Under Bayh-Dole, however, it's impossible (though it is still done, of course) because Bayh-Dole displaces executive branch patent policy with a Congressionally mandated patent policy that does not include any requirement in federal funding agreement that the federal government has a claim to inventions made with federal support unless a contractor intervenes. Not there. Darn.

It's all wickedly clever thinking, at least if one intends to co-opt inventor rights.

This conflation of university interest and compliance interest exploits a further characteristic of federal funding agreements with universities. These agreements are for the most part subvention awards, "grants-in-aid" rather than procurement contracts. There are no "deliverables" in subvention funding but for the work that's proposed getting done, and getting done in a manner that benefits the public. The scope of the work is what is proposed. The deliverables are destined for the public--through publication, instruction, graduation, and assistance. Patents might play a role, but the purpose of federal funding was not to provide a subsidy for speculative exploitation of monopolies as a paywall between subvention research and public access. The apparatus in federal funding that introduces a concern for patents has to do with limiting monopoly speculation in research results in favor of public access.

There are three elements to these limitations, repeated all the way through Bayh-Dole: first, that the government gets a license--so the government cannot get sued by an owner of a patent on an invention made in subvention research, but "subvention invention" rather than merely "subject invention." This distinction creates the difference between a private market and the federal market for the invention. Put another way, the federal use of any invention made in subvention research is always public domain. The government in asserting this right to be free of infringement claims takes nothing away from the owner of a patent on a subject invention; rather, this freedom is part of the basic bargain under which the government decides not to require inventions as deliverables in subvention funding.

Second, the government imposes restrictions on the use of the patent system with regard to inventions made with subvention support. These inventions are to be made broadly available, and earlier than one might expect from inventions made in other contexts--even typical commercial contexts. Thus, there's an interest in private capital becoming available ("call forth risk capital") to speed development of any invention at a pace that does not wait for savings to accumulate or to pick the perfect time to introduce a new product for maximum gain (such as when need becomes greatest, or when wealthy folk are ready to buy, long after poorer folk would have benefited). These restrictions take the form of a default for non-exclusive licensing and a default that such licensing be royalty-free or "reasonable"--that is, not based on monopoly rates, but on something less than what the patent monopoly might produce.

And for exclusive licensing, these restrictions limit the term of the exclusive license, so that there will be competition for producing products based on the subvention invention within the term of the patent. These restrictions form the public covenant that follows inventions made with federal support. In Bayh-Dole, which was made part of federal patent law--perhaps the strangest aspect of the law and certainly an innovation in executive branch patent policy--expresses the public

covenant as both a restriction on the property rights of a patent on a subject invention and as a set of contract provisions that limit, if the federal agency chooses to enforce them, what patents on subject invention owners can do with their patents on subject inventions. The public covenant is directed at the patent on subject invention owner's behavior in the private market for the invention and reflects the idea that whatever the patent system's strengths and weaknesses might be in the general case, with regard to subvention research, where the government intervenes to bolster funding and give preference to some private efforts over others, exploitation of the full patent system is not appropriate.

For example, it is not appropriate for a patent on subject invention owner to prevent all use of a subvention invention (through indifference, or receiving payments to prevent all use in favor of a company's business position). We can rattle through the other issues--pricing at monopoly rates, preventing others from doing research and enjoying the benefits of their discoveries, stifling competition, placing unreasonable terms on access, delaying availability. The public covenant adds both diligence (a kind of working requirement not in U.S. patent law otherwise) and restriction (so that some legal forms of patent exploitation--limited only by antitrust law--are excluded in favor of requirements arising from subvention funding). To argue against these restrictions and diligence, as advocates of Bayh-Dole have been doing for years and getting the law changed to reflect their views, is in essence to reject the argument that subvention funding should not create a subsidy for speculation in the value of patents taken out on subvention inventions, that these patents on subject inventions must have a more restricted use, in favor of the public and not the patent owner. As 2 CFR 200.316 has it, the grantee must act as a "trustee" for public benefit, not as a mere "owner" pursuing a private interest.

We end up, then, with the argument against the public covenant that reduces to "universities may do anything with a patent that the patent system allows, because all that they do, they do for a public mission, and if they earn money from the value of a patent, that money goes to a public cause (after paying all those involved in producing that money--so, given typical royalty rates and royalty-sharing schedules, perhaps the public share of the value of the income retained for a university's use after costs is perhaps 2% of the total value of each patent on a subject invention. The industry and patent broker system gets 98%. The university holds 2% for its own use. The public gets virtually nothing--not less than monopoly prices, not a greater freedom of access and use, not the donation of the balance after costs to public needs rather than institutional needs.

This argument--what's good for the university financially is good for the public--is pernicious and difficult to cut through with sound-bite style teeth. Arrogant, selfish, corrupt, faux, wrong--these end up being, in their way, badges of virtue that show the degree to which university administrators so value the potential for public benefit from research inventions that they have to, at times, bend the awkward red tape of government bureaucracies in order to deliver results.

It's just that there are virtually no results. The results are kept secret. We see selective "success stories" attributed to institutional bureaucratic ownership of a patent on a subject invention, but we see no connection that shows that institutional ownership advanced public access to the invention and that whatever came about did so because of institutional ownership and not in spite of that ownership.

Further, we see nothing about the status of all the rest of subvention inventions claimed by institutions--and it would appear that over 80% of these are never licensed (and never released for public use), and of those that are licensed, 1 in 40 might become a commercial product. Even rarer is the commercial product that meets the standard of "use such that benefits are available to the public on reasonable terms." We see, further, no account of the effects of this combination of monopoly licensing and the withholding so many research discoveries from public access. These effects are not observed, not reported. It's a "don't look, don't tell" kind of thing.

The third class of restrictions we recognize as "march-in" rights, under which the federal government can compel an owner of a patent on a subject invention to license the patent to meet government requirements for the public interest in the private marketplace. In the Kennedy patent policy, such march-in could take place if the federal government adopted regulations that required public use of a subvention invention. In such a case, it did not matter what a contractor had done with its "principal rights" in an invention made with federal support (subvention or procurement--didn't matter). The contractor would have to release the invention non-exclusively for public use because the invention's use now was a subject of federal regulation.

You can see why. If the government makes a law that everyone must use some invention, and that invention is held as a monopoly, then the law basically creates a huge demand butted up against a private monopoly that itself was created through government action. It's a nice system, if one has the monopoly, but it grates against the idea that the public should allow such monopolies in the first place when it has available to it the opportunity to prevent those monopolies from forming by not giving up patent rights at the time of contracting, or any time after. Thus, march-in was conceived as a way for government to address private-market side patent behaviors to address such things as nonuse, lack of availability, breach of contract, government treaties, and government regulations. Some of these practices might be breaches of the public covenant, but others arise simply as a matter of government actions involving the private marketplace.

Wisconsin's Representation of an Inventor's Options

Consider, then, how Wisconsin's 1969 patent policy is a bit mealy-mouthed when it announces the inventor's options when there's federal funding. Here's how the policy sets up the situation when there is no obligation to a sponsor:

When, after review by the Dean and the Business Office, it has been determined that no third party is contractually entitled to control over the property rights in the invention, the inventor will be so advised and will be free to dispose of his invention according to his own discretion. Practically speaking, any one of

But under the IPA, the university is not a "third party" that "is contractually entitled to control over the property rights in the invention." The IPA requires the university to require assignment of an invention to the university if the university has chosen to file a patent application. In the case of an IPA grant, the dean and business office are determining the *university's rights*, not the sponsor's rights. But they can only do that if the Wisconsin patent policy has been changed so that the university asserts ownership over inventions made with federal support. The IPA requires the university to do so when the university has made the decision to file patent applications, but the IPA does not require the university to make such a decision. University policy does not allow the university to make that decision without the inventor's approval. But the IPA gave administrators leverage to make it appear that the federal rules forced the change in university policy, resulting in "greater latitude" (according to Wisconsin policy) for inventors.

The Wisconsin IPA eliminates the "third party" for HEW-sponsored research and replaces that "third party" with the university itself. Thus, the policy creates an unmanageable institutional conflict of interest in which university administrators acting in the interest of the institution (i.e., in the interest of the programs they control within the institution, such as patenting and income from patenting) decide what inventions meet a contract deliverable with a third party--because that contract deliverable then becomes their contract deliverable. Such a thing shouldn't happen, but under the IPA, that was the bargain the university administrators made to gain access to inventions in the research they hosted, which otherwise they disclaimed an interest in.

This change is reflected in the form of the "patent agreement" implemented by Wisconsin:

PATENT AGREEMENT

In consideration of my employment by The Regents of the University of Wisconsin (hereinafter referred to as the University) in connection with work which has been conducted or may hereafter be conducted in the performance of a grant, contract or award made to the University by any extramural agency, I hereby agree to refer promptly to the University (through the Dean to the Office of the Vice President for Business and Finance) any personally conceived discoveries or inventions arising out of the work sponsored or in any way aided by the grant, contract or award in order that the University may report the matter to the Grantor, Contracting Agency, or Awarding Agency for disposition in accordance with its established policies, procedures, and requirements. I hereby agree to cooperate with the Grantor, Contracting Agency, Awarding Agency, or the University's designee in the preparation and prosecution of any patent applications relating to such inventions and to execute all documents necessary or incidental to such applications and further agree to assign all rights to such inventions to the Grantor, Contracting Agency, Awarding Agency, or the University's designee if assignment is required under the terms of the grant, contract, or award.

In witness whereof I have hereunto set my hand this ——day of ——, 19 ——.

Signed:

____

____

The foundation in the IPA for assignment is simply that the assignment is required by the IPA when the university has prepared a patent application. But here in the new Wisconsin patent agreement the premise of assignment is "employment . . . in connection with . . . work in performance of a grant . . . ." Employment is the stated "consideration." This is all very strange if the agreement is for a promise to assign inventions to a sponsor of research. In that case, it is the receipt of funds for the inventor's use that might constitute the consideration for the promise to assign inventions. So "employment" and "consideration" here are mealy-mouthed. Further, if employment is the consideration for assignment, then sharing royalties clearly has nothing to do with it. The Wisconsin policy makes it clear that this is the case:

quickly and effectively into public use. In keeping with its traditional policies, WARF will pay the inventor annually 15% of the net royalties earned by his invention.

That is, the royalties paid are not consideration for anything. They are "in keeping with" WARF's "traditional policies." That is, WARF here is described as complying with its own policies to pay inventors; it does not pay inventors in consideration for an assignment of patent rights.

But the Wisconsin patent agreement makes sense (in a convoluted way) if it is intended to work as an agreement to promise to assign inventions to the university (or to WARF). The insertions of "the University's designee" into the patent agreement explain the use of employment as consideration:

by agree to cooperate with the Grantor, Contracting Agency, Awarding Agency, or the University's designee in the preparation and prosecution of any patent applications relating to such inventions and to execute all documents necessary or incidental to such applications and further agree to assign all rights to such inventions to the Grantor, Contracting Agency, Awarding Agency, or the University's designee if assignment is required under the terms of the grant, contract, or award.

The university itself is not even mentioned. The "designee" is put in a list of "third parties"--sponsors of research. Take out "the University's designee" and the obligations to disclose and assign make sense--comply with the terms of the research award that benefits your research work. But inserting "the University's designee" mixes the issue--now the prospective inventor is required to assign to the university (i.e., the designee--which could be the university or WARF or most anyone) to fulfill the terms of an extramural contract for research. It's easy to see how this language slips from federal requirements to any sponsor requirements, and that the pathway for compliance with any sponsor requirements for inventions as deliverables must then first pass through the hands of university officials (or designees), and that this passage ends up as troll bridge requiring a license and payment.

Notice as well in the Wisconsin patent agreement that the scope of rights is drawn broadly:

I hereby agree to refer promptly to the University (through the Dean to the Office of the Vice President for Business and Finance) any personally conceived discoveries or inventions arising out of the work sponsored or in any way aided by the grant, contract or award in order that the University may report the matter to the Grantor, Contracting Agency, or Awarding Agency for disposition in accordance with its established policies, procedures, and requirements. I here-

The patent agreement is not directed at HEW funding but rather to "any extramural agency." It is a general document that manages compliance with extramural awards. In this regard, it is not particularly noteworthy. The noteworthy part, however, has to do with the scope of reporting in relationship to the scope of the promise to assign. The scope for reporting is broad--any invention "arising out of work sponsored" or "in any way aided by the grant, contract, or award." That scope is much broader than the interest claimed for "subject inventions" in the IPA, which focuses only on patentable inventions (inventions that are or may be patentable):

(a) The Grantee shall obtain patent agreements from all persons who perform any part of the work under a grant or award from the Department of Health, Education, and Welfare, exclusive of clerical and manual labor personnel, requiring that such persons promptly report and assign all subject inventions to Grantee or its approved patent management organization.

The scope is "any part of the work under a grant or award." "Under" is narrower than "arising out of" or "in any way aided." In fact, the university's scope and the IPA scope are entirely different models. The IPA's model is that of a specified contract deliverable, something set forth in writing. The invention either matches that deliverable, or was made "in the course" of creating that deliverable. One can look at the invention and at the written statement of the proposed research and determine whether the invention was made "under" the grant. But the university does not use this model at all. Instead, it looks at the grant as a stimulus--did the grant work "aid" in making the invention? did the invention "arise" out of the grant work? These are not questions regarding specified deliverables but rather have to do with "assistance" or "use of resources" or "the consequences of having access to grant funding." These claims are much more general and, for employers, fall outside of what federal common law permits an employer to claim as a matter of equitable title.

The use of the employer's resources to invent, or even being paid by an employer, does not create in the employer a right to own an employee's invention. One has to look at the scope and course of employment to get to an argument for equitable title. Otherwise, an employer obtains a "shop right"--a freedom to use such inventions for the employer's purposes without fear of a claim of

infringement by the employee. But Wisconsin's new 1969 patent policy sets up the disclosure requirement to be broad--any invention "arising out of" or "in any way aided." And then the policy turns that scope into what may be required to be assigned--not just to any sponsor, but to the university's own designee--which is not a sponsor at all. The university's designee is just proxy for the university itself--and the university might designate itself, for all that.

However, the addition of "the University" in the list of assignees is noteworthy, as this is the effect of the IPA with HEW. The university, not HEW, gets to decide whether under the IPA assignment to the university is "required." That is, the university gets to interpret the language of the IPA relative to its own interest against that of its inventors.

Other federal agencies followed the Kennedy patent policy according to their own contracting requirements. Some allowed contractor ownership. Others did not. The Wisconsin patent agreement here is more than just wrong, more than violating Wisconsin's own policy--it's taking ownership of stuff that the university has no right to take ownership of.

The new 1969 Wisconsin patent policy broadens the scope of the university's interest in patents yet further:

> Office of the Vice President for Business and Finance) any personally conceived discoveries or inventions arising out of the work sponsored or in any way aided by the grant, contract or award in order that the University may report the matter to the Grantor, Contracting Agency, or Awarding Agency for disposition in accordance with its established policies, procedures, and requirements. I here-

Here is the Wisconsin IPA definition of "subject invention":

> (a) The term "subject invention" as used in this Agreement means any process, machine, manufacture, composition of matter or design, or any new or useful improvement thereof, and any variety of plant which is or may be patentable under the Patent Laws of the United States made in the course of or under research supported by grants and awards from the Department of Health, Education, and Welfare.
>
> (b) The term "made" when used in relation to any invention or discovery means its conception or first actual reduction to practice.

Both elements are essential to the definition. First, a subject invention is not just any invention "arising out of" or "in any way connected" with a federally funded project. Rather, that invention must be "made in the course of or under research supported" by HEW grants. "Under research" means that the research specifies that the inventive work. "In the course of" means what is done

to achieve the specified work. "Made" means that the specified work anticipates conception of the invention or the first actual reduction to practice. This definition is a limiting definition of invention deliverables. The government bargains for inventions that are anticipated in the work proposed, or made in the course of doing that work--as evidenced by the grant documents.

Wisconsin, however, construes the claims broadly, so that not only are inventions to be reported more broadly than the IPA requires (but Wisconsin might require such reporting since it does so in the general case, regardless of any ownership claims by sponsors) but also requires the assignment of such inventions "if assignment is required under the terms of the grant, contract, or award." The university gets to interpret the IPA to decide what is assignable to the university--but the investigators and inventors apparently have no access to interpretation of the IPA and so are caught in the scheme--they are stuck with whatever the university decides the university must do to comply with the IPA requirements on assignment of subject inventions.

The university, of course, represents itself to be "scrupulous" in compliance, and so it will have to be safe in making sure that it accounts to the government for everything that the government might have intended in its definition of subject invention. The university has given up its neutral position and presents its diligence to the inventor as if the university is merely complying with sponsor requirements, when the university has actually put itself in the position to negotiate for itself those requirements and eliminate investigators or inventors in having any say in the matter. The say goes to the deans, business officers (for whatever reason) and to university administrators in "Central Administration." In just this little bit of clever work, Wisconsin turns a remarkably open patent policy controlled by investigators (in their negotiations with sponsors over iP) into a compulsory one operated by administrators, to which inventors have no access to negotiate anything.

It is this alignment of bureaucrats standing between faculty investigators (and inventors) and federal research sponsors that creates the conditions for bureaucrats to stand between investigators and investigators in all funding agreements--to insist on university ownership as if the sponsor were insisting in such ownership, and making sponsors agree to such a requirement, whether the sponsor wanted it or not, and then enforcing that agreement on investigators and inventors, to their disadvantage and without "protections" (as the Supreme Court put it, in *Stanford v Roche*).

The Wisconsin patent policy also opens up the question of how inventions become patentable. In doing so, it also suggests a line of thinking that expands institutional interest in patents. The patent policy includes a discussion of what constitutes an "invention." There are two kinds of inventions, according to the policy--patentable and not patentable. The ones that matter, obviously, are the patentable ones. But under the IPA, the issue of ownership--of assignment--is

directed at the invention, not specifically at the patent on the invention. Thus, the requirement in the IPA that Wisconsin require assignment of inventions is easily misread. The IPA requirement for assignment depends on the university deciding to file a patent application--that is, it depends on the university determining that an invention is at least potentially patentable. But it is easy to switch things around and claim that inventors must assign all inventions--patentable or not--and the university will sort out which ones are patentable.

This review for patentability creates a second institutional conflict of interest. Let me show you how it works. Here's the interesting bit of 1969 Wisconsin patent policy:

> Whether an invention or discovery is patentable may best be judged by those experienced in patent law and often requires painstaking study of its relationship to the pre-existing knowledge in the art to which the invention belongs.
>
> If there is doubt as to patentability and utility, expert opinion should be sought promptly. The Wisconsin Alumni Research Foundation (Licensing and Development Division) is prepared to assist any University inventor in helping him to judge whether or not the invention or discovery contains patentable subject matter.

Patentable inventions have various attributes. The common ones are that such inventions are "new, useful, and non-obvious." But it is also the case that patentability depends on an inventor (or someone else with access to the invention) recognizing that the invention is an invention--this was called the "contemporaneous recognition and appreciation of the invention." Only when someone recognizes some development as inventive is that development also potentially patentable (all other requirements for patentability being met).

For an inventor working in a garage (where inventors frequently park), it's entirely up to his or her own decision whether to recognize something as inventive. If an inventor says, "No, that's not anything important, not an invention" then whatever it is, invention or not, is not yet patentable because there's been no "contemporaneous recognition."

The U.S. transition to "first inventor to file" procedures makes the issue of "contemporaneous recognition" a non-factor in determining who is entitled to a patent ("first to invent"), but the underlying concept remains in effect. If an inventor does not recognize work as inventive, the inventor has no standing to sign the affidavit and oath that accompanies a patent application that he or she is a "true inventor." An inventor must be persuaded that he or she has contributed to a patentable invention before that invention is indeed patentable.

The effect of the Wisconsin patent policy is to encourage university personnel to take their inventions--or potential inventions--to be reviewed for patentability. This is a typical corporate approach--report all inventions (patentable or not) and we'll have experts determine whether an

invention is patentable (and then persuade you of it, too). Since corporations typically enforce trade secret requirements, they can assert ownership of all inventions, patentable or not as a matter of non-disclosure and use only for the benefit of the corporation.

But a university with an open policy on publication and academic freedom does not so readily have the means to create a trade secret regime. To do so now would move a university out of exemptions to basic research in export control law, requiring the university to apply for export licenses to allow various foreign nationals (including students and visitors) to have access to research information subject to university trade secret requirements. Thus, a university is not in a position to claim ownership of non-patentable inventions--though many universities these days have just this claim in their patent policies. Some goofball administrator must have thought it sounded "comprehensive" to claim all inventions, whether or not patentable, making a patent policy also be a non-patent policy.

Thus, here's the challenge for administrative compliance with reporting inventions to research sponsors. If the purpose of the reporting is to establish rights in those inventions--that is, the right to patent, or a right to a license under a patent--then the inventions to be reported are patentable ones--ones for which a patent might be obtained. If the reporting obligation is any "new technology"--then investigators report what they have done that's new, regardless of whether it is merely new to their work or a new thing on the face of the earth for the first time. Absolute novelty doesn't matter, originality doesn't matter. Whatever has been produced gets reported. (This is how NASA handles New Technology, by the way.) There is no need for any dean or business officer to review reports of new technology. There's simply nothing for them to do that a researcher doesn't already know. The only way that the dean or business officer has anything to contribute is if the dean or business officer does not represent a university ownership interest as a result of the review--that is, if the only concern is whether the new thing was made within the scope of the statement of work governing the research project.

Review for Patentability

It's when the review is for patentability that things get interesting. Then "experts" can consider whether some new thing is also patentable. That's where we get to the Wisconsin policy approach--experts should decide what's patentable. Now, it is certainly the case that it's a legal matter whether something new meets the legal requirements for "new, useful, and non-obvious" and is directed to statutory subject matter, and whether a specification is enabling and discloses the best mode of use, and the like. But it is *not* a legal matter whether an individual recognizes something new as inventive. (It may be a legal matter to determine if and how an individual recognized something new as inventive--but that's different, and later). Either an individual recognizes something or doesn't. No attorney is needed for the recognition part of patentability.

But of course if an attorney does get involved, he or she can make an effort to bring about that recognition in the inventor. That's the gist of Richard Feynman's story about inventing--he could think up any number of things, and told a few to the patent attorney at Los Alamos, and next thing you know, he has patents to his name: "I just mentioned all these obvious things." Here's the thing, then. What to an expert scientist might seem obvious by way of application could be considered patentable to a different audience. It's not that such inventions are rare; rather, it is that expert scientists don't have the time in their day to begin to write them all down. It's different when an expert scientist recognizes something new as inventive--beyond the obvious, beyond what's ordinarily the subject of work. The recognition step is deeply important to separate anything that might be patentable, if a patent attorney gets the chance to spin it right, and what might be patentable and important as a matter of discovery, of scientific advance.

The standard of "obvious" for patentability is referenced to one with "ordinary skill in the art." It's a big question whether university researchers have such "ordinary" skill or perhaps "extraordinary" skill, in which case most anything they happen to burble out may well be patentable, even if they don't recognize it or acknowledge it or even respect it. They are not in the habit of assessing their thoughts from the perspective of a legal definition of "ordinary skill in the art." Think then about the problem of deciding whether some new thing thought of by a university faculty researcher is inventive, is patentable. From the researcher's perspective, few things may be. From a patent attorney's perspective, patentable inventions may be dropping like manna every morning.

It's even worse if one adds in now the matter of compliance with a research agreement. How does one decide when an invention-like idea arose in doing that research or just happened to arise like any number of such ideas arise every day. Was that invention made in the scope of the research--in doing what was proposed in writing--or is that invention just another idea that has flitted from head to hand or mouth and made its way into the world? For the procurement world, the response is straightforward--define what it is that you want to procure, and when you get that, it comes with whatever rights might be attached to it. If those presenting the work haven't thought about invention and the sponsor's attorneys think something in those deliverables is patentable, then it's up to the sponsor to persuade the putative inventors of the fact and obtain their assignments (or licenses, as the case may be).

In the subvention world, however, the response is almost impossible. The deliverables are whatever it is that the project has proposed to do--and the delivery is not to the sponsor, but to whomever the investigators have promised their work. The subvention is a grant-in-aid, not a procurement of deliverables for the sponsor. This is actually a tough problem, one that federal contracting officials haven't worked out. The Kennedy patent policy did a pretty good job with it, but conflated procurement and subvention. The IPA program end-ran the Kennedy patent

policy, creating a patent monopoly pipeline that ran from university to corporation, taking advantage of federal funding to faculty and turning those funds into an unacknowledged subsidy for shareholders, all the while pitching the pipeline as something in the public interest. Bayh-Dole makes the pipeline even bigger, but with no protections for inventors and few for public interest--and none that are enforced.

In all this apparatus regarding patents on subject inventions, there's next to nothing that indicates how it is that any given invention comes within the scope of a federal funding agreement. The implementing regulations for Bayh-Dole try to explain things (see 37 CFR 401.1), but the best they can do is stipulate that an invention must be made in the "planned and committed activities" of the project or must otherwise "diminish or distract" from the planned and committed activities. That is, the invention must be anticipated by the written statement of work or there's documentary evidence that money that should have been spent to get that work done was spent elsewhere--on the invention--and that prevented the planned and committed work from getting done. And the invention must be patentable ("is or may be patentable"). And for an invention to meet this definition, it must be recognized as inventive by the inventor.

By now it must be apparent that there's a huge problem for university patent brokers. If they "walk the halls" they can, like Richard Feynman's patent attorney, elicit all sorts of ideas that may well turn out to be patentable inventions. They could file patent applications until patents came out the university's wazoo, if only university researchers would cooperate, or participate. But this sort of hunting for inventions is rather different from the sort of inventive activity that arises because researchers recognize in their work something inventive. One can sit around and invent--that's what sessions at Intellectual Ventures are reported to do, with patent attorneys ready to reduce each idea to a patent application and so paper over swaths of the possible future, just in case. Or one can work on a project and recognize an invention, and focus on that. Or one can, while also working on a project, recognize other ideas as valuable--perhaps for other projects, even related projects. The open question is just what inventions are within the scope of the "planned and committed activities (as Bayh-Dole's implementing regulations put it) of a subvention project and what ones come about because those involved in the project could be spilling patentable ideas left and right, and all that's needed is an expert (like the attorney that Feynman dealt with) to tell them what's inventive, what's patentably inventive.

The new 1969 Wisconsin patent policy, then, by requiring reporting of all inventions and asserting the importance that someone other than the inventor--"expert opinion"--should decide whether an invention is patentable creates another institutional conflict of interest. The university, by directing research personnel to "expert opinion" creates the conditions under which patentable inventions may multiply, creating more opportunities for institutional ownership claims as these inventions can be associated with federally supported research. For the

IPA, a "subject invention" is any invention "which is or may be patentable" that has been "made in the course of or under research supported by grants and awards" from HEW. The university's assertion of the need to be "scrupulous" in monitoring compliance takes on a different sense. Under the IPA program, the government is not concerned with inventions that are published openly and so avoid issues raised by patent monopolies. The problem comes when patents are obtained. When the university intervenes to encourage "expert opinion" to determine whether an invention is patentable, it is also creating an environment to generate many more apparent inventions and to associate those inventions with federal funding and so gain the benefit of the claim on ownership that the IPA provides.

This potential for intervention, then, creates an institutional conflict of interest. If the institution does not intervene, a great many things may be published or disclosed that will have no patent significance because the inventors of those things--faculty scientists--simply don't recognize these things as inventive. Further, once the institution does intervene, the IPA with HEW creates an incentive to expand the interpretation of "course or under" scope of subject inventions and thus come into a claim of ownership of those inventions ahead of the federal government. Thus, "scrutinize" and "fully examined" and "expert opinion" all work to create a theme that the university, not individual investigators, determines when an invention has been made, when that invention is within the scope of a funding agreement, and what is then required to comply with that funding agreement. And the funding agreement that matters, the one that prompts the new policy, is the IPA. The university--administrators acting for the university rather than faculty acting for the university--"have the responsibility for determining if an obligation to a grantor does exist and to insure that any such obligations are fully met." Put simply, university patent brokers will decide whether each invention is a patentable invention and whether it has been made under the IPA and therefore whether those same university patent brokers will take ownership of the invention.

Wisconsin patent policy in this way distinguishes between "restricted inventions" and "unrestricted inventions." One is led to understand the distinction as one of compliance with research contracts, but actually the distinction is one created by institutional conflicts of interest. Nothing in the IPA restricts any invention. If there were federal requirements on inventions, those requirements were in the funding agreements, not in the IPA. The IPA worked to disrupt those federal requirements, by contract, and gave university administrators incentives to scope federal research broadly and require the disclosure of all possible inventions, for "compliance" with the IPA. It's a complex apparatus presented as providing faculty inventors with "greater latitude" in the management of inventions. But really, it does no such thing. Instead, the patent policy works to undermine the university's disinterest in inventions made by the personnel it hosts.

> The University has no wish to influence investigators regarding the disposition of their discoveries or inventions except where the University has an obligation as the result of being a signatory to a contractual arrangement which has a relation to the discovery or invention. In order to assure that its obligations are scrupulously met, the University administration requires that all inventions emanating from The University of Wisconsin, regardless of the source of support, be reported in a prescribed manner in order that they may be fully examined and a determination made with reference to any proprietary interest in them and to their disposition.

The wish the university has, at least expressed by its patent administrators, is to create contractual arrangements that transfer control of inventions from inventors to administrators. That control includes whether an invention has been made, whether it is within scope of a contract, and whether the invention should be patented. By entering into the IPA, university administrators overrode the long-standing policy by which the university did not take an interest in inventions. They then turned institutional invention ownership into a matter of federal compliance. From there, the institutional conflicts of interest that arose could be dismissed as fulfillment of federal requirements. This practice has persisted and spread across the country, reaching its fulfillment in the ubiquitous misrepresentation that Bayh-Dole requires these same things as a matter of compliance.

WARF's Cleverly Crafted Scheme

If you find all this complicated, you aren't alone. It's a "cleverly crafted scheme," as WARF called it (in reference to Bayh-Dole) in an amicus brief filed in the case of *Stanford v Roche*. As a scheme, it is difficult to unravel by design. Once the scheme had been given the attributes of federal compliance, a public mandate for institutions to patent and commercialize, and a prophetic claim that such activity will lead to all manner of public good, it takes a huge effort to show how it works (or doesn't) and expose it for what it is. Bayh-Dole makes invention reporting a state secret. Universities are unwilling to report the actual condition of their patent portfolios. And research activity gets encumbered with FOIL practices--fragemented ownership, institutionally licensed technology (except most institutionally claimed technology is never licensed, and if licensed does not produce the asserted benefits).

We might observe that patenting is "up" at universities less because research is more inventive than in the past, but rather because university administrators, having been given the incentives offered by the faux version of Bayh-Dole, set out to control not only research deliverables but also any invention, however trivial, on the prospect that some day, some few of these inventions would turn out to have great financial value. All that's needed, it turns out, is one lucrative deal every twenty to thirty years. One may as well be predicting UFOs arriving from Planet Clarion as to be arguing that by 2047, at least, we'll surely have found a big hit patent license in all the inventions we have been accumulating. Maybe. But I have greater expectations for the UFO than

for the success of the cleverly crafted scheme, for which the 1969 Wisconsin patent policy is the type locality, the ground zero, the place where university patent administration went from hopeful to very bad.

In 1999, Edmund Cronon and John Jenkins included a chapter on the Wisconsin Alumni Research Foundation in their history of the University of Wisconsin. The discussion of WARF is interesting for its spin and what it leaves out. WARF represents not only a piece of the now widespread way of thinking about university patenting but also in many ways is the first primary representative of this thinking, the origin as it were, the place where the tick bit into the neck and introduced the systemic changes that have properties not unlike Lyme disease but adapted for university patent management.

Working through Cronon and Jenkins's account of WARF provides an opportunity to gain a sense of perspective on what now are taken as obvious truths. At the time, WARF was a work-around to popular expectations of university work, and a work-around to the way that the Research Corporation proposed to do things. It's only fitting, then, that WARF is started by an invention at the University of Wisconsin which was itself a work-around to federal regulations. The mindset that WARF brings to the development of university patent policy and practice is one of clever work-arounds to public policies. One might say, WARF institutionalized the idea of gaming the system of university research, which led to the IPA program, which led to Bayh-Dole. And in Bayh-Dole we find the same mindset, the same gaming, the same work-arounds, cast in a vocabulary of public interest but in practice being something entirely different.

According to Cronon and Jenkins, WARF was something revolutionary:

> An especially convenient source of external private funding was the Wisconsin Alumni Research Foundation (WARF), the captive pioneering venture established in 1925 to manage and market patents based on UW faculty research discoveries.[21] WARF was predicated on a simple yet at the time revolutionary concept: to patent and market the results of faculty research and thereby generate income to support additional UW research. It was also a highly controversial undertaking, because at the

But WARF's revolutionary nature was not that it provided a means for university inventors to have their inventions managed by an agent. Rather, WARF was revolutionary precisely because, as Cronon and Jenkins put it, WARF was "a captive venture."

WARF came a decade after Frederick Cottrell had set up Research Corporation as a national resource for university inventors. WARF was not revolutionary in the sense of offering invention

management services to university inventors. Rather, WARF was competitive. That in itself is fine, but it is also worth noting the differences between WARF and Research Corporation. First the similarities: both are foundations, both act as agents external to universities, both return money from licensing to universities for research support.

Now the differences. Research Corporation was chartered by an act of Congress. It stands outside federal income tax laws. Research corporation was led by a board of directors drawn from industry. In effect, industry leaders consider each university invention and decide whether Research Corporation should assist in patenting the invention and presenting the invention to industry for use. To move an invention to Research Corporation for management is, in a real way, already "transferring the technology" to industry. After recovery of its expenses, Research Corporation provided money to the Smithsonian Institution to support research across the country, not just at the university that hosted research leading to a patented invention. Later, Research Corporation worked out arrangements with universities to share royalties on inventions provided to Research Corporation for management, but under the influence of the WARF model.

By contrast, WARF's board consisted of rather wealthy alumni of the University of Wisconsin. They set up the foundation to make money, not only from patent royalties but also from the investment of patent royalties in the stock market. Each year they declared a dividend and "gift" a sum to the University of Wisconsin. WARF shared royalties with inventors, but it shared a portion of its overall profits with the University of Wisconsin. And in this, WARF is provincial, a "captive venture." Money from its operations goes back only to Wisconsin, and in return, Wisconsin requires its inventors to assign to WARF if they are going to pursue patenting at all. Put another way, regardless of the merits of any other invention management process or agent, the University of Wisconsin requires its inventors to deal with WARF: they cannot choose Research Corporation or any other agent, or license/assign inventions directly to companies.

In transferring an invention to WARF, one is not transferring the invention to industry for review, but to speculators on the activities of industry--wealthy alumni looking to make the University wealthy. Certainly there is a version of public spiritedness in such an effort, but it is a noticeably different sort of public spirit than the one evidenced by Research Corporation, which takes a national view and operates to benefit industry generally rather than any specific company, and similarly operates to support research wherever it may be proposed rather than simply funneling money back to research at the same institution that hosted the original work. WARF, by contrast, made its gifts available to support "natural sciences" and "education."

But WARF was revolutionary in another way:

research. It was also a highly controversial undertaking, because at the time the common expectation was that a university ought to preserve, expand, and spread learning, not restrict and profit from it. Since UW researchers and their laboratories were taxpayer supported, moreover, it could be argued (and frequently was) that any resulting discoveries ought to belong to the public. To distance the University from charges of commercialism, WARF was incorporated as a legally independent private foundation, run by a board of trustees consisting of devoted UW alumni and supporters, whose stated corporate purpose was "to promote, encourage, and aid scientific investigation and research at the University of Wisconsin."[22] The first of the WARF patents, and the reason for the

Thus, as a separate entity, WARF also was designed to end-run the expectation that publicly funded work ought to be made available to the public by publication, not by patent. It's this expectation--that public funding should result in public benefit--that lies at the heart of the debate about what role patents should have in research work. This is the heart, too, of the idea of a public covenant that runs with patents of a certain kind--patents that cover inventions that might improve human health, for instance, if not patents on inventions made with public support.

But even here, at the heart of the matter, we also have a dilemma. Why, if research the public has funded should be made available to the public, should anyone hold a patent in any findings? Why not just publish findings and go from there? And that, basically, was the federal government position for the research it funded--which wasn't all that much, beyond agriculture, prior to 1947. Why should one go to the work to obtain a patent, only to make licenses available to all, royalty free? And worse, why would anyone charge for such licenses? Wouldn't that just add to the cost of using any such invention, and thus be a barrier to use?

It is in response to such questions that we end up with two distinct forms of answer. In the first, patents are taken out because patents are possible, and also are monopolies, and patents can be used to break monopolies as readily as creating them. For discoveries made in research, then, a patent might be used to create a commons rather than merely leave an invention to the public domain. A commons permits access to inventions on common terms--thus, a monopolist must contribute to a commons, or refrain from threatening practice within the commons, to enjoy access to the technology placed in the commons. This is the same thinking that underlies the "copyleft" idea in software licensing--use copyright to limit certain uses of copyright. A similar thought goes into commons based on patents: "you may use if you don't threaten to stop others who are also using."

The second distinct form of answer follows a different line of reasoning. Patents can be used to attract risk capital, and that capital may then compete with monopolies (whether private ones or merely ones that arise out of habit, or standards, or even commons that become too powerful and so appear as patent pools). The product of risk capital, then, is a new product, an invention made useful as an engine of both public benefit and wealth creation. The patent monopoly, in this line of reasoning, is essential to the task of raising capital to compete with the status quo, with market monopolies, with the dullness of technological stability advancing at a snail's pace of complacent ignorance. The patent represents a new hope, that of "creative destruction" (to use Shumpeter's term, perhaps badly)--undo current investments with something new, something defended by a patent, and so able not only to create new opportunities and benefits, but also create new wealth for inventors, for those taking risks--as distinct from those managing and profiting from the status quo.

Each of these lines of reasoning has its merits, and each has its limitations and corruptions. The first line can end up in rejecting the patent system--that inventors should have no interest in their work, simply because public funds are provided to support their work. It's one thing to reject the patent system entirely (and then we are back to the problems of trade secrets); it's another to reject the patent system because public money or resources were used in research that led to an invention. If public money in research permits a researcher to have a livelihood with income (and thus spend salary on private goods) and also permits a researcher to gain prestige through discovery and invention (and thus gain consulting contracts and offers to work in industry or government) and the like, why are these ancillary benefits also not forbidden? What do we have left, but for some sort of self-effacing research robot, serving the "public" and having no interest in the results of the work? Mindless, cruel.

The second line can end up rejecting public interest. Power corrupts, and the power of a patent then also may corrupt. Corrupt, here, is used loosely, of course. One might say that any pursuit of power is merely a form of self interest, and according to a very loose reading of Adam Smith, an "invisible hand" guides cumulative self interest to society's greatest good. Even Ayn Rand doesn't go so far as to admire all forms of self-interest as ultimately beneficial. She takes pains to describe the special forms of self-interest that are virtues--having a purpose, seeking one's own achievements without the need for approval, not compromising with parasitic claimants--and the others that are vices.

But worse, this second line can end up making it appear that it has the public interest more deeply in mind than might any mere inventor. That institutions can care about the public interest in greater, more productive ways than can individual inventors. That somehow, those individuals authorized to act on behalf of institutions can care better about and for inventions than can inventors themselves. In this second line of reasoning, bureaucrats decide who is best suited to

enjoy the monopoly power of patents on inventions made with public support. And thus we end up with an argument that universities should own inventions made with public support, that they should pass patents on these inventions on to monopolists to extract maximum value from them, and that by sharing in that value in the form of payments, royalties, research funding, equity in startups, and settlements for infringement actions, the university gives back to the public a portion of what the public has paid to support the research. Except the university, of course, gives nothing back to the public--it keeps the money for its own activities.

In this line of reasoning, however, we see the outline of the arguments behind Bayh-Dole, which are not about American innovation keeping up with the Japanese and the Germans, but rather about how middlemen designated by university administrators should have free access to patents taken out on publicly funded research, so long as inventors receive a share of the action. Although inventors should have no personal right to their inventions--that would be inefficient if not corrupt--middlemen should have such a right, but on behalf of a worthy institution. That's the argument--or perhaps it is just the illusion of an argument. It starts as a business proposition for inventors--"choose us and we will help you advance your dreams." It ends as a compulsory assignment scheme combined with a fixation on profiting from monopolies in whatever way profit is to be had--speculating on the future value of patents, trolling industry for infringement, breaking up existing monopolies, increasing the power of existing monopolies, creating new monopolies to "roll up" existing practice, and even creating new products that might benefit the public. There's a thread of public interest in this line of reasoning, but the fabric itself is simply an interest in exploiting patents for profit, no matter the underlying invention, the effect on the market, or the nature of public benefit.

WARF's charter was designed to prevent the University of Wisconsin from using its money for non-scientific research--social sciences, humanities, and the like. The charter also prevented WARF from funding as well as university public service. The idea was that research in the sciences would produce more inventions, and the inventions when patented would produce licensing income, and that income could then be invested in stocks, and each year this financial engine could turn a profit while accumulating capital, and that capital could then be used to generate more inventions. WARF was designed as an engine to accumulate capital, use that capital to make more capital through investment, and return a portion of the profits to the University. In that, by any estimate, WARF has been wildly successful.

In WARF's focus on natural sciences research, we find Bayh-Dole's requirement that nonprofits use any balance of licensing income for "scientific research or education." The provincial interest of WARF founders became, when WARF officials worked alongside Norman Latker at the NIH to expand the IPA program government-wide (and therefore nation-wide), a national provincialism. Each university was set up to compete with other universities to gain a share of

patent royalties from the inventions from research each university hosts. As hosts to federally supported subvention research, universities are generally not employers and ought to have no interest whatsoever in the inventions made by personnel working with their resources. But with the WARF model, university administrators have come to believe that each of their universities is distinctly entitled to the lion's share of proceeds from the exploitation of any invention made at their universities.

One can see the present dispute between the University of California and the Broad Institute of MIT and Harvard as another working out of this competition among universities for patent income--and it goes directly back to WARF's revolutionary idea that patents should serve a local money-making interest of institutions rather than to create a rich public domain from which all companies might draw (or, alternatively, to provide resources for funding science nationwide, or to allow inventors to pursue their own interests or to choose their own invention management strategies, agents, and gestures toward supporting research or innovation or community--all of these alternatives are foreclosed by the revolutionary WARF approach of the "captive venture."

WARF's Antitrust Problems

WARF was founded to manage an invention involving generating vitamin D in milk. The term "vitamin" itself emerged from research at the University of Wisconsin in the previous decade. Essentially, Steenbock figured out a way to irradiate milk to produce vitamin D, thereby by-passing federal regulations that limited placing additives into milk--a clever end-run, if you will, of federal regulations. But there was more to it than this. Here's how Cronon and Jenkins describe the invention:

> even cure the then common bone disease of rickets. Steenbock had insisted on patenting his process in 1924 to make sure it was not used to undermine Wisconsin's dairy industry by improving the nutritional value of oleomargarine. He had no interest in handling the marketing and licensing

This position came back to haunt WARF some years later, when WARF was sued for antitrust violations in its licensing of Steenbock's invention. Here's a bit from the court decision against WARF (1945):

> This raises the question, not argued, whether the effect on the public health of refusing to the users of oleomargarine, the butter of the poor, the right to have such a food irradiated by the patented process is against the public interest. As seen, the general business manager of the Wisconsin corporation testified **that it is the poor people suffering with rickets who constitute the principal market for appellee's monopolized processes**

> **and products.** The evidence and appellee's briefs are replete with well verified statements of the great boon to humanity of Dr. Steenbock's scientific discoveries for the prevention and cure of rickets. **The truth of such statements make the stronger the contention that it is a public offense to withhold such processes from any of the principal foods of the rachitic poor, or, indeed, from those of any such sufferers.**

In other words, WARF managed Steenbock's invention not to make the invention publicly available for use in all areas in which it might help the health of those in need of it, but rather to prop up the Wisconsin dairy industry in its competition with margarine, the buttery-like spread of the poor. The court goes on to point out that Steenbock reports that European countries require vitamin D to be added to margarine for just this reason--to improve the health of the poor. Thus, WARF commits what the court calls a "public offense" by using its patent monopoly to prevent the use of Steenbock's process in the making of margarine. The court invalidates WARF's Steenbock patents--the ones used to start WARF. The premise that WARF starts on is a work-around on federal regulations involving additives to milk, using a patent monopoly that turns out to be invalid, and using that monopoly to make milk product better compete with margarine, at the expense of the health of the poor. That's the intellectual tradition that leads, eventually, to Bayh-Dole.

The WARF antitrust court's reasoning gets at another problem side-stepped in the drafting of Bayh-Dole's "march-in procedures." In Bayh-Dole the procedures make an effort to focus march-in on the "reasonable availability" of each subject invention. There's nothing that indicates that a monopoly on one area of use might create a limitation in another area of use that could trigger a federal march-in. All that's needed to preclude march-in is that an invention is being used with public benefits and is reasonably available. What's not considered by the march-in procedures--or, better, what is carefully omitted--is exactly the problem of how a patent may be used to prevent many uses in favor of a few. Thus, with Xtandi, only one of hundreds of compounds has been developed for clinical use, while the rest are made by the patent(s) unavailable for public use. No march-in, technically, because "the invention" is being used--but it is *the use of the patent* that is the issue when it comes to public access and benefit.

The WARF antitrust court, citing other cases, asserted that a patent carried with it an element of public interest (I've omitted the citations):

> It is now well established that a patentee may not put his property in the patent to a use contra to the public interest. The grant of a patent is the grant of a special privilege "to promote the Progress of Science and useful Arts." However, as stated in Mercoid Corp. v. Mid-Continent Inv. Co., it is not the private use but "the public interest which is dominant in the patent system. . . ."

While it may be that courts are relatively disinterested in antitrust behaviors now (and thus university patent administrators are happily embolden to sue for infringement and to include language in exclusive licensing agreements that gives incentives to licensees to sue for infringement), one can see in the WARF antitrust court decision a form of public covenant that is inherent to the patent system. While a patent may have the "attributes of personal property," it also has attributes of public interest. The court quotes from the same case as above to bring this home:

> "Respondents ask the equity court for an injunction against infringement by petitioner of the patent in question and for an accounting. Should such a decree be entered, the Court would be placing its imprimatur on a scheme which involves a misuse of the patent privilege and a violation of the antitrust laws. It would aid in the consummation of a conspiracy to expand a patent beyond its legitimate scope. **But patentees and licensees cannot secure aid from the court to bring such an event to pass, `unless it is in accordance with policy to grant that help.'**

One thinks, then, about the use of the term "policy" in Bayh-Dole's statement of "policy and objective" at 35 USC 200, which is made a part of federal patent law. The addition of "policy" has import--"policy" is not merely an intensifier for "objective." The "policy" set out in Bayh-Dole displaces executive branch patent policy, to be sure, but it does more than that--it also sets out the public policy to be considered in any action to enforce patents on subject inventions. Again, the primary policy is "to use the patent system to promote the utilization of inventions arising in federally funded research." Any court asked to rule on a claim of infringement of a patent on a subject invention must consult this statement of public policy. How does stopping the use of a subject invention or demanding an accounting for such use *promote the use* of the invention? It would appear that Bayh-Dole sets a high standard for what can pass as a legitimate enforcement of a patent on a subject invention *in the public interest*.

WARF encountered multiple antitrust problems. Consider this account from Cronon and Jenkins:

> A less happy WARF undertaking was the decision to patent the anti-cancer drugs 5-fluorouracil (5-FU) and 5-FUDR developed by oncology Professor Charles Heidelberger at the McArdle Laboratory for Cancer Research in the mid-1960s.[24] 5-FU turned out to be one of the most effective chemotherapy agents for treating some forms of cancer. WARF granted an exclusive license to the drug giant Hoffmann-LaRoche, which had helped fund Heidelberger's work, to manufacture and market 5-FU. Because

This is pre-Bayh-Dole, of course, but also pre-revived IPA, and also pre-Kennedy patent policy. The patents issued in 1959 and 1961. The co-inventors' work (one from the University of Wisconsin and one (apparently) from Hoffman-LaRoche) was funded by federal money, foundation money, and company money. WARF gets patent rights and licenses the patent exclusively to the company. The public money? That gets noticed as the royalty and diligence provisions in the exclusive license (as if, ahem, there would be no such royalty or diligence requirement otherwise). And what happened then?

> fund Heidelberger's work, to manufacture and market 5-FU. Because Heidelberger's research had also been supported in part by grants from the U.S. Public Health Service and the American Cancer Society, the PHS objected to WARF's patents and its exclusive license to Hoffmann-LaRoche. Accusing WARF of restraining trade in violation of the federal anti-trust statutes, the agency claimed at least partial ownership of Heidelberger's research and threatened to cut off PHS and perhaps other federal funds to the University. Under prodding from UW President

Look at it from the PHS perspective. PHS provides subvention funding to a researcher at a university, expecting results to be published and public benefit to come from everyone's access to those results. A richer public domain, you might say. Instead, WARF gets patents and creates a monopoly, granting the right to exploit that monopoly to a company research partner. One argument (made by Phyllis Gardner, a BIO representative at a Congressional hearing in 2003) was that the federal government's intervention to put the WARF patents on 5-FU into the public domain delayed the creation of commercial products.

Another argument (not made by anyone that I know of) is that WARF patents on 5-FU restricted research on finding more effective and less toxic forms of cancer therapy by claiming by patent a wide range of compounds, of which 5-FU is a part. It may well be that it is expensive work to choose one of these many compounds and prepare it for as a commercial product--but it is even more expensive if one has to do that work alone, without anyone else contributing insight and resources. Perhaps if one is a wealthy company, or has wealthy backers, it is desirable that the cost be sufficiently great that no one else would attempt development. Perhaps that is the effect of patent monopolies--to ensure that the investment opportunities go to those with access to sufficient wealth to pay for whatever work is needed to create a commercial product. If there are to be "high returns" from such "high risk" activity, then those returns should properly be directed to those who have the wealth to command the opportunity in the first place.

One does not have to go down the road toward stripping patent rights from all inventions made with public support to wonder whether patents in the hands of institutions results in creating a

betting parlor for wealthy speculation--that betting parlor may well also result from time to time in commercially valuable products, and even in public benefit. The question is not whether such things happen but rather whether it's good public policy to set things up so that such things happen preferentially, so the system is rigged, as it were, for this result.

So what happened with 5-FU?

> federal funds to the University. Under prodding from UW President Harrington, the dispute was quietly settled in 1965 with WARF assigning a quarter interest in the five Heidelberger patents to the Public Health Service. The agency thereafter declined to grant exclusive rights to manufacture 5-FU, thus effectively placing the drug in the public domain. Following this dispute, WARF and University officials developed new WARF guidelines ending the practice of exclusive licenses and seeking

Of course, there was no "drug"--there were multiple--many, a plurality--of compounds claimed by the patents, along with processes to make them. And the compounds were not placed in the public domain--they were made available under the government's patent rights. What was lost, "effectively," was a monopoly held by the company that had done the synthesizing of a compound in support of the research at Wisconsin.

Public Health Service Invention Policy

Should some public money involved in the research prevent an researcher from obtaining a patent? Should that public money require the patent to be licensed non-exclusively (even if not royalty free)? Or, should that public money require the researcher to give up rights to the invention to the university, to be passed over to WARF, to be managed so that WARF and the university get a majority cut of whatever income they make from licensing the patent? Under the Kennedy patent policy (1963), companies with commercial positions and capability were allowed to "retain principal rights" in inventions made with federal support. One would think, if things were being managed at the PHS consistent with the Kennedy patent policy in the mid-1960s, that Hoffman-LaRoche would be allowed to retain principal rights. But that's not what happened.

The PHS issued regulations in 1963 ahead of the Kennedy patent policy that appear to address the WARF situation:

1. *Formal reports of inventions.* Department of Health, Education, and Welfare regulations (45 CFR, parts 6 and 8) provide that all inventions arising out of the activities assisted by Public Health Service grants and awards shall be promptly and fully reported to the Surgeon General. In respect to inventions reported, the institution and the principal investigator agree either: (a) To refer the inventions to the Surgeon General for determination, in accordance with Department patent regulations, of the ownership and manner of disposition of all rights therein and whether patent protection on such inventions shall be sought, and, if so, the manner of obtaining, administering, and disposing of the patents in the public interest; or (b) where the institution has a separate formal patent agreement with the Surgeon General covering inventions deriving from Public Health Service support, to make a determination of ownership and disposition in accordance with its policies as approved or as modified by such agreement. *In no event, shall patent applications be filed on inventions reported under (a) above, without prior written consent of the Surgeon General.*

That is, reporting of inventions is rooted in a concern that organizations such as WARF might pop off on their own and patent inventions in which there has been PHS funding, and then have to be brought to heel for it with litigation. Instead, inventions are to be reported first, not afterward. There are two options:

> 1) the institution and principal investigator report the invention to the PHS, and the PHS decides what to do to "dispose of the patents in the public interest" (since, apparently, inventors cannot be allowed to use the patent system on their own, which in this line of reasoning would not on its own without public oversight be in the public interest--despite what the court in WARF antitrust case involving irradiated milk had to say. The PHS here aimed to prevent having to go to court to enforce its public policy specific to research to improve health care. Whatever the patent system might be good for in general, the PHS insisted that a public covenant should follow any invention made with federal support--antitrust law was not enough, not soon enough, and expensive to use.
>
> 2) if there's an IPA (the IPA program started in the early 1950s, but only a few universities obtained an IPA before adding institutions was suspended), then the institution and principal investigator "make a determination of ownership and disposition in accordance with [the institution's] policies"--including any modifications to policy required by the IPA.

Regardless, the PHS is adamant that no patent applications can be filed without PHS approval unless there's an IPA. The reporting requirement gets further attention:

The Public Health Service patent policy is a part of the terms and conditions of a grant, and is accepted by the principal investigator and the institution when an application for Public Health Service support is completed and signed. The grantee institution and the principal investigator have joint responsibility for abiding by Public Health Service patent policy and for reporting any conflicting commitment or obligation entered into by either entity. Early reporting of inventions and related technical data is required; that is, no later than at the time a manuscript is prepared for publication, or at such other time and in such manner as the Surgeon General may prescribe.

Progress Reports, which may include descriptions of possibly patentable inventions, may *not* substitute for formal reports of inventions.

That is, the PHS patent policy is part of the funding agreement. Both the institution and principal investigator are parties to the funding agreement and have "joint responsibility" for compliance, including reporting inventions.

2. *Annual invention statement.* An Annual Invention Statement must be provided as part of the request for renewal of each type of Public Health Service grant and award. This statement must be submitted even if no invention has occurred during the current period of grant support for which renewal is being requested, and even if an invention to be reported was only partially supported by Public Health Service funds. *The statement should include all inventions which might possibly be construed in any manner to be Public Health Service grant supported or related.* Renewal of a grant will not be paid until the Invention Statement has been received.

When an award terminates and no renewal is planned, an Annual Invention Statement must be submitted as part of the required final progress report.

The italicized portion represents the point of concern: the PHS wants to know of any invention that is grant supported or even *grant related*. That is, the claim is that inventions made regarding public health and related ("might possibly be construed in manner") to PHS funding must be reported.

The PHS language is reminiscent of the 1958 Space Act requirements on federally funded research involving space technology.

> Sec. 305. (a) Whenever any invention is made in the performance of any work under any contract of the Administration, and the Administrator determines that--

> (1) the person who made the invention was employed or assigned to perform research, development, or exploration work and the invention is related to the work he was employed or assigned to perform, or that it was within the scope of his employment duties, whether or not it was made during working hours, or with a contribution by the Government of the use of Government facilities, equipment, materials, allocated funds, information proprietary to the Government, or services of Government employees during working hours; or
>
> (2) the person who made the invention was not employed or assigned to perform research, development, or exploration work, **but the invention is nevertheless related to the contract, or to the work or duties he was employed or assigned to perform, and was made during working hours, or with a contribution from the Government of the sort referred to in clause** (1), such invention shall be the exclusive property of the United States, and if such invention is patentable a patent therefor shall be issued to the United States upon application made by the Administrator, unless the Administrator waives all or any part of the rights of the United States to such invention in conformity with the provisions of subsection (f) of this section.

That is, under the Space Act, if an invention was made under a federal contract, or with a contribution of resources from the federal government, or related to the contract and made during working hours, the government owns the invention unless the government waives its rights to own.

The PHS policy suggests much the same thinking, but as a matter of federal contract rather than statute. Matters of public health are comparable to those of space exploration--if the federal government has contributed, then the disposition of patents rests with the federal government unless it has agreed otherwise. It does not matter if the invention was made in the performance of work or is just related to the performance of work; the disposition of any such invention is a matter to be decided by the federal government in the public interest--and not, then, in the private interest of any particular inventor, university, patent broker, or company.

On the one hand, this requirement makes perfect sense. The federal government need not be in the business of supporting research to aid the public only to have everyone involved trying to clean up financially with patent monopolies and creating patent gridlock when they are not creating monopolies to gouge the public (and the federal government, if they can get away with it). On the other, the requirement appears over-reaching. It aims to do by policy what ought to be a matter of statute. If there are to be limitations on the patent system, so that inventions of a given sort should not be issued to the inventors, and the inventors are not free to manage their

interest as they wish, then shouldn't those limitations be expressed as statute and not simply as the demands of a federal agency?

Bayh-Dole, as it turns out, will be that statute that limits federal patent law, but in such an obtuse way that in effect it creates only administrative burdens (despite its gestures otherwise). Because Bayh-Dole is largely unenforced, with no provisions to protect inventors or third parties, or to provide the public with accounting or procedures by which to object to the private disposition of patents, it stands as not only a repudiation of the overreach of the PHS but also of public oversight of inventions made with federal support or related to that support. Federal research funding becomes, under Bayh-Dole--that is, unenforced Bayh-Dole--a subsidy for private patent monopoly exploitation. And university administrators have adopted that approach *whole hog*, as the expression goes.

What should the scope of claim by any sponsor of subvention research be in the disposition of results? For procurement, the matter is easy--start with the sponsor enjoying the freedom to practice what has been specified as deliverables. Anything else that's made or invented or discovered along the way is irrelevant, so long as it does not interfere with what has been ordered. Of course, research is weird this way, as even in procurement, one can specify research services "to explore," so that anything that's found in exploring is the deliverable. The problem then is to specify what's exploration on contract and what's exploration in one's spare time. How does one set limits on exploration, so that exploring in one's spare time, in the same area that one is to explore "on the clock" does not result in the production of yet more deliverables for the all-consuming sponsor?

Perhaps the very idea of deliverables from "research" is unworkable because it lacks scope. One might procure the solution to a problem, but not the research that goes into finding the solution and proving it out. One might get the benefit of something that works, and not demand also all that someone has learned or thought about or created along the way to deliver that something in working condition. The PHS claim to anything "which might possibly be construed in any manner" to be PHS supported or related amounts to a requirement not to use the patent system for such work, unless approved to do so by the PHS--and then with conditions running on top of the patent system and antitrust laws.

The argument that's latent in the PHS requirements is the same one in the Space Act--there should not be a proprietary "market" for advances in the area of new technology that might alleviate suffering and disease. A surgeon should not prevent other surgeons from saving lives with a new technique or tool. A company should not prevent doctors from using a new compound to treat disease or prevent other companies from supplying that compound or variations of the compound or different formulations involving that compound or different methods of delivering

that compound. The only market in alleviating suffering and disease ought to be in the expert provision of responsive services, without limiting the services (or products) that others may also provide. That, at least, appears to be the determination at the heart of both the PHS and the NASA approach to patents in their respective areas of research support.

In such a "market," especially one created or stimulated or entered by government research funding, the idea goes that patents serve no good purpose. The government, one might say, need not consider granting patents when there is or should be no domestic "market" in which goods should be proprietary. It's like "patents in space": who is going to worry whether some use of a technology on board a space craft infringes a patent.

> "The only way to save the crew is for them to use their lithium crystals as a radiation shield."
>
> "But that would infringe Bobblespace's patents!"
>
> "The crew will have to take that risk."

Think of health care on its own frontier of science and technology, and the idea of patents fades as beyond useless--immoral. Wagon train folks who can't fix the wheel on their cart because the process of fixing wheels has been patented. People in a drought-stricken region cannot drill for water because the drilling process and tools they would use are patented.

Put it this way: there are some areas that form markets and others that do not and should not. Patents are not appropriate in areas that don't and shouldn't form markets. The government should not issue patents in these areas. Thus, for a long time, space or nuclear power did not form markets--all there was, for the most part, was government funding for procurement or research. The government got all the reports and decided what to hold and what to publish. It did not need the patent system to give people an incentive to publish what would otherwise have remained trade secrets. There was no purpose to patents--all patents would do is to prevent companies from bidding for more work from NASA. That is, patents would quickly make a hash of competitive bidding or open use by one contractor of what had been supplied to the government by another contractor.

In a similar way, from the PHS perspective, if the government was to be involved in meeting the public health needs of the country, then those people working with the government to discover useful things that might serve to alleviate suffering and disease should adopt service without the need (or "incentive") to exclude others from using what has been put forward.

In both of these developments, we are dealing with the provision of services--commercial or university-hosted--that do not require the production of "products." While "products" may be produced once an "intervention" has been developed, the "market" in the meantime is "exclusion-free." Once a product has been defined, then companies may compete, may create proprietary positions in improvements and add-ons and methods that improve efficiency of production and the like. One might recognize in this account the use of a commons to form a "platform" that establishes a standard, for which there are "essential" rights (ones that all should have access to) and "non-essential" rights (those that may be proprietary and for which one may have a competitive advantage).

The digital computer and the internet both followed this approach. In the early history of the U.S. aircraft industry, the government had to intercede and get competing companies to create a common standard--otherwise their various claims created patent gridlock and stalled domestic development while other countries moved ahead with aircraft development. A similar thing has happened with nanotech in the U.S., led by universities filing patents on every tiny (so to speak) detail of such things as carbon nanotubes--essentially stalling out development rather than promoting it.

Imagine if you will getting mining rights that apply only to the top foot of earth, and to dig at any depth, one must acquire mining rights from fifty or a hundred other rights holders, who have filed claims beneath your own. These other claimants, of course, have the same problem--they need permission from you and a hundred others to get to their foot of earth.

The idea then, is not that patents are in general useless (that's a different discussion), but rather that there's a point at which the government might issue patents, and that point happens after there's been research and testing and application. Competition based on exclusion of others based on government-issued patents happens later, not during government-supported research, not during work within the government's domain of primary interest, working on behalf of a general good. The debate, then, is about when the government should start issuing patents in a given area of research that the government has chosen to support for a public purpose (rather than merely to procure goods and services that are generally available). The PHS answer is--later or never. And that, interestingly, was the answer that many university faculty members in schools of medicine gave as well, circa 1950. Here's Harvard's policy in 1962:

> No patents primarily concerned with therapeutics or public health may be taken out by any member of the University, except with the consent of the President and Fellows; nor will such patents be taken out by the University itself except for dedication to the public. The President and Fellows will provide legal advice to any member of the University who desires steps to be taken to prevent the patenting by others of such discoveries or inventions.

One might see, then, where the PHS was coming from in expecting that faculty at the University of Wisconsin, and using WARF's services, would follow along. To exclude others in this area of research, at this point in the research, was immoral. Exclusion prevented other researchers from working on the same findings. Exclusion created institutional conflicts of interest. Exclusion pitted investigators against one another for funding. Exclusion created opportunities to exploit public suffering using government-created monopolies. Why would the government participate in such activity by issuing patents and leaving folks to create fragmented ownership, institutionally licensed new technology? One cannot get to platforms that way, nor to public availability.

Two distinctions were made about when patenting might take place based on government funding. These both show up in the Kennedy patent policy in 1963. The first is when a contractor has an established commercial position and capability. Then the contractor can be left with patent rights if the contractor wants them, so long as the government has free rights for its purposes. This distinction separates a private market for inventions from the government market for inventions. The government market is "exclusion free." The private market can deal in exclusion for competitive reasons. One might see in this distinction the makings of the "dual use" idea in military research--that there might be a civilian, non-military use for technology originally developed for the military. Thus, sonar might result in a dual-use fish-finder for commercial and recreational fishermen. In this line of thinking, the Kennedy patent policy gave a contractor three years from the date of patent issue, or about five or six years overall, to get something developed commercially or explain why, again, the contractor should have a monopoly.

The second distinction has to do with "calling forth risk capital" when a contractor lacks a commercial position or capability. In this case, the government may permit private funding to do the work that otherwise would fall to the government to fund or would not be funded at all. In either case, however, the risk capital comes forth to do work in the public interest--to bring an invention to the point of "practical application" so that everyone has access and might benefit "on reasonable terms." Once the risk capital has performed its public service, recovered its investment, and received a reasonable profit, the incentive of patent exclusion should end and everyone again should have access. To the extent that commercially viable products are now possible, the opportunity should be shared among all those that wish to pursue it. In effect, the private risk capital creates a platform, is allowed to exploit that platform for a time to recover costs, and then releases that platform for all to use. Just as with commercially positioned contractors, the risk capital supplier has five or six years of monopoly to get something done, make it available, and recover costs with some profit.

Again, from the government's perspective, given that it is providing the funding, it can require inventions as deliverables and dedicate the inventions to the public--expanding the public

domain, just as if the research had been done in another country, or we just realized naturally what it had taken some effort to reveal. The advantage in such cases is not in what one knows, but in what one does with that knowledge--commercial proprietary advantages then lie in the improvements to the platform, especially the "non-essential" improvements. Where the purpose, however, is to alleviate human suffering and disease, the government's supply of monopoly powers in the form of patents still may require limits on the use of patents relative to patents in general. That's the concern--that in matters of public health, if patents are go be used, then there must be a public covenant on that use that limits the patent.

In these two distinctions, then, we find a critique of the patent system when applied to research conducted to advance the frontiers of science or to address matters of health, supported by federal money. In these areas, the patent system on its own permits a term that's too long and allows a patent owner to do things that run against expectations, such as preventing all use of an invention or charging exorbitant fees for use of an invention or delaying development and then suing all who use the invention anyway, in essence taxing them for doing what the patent owner chose not to do.

If the need is urgent, as is the case with public health where people are suffering and dying, then leaving a patent owner to fuss around for two decades doesn't work. If the need involves things where there really shouldn't be a "market" based on exclusion, such as medical care, then a patent fails to protect the public from exorbitant prices, meaning that only the rich gain the benefit of access, or the government (or insurers or charitable organizations) must pay the cost *as if everyone was wealthy*. This is a wonderful result for patent owners and speculators on the future value of such patents. Where people are dying, the price charged can be sky high, since you have got them, as it were, by the throat.

Medicinal Chemistry

The IPA program, revived by the NIH following the Harbridge House report, which singled out medicinal chemistry as one of the few areas where there had been a disagreement by industry with government patenting policy, addressed both patent term and public access. But the IPA did so by pushing the limits toward private control. Where the Kennedy patent policy said three years from patent issuance, the IPA ignored that term and substituted the sooner of three years from the date of first commercial sale or eight years from the date of an exclusive license. One could then, with option terms and the like, run a patent monopoly for close to fourteen years rather than six. Extension of the monopoly also became a matter of agency approval, without any provision for public input. March-in rights were a matter of the government exercising its non-exclusive license. The government could break any private patent monopoly at any time for any government purpose. That is, the government could choose to expand the government-side

approach to health care and break or shorten exclusive positions that the government had permitted patent owners to take up on the premise that the government was not operating in those areas (yet).

Bayh-Dole repudiates the public covenants on term and use altogether, while retaining an apparatus that makes it appear that those public covenants still operate. The original version of Bayh-Dole contained a term limitation for exclusive licenses--*five* years now (rather than three) from date of first commercial sale, or eight years overall. That limitation was removed four years later, along with other changes that gutted the public covenant and public oversight (such as making all information in use reports exempt from public disclosure rather than only the privileged or confidential portions of those reports). Because Bayh-Dole is structured as requirements to be placed into a federal funding contract as defaults rather than as a statute that expressly limits the patent rights available on inventions made in federal subvention funding, there's nothing in Bayh-Dole that requires federal agencies to enforce any aspects of the patent rights clause in any funding agreement. Agencies appear to enforce consistently only the placement of a federal funding statement in patent applications and U.S. manufacture for exclusive licenses to use or sell in the U.S.--and even U.S. manufacture Bayh-Dole allows to be waived.

Thus, Bayh-Dole, as public policy, uses an apparatus that appears to offer limitations on the behavior of patent owners on subvention inventions--and especially inventions made in biomedical areas--but in fact opens up the use of the patent system for any use a patent owner may choose--including non-use, trolling, and monopoly pricing. While these activities might be "legal" in the general case of patents, the particular area of public health supported by public funding has, for good reason, not been considered just any area for "whatever the market for suffering and dying people might bear." In this mindset, suffering and dying people represents the absolutely best market profile for monopoly positions. If a corporation owes its shareholders a duty of maximizing income, then a corporation with a monopoly in an area of alleviating suffering and dying is the best possible investment opportunity. "High risk, high return" indeed. At some point, advantage becomes gouging and gouging becomes immoral and the immorality breeds popular hatred.

The question for public policy around research patents that have come about because the government funds the research and the government issues the patents and the government permits the patents to be used to gouge or restrict access is simply "why?" Why should the government conduct its affairs so that such a result comes about? One might argue--this is the way of the world, let it be. But it's not that at all, since it is a government-enabled situation all the way around. It ends up being "government in the service of creating hated monopolies that exploit the suffering and the dying." Responses might include eliminating federal research

funding from these areas. Or redistributing federal research funding so that funding follows significant findings from laboratory to practical application--and requires inventors making claims to make themselves available to follow those claims toward practical application. With a redistribution, there is no need for the government to use the patent system (or charity) to "call for risk capital." The government with a wink can provide more funding for research and development than all the "fun runs" for breast cancer combined, all time.

There is no need for companies to own monopolies on any therapeutic compound--they can provide contract services. Heck, that's exactly what the nearly virtual company Medivation (now part of Pfizer) did with Xtandi. The company existed to find a drug commercialization opportunity. It obtained a class of compounds from UCLA, made with federal support. It outsourced the development to contractors, spending (as best I can tell no more than $300 million across two drug candidates, one which failed and wasn't part of the UCLA deal). The drug itself earns billions per year, is priced north of $80 a dose in the U.S. and can be made profitably for under $5 a dose. Why could not the government do what Medivation did, and outsource the development to contractors? Yes, doing so would turn a multi-billion dollar patent asset into nothing, but it would also shift the transfer of wealth from the government, from charitable organizations, from private insurance companies (and thus, from the insured) to the speculators that use public suffering as the premise for maximizing their investments.

The Bayh-Dole Act is premised on the idea that the government funds research and then ignores the results, and goes off to fund more research. To develop results to practical application must, in this idea, be "left to the private sector." That is, there are no special environments--everything that can be turned into a market must be a market, and everywhere a market can be dominated by those with substantial wealth (enough to secure and enforce monopoly patent positions, for instance, plus pay to develop technology) must be allowed to be so dominated. Of course, Bayh-Dole does not forbid special environments--it even has a section devoted to "exceptional circumstances" and another to "march-in"--but it has set these up to be unusable, as if the government is "taking" private property from the institutional speculators by placing limitations on the scope of their patent rights or use of their patents on inventions made with public support. And we aren't even talking about the principal investigators or the inventors themselves--Bayh-Dole enables them to take inventions with impunity, without any thought that they are "taking" personal property and ought to show due process and just compensation (for which sharing royalties is hardly just, given there's no diligence obligation and no assessment regarding what the value of the future value of any given invention is at the time of the "taking."

We have gone a long way around to place some context on the response of the PHS to WARF's 5-FU patenting behaviors. The PHS responds by requiring disclosure of everything and restricts patenting until approved by the PHS unless there's a patent agreement in place with the PHS that

provides otherwise. It's the IPA, then, that Wisconsin and WARF lacked that got them into trouble. Here are the two provisions in new PHS policy that appear to go directly after WARF's 5-FU patents:

> 3. *Amended patent agreement.* In the following instances, procedure requires the completion of an amended patent agreement, which, when signed, becomes a part of the terms and conditions of a grant or award:
>
> (1) Where the institution proposes to subcontract with a commercial organization for a portion of the research to be conducted under the grant.
>
> (2) Where the investigator proposes to submit compounds to be synthesized and/or developed with Public Health Service support to a commercial company for screening purposes.

The subcontractor cannot walk away with patent rights free and clear of PHS oversight. The terms and conditions of the prime funding agreement must flow down to the subcontractor, especially when the subcontractor is a for-profit. And second--and this is what Heidelberger did--if the investigator sends compounds out to be synthesized or screened, then that work, too, must come within the scope of PHS oversight. Otherwise, these are two easy work-arounds to any public covenant on inventions made with federal support. One might argue (as WARF did) that only a small amount of the funding for the research came from the federal government. In its reductio ad absurdum version, the amount of material federal funding becomes $1, no more than a Cheshire cat's grin. The issue, however, is circumvention of public service by offering (or selling, or licensing) the opportunity for a monopoly position to others who may then operate outside public oversight.

One can see why the concern at most companies that had a concern (according to the Harbridge House report) was in "mixing" federal funding with any other effort. Federal funding had to be firewalled from any other company activity. Put that work in a separate division, a controlled lab space. The universities, however, had little interest in doing such things, other than for defense classified work, and there only grudgingly--and again isolating the work in controlled spaces.

We can then construe the debate a different way. Rather than worrying the proper range of patent rights (term of exclusivity, nonuse, trolling, monopoly prices) or whether there should be any special environments (scientific frontiers research, public health) in which commercial activity based on patent rights should be limited or regulated, or when in those markets full exclusionary patent positions should be made available by the government, we might ask whether public money should drive out personal opportunity or replace private opportunity with government controls.

As with most anything in this area, things are wrapped up in other things. Turtles on turtles, in a long stack of turtles. But let's try to unwrap and unstack just a bit. The private opportunity lies with an inventor working in an investigation. The premise of the investigation is that it is in the "public interest" and so may be done with university resources and government or charitable money. Is this premise legitimate? Is it somehow binding? Should it follow through when a research finding takes the form of a patentable invention? If so, should the premise necessarily prevent the government from issuing a patent, or if it issues a patent, should it issue that patent to itself? Or if it allows the patent to issue otherwise, should it be to the inventor? to the principal investigator? to the university? to anyone who shows up with a proposal for managing the patent? or to the highest bidder? or to a government or university favorite, such as someone who starts a new company to exploit the patent right?

Here, we might challenge the notion of "public interest." Is there a *res publica*? Or is there just private interests, exerting power when they can, and laws are the collusion of the weak to bring down the natural right of those who are strong? We here have Callicles's argument in Plato's *Gorgias*. Or are there common things that no one should own, or should own only in trust, and should be used for all rather than in self-interest only. And if so, how ought we decide what those things are, and with what trust, and with what limits? Is it a matter of personal integrity, of wisdom and judgment, of duty? Or are there rules, a system, so that such things are "objective" and reduced to formalities?

Do we form our community so that the business person's responsibility is to alleviate suffering with market-based products, so that the "market" consists of those with injury or disease and the sellers with the best remedies have monopolies created by our government, because the business folks have got the capital to buy up every new thing in sight before its value might be spilt in providing ready access? What sort of "market" is this? Is it the market that would prevent public parks, and instead propose to sell access to parks to those that can afford to pay, and to those who can get someone else to pay for them? Yes, it might be a nicer park, but is a community composed this way even "public"?

It may be a big, unresolvable dichotomy--commons and capital fighting it out. On the one hand, freedom that can become enforced freedom, so that any advantage is prohibited, innovation is thwarted, and administrative authority to preserve a commons becomes more important than the commons itself. Stewards become kings, and the like. On the other, sufficient money may buy up what it wants, including the best opportunities to make more money, and so old money makes more money until making money in the abstract is more important than any activity one might undertake. Betting on baseball is more interesting and valuable than the game itself. Or, betting on the future value of biomedical patents is more important than the underlying inventions. The

goal is to preserve the value of the patents as long as possible--healing people is an ancillary outcome (good for PR) but entirely uninteresting in the great scheme of things.

Capitalism and Commons

The dichotomy between capitalism and commons is even evident in the history of WARF. Here's a footnote from Cronon and Jenkins on the problem WARF faced.

> [23]WARF was for many years a highly controversial undertaking, regularly chastised by the Madison *Capital Times* as an evil corporate monopoly, even when its actions were clearly in the public good, as when it acquired and held much of the river frontage around Wisconsin Dells in order to preserve its natural beauty from commercial development.

Here in one sentence we see both elements at play--WARF criticized for being a monopoly even when it acquires lands to be held in trust and kept away from "commercial development." That is, uses ownership to *prevent* commercial development in favor of creating a commons for all to enjoy (which, in my youth, I visited and had a great time--thank you for the memories, WARF). For patents, WARF makes the argument that monopoly enables commercial development, but when things are "clearly in the public good" (as that's considered by the authors), WARF is holding property in trust, for public access and to preserve "natural beauty."

While the dichotomy may be unresolvable--I think of it as a cognitive illusion--in a democracy we have access (in theory) to public policy behind having a patent system, which we might admit is not perfect, though we prefer it to be stable rather than changing every year. Further, many people have recognized that even if the U.S. patent system is perfect in general, there are still somethings that it is poorly suited to--surgery techniques, for instance, or certain kinds of business methods. We might say that it is not appropriate to patent football defenses, so that an opposing team cannot use that defense against your proprietary plays. Games ought to be games and not patent market places. "The game has stopped for a legal review. Tune in again in three years for a preliminary finding." We might say that it is not appropriate to patent a method of identifying and fixing software security defects, so that no software maker can fix that particular security defect without infringing the patent. The court in the WARF vitamin D case ruled that it was not appropriate to allow irradiation in milk products but not in margarine, when it was the poor that bought margarine and suffered from rickets. That is, you might have a patent, but the patent is itself a matter of public trust, and to suppress the use of a beneficial invention in such a way runs against the public trust and is (in an odd sense) anti-trust.

The government issuing a patent starts the stack of turtles teetering in the void of the universe. We could do without, in the context of subvention research. But we also operate in an environment in which the government also issues patents to others not receiving federal funds,

and those patents can then disrupt the path of research and the use of research results. Not everyone wants patents, even "valuable" patents. There's no requirement that every researcher use the patent system. Not even Bayh-Dole requires anyone to use the patent system. Bayh-Dole's primary mandate is to use the patent system--but with the qualification that the patent system is used to promote the use of inventions. There would be absolutely no need for Bayh-Dole to state that the use of the patent system does promote use of inventions. That would be meaningless, like a little Congressional aside to justify the law. Nor does Bayh-Dole assert, as a matter of law, that any use of the patent system must be regarded as promoting the use of inventions. That would be a restriction on the freedom of speech. Bayh-Dole instead places a fundamental limitation on when the patent system should be used, and how, for research inventions. But there's no mandate that the patent system be used at all.

Thus, even now, the turtle stack comes down to judgment. Who should decide when to ask that the government issue a patent? and with what conditions? Should it be the inventor? That's the way the patent law is written. It makes some sense to use the patent system in this form. But it is the principal investigator that proposes the project and chooses the people to work with to do the project. Should the principal investigator decide when a patent should be sought? Should the principal investigator have the right to make this decision a condition of collaboration (or use of public funds) in any research project. That makes some sense, too. The director of a project ought to have something to say about how anyone stakes out proprietary positions on inventions, just a director might with regard to data that's collected, or findings to be published, or tools that have been developed. "I made these glass beakers, and no one else may use them for this project or any other project without my permission, which right now, I'm not giving." Hmmm.

The PHS policy from 1963 argues differently. The Surgeon General should decide. That's the judgment that matters, what the Surgeon General thinks, or what advisors to the Surgeon General think, or what advisors to those delegated with making the decision on behalf of the Surgeon General think. How is that thinking doing? and will it be better informed than that of the inventor or the principal investigator? The objection to PHS administrators making decisions about the role of patent rights in health-related research inventions is that they did a lousy, slow, inconsistent, and unfair job of deciding on patent rights. They were a machine to create wasted opportunities, under the spell that public domain and public interest were somehow synonymous or that the equation of the two was desirable.

The argument opposing the PHS was not that inventors or principal investigators had the better judgment, but that patent brokers acting for institutions would have better judgment than federal administrators. "Our bureaucrats are better than your bureaucrats." While the IPA program's premise was that nonprofit organizations might in some cases do a better job deploying inventions in the public interest than a federal agency could do, and calling forth risk capital using

patents only as necessary to make deployment happen better and faster and at lower cost to the public, the exploit of the IPA was that institutions have better judgment on the use of patents than inventors or investigators, better judgment than federal grants officers or Surgeon Generals. University of Wisconsin administrators have better judgment. WARF patent attorneys have better judgment. Wealthy Wisconsin alumni serving on WARF's board have better judgment.

The Crux of the Policy Debate on Subject Invention Management

At least with the IPA program, there was some public oversight for the claim. Wisconsin had to have its policies and practices reviewed and approved before it could get its IPA from the NIH. Bayh-Dole ignores all this. There is no requirement in Bayh-Dole that a university have a patent policy, or that its patent practices meet some threshold for competency or public spiritedness (such as expertise in royalty-free licensing that stimulates rapid development of research inventions). There's no review of anything--if an investigator at the institution can win a federal grant, then the judgment of institutional administrators is better than the judgment of the investigator or inventor or anyone employed by the federal government. That's Bayh-Dole--or at least the faux Bayh-Dole--in a nut-case.

Again, nothing in Bayh-Dole out and requires a university to take ownership of any invention made with federal support. The Supreme Court in *Stanford v Roche* was clear about that. All that's required of a university is to report inventions, educate personnel about reporting inventions, and require the (f)(2) written agreement. Everything else is a conditional--flow down requirements in a subcontract, flow down requirements in an assignment (even if labeled exclusive license), notify the government if one elects to retain title, file patent applications, include a federal funding statement, prefer small businesses, require if possible U.S. manufacturing for exclusive licenses to use or sell in the U.S.--all this stuff is extra, after a decision to own has been made. But Bayh-Dole gives no guidance on the judgment about when to own, and university administrators have--all on their own--decided to own everything they possibly can. Without Bayh-Dole, it's difficult to believe that they would have come to this position, and certainly not so quickly and so uniformly--it's almost like they conspired to reach this policy practice, as if they talked with each other and decided that taking all inventors' and investigators' interest in inventions would be the best thing in the world, and they could do so by saying that Bayh-Dole required it, or encouraged it, or vested that title, or prevented inventors from assigning title to anyone else.

The PHS makes clear in its 1963 policy that if there's a patent agreement--what would become the revitalized IPA program in 1968--then the patenting decision is a matter of the play of the policy at the institution. At Wisconsin, in 1963, that policy was that inventors owned their inventions and could do anything they wanted with them, other than as required by contract. The

PHS says that principal investigators and institutions must jointly comply with PHS regulations on patenting, But the PHS does not require institutions to own inventions, but rather that institutions should follow their policies. For Wisconsin, before 1969, that means leaving inventors alone to decide what to do.

WARF, in its turn, established policies that focused again on non-exclusive licensing, according to Cronon and Jenkins. That is, WARF accepted PHS requirements that patents on inventions made with federal support or related to that federal support would be made available non-exclusively--that is, the patent owner would break up the monopoly represented by the patent right. The idea was, then, that the purpose of holding a patent monopoly on a health-related invention was to break that monopoly up. How that breaking up happened--timing, with whom, for what consideration--was a matter for strategy, with the objective being timely use and public benefit. In other words, licensees paid for the value of breaking the patent monopoly and using that monopoly only to mitigate threats made against the use of the underlying invention. A single licensee did not pay for the value of preserving the patent monopoly. That offer was no longer on the table.

The result of the PHS's 1963 policy, directed apparently at WARF's 5-FU practice, was the pharmaceutical industry boycott of PHS-supported compounds. Pharmaceutical companies refused to screen these compounds or otherwise work with them unless the company involved could obtain exclusive rights. This is the crux of the policy debate. This is the basis for the Harbridge House report chapter on medicinal chemistry. That in turn was the rationale for restarting the NIH IPA program as a work-around to PHS policy by providing a pathway for exclusive licensing (in sort of keeping with the Kennedy patent policy, but in defiance of PHS policy). And when the effort to expand the IPA program government-wide was blocked, and the PHS terminated the NIH IPA program, all the tools were in place to create Bayh-Dole, to stick it to the competing public policy that government administrators should decide the disposition of inventions made in federal research, with a default of dedication to the public. Bayh-Dole upset that policy and made commercialization through exclusive licensing the default, but with an apparatus that concealed this default behind a vocabulary of public interest--an apparatus that has never operated. In both formulations, both PHS and Bayh-Dole, inventors and investigators have no role. They are hens that lay eggs. The public policy dispute was how the eggs should be served to the public--given away like an invention food bank? or held in vast refrigerators until there's an opportunity for some few to be sold at a high price?

One might think that neither approach is very good. One might begin to think that the principal investigator or the inventor might have judgment regarding the proper role of patents on their particular research discoveries and inventions that is every bit as good as that of any government official or university administrator. Indeed, in the voluntary approach to patents that most

universities took--inventors or investigators did decide when something ought to be patented, and then how that patent might be used--and sought outside agents such as Research Corporation or WARF to do the work. That approach was doubly selective--the inventors decided what should be patented, and the agents decided if it was worth their effort to patent. That approach did not address the particulars of biomedical inventions made in university research, or especially with federal funding, but it got a lot further toward being focused on inventions that might be suited to commercial investment than either the PHS or the IPA/Bayh-Dole approaches.

Wisconsin, then, in describing the options for inventors, gets its policy statement wrong with regard to the PHS requirements. Inventors don't have two choices under the PHS policy, as Wisconsin has it:

> Option 1. He *may submit* the invention to WARF
>
> Option 2. He *may assign* the invention to the Federal government

Actually, Option 2 should have read "He may *submit* the invention . . . " and actually, Option 1 should have read "He may submit the invention to any invention management agent . . . ." The university, under its informal patent policy--and even in its 1969 patent policy created to accommodate the IPA program--doesn't give the university administration standing to require inventors to assign inventions simply because there are federal funds involved. That is, the administrators have no standing under policy to negotiate an agreement with the federal government that requires inventors to assign to the university, nor do they have standing, even if they negotiate such a deal, to dictate what agent that university should "designate" to manage any given invention. Yet, of course, administrators did these things anyway. The IPA requires the university to obtain assignment but leaves open who the university might designate to manage inventions. But administrators create a policy in which they decide it should be WARF, regardless of other options (such as Research Corporation) that were available to inventors. WARF becomes a "captive organization" in another way--holding inventors "captive" to its money-making interests.

Cronon and Jenkins provide a coda to the 5-FU dispute.

> WARF patents. In recognition of WARF's value in both supporting research and bringing out scientific discoveries, a subsequent agreement between the University and the federal Department of Health, Education, and Welfare–the parent agency for the Public Health Service–required HEW-funded researchers at the University to notify the granting agency of any inventions and to assign them to WARF for possible patenting and development.[25] Thus the 5-FU controversy ended on a more positive note for WARF and the University.

The agreement that's mentioned is of course the IPA that we have been working through, that Wisconsin had wanted for some time. Our authors, citing an authority, get the assignment requirements of the IPA wrong, but then they aren't aiming to be experts. The IPA requirement is that the university requires an agreement to assign inventions if the university (or its designee, WARF) decides to file patent applications--so things work the other way. If WARF's patenting is *definite*, not *possible*, then the inventor must assign. Even then, the ending is not a "more positive note" with regard to the rights of inventors--the IPA induces the university to undermine its own long-standing policy and force inventions to WARF.

What Do We Learn?

Why spend all this time on a lost university policy from 1969 in response to a canceled IPA program? After all, we have the wildly successful Bayh-Dole law now, with university policies all changed to "comply" with the law. Why not focus on that and leave history alone? What university research administrator reads history, other than the twisted political history made up by Bayh-Dole advocates in lobbying to preserve Bayh-Dole, Billy Joel fashion, just the way it is? Here are some reasons:

First, because WARF's behavior illustrates the reasons why the Public Health Service and then the Department of Health, Education, and Welfare instituted policies in the early 1960s to preclude private patent monopolies on federally supported inventions directed at improving public health.

Second, because the circumvention of PHS/HEW patent policies morphed into NIH's revised IPA program, which gave universities a clear shot at enabling private patent monopolies and gave them a financial incentive to do so, all the while making it appear that there was a substantial apparatus to protect the public interest, making a show of a default non-exclusive patenting program--which never happened.

Third, because the revised IPA program, when folks aimed to make it government-wide (under the guise of needing a uniform (meaning arbitrary) federal patent policy), resulted instead in the

statutory scheme called Bayh-Dole, embedded in federal patent law, designed to prevent the executive branch from asserting rights in inventions made with federal support and further designed to make it difficult or impossible for federal agencies to enforce the various public protections that Bayh-Dole makes a show of providing. As a result, Bayh-Dole is a do WTF you want sort of law, allowing universities to exploit patents on federally supported inventions at will--to do nothing with them, to troll industry, to enable private patent monopolies, to assign patent rights under the guise of exclusive licenses, and to benefit financially from all these things regardless of whether any product ever reaches the market or if in reaching the market it is offered on less than monopoly terms.

Finally, it is worth seeing the history because even those arguments for circumventing PHS/HEW patent policy might appear in their way reasonable, the circumstances have changed--for instance, there is Bayh-Dole--so the reasoning about university-side patent policies must also change. Holding onto old arguments in changed circumstances can lead to failed management, and that's what we have at universities. Yes, the university licensing programs have slick web sites and in many cases capable people--but the fundamentals of the activity are skew from the reality that presents. It's like having well run plantations with orderly slave labor in a time of freedom, and machines--there's both a moral argument for change and a pragmatic (if not financial) argument for change.

In its way, WARF's attempt to turn 5-FU (and its analogs) into a private monopoly as a way to create commercial products for those suffering from cancer follows a cascade of events that lead, eventually to the faux Bayh-Dole environment we have today. The PHS response to WARF's action was litigation, followed by dedicating its share of WARF's 5-FU patents to public access. Once the federal government had co-ownership of the patents, all it had to do was to refuse to enforce its share and WARF's exclusive monopoly was broken, ruining the monopoly business deal it had worked out with the company that got involved in the federally supported work.

There are two obvious ways to interpret these events. In one, it's utterly unreasonable that PHS can assert it has a right to decide the disposition of inventions that "might possibly be construed in any manner" as supported by federal funds. That's over-reaching and all the worse because the PHS then mindlessly claims that giving inventions away to everyone is the default public interest. By asserting control over inventions made with federal support in this way, the PHS creates "uncertainty of title" because no one can tell just what "construed in any manner" might mean until the PHS announces what it means. Thus, it's impossible to collaborate with others, mix in funding from non-federal sources with different requirements, or even to take "invented" compounds to companies for screening for possible therapeutic use. Almost everything we have in Bayh-Dole and faux Bayh-Dole comes about as a reaction to this interpretation.

In the other interpretation, the PHS has established a policy that makes perfect sense, given the history of the pharmaceutical industry--monopoly pricing, deceptive if not outrageous claims of benefits, refusal to reveal ingredients, no standards for testing or safety, and generally suspect manufacturing practices. Every few years, hundreds of people die or suffer from tainted, mis-marketed, mis-prescribed, often ineffective (but otherwise dangerous) compounds. We are only twenty years from the 1938 FDC Act, which required at least a modicum of attention to safety, and only a few years into the Durham-Humphrey Amendment that set standards for drugs available only by prescription. And we are just getting (1962) to the law that requires drug makers to submit evidence for the efficacy of their products before they are permitted to sell them. That the PHS steps into this rat's nest of money-seeking at the public's expense and separates the inventive work that it supports in the public interest from that of the pharmaceutical "industry" and does not permit monopolies (by default, at least) on new potentially therapeutic compounds is a public service, a matter of more than blind principle but pragmatic reality.

In this interpretation, the PHS does not have any pressing reason to make a commitment to subsidize academic research into new therapeutic agents merely to serve the financial interests of such a drug "industry." Chemistry might be the way to new medicines, but the PHS operates to produce benefits in the public interest, and expects companies, if they are to participate in the effort, to subordinate their desire for monopoly positions and maximum profits to public service. Before you go all Ayn Rand on me, consider the fundamental premise operating at the time, derived from Vannevar Bush's *Science the Endless Frontier*. If new technology could be developed urgently to meet a military need in a time of war and without companies worrying about monopoly positions in order to provide services and products to the government in the public interest, then could not this same mindset--*of urgency in war for the public good*--also apply to *a war on disease and suffering*?

Here's Alvin M. Weinberg, writing in 1965 ("Scientific choice and biomedical science"):

> Of all the sciences, the biomedical sciences are most directly aimed at and most relevant to alleviating man's most elementary sufferings-disease and premature death. There is urgency of the most excruciating kind in getting on with this job. The assault on human disease, insofar as it may result in alleviation of immediate everyday human suffering, has an urgency about it comparable to the urgency with which a nation prosecutes a war. Indeed, I would draw an analogy in this regard between war-time research in physics and present-day research in the biomedical sciences.

If the PHS makes this "assault on human disease" metaphor real, then the circumstances do not call for minding the profit motives of incumbent companies. While drug companies may have the best resources for screening compounds, they ought to provide those resources, if they care to

participate in the government's assault, without holding out for monopolies on what they find in sorting through the thousands of possible compound variations included in any single discovery made with federal support.

Thus, we have a case for the intrusion of the government into an area of research dominated by established companies, and that intrusion carries with it an urgency that only considers financial matters in the context of public service. Yes, companies should be compensated for their participation. No, companies should not get monopolies on federally supported discoveries in order to exploit for maximum profit the very thing that the government has targeted as a matter of public health. Put it another way: the government, by moving into research in medicinal chemistry and reciting the urgency of war, seeks to take control of the public market for medicines. The PHS position is consistent with a claim that as a matter of public health, in which the federal government has a legitimate interest--including research to enable new medicines--the "market" for drug is principally a government market, just as the market for major weapons is principally a government market, just as the market for space hardware is a government market, just as the market for nuclear energy is a government market. There may be tools and vacuum tubes and all sorts of new things that could spill over to a private market, but the primary discoveries, and anything that enables them, is for a government market, that off health.

We might say that in the period 1945 to 1968, there was a war over who would control the market for medicines--drug companies or the federal government. In other areas, such as that for surgery methods, the decision was made that patent rights cannot be enforced. Medical faculty argued the same should hold for any biomedical discovery--no government-created monopolies. Why, then, should medicines--especially "life-saving" ones (as APLU and AAU champion in their recent infograph)--be unlike surgery techniques? Why should there be patents at all on medicines that have an essential life-saving quality, whether as a vaccine, antibiotic, cancer therapy, blood thinner, antidote, replacement hormone--whatever? The PHS did not go after the scope of patent rights; instead it went after the territory covered by the scope of the research it funded.

One might not agree with these ideas--that public health is an urgent matter, or that research in biomedical fields is a matter of war, or that medicines should be more like surgery techniques than television sets. But at least you might get a sense of what was at stake. For the drug companies--their livelihoods were threatened, at least in the form they had come to know, taking monopoly positions (a step up from "patent medicines") and relying on those positions (trade secret at first, and then patent when forced to disclose all ingredients). The government was moving in on their territory, disrupting the relationships they had formed with academics, who served as their advance scouts looking for new compounds and classes of compounds to try, based on developing discoveries in physiology. The battle was fought on multiple fronts--government regulation, divulgence of trade secrets, reform of advertising, requirements to prove

efficacy and establish safety guidelines, controls on manufacturing, availability, and reporting of adverse effects. One of these fronts, too, had to do with the government moving into research in medicinal chemistry. And there, the fight was over patent monopolies.

Imagine the federal government moving into the superhero business and recruiting not only the best graphic artists but also proposing to take over the further adventures of Superman--or worse, make existing superheros obsolete and make any future superhero characters public domain. Sure, write all the adventures you want, but you can't stop anyone else from writing their own, either.

Harbridge House Report on Patents

Let's work through the patent situation using the Harbridge House report and then discuss the present.

According to the Harbridge House report on federal patent policy, from the 1930s until the 1950s, the pharmaceutical industry was the primary source of funding for university investigators in the area of medicinal chemistry--looking for compounds that might become prescription drugs. The pharmaceutical industry operating model relied on patents, and drug companies offered free "screening" services to university faculty in exchange for exclusive rights in any compound that turned out to have biological importance.

An invention in this area generally was not a single compound but a class of compounds--hundreds, perhaps thousands. The standard form of claiming a chemical invention involved the use of a "Markush" claim, first used in 1925, allowing broad groups of chemicals to be combined in many arrangements, each combination covered by the claim. Thus, once one had identified one potential compound of interest, a patent could be secured on hundreds (or more) variations on that compound. Those variations, then, might be subject to screening efforts to identify those with significant biological activity. The number of combinations, however, means that it is possible one would never get through screening all of them using a systematic, brute-force method.

The Harbridge House report cites one drug company that of 6,500 compounds obtained from university research (out of 40,000 total), 2 had resulted in products, 2 more were in development, and 2 more were of some interest. Thus, researchers could produce many compounds of potential interest, but only a very few might be of any importance. We might think, then, of such research as one of securing mining claims--finding some evidence of possible biological action (such as collecting a sample of a compound in use for another purpose, such as Brazilian tribes that used pit viper venom on arrow tips--later to become Captopril, a medicine to treat high blood pressure)--and then creating a patent claim that extends to as many conceivable

variations on that compound as possible. The patent "protects" not only a future potential compound, which may be one in thousands, but also the exclusive right to look for that compound among all the ones that have been claimed (and thus are not available to anyone else).

When the Public Health Service ramped up research funding to universities in the area of medicinal chemistry, it was moving in on territory that the pharmaceutical industry already largely controlled. The interplay between industry expectations--monopoly in exchange for early screening and synthesizing of compounds--and the PHS expectation--open publication and available to all--created a huge problem. The PHS published new requirements for inventions in 1955, insisting that the government should have ownership of any inventive compound made with federal support unless there was some compelling reason otherwise., meaning that it would be up to the federal government to decide whether there would be any ownership claim by means of patenting, and if so what scope those claims would have in terms of classes of compounds. Until the government decided, there was "uncertainty" for everyone else who might have an interest.

In 1962, the PHS required investigators and universities to identify any parties to whom they owed commitments that might interfere with the PHS patent policy, and obtain from those parties a patent agreement that placed PHS requirements ahead of their own.

One might see the prospect for disagreement. If an inventive compound really was a class of compounds, then sending a compound to a company for screening could result in identifying new variations of the compound that were even better--but these new variations would also be compromised by the federal support, and thus unavailable for a commercial monopoly--or, rather, potentially unavailable for a commercial monopoly--there would be uncertainty with regard to the outcome of the PHS's determination of rights. And as shown with the WARF 5-FU situation, the PHS was ready to undermine monopoly commercial positions based on patents to work that it had supported. No public subvention should be turned so readily into a subsidy for any single monopolizing commercial interest.

The pharma companies refused to sign the PHS patent agreement and therefore refused to provide screening services for potentially interesting compounds identified with federal support. University investigators sought alternatives--there were two federal screening organizations, various commercial screening companies, and some university labs that could provide services. According to the Harbridge House report and a parallel GAO report on the NIH's problems with medicinal chemistry research, the alternatives were generally viewed as inadequate. Thus, the argument went, many compounds were not screened. We are talking about hundreds of thousands of potential compounds scattered out from a few hundred identified compounds--it is easy to see that many such compounds would never be tested anyway. And beyond these, millions upon millions of possible compounds yet "undiscovered."

It is easy to see how one could construct an argument that the PHS invention regulations were disrupting available screening services offered by the pharma industry over the issue of patent monopolies. Furthermore, if commercial services provide the most ready path to the preparation of a new drug candidate, and the stream of new federal regulations put out of business all those companies unable to afford the expense of navigating these regulations, then refusing to allow monopolies on newly discovered compounds prevents these compounds from being screened and developed for public use. The PHS regulations fail the argument for urgency, fail the argument for expeditious development, fail the argument for collaboration between academics and industry. If the assault on human disease is a matter of war, then the public should expect to sacrifice to achieve victory, and the fundamental sacrifice is that they pay more for twenty years than they would otherwise, and in return they get the safest, most effective medicines known to humanity.

Everyone, it appeared, was working to circumvent PHS patent policy. Here's the Harbridge House account of it from their 1968 report describing in detail the problems with the PHS (now HEW) patent policy:

> ***Incentive to circumvent the HEW procedures for patent policy administration.*** Another important effect of the lack of availability of drug industry screening services is the incentive it provides the academic community to circumvent the rules. Virtually every chemist interviewed in this study mentioned ways in which it might be possible to "get around" the situation. One man indicated

The rules may sound nice, but the rules also weren't responsive to the situation. As a result, the NIH resumed the IPA program, but now designed to circumvent PHS rules but not make a show of doing so. When the IPA program got caught out, then the same folks moved on to produce Bayh-Dole, billing it as a "uniform" policy for all inventions, government-wide rather than as a special program to address problems in medicinal chemistry.

Both arguments have their merits, but neither is compelling. But that's politics. There's nothing about the "uncertainty of title" that really matters, though the problem is pivotal. Prescription medicines could be placed beyond the scope of patent property rights--along with laws of nature, business methods, and surgery techniques. Other forms of government regulation might provide exclusive commercial positions to reward private investment, by-passing patent issues altogether. Alternatively, the federal government could have done a better job working through the entire system. Rather than merely fund "basic research" into medicinal chemistry, it could have developed its own high-throughput screening operations and from there pushed new therapeutic

compounds all the way to the market--to a federal market established to improve public health. Like space. Like nuclear energy. Like atomic bombs. You see the pattern anyway, along with the ironies.

Instead, the stasis of the argument involved "certainty" of title to inventions. Companies wouldn't participate in screening unless they were sure of their future monopoly for whatever they "discovered" in screening. (Here's the irony for you--clinical trials are an advanced form of just such screening, and in those, drug companies insist that universities give up all rights in anything "discovered" while conducting the clinical trial--one of the few areas in which universities do not routinely claim an ownership interest in inventions made in sponsored projects--one might think, then, that if the PHS (then HEW, then DHHS) were the prime mover in an effort to find new therapeutic compounds, from the bazillion of such compounds possible, then anyone involved--academic chemist, drug company screener, manufacturer, pharmacist, physician--owed the PHS any monopoly interest in anything discovered along the way that might assist the effort. To fail to give up such monopoly rights was to assert the right to disrupt the effort for money--a kind of extortion. So *screw the monopolists* (this is a technical phrase to put an edge on it).

But this sort of screwy thinking fails to take into account social behaviors--even rational folks (other than chimpanzees) tend to decline deals that are otherwise in their interest to teach others a lesson in how to share opportunities. And this is what the drug companies did to the PHS--and beneath the surface, academics investigators and even the patent counsel at the NIH agreed with the circumvention. But it was the patent brokers--and especially folks at WARF--that made the public argument in favor of industry monopolies in matters of medicine.

But the argument they constructed to get their way was based on the perception that there were 28,000 unlicensed government patents (even though the vast majority of these were DoD inventions that contractors had declined to own); (ii) that the federal government had no expertise in licensing to encourage private development (even though federal licensing rates for biomedical inventions were 5x better than the research foundation rates for federally supported inventions); (iii) that "uncertainty of title" was the issue that blocked private management of federally supported inventions in the public interest (even though the issue was actually not title but private monopoly); (iv) that a "uniform" government patent policy was needed that gave subvention contractors (nonprofits and small businesses) the clear right to hold title in patents (even though there was a uniform policy already and what was proposed in its place was arbitrary); and (v) that various protections for the public interest placed in the regulations would take care of any problems that might arise (even though these protections would be designed not to operate).

It's all very clever, very political--and how the drug companies won the battle to preserve their territory, drive out of business the small companies that lacked the resources to meet the regulatory requirements, and obtain the benefit of federal funding as a subsidy for their own drug discovery efforts. Even if we accept the idea that patent monopolies were designed precisely for the purpose of developing medicines as a lucrative commercial venture, there's nothing that leads one to the idea that such a policy should be applied uniformly to all inventive work in all markets for all products and expect a comparable "public benefit." Here's the Harbridge House conclusion:

> **However, this does not mean that either a title or license policy will equally serve the government's interests under all the above circumstances, since the policy selected may also affect industrial decisions to use contract inventions commercially. Here again, a balancing of government objectives appears necessary to ensure that the net effect of the patent policy promotes the government's overall goals.**

That is, no arbitrary government-wide patent policy will do. "A balancing of government objectives" is necessary. Kennedy's executive branch patent policy says as much:

> From the extensive and fruitful national discussions of government patent practices, significant common ground has come into view. First, a single presumption of ownership does not provide a satisfactory basis for government-wide policy on the allocation of rights to inventions. Another common ground of understanding is that the Government has a responsibility to foster the fullest exploitation of the inventions for the public benefit.

The argument behind Bayh-Dole disagrees with both of these statements and implements an arbitrary default government-wide patent policy, but calls it "uniform" and ignores the findings of the Harbridge House report, which identified two areas in which the government might productively allow contractors to hold title in inventions made with federal support. First, what's now called a "dual use" situation in which the invention developed for the government isn't suitable for a non-government market. In such cases, if the contractor has commercial experience, then allowing the contractor to obtain a patent position to develop the invention for a private market appears to be a good idea:

> (i) Where the inventions as developed under government contracts are not directly applicable to commercial uses and the inventing contractor has commercial experience in the field of the invention. This occurs most frequently with DOD, NASA and AEC inventions. In the case of DOD, the fact that it does not actively promote commercial use of its patents is an added factor. In these instances the inventing contractor with commercial experience appears to be the logical candidate to attempt utilization either directly or by licensing others; and

Second, we have work that's left incomplete by the federal agency and involves an area of industry that's patent sensitive:

> (ii) Where the invention is commercially oriented but requires substantial private development to perfect it, applies to a small market, or is in a field occupied by patent sensitive firms and its market potential is not alone sufficient to bring about utilization. Inventions in this category may arise with any agency and may have had only limited government development toward a commercial application.

This is the invention of the form that is now depicted by university licensing offices as the only sort of invention that exists. The pattern of testimony regarding inventions from 1978 to the present routinely describes inventions as "early stage" and in need of "industry investment" which will be much greater than the cost of the research that has led to any given discovery or invention. The Harbridge House report makes clear that it's just not the case. In particular, the report found that in the Department of Agriculture and Department of Interior, the "public service" agencies, all inventions that were reviewed got to market without any private patent monopoly:

> The public-service agency inventions all achieved utilization without exclusive rights. Utilization was achieved primarily because the inventions were highly commercial in nature and because they were extensively developed and promoted by the sponsor agencies.

That is, the inventions as produced under contract were sufficiently useful that no one commercial firm had to allocate significant development money to complete the work to make the invention useful as a matter for sale.

Special Cases Dictating General Policy

We can then distinguish three sorts of invention arising in federally funded research at universities: inventive tools, inventive tools that can be sold as products, and articles that can be used only as products. An inventive tool is anything useful for a purpose. In research, the proximate purpose is the research activity itself. Thus, resistive touch materials were developed to more easily mark x-y coordinates. As an inventive tool, such new technology has an immediate use--"research with" the tool. Closely related, others may use the tool to verify the claims made about the research (and thus also examine the tool for its reliability)--"evaluation of." And others may study the tool to learn how it operates and how it might be improved, extended, or adapted--"research on."

In terms of the Harbridge House accounting, where an inventive tool is useful for the government's purposes, but not for much else, then allowing the contractor to retain rights to the tool for private market development beyond research uses makes sense. Where the inventive tool has been developed by government contracts with an eye for that private market all along, then allowing any one contractor to monopolize that market makes much less sense. Even if private market development was not a purpose of the federal research, if the inventive tool can be used broadly in research--then, there too we might expect that the tool should be made available non-exclusively. And this, in fact, is just what the NIH advocates for what it calls "biomedical research resources."

We are left, then with what we should do if all the government does is fund a tiny bit of initial work in an area that has both commercial and public implications, and the government does not bother to pursue either. This is not a situation of "basic" research as Vannevar Bush described it, but rather of research that has a public policy purpose (such as alleviation of suffering) but also runs parallel to companies that make their livelihood in this same "market" and rely on patents to preserve their financial positions. We might say this is a highly specialized set of conditions. Harbridge House identified two agencies that do this sort of thing--HEW and Interior:

> **The Departments of the Interior and Health, Education, and Welfare (HEW) perform research in more speculative areas such as water desalination and medicinal chemistry relating to industries that are highly sensitive to patents (see Volume II and Volume IV, Part III). Here, the question ofpatent protection is very much an issue.Some exclusivity may be required to promote utilization or at the very least to induce investment of private funds to carry forward promising lines of research begun by the agencies.**

When research is supported in "more speculative" areas and then left unattended--no follow-up--then patents become an issue. Imagine randomly plowing acreage in the middle of nowhere, on the great plains, say--but some of it is good land. Break up the sod, but don't bother to plant. Erosion becomes an issue. And while you are at it, shoot as many buffalo as you can. Why on earth would the government (or anyone) tear up a place (even with the excuse that it's research) and have no will to follow up on what's discovered? This is the mind-bogglingly strange policy decision at the NIH with regard to "basic" research in areas such as medicinal chemistry. Why fund academics at all, when they are already working with industry? Why not fund the drug companies directly to augment their access to new compounds wherever they might find them, even in university labs? Viewed this way, while the PHS position on patents makes sense, the underlying research policy makes no sense at all. Where the PHS did pursue development--in areas such as cancer and malaria--it appears to have done well. Where it has pulled out (even with Taxol), things have ended up in disputes and strangeness.

It was this special combination of the PHS's determination to fund "basic" research in medicinal chemistry and not generally carry through to support the results that has led to the arbitrary, rather disastrous government patent policy set out in Bayh-Dole. To get there, the university patent brokers and drug companies made a distinctive situation appear to be the general case. They kept the idea of urgency, but shifted it to private development because the PHS may have been fighting a war, but only in the abstract and never taking things to the front lines. The patent brokers and drug companies also kept the idea of "high risk" but transferred that to inventions rather than to what Harbridge House noted was the case of leaving inventions in the ownership of universities:

> Industry can profitably keep an innovation "on the shelf" until the time is right to market it. Furthermore, cross-licensing agreements between firms extend the economic utility of the industrial patent. Nonprofit inventions, on the other hand, remote from the market to begin with, are perishable if unlicensed, since the nonprofit organizations do not have manufacturing operations. All the above characteristics of inventions developed by nonprofit institutions make them high-risk commercialization ventures.

And here we get to the nature of the circumvention. If universities hold patent rights, it is in the nature of the data to say that their licensing efforts are "high risk." Another way to put it is: "more likely to fail" than if the rights are held by a company that already has commercial experience in the area of the invention. Thus, why should universities hold any patent rights in potentially therapeutic compounds? What value at all did UCLA add to the Xtandi patents? Nada, other than filing the patent applications. Wouldn't it be much better to direct the assignment of such inventions to commercial firms outright, regardless of whether they have contracted for the research that did the inventing? After all, the university administrators also did not have any say in what research would be undertaken. Why, should university administrators be favored over companies? Why should administrators "walk the halls" of a university rather than company representatives? Why not treat therapeutic compounds as we do the radio spectrum and license them out to bidders who then may hold a licensed monopoly? Take title to the invention, file patent applications, re-issue the invention to a capable company, require the company to pay the inventors a share of the action (how about 0.25% of net sales if ever there are any or a lump sum cash amount) and be done with it?

We get, then, to the university patent broker role. Here's Harbridge House on the idea:

> The medicinal chemistry problem suggested that universities and nonprofit institutions, acting as buffers between government and industry, might play an important role in the transfer of new technology if permitted to acquire patents and promote their utilization. With this in mind, and recognizing educational

If the PHS (and its successors in name) won't change its research ways or its patent policy, then despite universities' lack of licensing success, they can resolve the problem by allowing the PHS to continue to fund academic research with no follow-on support or interest (what a crappy sponsor--loaded with money but disinterested in seeing anything through to completion, worse

than the military, incapable with regards to the frontiers of science, plowing up the plains and shooting the buffalo, but with a policy that makes a virtue of leaving it all to blow away and rot.

The university patent licensing shop then is recruited as a "buffer"--as an intermediary that funnels PHS inventions to drug companies, restoring for federal funding the monopoly practices that the industry relies upon, and saving appearances that the public money is not merely a subsidy because the companies pay licensing fees to the universities, and for a successful drug those fees will be in general far greater than the amounts that the government paid to support the exploratory research that produced the patentable invention. As far as it goes, it makes some sense--it's a compromise in a good political sense of something crappy all the way around but better than a standoff.

Why, then, did the political compromise that was framed initially as the revived IPA program in 1978 have to be expanded to government-wide, where it was reviewed, the expansion effort stopped, and the IPA program itself shut down? I will venture some thoughts in the absence of smoking documents. First, the IPA program was criticized as failing to extract sufficient payments from drug companies. The companies were getting sweet-heart deals from the university patent brokers. Good money for the universities, but paltry. That's the same argument that private investors made when they took over the UCLA patent licensing office with a shadow office of their own. But the IPA program was also a ruse--it had the appearance of a public covenant, that patents made with federal support in subvention research were different in character than other patents, and should be used not only to speed development of commercial products but also to limit the profits from those products in areas of public health. But the IPA in practice did no such thing. The apparatus of public interest was for show and didn't operate, just like the public interest apparatus in Bayh-Dole is never enforced.

The effort to make the IPA program government-wide--realized with Bayh-Dole--was also an effort to protect the ruse. By focusing on patentable inventions, attention was deflected from the arena of public health; by making all inventions appear to be "early stage" requiring vast private sums, the pharmaceutical operating conditions would appear to be the same as those faced by all industries; by emphasizing the idea that all inventions were "early stage," exclusive licenses looked reasonable as defaults. Anyone who wished to impose special conditions on the pharmaceutical industry's use of federally supported inventions--such as to regulate pricing--would have to do it for every industry.

If we went at things another way, we would repeal Bayh-Dole except for medicinal chemistry and other disease and injury-specific inventions. There we would develop a federal patent policy that directly addressed the problem that Harbridge House identified sixty years ago--what to do with a federal agency that tears up the plains and shoots the buffalo but doesn't follow up to plant

anything or pack the meat? One response is to rethink its allocation of research money; another is to rethink its role as a research patron--anyone knows that lousy patrons make for lousy work; yet another is to try to lipstick the pig and create a patent policy responsive to the snout we have.

If we follow the lipstick option, acknowledging that we are hacking a defective research policy architecture, then we might create an option under which drug companies can obtain exclusive positions on federally supported inventions and rather than paying out licensing fees (or even having to negotiate licenses), they are assigned (or re-issued, as it were) patents in exchange for, say, reasonable terms for public benefit. Those reasonable terms might include moderate pricing after recovery of their total allowable development costs (which they would then report), where moderate pricing would be set as some amount over the cost of manufacture, similar to what a generic drug might sell for in an environment in which there are multiple vendors of the drug. Reasonable terms might also include making the manufacturing information and any required proprietary rights available for use by generic manufacturers if the company ends its own manufacture of the drug.

Would drug companies take such terms? Right now, they like what they have got and show no signs of being open to changes in Bayh-Dole. Thus, one returns to the other two options--either the federal government should get out of the business of supporting public interest research that it will not follow up on, or it should shift its research policy to follow up on the research it does support. Otherwise, the patent policy ought to be the one that Vannevar Bush proposed--leave the inventors alone to decide what to patent, and give the government a royalty-free license to do what it will for government purposes.

At present, the government-purpose license right that the government receives in each subject invention is itself outside of Bayh-Dole. 35 USC 207 and 209 concern only inventions that are federally owned. There's no guidance whatsoever on inventions that the government does not own but holds a broad license to practice and have practiced. If one wanted to gain some leverage on the pharmaceutical industry's happiness with Bayh-Dole, then establishing a federal mandate to use the government's broad license to practice and have practiced each subject invention in the area of biomedical practice is the place to start. The federal government (and state governments, and even municipal governments) could license rights under patents the government does not own for contractors to make, distribute, and sell products within the scope of governmental authority and purpose.

The government license is the essential piece of the bargain. The antitrust violation that keeps drug prices 10x higher than one would expect is the result of government inaction on the rights it holds. That is, it is the federal government itself that creates the monopoly position, not by issuing patents on federally funded inventions and failing to enforce the public covenant

apparatus, but rather by failing to act on its own right to serve the public through the government-side market for new therapeutic drugs. Exercising that right will change the discussion and perhaps we'd see the drug industry more than ready to consider alternatives to Bayh-Dole.