S. HRG. 110–470

THE ROLE OF FEDERALLY FUNDED UNIVERSITY RESEARCH IN THE PATENT SYSTEM

HEARING

BEFORE THE

COMMITTEE ON THE JUDICIARY UNITED STATES SENATE

ONE HUNDRED TENTH CONGRESS

FIRST SESSION

OCTOBER 24, 2007

Serial No. J–110–58

Printed for the use of the Committee on the Judiciary

U.S. GOVERNMENT PRINTING OFFICE

43–657 PDF WASHINGTON : 2008

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2104 Mail: Stop IDCC, Washington, DC 20402–0001

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THE ROLE OF FEDERALLY FUNDED UNIVERSITY RESEARCH IN THE PATENT SYSTEM

WEDNESDAY, OCTOBER 24, 2007

U.S. SENATE,
COMMITTEE ON THE JUDICIARY,
Washington, D.C.

The Committee met, Pursuant to notice, at 1:40 p.m., in room SD–226, Dirksen Senate Office Building, Hon. Patrick J. Leahy, Chairman of the Committee, presiding.

Present: Senators Leahy, Cardin, and Grassley.

OPENING STATEMENT OF HON. PATRICK J. LEAHY, A U.S. SENATOR FROM THE STATE OF VERMONT

Chairman LEAHY. Thank you all for being here. Senator Cardin, thank you, and I know that Senator Grassley will be joining us.

As we know, universities conduct much of the research that advances our understanding of the world around us. Since the passage of the Bayh-Dole Act in 1980—and I remember that one well—they have played an increasingly important role in the patent system and commercializing innovation.

Under Bayh-Dole, universities may take title to inventions developed with Federal funds, and they can retain all the profits from licensing those inventions, without reimbursing the Government. There is, of course, one exception to that rule, and that is when the university's work is being done in a facility that is actually owned by the Federal Government. Then the university has to return a portion of the royalties from the invention if those royalties exceed 5 percent of the facility's budget.

Iowa State University operates such a Federal facility—Ames Laboratory—and they showed a great deal of ingenuity and commercialization. Ames last year exceeded the 5-percent mark and, as a result, repaid the taxpayers nearly $1 million. They actually became the first such facility to do that. At the close of the last Congress, the House had hoped to raise the threshold to 15 percent, so Iowa State would not have had to make any reimbursement. The bill was introduced on December 8th and it was passed on December 9th. I said at the time that regardless of whether the threshold should be 5 percent or 15 percent, we should not make that kind of a step at the 11th hour, because process is important. It will illuminate and let the public know if we are going to make such substantive changes.

So this hearing gives us that kind of process. It will give us a long overdue opportunity to begin an examination of the successes, as well as any shortcomings, of the tech transfer provisions.

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In saying that, I do want to acknowledge that American research universities are the envy of the world. I hear about them everywhere I go in the world. Patented inventions developed at these universities with Federal dollars have created businesses and jobs; they have boosted local economies. Medicines developed there have saved lives. Federal taxpayers fund more than 60 percent of research at universities, however, so it is proper to ask whether the taxpayer is getting an adequate refund.

At the end of the 109th Congress, I introduced the Public Research in the Public Interest Act to ensure that medical product innovations created with Federal funds were available in developing countries at the lowest possible cost. I imagine that will be a matter of debate here.

[The prepared statement of Senator Leahy appears as a submission for the record.]

We were speaking of Ames, Iowa, and as we spoke of Iowa State University at Ames, in walked the senior Senator from Iowa. Senator Grassley, I will yield to you for any kind of a statement you wish to make. Of course, Dr. Hoffman, the Vice President and Provost of Iowa State is here.

STATEMENT OF HON. CHARLES E. GRASSLEY, A U.S. SENATOR FROM THE STATE OF IOWA

Senator GRASSLEY. Thank you very much.

Well, first of all, I appreciate your willingness to hold this hearing on the Bayh-Dole Act and include in that hearing a discussion of a patent issue that has been before Congress for a few years now concerning Iowa State University. You said you would hold a hearing, and I know you always keep your word, and you surely have and I think you need to know that I really appreciate that very much.

This is an important hearing that you have noticed today because of the many benefits that have been derived since enactment of the Bayh-Dole Act. The Bayh-Dole Act promotes the utilization of inventions arising from federally supported research and development. This law has proven to be a very effective incentive for small businesses and nonprofit organizations, including universities, to collaborate in researching and developing new products and technology with the support of our Federal Government. Ultimately, promoting university-based innovation and technology transfer to industry helps boost the Nation's economy and gives us a better world through new cures and inventions.

The Chairman has assembled an impressive list of witnesses. I thank all of you for being present. In particular, I am pleased to welcome, as has already been mentioned, Dr. Elizabeth Hoffman, who is Executive Vice President and Provost at Iowa State University. She is going to discuss the patent issues around Iowa State's concerns and the legislative fix that they would like to see in the Bayh-Dole Act.

As you know, in the 109th Congress, the House of Representatives passed a bill that would have changed the royalty formula under Bayh-Dole for small or nonprofits because they saw a basic issue of fairness. I agree with that assessment. In fact, I circulated the same language of that bill as an amendment to a comprehen-

sive patent reform bill that was considered by the Judiciary Committee earlier this year. The change that Iowa State University is seeking to the Bayh-Dole law would allow for a modest increase in the royalty threshold for smaller budgets, thus preserving the necessary incentive for smaller institutions and laboratories to continue investing in cutting-edge research and development.

Currently, the Bayh-Dole Act allows nonprofits to patent any new discoveries, sell and license the inventions, and keep a portion of the profits. The law places a limitation on the amount of royalty income that can be retained in a given fiscal year once a ceiling of 5 percent of a Government-owned, contractor-operated laboratory budget has been reached. Seventy-five percent of the remaining income is paid to the U.S. treasury. The remaining 25 percent is shared between the laboratory and the university nonprofit.

Unfortunately, this one-size-fits-all ceiling creates a situation where smaller institutions end up paying royalties back to the Government a lot sooner than institutions with much larger budgets. Smaller contracts should not be penalized for their successes just because they naturally will reach the current statutory ceiling much more quickly than the larger contracts of hundreds of millions of dollars.

The bill that the House of Representatives passed last year would have allowed small Government-owned, contractor-operated labs and their affiliated universities or nonprofits to receive a fair percentage of revenue from successful patents that they license. Specifically, the legislation raises the threshold for smaller annual budgets, $40 million or less, from 5 percent to 15 percent for Bayh-Dole. The bill left in place the current 5-percent threshold for budgets over $40 million. In this way, everyone would pay back to the Federal treasury once revenues reached a certain amount, as is appropriate.

I know this is just one small issue in the scheme of things, but I do think that such a tweak to the Bayh-Dole Act will produce an equitable result for small entities that perform research in many scientific technological fields. This small but important modification in the law will allow these institutions to continue to reinvest in their research and educational operations, which, of course, greatly benefit our public.

I look forward to Provost Hoffman's more detailed testimony on this issue and how a modest change in law will improve the incentive for little people to continue reinventing in their research and development activities. I also look forward to all the testimony of witnesses on Bayh-Dole, and I ask permission, Mr. Chairman, for the Congressman that includes Story County and Ames, Iowa, where Iowa State University is, Congressman Latham, for a statement of his to be inserted in the record.

Chairman LEAHY. Without objection, it will be.

Senator GRASSLEY. Thank you, Mr. Chairman.

Chairman LEAHY. Professor Rai, we will start with you.

Did I pronounce that correctly? Is it "Ray"?

Ms. RAI. "Rye," as in the bread.

Chairman LEAHY. Thank you.

STATEMENT OF ARTI K. RAI, PROFESSOR OF LAW, DUKE UNIVERSITY SCHOOL OF LAW, DURHAM, NORTH CAROLINA

Ms. RAI. Good afternoon, Mr. Chairman and distinguished members of the Committee. Thank you for the opportunity to speak on the role of federally funded university research in the patent system.

I am Arti Rai, a law professor at Duke Law School. I have studied technology transfer issues for the last 10 years. Currently, I am funded by both the NIH and the Kauffman Foundation to study these issues in both the life sciences and in information technology. So my current research is examining both sides of the life sciences versus information technology divide that we sometimes see in debates over patent issues.

Before I delve into the details of my testimony, let me state my bottom-line conclusions.

First, although I do not think that we need a major overhaul of the current system, we do need to recognize that a patent and exclusive licensing model is not necessarily appropriate for all technologies.

Second, one mechanism of ensuring that universities pay attention to the idea that "one size does not fit all" might involve bolstering particular provisions of Bayh-Dole that allow funding agencies to be attentive to differences between technologies.

Third, we need to be cautious about efforts to recoup royalties from technology transfer efforts. I understand that the immediate catalyst for the hearing today surrounds this question of royalties. In the context of Government-owned, contractor-operated facilities, there is a recoupment provision. In general, however, there are no recoupment provisions in Bayh-Dole, so this is an important question.

In order to understand whether we should have more or less recoupment by the Government, I think it is important to understand why we have Bayh-Dole and Stevenson-Wydler. Both of these statutes aim, one, to promote university-industry collaboration and, two, to commercialize federally funded research through the use of patents. The theory is that if federally funded research is patented, then private sector firms will have a powerful financial incentive to collaborate and to commercialize.

For certain types of inventions, this commercialization theory makes a lot of sense. Drugs are the classic example. Outside of the life sciences, however, the importance of patents for collaboration and commercialization is not as clear. And even within the life sciences, commercialization of certain basic scientific research tools might be achieved through the lure of more downstream patents on specific applications of those tools.

So one size does not fit all. Unfortunately, it is not clear that universities always pay attention to these differences. In fact, there have been some recent court cases in which it appears that the university patent did not so much aid in technology transfer as it allowed the university to extract money from an entity that had already commercialized.

In the recently settled case of *Eolas* v. *Microsoft*, for example, Microsoft and various other firms did not need an exclusive license to commercialize the Web browser software that was the subject of

the patent dispute. Of course, one never knows how representative litigated cases are. Universities may generally be doing a good job, with these litigated cases being the exception.

A more troubling indicator emerges from some research I have done which indicates that the most important predictor of the number of university software patents that are sought is simply how many other patents the university tech transfer office has. In other words, large tech transfer offices just patent a lot of what comes in the door. They do use a one-size-fits-all approach to their invention. And so it should come as no surprise that some prominent information technology firms are somewhat troubled by what universities are doing.

Even so, I would not endorse taking the decision about patenting away from universities. The question is always a comparative one, and Federal agencies are not always or even generally better placed to make these decisions.

There is also reason to believe that universities are beginning to understand that technologies differ from one another and that not all of them should be promoted through a patent and exclusive licensing model.

Still, it might be worth doing some tweaking of particular provisions of Bayh-Dole and giving Federal agencies a little more authority in certain circumstances to work with the universities in determining situations in which one size does not fit all.

Let me conclude by returning briefly to the issue of royalty recoupment. Currently, outside of special circumstances like GOCOs, Bayh-Dole does not provide for such recoupment. One might argue that the Federal Government should get a return on its investment. However, there is little evidence to support the idea that the Federal Government would be making large sums of money even if it did have a general recoupment provision.

More importantly, part of the problem that I see with current university tech transfer efforts is that there is sometimes too much focus on generating revenue. I have mentioned, for example, some cases in the software context where these patents appear to be used as a mechanism for revenue extraction rather than a mechanism for promoting collaboration and commercialization. So anything that gets universities to pay even more attention to their revenue generation seems to me a bad idea.

In sum, I think there is little reason to do a major overhaul of the current mechanism for technology transfer that we have. However, universities should be educated about the reality that one size does not fit all, and some tweaks in Bayh-Dole might help with that education. Relatedly, I think because we do not want universities to focus on generating revenue but, rather, on commercialization and collaboration, we should be cautious about using technology transfer as a mechanism for raising revenue.

Thank you very much.

[The prepared statement of Ms. Rai appears as a submission for the record.]

Chairman LEAHY. Thank you. And, Professor Rai, your full statement and the appendage you had for it will be part of the record.

I should have noted that Professor Rai is a Professor of Law at the Duke University School of Law, where she teaches courses in

administrative and patent law. Her publications have concentrated on intellectual property law, and her current research focuses on IP issues raised by collaborative research and development.

Dr. Hoffman, as Senator Grassley pointed out, is the Executive Vice President and Provost of Iowa State. She earned her Ph.D. in history from the University of Pennsylvania, and a Ph.D. in economics from the California Institute of Technology. Prior to coming to Iowa State, Dr. Hoffman served as the 20th President of the University of Colorado System. I know Senator Harkin also wanted to be here today. He is down at a place where I am going to be leaving for in a few minutes, in the Senate Agriculture Committee, where we are trying to mark up a farm bill. I will place a statement from Senator Harkin in the record.

Dr. Hoffman, please go ahead.

Incidentally, I should note that at some point I will have to leave. When I do, I will turn the gavel over to Senator Grassley, who has had as much experience as I have had in handling a gavel and will continue the hearings.

STATEMENT OF ELIZABETH HOFFMAN, EXECUTIVE VICE PRESIDENT AND PROVOST, PROFESSOR OF ECONOMICS, IOWA STATE UNIVERSITY, AMES, IOWA

Ms. HOFFMAN. Thank you, Mr. Chairman, Senator Grassley, distinguished members of the Committee. I am Elizabeth Hoffman, Executive Vice President and Provost of Iowa State University. I am here first to convey our emphatic support for the Bayh-Dole Act. I am here also to propose a limited, technical fix that would eliminate a restriction we believe has an inequitable impact on small, Government-owned, contractor-operated laboratories—namely, the current limit imposed on retaining royalties that result from tech transfer activities.

My colleague Charles Louis will address the broader benefits of Bayh-Dole, and we have included our support in our written testimony. I will speak to the experience of Iowa State and Ames Laboratory.

The effectiveness of Bayh-Dole incentives can be seen in the upward trend in technology disclosures and licenses at Iowa State University. Technology disclosures increased from 46 per year in the 1970s, prior to the adoption of Bayh-Dole, to 118 per year from 2000 to 2007. In 2005, Iowa State University was second in the Nation—behind the entire University of California System—in licenses and options with 218, and we were sixth nationally in the total number of active licenses, with 245. In the past 8 years alone, fully 20 new companies have been started on the basis of 41 licensed technologies, contributing to the economy of our State and our Nation.

Now I would like to turn to look more closely at the Ames Laboratory. No better illustration of the success of Bayh-Dole can be found than the example of lead-free solder, a result of Federal support that has been developed jointly at the Ames Laboratory and Sandia National Laboratory. The research team that created this remarkable and remarkably marketable innovation was led by Ames metallurgist Iver Anderson. You are all familiar with the en-

vironmental impact of leaded solder in landfills. By removing the lead, we protect the environment and avoid a serious health risk.

The so-called Iver Patent for this lead-free solder is licensed by Iowa State to 28 companies under very reasonable financial terms, and over 60 companies around the world—including a small company in Iowa—use the patent. Thus, our experience has been that the principles, practice, and impact of Bayh-Dole are sound.

However, we want to discuss with you today one technical concern that we believe can have an unfair impact on small GOCO Federal laboratories and that has had an inequitable impact on the Ames Laboratory.

As mentioned before, Bayh-Dole, as modified in 1984, limits the earnings from royalties for these laboratories to 5 percent of their annual budget; and then after reaching the 5 percent threshold, 75 percent of additional royalties are returned to the Federal Government. All royalties retained by the contractor must be expended for research, education, and technology transfer purposes.

Because of its small budget and successful patent portfolio, as the Senator mentioned, the Ames Laboratory is alone in the Nation in coming up against the 5-percent royalty cap. Last year, we returned nearly $1 million to the Federal Government, and we anticipate returning about the same amount per year for the foreseeable future.

My contention today, which I respectfully offer for your consideration, is that the authors of Bayh-Dole and subsequent modifying legislation did not intend to incorporate a provision that would have a disparate and deleterious impact on the smallest of the DOE laboratories. Therefore, we ask you to re-examine this technical clause and to modify the limitation in accord with the spirit of Bayh-Dole.

To bring home the inequitable impact of this technical limitation on small, successful, federally funded research centers, let me point out that Ames Laboratory's partner in the development of lead-free solder—Sandia National Laboratory—has not had to return any of their royalty stream to the Government. Sandia has a much larger budget—$2.27 billion—as compared to Ames's approximately $30 million. In this successful, partnership, then, is a case illustration of our contention that the 5-percent royalty cap is a discriminatory tax on small, successful, nonprofit laboratories. Accordingly, I propose for your consideration that the royalty limitation in the House legislation be increased to 15 percent of the annual budget for GOCO contractors with annual budgets of less than $40 million. If the Committee, in its wisdom, feels that these exact numbers are not the right ones but accepts our basic argument and request for relief from inequitable impact, we will be immensely gratified.

Thank you for your attention and for your leadership here in Washington. Thank you, Mr. Chairman.

[The prepared statement of Ms. Hoffman appears as a submission for the record.]

Chairman LEAHY. Thank you very much, Doctor.

Mr. Robert Weissman is Director of Essential Action, a nonprofit advocacy organization that works to promote access to medicines. Through Essential Action, he has experience petitioning the NIH and other Government agencies to exercise their rights under pro-

visions of the Bayh-Dole Act. A graduate of Harvard College, Harvard Law School, Mr. Weissman, please go ahead, sir.

STATEMENT OF ROBERT WEISSMAN, DIRECTOR, ESSENTIAL ACTION, WASHINGTON, D.C.

Mr. WEISSMAN. Thank you, Mr. Chairman. Thank you for inviting me to be here today.

At the time of passage of Bayh-Dole and the years leading up to passage, there was even by proponents a recognition that there were serious risks in the proposal to enact the Bayh-Dole approach. There were concerns about whether the Government would get a fair return on its investment, about whether there would be reasonable pricing of Government-sponsored inventions and access to the fruits of Government-sponsored inventions. There was concern about windfall profits for those who gained exclusive rights to Government-funded inventions, and concern about whether those exclusive rights might lead to market concentration and anticompetitive behavior.

The final bill included safeguards to deal with many of these concerns, not so much on recoupment but on many of the other key issues. Unfortunately, it has been our experience and I think the global experience that the Government has failed to exercise the safeguards that were included.

In the area of pharmaceutical products, the result is that the Government uses taxpayer money to develop important new medicines. It gives away the inventions. Then the companies that take the federally sponsored inventions charge very high prices, price-gouge the very taxpayers that have paid a considerable part of the development, and even the Government itself, which is the largest buyer of pharmaceuticals in the world. Our experience is that even in the worst cases of abuse, the Government has failed to exercise the safeguards designed to limit these kinds of problems.

Our organizations have requested that the National Institutes of Health use its rights to license inventions to the World Health Organization to enable access to cheap medicines in developing countries. That request was declined. We have requested that the Office of Management and Budget use the Government rights to purchase generic versions of pharmaceuticals that it helped develop. That request went unanswered. And we petitioned on two occasions for the NIH to exercise march-in rights where there were particular cases of pricing and market concentration abuses.

One example involved an Abbott Laboratories product, the generic name of which is ritonavir. That is an anti-AIDS drug. It went on the market in 1996. The company in 2003 suddenly announced a 400-percent price increase for the drug, which would have made it as a stand-alone drug cost $45,000 a year per person. However, ritonavir's main role is not as a stand-alone drug but as a booster to be used in conjunction with other pharmaceutical products. As a booster, the price went from roughly $1,500 a year per person to more than $8,000 a year per person. However, Abbott did not apply the price increase uniformly. It did not apply if the booster ritonavir was to be used in conjunction with Abbott's own product. As a result, the combination of Abbott's drug with this ritonavir booster is much cheaper than competitors in the same

class who want to combine with ritonavir. The effect is a massive price increase for all other medications except for the Abbott product. It has tilted buying and prescription decisions, and it has, unfortunately, limited investment by other pharmaceutical companies in this category of medicine because they know they cannot compete with the Abbott product.

We petitioned in this circumstance for NIH to exercise its march-in rights. The Abbott product was developed with a high degree of Federal support, and the Government does have Bayh-Dole rights in the invention. The National Institutes of Health declined our petition. They said in their written response that Abbott was meeting its requirements to achieve practical application of the invention by simple virtue of putting the product on the market. Whatever price Abbott charged from NIH's point of view was irrelevant.

Unfortunately, NIH read out of the statute the definition of practical application, which specifies that it means putting a product on the market on reasonable terms available to the public. There is no way, in our view, that the Abbott pricing arrangement could be considered reasonable. It is not clear that NIH thinks it reasonable either. They did not address the issue at all.

As I discuss in my written testimony, we think there are a number of reforms that should be made to the Bayh-Dole Act to address this and other concerns. Generally, there needs to be much more purposeful management of the Government's patent portfolio and the products in which it holds intellectual property rights. The basic principle should be that there should be some reciprocity for the Government's funding of R&D. It does not need to be in the form of royalties. Much more important from our point of view is the area of pricing and access.

The requirement for reciprocity should apply in more than the worst-case circumstances as well. In our petition on the march-in, we proposed a standard that the march-in should be exercised where U.S. Government-funded inventions were priced more for U.S. consumers who paid for them than they are for other consumers in other high-income countries. Whatever is done in this area, we think there needs to be specific direction on the use of the march-in right.

Finally, one other point. There are other areas that need careful investigation, as Dr. Rai suggested, besides pharmaceuticals. There are going to be major increases in Federal research money devoted to climate change-related technologies. It will be hugely important to consider how those resulting technologies are managed and licensed to look for ways to promote open and collaborative means of development rather than relying exclusively on exclusive models.

Thank you very much.

[The prepared statement of Mr. Weissman appears as a submission for the record.]

Chairman LEAHY. Thank you, Mr. Weissman.

Dr. Charles Louis is the Vice Chancellor for Research at the University of California, Riverside, holds an appointment as professor of cell biology and neuroscience. As Vice Chancellor, he is responsible for advancing the research mission of the university, including technology commercialization. He received degrees from Trinity

College in Ireland—the only one of my colleagues whom I know of that studied at Trinity is Senator Cochran.

Mr. LOUIS. I was unaware of that.

Chairman LEAHY. The senior Senator from Mississippi.

He reminds me of that any time we have been in Dublin walking by Trinity. Dr. Louis also received a degree from Oxford University in England, and received his postdoctoral training at Stanford University. Doctor, the floor is yours. And as with everybody, your whole statement and any additional material you have will be put in the record as though read.

STATEMENT OF CHARLES F. LOUIS, VICE CHANCELLOR FOR RESEARCH, UNIVERSITY OF CALIFORNIA, RIVERSIDE, CALIFORNIA

Mr. LOUIS. Thank you so much. Good afternoon, Chairman Leahy and Senator Grassley, and thanks for this opportunity to speak before you today.

Thanks to the support of Congress, I have been very fortunate over 25 years of continuous NIH funding to support a biomedical research program that has allowed me to train a large group of graduate students and postdoctoral fellows. I would also like to thank the U.S. Senate, and this Committee in particular, for its hard work in passing the Bayh-Dole Act almost 30 years ago, which first allowed universities to take title in federally funded inventions and translate them into good and useful products for the public. It is a privilege to be able to thank so many of the original sponsors of this law in person here today, including yourself, Mr. Chairman, because I am also an inventor of a patent with colleagues at the other Iowa University—the University of Iowa—and also the University of Minnesota, where I spent many years.

According to the Economist magazine, the Bayh-Dole Act is "perhaps the most inspired piece of legislation to be enacted in America over the past half-century." The piece goes on to state that "[m]ore than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance."

The benefits of this Act are well recognized by our economic competitors around the world for converting early stage inventions into products. My written testimony documents many of the well-known products that have resulted from these inventions.

Prior to Bayh-Dole, few of the federally funded patents, less than 5 percent in 1980, were ever licensed for development, in part due to the Government's prior practice of issuing only non-exclusive licenses. This practice failed to provide an incentive for a company to risk investing its own money in resources in commercializing a technology because its competitors could reap the benefits of its development efforts for free. Bayh-Dole established a consistent and uniform policy across agencies, allowing universities to elect to retain title in inventions created by their researchers in the course of federally funded research, on the condition that the universities diligently work with private industry to ensure that the technology is developed in a timely and beneficial manner.

This shifted development of the technology from distant Federal agencies with little knowledge of the applicability of the invention, to the local university which possessed the most knowledge about

the technology and could more effectively determine what inventions to patent or not.

While U.S. universities have a mission of conducting research and furthering human knowledge, they are neither positioned nor equipped to develop their discoveries into commercial products that can be used by the general public, and this is where the partnership with industry comes in.

As a result of the Bayh-Dole Act, university technology transfer activities skyrocketed. More than 230 universities have technology transfer offices. The University of California is very proud to have one of the top offices in the country. Indeed, 4,300 new products were introduced between 1998 and 2006, with over 5,700 new spin-off companies created in the U.S. since 1980 as the result of university technology transfer efforts.

A personal example. At the University of California, Riverside, Dr. David Bocian has been doing research in creating molecular-scale features that can function as the circuit elements in microelectronic chips. The technology will lead to significant advances in memory capability, playing a key role in new generations of electronic devices, both large and small. And UC Riverside has licensed this technology to a startup company.

Dr. Rai suggests that universities focus on making money, and many outside observers make the erroneous assumption that technology transfer is undertaken by universities to do just this. Well, at the University of California, Riverside, like the majority of university technology transfer offices, licensing income rarely covers the costs of the office. In fact, we view technology transfer in both the licenses we issue and the students we train as an important means to advance the university's mission and serve the public interest. Universities do not have the resources to file patents on everything that is discovered by their researchers, and we have to pick and choose the ones which have the potential for commercialization. I would love to have so much money I had the flexibility to license everything that came in the door, but we have to be far more sensitive.

Any policy changes that would make it harder for universities to engage financially in technology transfer efforts or reduce the certainty that the public currently has in a patent's validity would serve to undermine the Bayh-Dole Act's effectiveness. Any legislative or regulatory actions that increase a company's risk or uncertainty or reduce their incentive to invest in a university's inherently early stage technology, such action would certainly undermine the current success of the Bayh-Dole Act. The Bayh-Dole Act lays a solid foundation for the success of technology transfer, including elements that ensure that the public interest is preserved, while at the same time providing recipients of Federal funding with tremendous flexibility to craft the best business approach to maximize utilization of a federally funded invention.

The Act was an inspired piece of legislation that has provided incentives and rewards for risk taking that has led to successful products. I am speaking for all of the University of California in asking the Congress to continue to nurture its success.

Thank you.

[The prepared statement of Mr. Louis appears as a submission for the record.]

Chairman LEAHY. Thank you very much, Doctor. And before I leave, Dr. Hoffman, you said in your testimony that the 5-percent limitation for small laboratories means, and I quote, "an atrophied incentive for innovation." Has Iowa State ever decided not to commercialize an invention because it might have to reimburse a portion of the royalties to taxpayers?

Ms. HOFFMAN. No, Senator, but much of our technology transfer is not through the Ames Laboratory. The lead-free solder technology is the first time that Iowa State or, as far as we know, any other federally funded laboratory has run up against the 5 percent. So we really view this as a future disincentive, especially for the Ames Laboratory.

Chairman LEAHY. Well, if it gets even more successful—say the next time it is—say we changed it to 15 percent; and then you run up against the 15 percent, won't you want to change it again?

Ms. HOFFMAN. Senator, I hope we are so successful. At this point in time, we would be happy with the 15 percent.

Chairman LEAHY. At this point.

[Laughter.]

Chairman LEAHY. I understand. Of course, I always ask the obvious question, and I was one of the people voting for Bayh-Dole in the first place that as the taxpayers put money into this, shouldn't they have some reimbursement of that, just so you understand. But I am going to turn the gavel over to Chairman Grassley, who I am sure has a number of questions. Chuck, thank you for requesting this hearing.

Ms. HOFFMAN. Thank you, Senator.

Senator GRASSLEY. [Presiding.] First I will start with Dr. Hoffman. The Trademark Clarification Act of 1984 amended Bayh-Dole, requiring return of royalties from Government contractors that exceed 5 percent of a contractor's operating budget. That law also stipulated how royalties retained shall be reinvested. Can you explain how the law functions in this regard and how Iowa State University specifically uses royalty income from federally funded research?

Ms. HOFFMAN. Thank you, Mr. Chairman. As mentioned, we are required to use the funds for scientific research, education, and further technology transfer. Under our contract with the Department of Energy, the royalties that have been earned by the Ames Laboratory in the last few years of approximately $7 million have been used, about $6 million, to support research, about $120 thousand to support education, and about $670 thousand to support further tech transfer.

To give you a few examples, one of the things that Ames Laboratory is doing now is teaming up with our biofuels group in our Plant Sciences Institute to provide seed funding for research in biomaterials to replace the use of petroleum in the development of things like plastics.

We also are testing materials for photonics, and this has been very important in retaining one of our key faculty members, Dr. Costas Soukoulis, who is one of the world's leaders in photonics technology in the experimental area. We have a world-renowned

theoretical group, and we are investing in further experimental work in photonics.

The numbers, of course, do not tell the whole story. We purchase or create specialized equipment. We provide this broad seed funding. We support graduate students' and postdocs' education as a very important part of what we do. And, of course, we provide seed funding for additional technology transfer so that more faculty can bring their technology to the marketplace.

So we have invested it as required by the law, and it has been immensely valuable in furthering technology transfer and research in the State of Iowa. Thank you, Senator.

Senator GRASSLEY. Thank you.

Now I would turn to you once again and to Dr. Louis. You understand that an investor is looking for an optimal return on investment. How would you describe the public's return on investment for the Federal Government's investment in projects at your institutions? Dr. Hoffman first.

Ms. HOFFMAN. Could you repeat that? I am sorry, sir.

Senator GRASSLEY. Yes. How would you describe the public's return on investment for the Federal Government's investment in projects at your university?

Ms. HOFFMAN. The return has been very high. I do not have the exact numbers, but if you would like us to look into that, I would be happy to. But, of course, if you look at the Government's investment in Iowa State very broadly, one of the largest investments of the Federal Government in Iowa State has been through agriculture-related research. The Green Revolution really started at Iowa State with the research of Henry Wallace and the development of Pioneer seed. We have partnered with Monsanto, with many small ethanol producers. Hawkeye Renewables is relocating to the city of Ames in order to take advantage of Iowa State's technology in biofuels.

Many of our faculty are very involved in working in developing new technologies for biofuels, new technologies for environmental protection, new technologies to improve land fertility, to sequester carbon in the land, all of which will have huge benefits to Iowa agriculture.

We work very closely with industry bringing our technology to Iowa industries, and as noted, we were ranked second in the country behind the University of California System in bringing our technology to the marketplace.

So that is the return on the investment. I do not have an exact figure for you. Thank you very much.

Senator GRASSLEY. That is good enough.

Dr. Louis?

Mr. LOUIS. Senator Grassley, the University of California obviously has been one of the leading universities in the United States. At the current time, it has 7,500 active inventions in its portfolio; 80 percent of these have generated interest, either the private or public sector. Of those interests generating inventions, over 50 percent have resulted in a financial investment in the development of a product. As of fiscal year 2003, over 700 products have been developed out of these discoveries. And I was looking earlier at a 2000 congressional Joint Economic Committee report on the bene-

fits of medical research and the role of the NIH where it estimates a return of as much as $240 billion in increased life expectancy benefits contributable to NIH-funded research, 15 times actually the very large budget of the NIH, even as it is at this point in time. So I think the examples—and we could also quote many of the great discoveries such as a vaccination for potentially fatal hepatitis B disease and the Cohen-Boyer original DNA methodology. Our own campus actually has a fertilizer which has produced superior qualities for plant growth.

So many, many inventions across the spectrum, from agriculture through engineering and human health.

Senator GRASSLEY. Dr. Hoffman, to take off from where Senator Leahy left off with a question, and that is in regard to changing the percentage from 5 to 15 percent for budgets less than $40 million. Could you explain the rationale behind the suggested cap? Is it kind of picked out of thin air, or is there a rational to 15 percent and the limit on the size of the operating budget?

Ms. HOFFMAN. Well, the idea for the 15 percent and the limit on the size of the operating budget was to continue to respect many of the issues that have been addressed today; the need for the Federal Government to be able to recoup some of its investment, especially for Government-owned laboratories. And so by raising it from 5 to 15 percent, we felt that it would not have an extensive impact on the Federal Treasury, but would remove this serious inequity. By limiting it to $40 million, you really are limiting it to small laboratories.

The average size of the DOE laboratories is over $500 million per year, so at $30 million, Ames is a very, very small laboratory. But we happen to have an extraordinarily successful patent portfolio in comparison. So when look at Sandia, for example, that is $2.27 billion, even if they are modestly successful, they are not going to run up against even the 15-percent cap.

So we were trying to balance the legitimate needs of the Federal Government to recoup their investment in the Government-owned laboratories against what we believe is an unfair tax.

Senator GRASSLEY. I think you have answered my next question. I will ask my staff to look at Question 4, but I think that that answers that. I would go back to you and to Dr. Louis again on how has Bayh-Dole affected opportunities at your two universities to partner with industry, and I think you have touched on this already with your examples of partnering with other industries. Do you hear concerns from your industry partners about the challenges in licensing and developing institution patents? How does the university strike an appropriate balance between partnering with and serving industry and preserving its core mission of research, service, and education?

Ms. HOFFMAN. The only complaint we tend to hear is that it takes a long time sometimes to reach an agreement. But over 90 percent of the time, research agreements are executed. In the last 5 years, we have executed 824 license agreements and options on Iowa State technology. So it is very, very rare not to reach agreement, and Bayh-Dole is generally not the problem. It is generally that we just simply cannot agree on which piece of the technology

belongs to whom and how much should be paid for it rather than the issues surrounding Bayh-Dole.

We do work very hard to balance research, education, and outreach with technology transfer. A lot of the royalty money goes to support graduate students. It goes to support the startup of new faculty members. It goes to seed new research funding. So there is a very important synergistic relationship, plus the young generation of scholars, particularly in engineering, life sciences, veterinary science, and agriculture, are very interested in being able to commercialize their technology. And by allowing them to do so, we retain them as researchers, teachers, and contributors, in our case to the Iowa economy; whereas, otherwise they might sever their ties with the university.

Senator GRASSLEY. Dr. Louis?

Mr. LOUIS. Yes, I would mirror what Dr. Hoffman says. The vast majority of our contracts with industry are successfully negotiated. I think, you know, my experience in academy is that industry and universities are very different animals. They have very different cultures. Industry is there to make a profit, and that is its goal, to be a successful company. For a university, of course, it is education, research, discovery, and then communication to the general public of what that information is.

So I think we do come from different backgrounds. If the industry with which we are negotiating understands that at the outset, the negotiations are always much easier. But I think I would mirror Dr. Hoffman's—the issues which tend to stick, and it is also publications. The University of California, we have a very strong belief that what is produced has to be published, and sometimes for an industry that may be restrictive and may break terms, but very, very rarely. Usually we can successfully negotiate.

Senator GRASSLEY. Can I ask all of you to listen to this question? Some of the witnesses feel that the Bayh-Dole Act has beneficially influenced university research, encouraged collaboration academically and with industry, and created productive partnerships. Others on the panel do not necessarily share the view. How do the panelists who support Bayh-Dole respond to those with concerns about it? And how do panelists who think there are issues respond? More specifically, has Bayh-Dole promoted innovation or created barriers? Would you start, Professor Rai? And then let's just go across the table.

Ms. RAI. I think in many cases Bayh-Dole is the elephant and we are all blind men examining different parts of the elephant. So in the information technology industries, I think it is fair to say—and if you look at the testimony, for example, of Wayne Johnson from Hewlett-Packard before the House Committee on Science and Technology this past May, I think it is fair to say that in information technology there has been some frustration. IBM has specifically sponsored particular research collaborations with the explicit requirement that there be no patents because in information technology patents just have a very different role than they do in the life sciences. And so if you examine the part of the elephant that is information technology, you will think it is one thing. And if you examine the part of the elephant that is life sciences, you will think it is quite another.

I have also suggested—and sometimes in the life sciences not everything is an end product drug that should be patented and exclusively licensed. But that is actually a relatively minor problem relative to the divide. And you have seen, I am sure you on the Judiciary Committee have seen this divide over and over again in the context of the patent system reform bill. The divide between the life sciences and information technology is quite acute when it comes to how they view patents.

Thank you.

Senator GRASSLEY. Now Dr. Hoffman.

Ms. HOFFMAN. Mr. Chairman, my experience at several different universities has been very strong partnerships between industry and the universities. I mentioned a number of the partners that Iowa State has. Pioneer, of course, grew out of Iowa State technology, in 1924 was formed by Henry Wallace, who had developed the new seeds with Iowa State technology. We have worked with Monsanto on the development of low-linolenic acid soybean oil, which is, of course, extremely important in the prevention of heart disease. While we have a little bit of dispute about that, we have worked it out, and we are very satisfied with the partnership that we have with Monsanto.

As I noted, we have partnerships with many, many, many ethanol producers and bio-based product producers in the State of Iowa. At our Research Park, we have spawned many new companies. Engineering Animation, which was acquired by EDS, began—this is a good example of an information technology patent that created a very successful computer that was then acquired by another very successful company based on Iowa State patented technology.

So while I am sure there are examples of instances where there are disputes between universities and the industry, our experience is that we work those out and that we continue to have extremely profitable and valuable relationship, longstanding relationships with our industrial partners.

Senator GRASSLEY. Mr. Weissman?

Mr. WEISSMAN. I think there is no question that the university contribution to innovation has been extraordinary and that the public investment from the United States has been extraordinary. It is really one of the great stories of American Government.

It is not necessarily the case, though, that every university invention or federally sponsored invention would not have come to market but for Bayh-Dole. The Pioneer example, of course, predates Bayh-Dole. There are many examples that do. I think we would agree with Dr. Rai, thinking globally, that it makes sense to think that different industries and different industry sectors have different models of development, that whether you have exclusive or non-exclusive licensing arrangements makes sense in different contexts or less sense in other contexts.

The pharmaceutical development sector is the best case, the strongest case for exclusive licensing, and it is one that we have focused on. And even there we feel like there are very severe abuses and a failure to exercise the checks that exist in Bayh-Dole to curb those abuses. I think an overriding principle, as I mentioned, should be that where the Government is making invest-

ments, even though the public may get some downstream return, there has to be some reciprocity from the recipient of the license, from the licensee. They, after all, are getting something of considerable value. In the area of pharmaceuticals, the most important kind of return is both restraints on price, ensuring access, and preventing anticompetitive behavior.

And again, also to reiterate a comment from before, as the Committee looks forward on this matter and as the Congress looks forward to greater investment in the area of energy technologies, it is going to be, I think, quite important to think very carefully about whether exclusive licensing regimes are always the best way to proceed, and if there are maybe other models of development that could promote more open and collaborative sharing approaches to moving early stage inventions to the marketplace.

Senator GRASSLEY. Dr. Louis?

Mr. LOUIS. Senator, many of the complaints stem from companies who want to be guaranteed university-developed technologies for free, including ownership, free licenses, and background rights. I can comment from the University of California that has entered into many agreements with for-profit companies, and really it has only been a handful where there are contentious negotiations. And in a university environment where there is a commingling of funds in a research laboratory with various sponsors funding projects within the research laboratory to get differing results, it is difficult for a university to make such promises at the time a research agreement is negotiated. And I read that testimony too, and I was really amused by the individual from HP who commented, well, of course, the university should know exactly where everything is. And while that is true, usually there is a commingling, and so there has to be a very careful analysis before one could commit something that maybe, because of Bayh-Dole, we already have committed.

Finally, some foreign universities will either provide the sponsoring company with sole ownership, joint ownership, or guaranteed exclusive rights. But as foreign countries adopt Bayh-Dole laws—and increasingly now the numbers are—they are going to become more savvy in their licensing operations. Understanding the importance of retaining ownership of their invention, they may be less likely to assign away ownership. And because there has been a suggestion, well, the companies are, therefore, going overseas to do their research because it is easier to get the inventions, I would point out the University of California is seeing an increasing amount of foreign-sponsored research by industrial corporations on our campuses, which I think is an indication that they understand that the structure of Bayh-Dole is one that they can work very well with and will be to the advantage of those companies.

Senator GRASSLEY. Professor Rai and Mr. Weissman, in looking at your testimony, it appears to me that you make a distinction between biotech and pharmaceutical patents and those generated by tech and software companies. Is it your view that Congress should consider creating product-specific or industry-specific patent rules?

Ms. RAI. I think in general, whether within the context of Bayh-Dole or within the context of patent reform more generally, industry-specific legislation is probably a bad idea simply because there

are all sorts of ways that I think it cannot foresee the ways that industries will develop, because what may look like an information science industry 1 day may look like a nanotech industry the next day and so forth. So I don't think industry-specific legislation is the way to go. However, I do think that other actors in the system need to be sensitive to industry context, and in that way, I think that universities are beginning to do a better job. My research has indicated and I think there is some evidence that universities are doing a better job about being sensitive to context. It may be also that Federal agencies could work with universities to make them sensitive to context.

I don't think that congressional legislation can adapt to the ways that industries adapt as quickly as it needs to. So I think it should be done at the private sector level in the case—the private-public sector level in the case of universities, and also in conjunction with the agencies that fund the research.

Senator GRASSLEY. What about Government oversight? Before I get to Mr. Weissman.

Ms. RAI. I think that is very important. I think it is very important for the agencies that are funding this research to look to see how the research is being licensed out in the context—I am most familiar with NIH and in the context of certain research that it funds. For example, in software it will say this software has to be open-source software, which is a way of developing software without patents. I think that agencies should have that flexibility because they may know in certain cases that this is the type of research that would be better developed. I don't think they should have the only word. Universities should also have some input. But it seems to me that both sides, both the Federal agencies and universities, can show sensitivity to these contexts and work together to show sensitivity.

Senator GRASSLEY. OK. Mr. Weissman, back to my original question.

Mr. WEISSMAN. Well, I think in general it would be—it is quite a challenge for Congress to make those kinds of nuanced distinctions because it involves a kind of hands-on engagement with issues that are specific and technical and Congress is busy. But I do think that the oversight—very busy.

[Laughter.]

Mr. WEISSMAN. The oversight issue is one that needs a lot of attention. In our experience with NIH, where the Congress has given significant authority to the agency to exercise march-in rights, the NIH has re-read the statute to not take into account the requirement that inventions be made available to the public on reasonable terms. For us that would be a priority area of oversight. It is a possible area for additional legislation or one where there should at least be some congressional engagement with the agency to ensure that the original language in the statute is acknowledged, implemented, and relied on. We think more direct tests about how the march-in rights should be used should be a priority area.

There is one caveat to my statement, again, about focusing on specific industry areas. It is an inevitability that there will be major increases in Federal spending on energy-related technologies, and it is just going to be very important to think about those issues

with an open mind rather than just relying on the historic Bayh-Dole framework, which may or may not make sense as Congress moves forward on a variety of programs that we cannot yet envision.

Senator GRASSLEY. Dr. Louis, do you want to comment?

Mr. LOUIS. Yes, I would like to comment, and I think, you know, sometimes in these discussions it is forgotten that in 1980, these sorts of discussions, as I understand from reading the literature and reading things that Senator Birch Bayh has written are exactly the discussions that went on at that time. And some of the concerns of march-in, for example, or some of the issues of price controls have sent fears through the community because of the concern that would weaken the strength of the patents and that, quite frankly, anything that weakened the security for what is often—as you know, with Bayh-Dole the goal is for small startup companies, small businesses such as the one I referred to from UC Riverside, those companies need to be very sure that the patent that they are licensing from the university is secure and that it will be defended and that that is certain. But if there is a possibility that, well, that might not be so and there might be situations where the Government or some agency would have to step in and set price or make some rules that could potentially minimize the value of that patent, that suddenly makes it a much weaker patent. And for the small business—and a very high percentage of the startups that come out of the University of California as result of patents and inventions in the university are to small businesses—they want that security.

So I guess my word of caution would be that I would much prefer that—and I think it is an evolving situation. I think the nine points, the principles that the research universities and many of the professional organizations enunciated and have published now address some of these issues and sort of the philosophy that we hope is the way to go; in other words, that the universities are very sensitive to these types of issues. But the Bayh-Dole was brilliant and we would prefer that those issues not be further altered.

Senator GRASSLEY. OK. Professor Rai and Mr. Weissman, and other panelists ought to listen, and if you want to respond, and I want to ask specifically these two witnesses: Have patent ownership rights provided by Bayh-Dole interfered with traditional operation procedures of academia and led to conflicts of interest?

Ms. RAI. That is an excellent question. There has been no systematic study, as far as I am aware, of exactly how conflicts of interest have been dealt with in some of these cases. One hears anecdotal reports of situations where professors or graduate students are asked to hold off on publication until a patent filing can be made, which is obviously an issue. It is not quite a conflict of interest issue, but it is an issue. It reflects a tension between the goals of academia and the goals of commercialization, but possibly inevitable and a tension we have to live with.

The one piece that I am happy to say has been systematically studied and I think has come out in favor of Bayh-Dole is that it does not appear—as far as we can tell, anyway—that the emphasis on commercialization has changed the research agendas of faculty. In other words, the faculty that patent also tend to be faculty that

are doing ground-breaking research, publishing in the best journals, et cetera, et cetera.

One fear about Bayh-Dole was that it would make, you know, otherwise potential Nobel Prize winners into something else, which is not something we would want. And that does not appear to have been borne out. On the other hand, there are tensions, and I think those have to be monitored as well.

Senator GRASSLEY. Mr. Weissman?

Mr. WEISSMAN. I think there is pretty good data that concerns with secrecy have risen quite significantly since passage of Bayh-Dole, that the proprietary nature of patenting has changed the culture of university science in ways that are not for the better. This is not an area of my focus and expertise, so I cannot comment on ultimately how serious that is.

I would highlight one area, though, where I think congressional attention is merited and where there are institutional conflicts that arise beyond those which may relate to any individual professor. That is university investment in the start-ups that then receive Bayh-Dole rights, and in massive corporate-sponsored research agreements, including one, for example, that the University of California, Berkeley, has proposed with BP. The $500 million investment by BP would involve BP building facilities on campus, having its own researchers on the campus engaged in proprietary undertakings that would not be published. They will be commingled and intermingling with university scientists who will be receiving Federal funds and engaged in Bayh-Dole-implicated research.

I think it is just very hard to see, assuming best intentions by everybody involved, how those arrangements cannot raise major challenges and institutional biases about how intellectual property is managed and rights are allocated. I think that would be an area worth further scrutiny. We are seeing a couple of these mega agreements on the order of half a billion dollars which are going to, of course, change the local university culture, but also directly implicate the patent issues and the control of Government-funded inventions.

Mr. LOUIS. Senator Grassley, could I make one comment?

Senator GRASSLEY. Yes. I invited you to if you wanted to, and Dr. Hoffman, too. But go ahead, Dr. Louis.

Mr. LOUIS. I was going to make the point that I have the privilege of being the institutional official in my university, which is the individual where the buck stops, because the conflict of interest committee, conflict of commitment, report to me. I want to assure you that I take that responsibility very, very seriously, and particularly when we have industry contracts and we have entrepreneurial faculty, there are challenging and more challenging issues that do require oversight.

I make sure that the committees—when I appoint the conflict of interest committee, I make sure it has senior faculty who are very understanding of this issue. I closely oversee how they operate and function. We put management committees in place that meet with the faculty to discuss the students and the progress on the research, if it is Federal and if it is industry research. And we make sure that that conflict is effectively managed and does not impact the students, the faculty members' performance in the university.

So I think I could speak certainly for all of the University of California and universities in the country. It is something that we are very sensitive to. But as the Vice Chancellor for Research, I can speak personally. It is something that I take very seriously, and my colleagues around the country take very seriously.

So something we are very aware of, and we deal with it increasingly.

Senator GRASSLEY. OK. Dr. Hoffman?

Ms. HOFFMAN. Well, as a land grant university, Iowa State has a long tradition of partnering with industry, and, yes, it does predate Bayh-Dole. It goes back to the formation of the Extension Service, the Agricultural Experiment Stations under the Hatch Act in 1887, the Cooperative Extension Service under the Smith-Level Act of 1914. All of the various industry partnerships I have already enumerated have long traditions at Iowa State. So Bayh-Dole has not in any way changed the focus of the research. What it has done is to allow our innovative researchers to be able to take advantage of the fruits of their invention. It has provided them with an incentive to actually commercialize those inventions that they may not have had before. And as I mentioned, it is helping us to keep this young generation of faculty who want to be both the great scientists, as Professor Rai mentioned, and innovators.

And as Dr. Louis indicated, every university with which I have been associated has had a very strong conflict of interest policy. We at Iowa State are in the process of reviewing our conflict of interest and our proprietary research policy to make sure that it is state-of-the-art and that the kind of safeguards that Dr. Louis mentioned are definitely in place. We believe they are. We think it is extremely important to maintain the publication of research, that any proprietary research should be published within a reasonable amount of time, that junior faculty, graduate students, and postdocs should be protected from any restrictions on their ability to publish.

As Dr. Louis mentioned, sometimes the negotiations break down over the issue of publication, which we think is an extremely important part of our mission. So I do not see that Bayh-Dole has changed the mission of Iowa State or the other universities with which I have been affiliated.

Senator GRASSLEY. OK. I am going to have one last question. It is only half the questions I had to ask, but I have got to go where Senator Leahy just went, to the Agriculture Committee. So if all of you would take a whack at this one, and it may be an easy one to answer, but we still need this information.

Are there any changes in Bayh-Dole that Congress should consider to improve the goals of this law? I will start with Professor Rai and go across the table.

Ms. RAI. Sure. Let me just also add—I do not mean to take up more time than I should, but let me add one point about the conflict of interest issue. There is one study, just to note it for the record, by the Thursbys at Georgia Tech on provisions restricting publication in industry-sponsored research conducted in universities, and that is a little bit disappointing in terms of there is some—I do not recall the exact numbers, but the study does indicate some significant percentage of those agreements include re-

strictions on publication. And that just came to mind so I bring that up.

Now, with respect to changes to Bayh-Dole, I do not think that anything needs to be done immediately. However, I do think that—and this goes back to something that Rob Weissman was talking about a little bit—that agencies should not be as shy about using their powers under Bayh-Dole as they currently seem to be, whether in the context of march-in rights or in the context of stating that certain types of research is not best commercialized through patents. So if agencies fund software research, for example, it might be the case that they should be emboldened and say, you know, this particular software research is best disseminated through an open-source model. And I would guess that those agencies would have a lot of support from industry on that score.

Senator GRASSLEY. Dr. Hoffman?

Ms. HOFFMAN. Senator, I definitely do not want to keep you from the farm bill, which, of course, is extremely important to the State of Iowa, so let me just reiterate that the one change that we are requesting is increasing the cap on GOCO laboratories from 5 percent to 15 percent for the $40 million or smaller laboratories.

Thank you very much.

Senator GRASSLEY. And for the record, I want you to say, "Chuck Grassley, you better get that bill passed or else."

[Laughter.]

Ms. HOFFMAN. Thank you, Senator Grassley. I will let you read that into the record.

Senator GRASSLEY. Well, if you say it, that is for the benefits of my colleagues, see.

Ms. HOFFMAN. For the benefit of your colleagues, please. Thank you.

Senator GRASSLEY. OK. Robert Weissman?

Mr. WEISSMAN. I do not want to delay you from your other engagements but a few suggestions, which may or may not be legislative. They certainly involve oversight and more direction to the agencies, and probably also some legislative reforms.

First is that the march-in right has to not be a dormant right. It must be used in some circumstances, and I think there should be direction from Congress on guidelines for how the agency should use that.

Second, relatedly, is the Federal Government has the right to use the inventions it pays for. At the time Bayh-Dole was passed, that was viewed, even by proponents, as the most important right to maintain for the Government. But it is not using that, at least on the biomedical side.

Third is thinking intelligently about how to manage the IP portfolio of the Government to facilitate U.S. global health policy objectives. I think the legislation that Senator Leahy introduced is one very promising way to do that. There are other ways that one might do it, including better use of existing Bayh-Dole rights.

A fourth area, probably not legislative, is there is very inadequate reporting, that is public at least, about what we get out of Bayh-Dole. There is quite good reporting, I think, to NIH, but it is all treated as proprietary for reasons that are not obvious to me.

And, finally, I think it is worth the Committee examining the areas where there is substantial Government funding, but the Government funding does not directly lead to a patentable invention. Bayh-Dole is an on-and-off switch. Right now the Government gets no rights if its funding does not lead to the invention directly. There is a logic to that, but it is also useful to complement the existing Bayh-Dole rights with other rights, contractual or otherwise, where the Government is putting substantial moneys into R&D.

Senator GRASSLEY. OK. Dr. Louis? I am sorry I mispronounced your name. For a person like me who minored in French and cannot say a word, if I can say—

Mr. LOUIS. Do not worry. I have been called far worse by my students. I will also strongly endorse Dr. Hoffman's comment of getting to the farm bill. California agriculture is still our No. 1 industry, so it is a very important bill for our State.

I would say that—

Senator GRASSLEY. Make sure your congressional delegation votes that way.

[Laughter.]

Mr. LOUIS. Thank you, Senator. I think you will gather the University of California and I personally strongly support Bayh-Dole as it currently is. I think the modifications that Dr. Hoffman suggests, we would accept those because that certainly would be something we would support. But any march-in price controls or modifications that would undercut the strength of patents, which is the brilliance of Bayh-Dole, would, quite frankly, likely destroy what is its greatest ability. So that should be done with great, great caution, even thinking of it.

And, finally, on the issue of pharma and drug control prices, I think the reminder is that of the nine points in the consider document, it encourages universities to consider in their licensing arrangements provisions that meet unmet needs. But university and research is just a tiny piece of the investment. For that invention to get to market, big pharma can invest $1 billion for a single drug and, you know, I think the argument is not with the universities, but maybe it is the cost of producing drugs, and we would love that to be less. But, again, that is not an issue with Bayh-Dole, I would argue.

Thank you, Senator Grassley.

Senator GRASSLEY. Two things before you go. One, myself included, any members of the Committee will have some questions maybe for you in writing, and within a week you might get some questions, and then I presume the answer to how long to get the answers back is as fast as you can, but keep open your testimony.

The second thing is for Senator Leahy, this Senator, and the whole Committee, thank you very much for your testimony.

The hearing is adjourned.

[Whereupon, at 3 p.m., the Committee was adjourned.]

[Questions and answers and submissions for the record follow.]

QUESTIONS AND ANSWERS

Responses to Written Questions

For Dr. Elizabeth Hoffman

United States Senate Judiciary Committee hearing regarding
The Role of Federally-Funded University Research in the Patent System
October 24, 2007

Responses to Written Questions

For Dr. Elizabeth Hoffman

United States Senate Judiciary Committee hearing regarding
The Role of Federally-Funded University Research in the Patent System
October 24, 2007

Questions from Senator Leahy

1. I asked at the hearing whether Iowa State has ever decided not to commercialize an invention at Ames Laboratory because it might have to reimburse the taxpayers from a portion of the royalties. You responded that, to date, that has not happened but that the recoupment provision may create a future disincentive.

Iowa State knew the commercialization of patents at Ames Laboratory were subject to the recoupment provision when it took title to and commercialized inventions created there. Did knowledge of the recoupment provision deter the successful commercialization of the lead-free solder patent? If so, please explain how. If not, please explain the circumstances under which the recoupment provision would cause you to forgo commercializing a valuable invention.

You are correct that up to now the recoupment provision has not deterred our efforts to protect, market, and license any Ames Laboratory invention that we believe may have commercial success. This is because up to now there has not been an established record of exceeding the 5% cap for multiple years. Although we thought lead-free solder would be productive, we could not have predicted with certainty that it would take us over the cap. We know that Bayh-Dole has provided a powerful incentive. Taking away that incentive works in subtle ways.

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First, good administrators care deeply about the overall health of their organization, making decisions that most effectively support success. As a small laboratory, what are small swings in federal funds may have serious impacts on Ames. Once the cap is reached and the return to the laboratory is diminished, it is conceivable that projects leading to further commercial production naturally will not be seen as strongly contributing to overall health.

Secondly, it is hard work to successfully patent and license inventions. It often involves development work with the risk of not receiving a viable return. So, if the return of income from commercialization of an invention is questionable -- which is the case with most of the inventions from a scientific laboratory -- it may be best not to expend the resources to develop, protect, and market the invention. The prospect of a reduced return will naturally result in a more cautious approach. The unintended consequence could be an inclination to protect and market only those inventions that are deemed certain to bring enough money to justify a payment of 75% of the royalties to the U.S. Government.

2. You testified that Ames Laboratory has been by far the most successful of the Department of Energy Laboratories at commercializing inventions. Iowa State is to be congratulated for that. It has received more royalty income than any of the other DOE laboratories, not just as a percentage of its budget, but also in absolute terms. Would it be fair for Congress to change the taxpayer recoupment formula from a percentage to an absolute basis, so that if a contractor earns royalties on inventions at Government laboratories over a certain threshold the contractor would have to repay the Government?

We requested the change to 15% for small laboratories because it is the simplest approach. There are other approaches, but they raise other questions.

Certainly one option is to enact in legislation a flat dollar amount as a floor below which royalties are retained, and then apply the 75%-25% split above that. Another would be to put in a flat dollar floor, and then apply progressively higher percentages of return to the federal government at defined levels above this amount.

We used a percentage basis because it is approach used in current law, and because we accepted the view that there should be a proportionate return to the federal government.

We are only asking that whatever recoupment formula is decided by Congress to be in the best interest of the US taxpayer present a level playing field for small FFRDCs.

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3. The taxpayer recoupment formula under which Iowa State had to return money to the Government last year for the first time has been in existence since 1984. When Iowa State took title to the invention under this system, it knew what the rules were for reimbursing the taxpayer. The taxpayers fulfilled their obligation in providing the funds to Iowa State; how is it fair to them to change the system now?

Were this merely a matter of our contract with the federal government, we would agree that mid-stream modification would not be fair to the federal government. Though we have a contract with the federal government, we must remember that the cap is set by statute as a matter of federal policy. We believe that as with the federal tax code, adjustments are appropriately made to support the purposes of federal policy.

Additionally, were this a matter of our taking the funds for private use, we would agree that such a modification would not be fair to the federal government. Because the law requires us to use retained royalties for purposes of further delivery of scientific and educational endeavor, the retained funds will continue to be used for the public purposes defined in Bayh-Dole.

We are simply asking that the small FFRDCs be placed on a more equitable level with the large FFRDCs. For example, a large laboratory with an annual budget of $500 million will only have to return a portion of received net royalties back to the government when they exceed royalties of approximately $25 million per year, whereas a Laboratory with an annual budget of $40 million must return a portion of received net royalties once they exceed $2 million per year. The change will give small laboratories an important tool to assure their overall health and success in an environment dominated by big players.

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Responses to Written Questions

For Dr. Elizabeth Hoffman

United States Senate Judiciary Committee hearing regarding
The Role of Federally-Funded University Research in the Patent System
October 24, 2007

Questions from Senator Grassley

1. How has ISU's technology transfer activity affected agriculture in Iowa?

Iowa State's beginnings were focused on technology transfer for agricultural purposes: The focus of technology application through extension outreach was a key element of the land grant model. Components of the extension outreach included the creation of the agricultural experiment stations under the Hatch Act in 1887 and the cooperative extension service created by the Smith-Lever Act of 1914.

That tradition continues today through teaching, research, and outreach activities that provide new technology to the market, assistance in making use of technology, and the development of new technology-based businesses.

Some examples of our successful technologies show the broad impact of our technology transfer activities on agriculture in Iowa.

In the area of agricultural production

- The development of the B73 inbred corn line, one of six corn lines that are the basis for much of the seed-parent lines used for hybrid corn production in the United States today.
- 400 Varieties of commercial germplasm under license, including 51,000 bushels of soybean seed used in Iowa alone, and .ow-linolenic acid soybeans that contribute to reducing unhealthy trans fats in America's diet.
- The process that resulted in Maytag Dairy Farms in Newton to create the widely acclaimed Maytag Blue Cheese of today.
- Vaccines for the protection of pigs from diseases such as influenza, Porcine Reproductive Respiratory Syndrome (PRRS) virus, dysentery, salmonella, and other economically important pathogens, and Vaccine adjuvants to improve vaccine efficacy and diagnostics tests for disease management that contribute to the biosecurity of livestock in Iowa and throughout the U.S.

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- A start-up company that commercialized the VerifEYE machine vision system used to detect food borne pathogens during slaughtering and processing operations, helping to ensure a safer and more wholesome meat product.

In the area of improvement of our environment:

- Impellicone, which enables the efficient application of nitrogen fertilizers, reduces the amount of anhydrous ammonia fertilizer application saving money and the environment.
- The Temperature Phased Anaerobic Digester (TPAD), which produces Class A biosolids during waste-water treatment that meet federal and state requirements for safe land application.
- Natural herbicides based on corn gluten meal, which have proven very popular with organic gardeners, landscapers, and nurserymen for the control of annual weeds without using toxic or hazardous chemicals.
- Benallure, a natural attractant for beneficial insects that aids in the control of damaging fruit crop pests reducing environmentally damaging pesticide use.
- New developments in biofuels, such as novel catalysts, which include one Iowa start-up company, and processes for the efficient production of ethanol from renewable feedstocks that promise to help reduce carbon emissions and reliance on imported oil, while creating new markets for farm products.

In the land grant university tradition, much of our technology transfer activity is related to agriculture. Since July 1, 1999, approximately 57% of all disclosures and 80% of all technologies licensed were related to agriculture.

It is important to remember that technology transfer is not simply a matter of developing and licensing products. Iowa State University also provides assistance to business in assuring the success of technology companies through such units as our Center for Industrial Research and Service (http://www.ciras.iastate.edu/), Research Park (http://www.isupark.org/) and the Pappajohn Center for Entrepreneurship (http://www.isupjcenter.org/).

Our efforts to transfer agriculture-related technology will continue to benefit not only Iowans but our society as a whole.

2. What kind of impact has the Bayh-Dole Act had on job creation and the economy of Iowa?

In the last 8 years, nearly 20 start-up companies have been formed based on 41 federally funded ISU technologies. Estimates of ISU technology

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based product sales by Iowa companies—the substantial majority based upon federal support—increased from $15 million in 2002 to $83 million in 2006. While we don't have exact numbers, these new ventures have resulted in very significant job creation in Iowa.

3. How do you think that we can improve the tracking of the federal contribution to a patented invention, given the nature of federal research and development funding and the way that universities perform research and development in their institutions?

Iowa State University informs the government of subject inventions that arise from federal grants and contracts. Wherever possible, we utilize the electronic reporting database, Interagency Edison (iEdison), which was developed by National Institutes of Health (NIH), to fulfill reporting requirements. What the agencies do with that information, however, and the particular agency's facility with that database (or with paper notifications if they are not subscribed to iEdison), is largely unknown to us. There appears to be considerable turnover in project managers within the three to four-year period between the beginning of the project and the identification of a subject invention. We do not know whether more consistent "ownership" of this information would be beneficial to the government's "tracking" of its contributions. At the least, we would encourage all federal granting/contracting agencies to utilize iEdison (or some other new government wide electronic IP database), and further to undertake development of procedures to maintain continuity of information when responsibilities change. Additionally, we know that Department of Energy's Chicago office is a central repository for invention disclosures from several DOE labs, thereby consolidating some of DOE's intellectual property in one central location. This consolidation has provided an incentive also for DOE to consolidate employees skilled in handling intellectual property issues. Perhaps that is a model that other agencies could consider.

4. What are your thoughts on what has been said about march-in rights by some of the other witnesses?

Of course, we agree that march-in rights were an important part of the debate when Bayh-Dole legislation was being crafted, and remains an important safeguard, even though it has not been used to date. Since one could not know the future, this appeared to be a "fail-safe" clause for particular circumstances that would have to be identified on a case-by-case basis. In her written testimony, Dr. Arti Rai simply pointed out that procedural precedents to utilizing march-in rights (administrative hearings, court appeals) might be examined in case those procedures represented a barrier to use. Since the use of this right could have drastic consequences, we are not in favor of weakened procedural barriers, in

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order to protect the rights of those involved. Dr. Rai also pointed out that march-in rights should not be weakened, and that they may have served as an effective deterrent, without actually being utilized. Perhaps the threat alone, then, is enough to have the desired effect.

Mr. Weissman was the only witness who spoke negatively of the government's lack of use of march-in rights. We consider that his experiences with the two march-in cases [Ritonavir for HIV/AIDS – Abbott; and Latanoprost for glaucoma – Pfizer] with National Institutes of Health were anecdotal. That is, they represented particular problems with pricing structure that NIH felt was better left to Congress to address. We agree with NIH's position as outlined in Mr. Weissman's written testimony (p. 12), that the exercise of march-in rights has global implications. We also agree with NIH's purported statement (also from p. 12 of Mr. Weissman's written testimony) that "[a]s a practical matter, it is reasonable to assume that companies will not undertake development costs of these inventions if they believe the Government will readily allow third parties to practice the invention." The right is there, and it should remain there. However, it is not an obligation of the federal government. Apparently, the case has not presented itself where the federal government feels that march-in rights should be exercised. We believe that careful consideration, on a case-by-case basis, as was done by NIH, is an appropriate course.

5. How does the taxpayer benefit from these partnerships if industry and nonprofits/universities keep the royalty revenues from the inventions funded by the federal government? What is the "return on investment"?

The return on the taxpayers' investment is the stimulation to the economy through the introduction of new technologies in which industry will invest additional development dollars leading to new products and services that improve the taxpayers' quality of life. This industry activity may be from newly formed companies or established companies. This growth is generated not only from those businesses that license our technology, but the businesses that provide support to them. This stimulation of the economy will provide jobs, hopefully more technological jobs.

From the perspective of the non-profit sector, the royalty revenue is a powerful stimulant to continue our activity through support of research, education and technology transfer activities. Without the incentive, there would not be funds for institutions to add value to the invention by spending the money to file patents or establish seed funds to support the further development of the invention. Without the protection that a patent would provide, there would be much less incentive to engage in the follow-on development work necessary to commercialize technology.

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6. Some contend that the Bayh-Dole Act has made collaboration with U.S. universities more difficult because they claim that it's harder to finalize intellectual property contracts with them. Do you agree with this assessment? Is it your opinion that U.S. companies are increasingly turning to foreign universities for research collaboration because it is easier to deal with them? How do the intellectual property and business practices at U.S. universities compare to universities in other developed and developing countries?

With regard to research contracts, we have heard that there are complaints about intellectual property terms causing difficulties in coming to agreement. That has not been our experience. The terms that actually cause more problems (for projects outside of the Ames Laboratory) are terms about control over publications.

With regard to license agreements, we have never failed to reach agreement because of Bayh-Dole requirements. Occasionally industry does not like the government march-in rights, or the requirements to move quickly to commercialize but we have been able to arrive at agreement. We try to address these agreement requirements up-front, prior to drafting language for a license agreement, and have been successful in that no company has walked away from a license due to these requirements.

Our experience does not support that industry is turning to foreign universities. Our research funding from industry has remained relatively constant over the past eight years, while nationally – until last year – industry sponsored university research was declining in the U.S. This fiscal year to date (through the first quarter), our industry funding has very substantially increased.

With regard to comparing US universities intellectual property and licensing practices with developed and developing countries, I can only say that increasingly over time, more countries are looking to emulate the Bayh-Dole approach.

7. What kind of interest and engagement have you had from students in technology transfer activity? What programs does ISU have to encourage technology entrepreneurship among young people?

The interest of students in technology transfer has grown over the years, just as business's interest in working with universities also has grown. Our graduate students are engaged in the research activity of our principal investigators. Most telling is that of all invention disclosures received in fiscal year 2006 and 2007, 35% included graduate students as inventors. As inventors, these students are entitled to a share of royalties.

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We have employed students to assist in the evaluation of technologies, business plan reviews, marketing activity, and legal review. We have also supported a mentoring program and our technology transfer staff serve as guest speakers to undergraduate and graduate classes.

Iowa State University operates the John Pappajohn Center for Entrepreneurship. While the Center is located in the College of Business, it serves students throughout the university. The Center has met the increased interest, as well as creating increased the interest, of our students in entrepreneurship by active engagement with the entrepreneurial world.

Courses in entrepreneurship are offered at Iowa State University at the undergraduate and graduate level. There also are internship opportunities for undergraduate and graduate students at companies located at the Iowa State University Research Park.

There is a program through the College of Agriculture with financial support from a local entrepreneur to offer education in entrepreneurship, mentoring and support to post-docs who are interested in forming their own businesses.

8. What percentage of retained patent revenues goes into student stipends and other forms of financial support?

Because of the many pathways in which patent revenues flow back through the institution and the many ways these funds support students, it is not possible in the time provided by the Committee to give a reliable estimate of total student financial support. For example, a significant portion of the funds from royalty income is used for faculty research support. Commonly, faculty to use these funds to hire graduate research assistants to start or maintain research programs.

There are three main pathways of patent revenues:

First, one-third of the net patent revenues are shared with the colleges and the departments of the inventors. The funds are used in a variety of ways in direct and indirect support of students.

Second, funds from net patent revenues are provided to the vice president for research and economic development office each year ($6.5 million in the last 8 years) for research and education. These funds are used strategically to support educational, research and economic development efforts that include direct and indirect support for students.

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Thirdly, commercialization and seed funds are used to further develop promising technologies in order to make them more patentable and more attractive to industry for commercialization. These funds often find their way to students working in these areas.

In some cases, funds returned to departments are specifically earmarked for students support. For example, the Ames Laboratory uses a portion of returned royalties for educational programs. While this does not constitute the majority use of such funds, but a large portion of monies directed to other purposes naturally returns to the benefit of students through:

- Graduate Assistantships
- Tuition support for graduate students
- Hiring of students in both research and administrative capacities such as in support of technology transfer
- Equipment and other support for student research projects
- Student travel to conferences to present student research and to hear from experts in their fields

9. I'm told that it's very expensive to develop intellectual property generally, and to secure patents, specifically. I'm not sure I fully understand - and expect many do not realize - that non-profit organizations such as universities need to do a great deal of diligence before deciding it is worth the cost of investing in patent development. I understand patent prosecution can be an expensive proposition too. Where does a university get funds to support these labor, expertise, and cost intensive activities?

The goal of submitting research proposals for funding is not the development of intellectual property, per se, but rather advancement of the scientific endeavor through the three academic missions of research, education, and public service. There is never any guarantee that commercially meaningful intellectual property will result from funded research, and that outcome is not the primary driver of the academic research enterprise.

It is true that the technology transfer process is expensive and risky. Each technology requires considerable investment of time and other resources to review for protection and commercial potential. Once licensed, it can take years or decades before a product is introduced to the market, if at all. For Iowa State University, all of the funds supporting this activity come from licensing income. Consequently, we must be diligent in evaluating the commercial viability of a given technology. In the case of ISU, we succeed because we have been very fortunate to have talented researchers whose technologies have produced sufficient income to pay for the expenses associated with our activity.

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In the 1990's, in order to buffer the risks, we took the step of taking income from a non-federally funded technology to establish an investment fund to provide us with operating income in years when income does not cover expenses. Many universities do not have the luxury of such an investment fund and must find other sources of income to cover this activity. Such support might come from many sources: development foundations, state funds, reimbursement of indirect cost received through research funding, and from licensees as reimbursement of expenses for the inventions they license prior to any product sales and royalty income. Because there is no guarantee that transfer of technology to a company will be successful, many institutions do request reimbursement of patent prosecution costs from the licensee.

In the case of Ames Laboratory it is important to remember that under ISU's Contract with DOE, ISU conducts the patenting and licensing activities on Laboratory-developed intellectual property, thereby assuming the associated costs and risks under what is known as "privately funded technology transfer." While ISU may recoup some, if not all, of these costs under the royalty sharing formula, the risk is assumed by ISU and not by Ames Laboratory using federal funds.

10. How do royalty revenues from federally funded research at your institutions attract and retain world class faculty? How does that revenue help that same faculty compete more successfully for other research support?

First, funds from net patent revenues are provided to the vice president for research and economic development office each year for research and education and used for new faculty startup research packages and retention packages, equipment purchases, or other efforts to support research that has the potential to lead to innovations that will impact economic development. Over the last 8 years, the amount of ISU's investment in these areas has been $6.5 million—a substantial majority of which has come from federal support. These start-up and retention funds allow faculty to pursue research ideas and to generate the initial proof-of-concept data that is necessary to successfully compete for federal funds. These funds allow the faculty to do innovative and creative research that is likely too high of a risk to receive federal funding: results of such higher risk research reduce the risk of federal investment and so make viable and productive paths of inquiry more "fundable" at the federal level. Additionally, most of this research is carried out by students, so these revenues are also directly supporting student stipends and education.

Second, and in a similar fashion, a commercialization fund of $200,000 per year is used to further develop promising technologies to a point that they become more patentable and more attractive to industry for

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commercialization. Since 1996, $1.8 million has been utilized from this fund to support Iowa State faculty research and the return on this has been 65 licenses and $15.2 million in royalty income.

In addition to these University funds, since FY2005, Ames Laboratory has committed $400,000 from its received royalty income to attract and retain faculty. Ames Laboratory also has committed over $165,000 of its royalty income for seed funded projects since FY2005; proposals are requested from new or young faculty members to develop new interdisciplinary collaboration with Ames Laboratory researchers on projects that fit broadly within the Ames Laboratory mission. The goal is to further develop the science so that it forms the basis of future proposals to DOE and potentially new research areas within Ames Laboratory.

Providing such funds makes a huge difference in hiring and retaining a talented group of researchers.

11. Unlike some of the big coastal states, both east and west, many Midwestern and rural states have no deep or extensive venture funding available for economic and business development. How does the Bayh-Dole Act supplement the Iowa economy in this regard? How does seed funding from royalty revenues support start-ups and spin-offs and other commercial development in the Ames and Iowa geography?

Royalty revenues are used to support startups in the following ways: The first year rent is paid in ISU business incubators; limited funding is provided for legal and other professional business services; assistance is provided at no charge for SBIR/STTR grant development; technology development is supported through the $200,000 commercialization fund; and funding is provided for faculty to travel to venture capital and other conferences to showcase their inventions.

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Responses to Written Questions

For Dr. Elizabeth Hoffman

United States Senate Judiciary Committee hearing regarding
The Role of Federally-Funded University Research in the Patent System
October 24, 2007

Question from Senator Hatch

Dr. Hoffman, I appreciate your comments on the impact that the 5% budget limitation has on small government owned, contractor-operated (GOCO) laboratories are compelling.

As you stated in your testimony, you'd like to see the royalty limitation be increased to 15% of the annual budgets for GOCO laboratories with annual budgets of less than 40 million.

How did you arrive at those numbers?

If I understand your proposal, it would leave intact the existing 5% royalty cap for GOCO laboratories with annual budgets above $40 million, correct?

Our goal is not to advocate wholesale change in Bayh-Dole. Rather, we seek relief from what we believe is an unintended and unfair penalty on small, successful federal labs.

Our proposal is based on what we regarded as a universally acceptable definition of a "small" laboratory. We believe that in the scope of the federal laboratory system, labs with annual budgets under $40 million represent such a definition.

We chose 15% because it creates what in our experience is sufficient headroom for incentive. There is unlikely to be a single invention—a homerun—that garners this amount of royalties. Given the uncertainties in the commercial life of an invention, the greater headroom provides for ongoing incentive to continue innovation even if at times the laboratory does exceed the cap. In other words, there is incentive to keep the stream of inventions moving forward even if the laboratory does from time to time reach the cap from time to time.

These amounts are to some extent arbitrary—just as the original 5% is arbitrary. While one could argue that the spirit of Bayh-Dole would commend altogether lifting the cap, we recognize that the cap exists in the first place

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because Congress regarded the federal laboratory system differently that it regarded mere sponsorship of science, because of the huge federal investment in facilities.

Questions for All Witnesses by Senator Hatch

1. How significant has Bayh-Dole been to the elevation of the U.S. economy and to economies and living standards of third world nations?

There have been many articles written touting the significant economic impact that Bayh-Dole has had on our economy. Some use various matrices to provide estimates of the impact to the economy, but an exact measurement of the level of significance is not possible due to the wide and permeating affect that, for example, a new successful start-up business would have on the economy. Start ups not only create new jobs and contribute to the GNP, but other businesses associated with the start-up develop as well. Also, the licensed invention may just be the start needed for the new company to build a portfolio of patents and technologies resulting in multiple products, an economic impact that might never have occurred without the licensed invention.

Many of the government funded projects do not result in patentable inventions. The public benefit impact that results from federal funding to universities is larger than patents licensed under Bayh-Dole. Research funding allows the researchers to build upon their past successes and develop new and interesting research proposals. Through publication they contribute to the scientific community so that other scientists can build on their research. Bayh-Dole provides the flexibility for the institutions to make the decision if patent protection is the best method to advance the invention for commercial use, or if publication only is a better method. Bayh-Dole also gives the government the right, should it disagree with that decision, to file for protection and to license it to others. At ISU we constantly evaluate our patent portfolio and will abandon patents for public use that under initial review appeared to have strong commercial importance but with time prove to be less valuable.

Some measures of success of U.S. universities, hospitals, and research institutes can be seen through publications of the Association of University Technology Managers (AUTM). AUTM's annual survey and Better World Project,[1] for example, provides data and specific illustrations of successful. contributions. Although the survey reports are results from all funded activity, not just government funded activity, on average 67% of all research expenditures are from the U.S. Federal Government (AUTM

[1] Association of University Technology Managers®, Better World Project (2006 – 2007, available at https://www.autm.net/shopping_cart/index.cfm/fuseaction/publication.category_detail/category_id/31)

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Survey FY2005[2], 191 U.S. respondents (universities, hospitals and research institutes a growth from 120 in 1991)). The Better World Project provides stories on inventions which have had significant impact in promoting the public good. The FY2005 AUTM U.S. Licensing Survey reports global statistics:

- 4,932 new licenses signed;
- 527 new products introduced into the market in 2005; 3,641 in the 8 years from FY1998 through FY2005; that is 1.25 new products every day over the last 8 years;
- 628 new companies created in FY2005; that is 1.7 new companies every day of the year; 5,171 new companies since FY1980; that is more than one company every two days; and
- The majority of licenses were to small companies, a primary focus of Bayh-Dole.

The overriding mission of U.S. universities is the dissemination of knowledge. Application of this mission to technology transfer includes the desire to disseminate new inventions for the good of society, including third world countries. There has been an increase in awareness of the hurdles that an exclusive license arrangement might have on disseminating new inventions to third world countries, and organizations such a Public Intellectual Property Resource for Agriculture (PIPRA) have been formed to educate and facilitate the transfer of universities' patented inventions to third worlds.

This is a topic discussed among university technology transfer personnel and increasingly, exclusive licenses are including language to facilitate third-world use of the patented invention. However, language within a license agreement is only one step in this process. There are other challenges which may be harder to overcome, which takes the cooperation and funding of the company licensee and governments.

2. Are there shortcomings of Bayh-Dole that have become apparent with time?

We believe the only substantial shortcoming of Bayh-Dole is the inequitable calculation of GOCO royalty sharing, which has triggered payment to the Federal Government by one small and successful federal laboratory alone.

3. There is still room for improvement of Bayh-Dole, despite its apparent success. What top three reforms would you suggest?

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[2] Association of University Technology Managers®, report titled, AUTM U.S. Licensing Survey, FY 2005: A Survey Summary of Technology Licensing (and Related) performance for U.S. Academic and Nonprofit Institutions and Technology Investment Firms, editors Dana Bostrom and Robert Tieckelmann.

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We suggest only the one reform mentioned above in number 2. We are aware of criticism that Bayh-Dole has caused universities to seek unrealistic royalties under license agreements, although no substantiated instances have been cited to our knowledge. A fair return is what we seek. It is not in the interest of the university to demand royalties that will diminish the return to the licensee, to the extent that that licensee might abandon development or launch of a product, or further collaboration.

Our experience has been that provisions related to our retention of rights to continue research, confidentiality provisions (overreaching into university know-how or delaying filings of patent applications) and due diligence to commercialization have presented the greatest difficulties in negotiating exclusive license agreements with industry. In general, industry wants to maintain long term market share by preventing further research (discussed further in number 4 below) and to retain complete freedom over its development process. Such complete freedom can lead to delay of development due to another product focus of industry or to delay the development of the invention in favor of a replacement invention that the company has developed internally. We do not view these terms as failures of Bayh-Dole, but are consistent with the desire of Bayh-Dole to have the resulting inventions utilized to advance the public good. They also meet the institutions' overriding mission to disseminate knowledge. It does take considerable effort by both parties to arrive at language that will meet the needs of both parties, but we do manage to achieve that goal.

4. Currently, Bayh-Dole provides an effective research exemption for federal government entities to practice the invention in the form of non-exclusive licenses to the government; however these licenses do not extend to universities or non-profit research institutions. This can give rise to the perverse situation where a university invention, if licensed exclusively, may be unavailable for use in fundamental, non-commercial research by the very laboratory where it was made. This creates an atmosphere of uncertainty and confusion that negatively impacts public research. What, if any, are the downsides to amending the Act to create a research exemption to use publicly-funded research results for noncommercial research in academic and nonprofit research environments.

Currently, universities retain rights under their license agreements to continue research on the subject invention. It is considered a best practice among universities to do so, and a document entitled "In the Public Interest: Nine Points to Consider in Licensing University Technology,"[3] endorsed by the Association of University Technology Managers (AUTM), states "Universities should reserve the right to practice

[3] "In the Public Interest: Nine Points to Consider in Licensing University Technology", p.2 (March 6, 2007, available at http://www.autm.net/aboutTT/Points_to_Consider.pdf)

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licensed inventions and to allow other non-profit and governmental organizations to do so." Since this is already common practice, amending the Act to create a research exemption is not necessary.

5. Perhaps one unintended consequence of Bayh-Dole was to establish incentives for universities to develop independent technology transfer programs and to manage IP in a highly individualized and even competitive manner with respect to other universities. The resulting fragmentation of IP rights has, in some cases slowed down or prevented the pursuit of projects that have limited profitability but high social or humanitarian value. The development of effective treatments for neglected diseases is an example that comes to mind. Can you see any framework that would allow and embrace the development of collaborative IP management strategies across multiple publicly-funded research institutions?

The early stage research activity that takes place at universities is not conducted with intellectual property production as a goal. Rather, IP is a by-product of the research activity, and there is never any guarantee that IP will result. Requests for proposals focused on projects with high social or humanitarian value certainly would attract research proposals from our faculty, but the pursuit of a research project based on its level of profitability would not be a criterion.

To establish a national collaborative IP management model for all U.S. universities would require some significant resources. Simply providing a repository for all IP probably would not be any more effective than searching the PTO's website for published patent applications and patents.

Some models now being used by universities are: UTEK (http://utekcorp.com/), a for-profit company which " utilizes its U2B® model to acquire and transfer socially responsible technologies from university and government laboratories worldwide," and PIPRA (referred to in question 1 above), a non-profit organization that brings together IP in the area of agriculture from over 40 universities, public agencies, and non-profit institutes and helps to make these technologies available to innovators around the world. Other organizations such as PIPRA, which concentrate on specific fields of technology, may be one method to aggregate inventions from multiple universities.

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Senator Orrin G. Hatch
Hearing before the
Senate Judiciary Committee

"The Role of Federally-Funded University Research in the Patent System: A Review of Bayh-Dole and Royalty Returns"

October 24, 2007

Dr. Charles F. Louis, Vice Chancellor for Research
University of California, Riverside

Dr. Louis, thank you for your testimony. Proponents of the Bayh-Dole Act say it gives universities and researches a financial incentive for useful innovation, and it induces universities to find a productive use for research that might otherwise go unused.

Critics say it promotes secrecy within academia because researchers compete to be the first to patent, creates conflicts of interest between profit and academic integrity, and allows for corporate influence over academic research.

In your experience how prevalent are these unintended consequences of the Bayh-Dole Act?

My experience based on a thirty five year university career is that these potential unintended consequences of Bayh-Dole are virtually nonexistent. While there may be isolated (and well-publicized) examples to the contrary, I certainly have not seen any trend in these directions that can be ascribable to Bayh-Dole. Academic researchers are, first and foremost, academic researchers. Their primary competition with one another is to be the first to publish a new finding from which real academic prestige arises. Most researchers would forego a patent in a heartbeat to be assured first publication of a new discovery; receiving the Nobel Prize is the dream of every researcher and this is awarded for ground breaking discoveries not the award of a successful patent. Where secrecy does occur due to such scientific competition it is unrelated to technology transfer, predates Bayh-Dole, and would continue to exist in the absence of Bayh-Dole.

Similarly, an academic institution is first and foremost an institution committed to the education of its students, the creation of new knowledge, and public service – a special role of land grant institutions such as the University of California. Since their reputation stems directly from their academic integrity, universities are sometimes fierce in their protection and defense of it. It is critical to understand that the primary objective of academic technology transfer is to help ensure that useful discoveries are developed into goods and services that ultimately benefit the public. The generation of income,

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while certainly helpful, is not what drives university technology transfer programs. Further, the majority of technology transfer programs do not actually make money, but even for those that do, the income potential from technology transfer is a fraction of 1% of the overall budget of academic institutions, so it is hard to see it as something that can significantly influence institutional priorities. Even at the University of California, which by all measures has a very successful technology transfer program, the net income produced through technology transfer is just over one-half of one percent of the University's overall operating budget.

Finally, you mention a concern that corporations may be influencing academic research. In fact, our insistence on preserving the academic nature of our research is sometimes a point of contention in negotiating research agreements with industry. As academic institutions, we rigorously maintain our right to publish the results of our research, even if those results are unfavorable to the business or products of our industrial sponsors. Companies are given absolutely no editorial control of our research publications which again can be a matter of contention in negotiating with industry. As an honest broker, a university tries to resolve conflicts between government and the private sector by providing sound, unbiased research to inform their debate.

In short, while there have been some isolated, and very well publicized instances to the contrary, I do not believe that the integrity of the academic enterprise is slipping as a result of the Bayh-Dole Act. We must continue to be vigilant, to be sure, but I am confident that academic integrity is still a concept with deep meaning and importance to the academic community. Every researcher knows that their academic integrity is their most precious possession because it defines their credibility as a researcher. Those well advertised cases where researchers have compromised their integrity and have suffered the consequences and lost their credibility serve as a strong reminder to us all that academic integrity can not be compromised without dire consequences.

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Senator Orrin G. Hatch
Hearing before the
Senate Judiciary Committee

"The Role of Federally-Funded University Research in the Patent System: A Review of Bayh-Dole and Royalty Returns"

October 24, 2007

General Questions for All Witnesses

Question #1: How significant has Bayh-Dole been to the elevation of the U.S. economy and to economies and living standards of third world nations?

The Bayh-Dole Act was passed in part to spur the transfer of federally funded inventions to the commercial sector not only for the development of goods and services that would otherwise not have been available to the public, but also to stimulate the then-flagging U.S. economy. By most accounts, the Bayh-Dole Act has indeed contributed to the elevation of the U.S. economy. The impact of the Act can perhaps be measured by such things as the number of commercial licenses (an indirect measure, at best), new products on the market, and university start-up companies. According to the following data reported by the Association of University Technology Managers (AUTM), Bayh-Dole has been quite successful by these measures:

- When Bayh-Dole was passed, about 1,500 of the government's portfolio of 30,000 patents had been licensed. Contrast this to AUTM's 2006 data, which show that almost 5,000 new licenses were executed in 2006 alone, with over 31,000 active licenses total.

- The same AUTM report indicates that almost 700 new products were introduced in 2006 alone, with a total of over 4,300 new products since 1998, or at least one new product every single day.

- Similarly, over 550 companies based on university research were created in 2006 alone, with a total of over 5,700 since 1980.

Some additional relevant study results also serve to underscore the direct and indirect impact of federally-funded research:

- In California alone, over 730 biomedical companies have spun off from California universities and research institutions, according to the California Healthcare Institute.

- Job creation can be evidenced by the fact that the 2,700 biomedical companies in California (of which over one-quarter are spun off from universities and research institutions) have generated almost 260,000 jobs.

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- A 2000 Congressional Joint Economic Committee report, "The Benefits of Medical Research and the Role of NIH," estimates a return of as much as $240B in increased life expectancy benefits contributable to NIH-funded research (1992$), or 15 times the annual NIH investment in research.

- A 2000 study commissioned by the Mary Woodward Lasker Charitable Trust concluded that the likely returns from medical research are so extraordinarily high that the payoff from any plausible "portfolio" of investments in research would be enormous. As an example, the study estimates reductions in mortality attributable to medical research from just cardiovascular disease at $500B.

When one considers that no government funds were expended (beyond the costs of the research), this is a remarkable success indeed.

Clearly, developing nations have benefited along with the rest of the world from advances in healthcare, nutrition, and even transportation, which has made it easier for healthcare workers to travel to and bring aid to such countries. Many of these advancements would not have existed if not for inventions and discoveries resulting from federally-funded research. A quantitative measure of impact on economies and living standards of the developing world is less documented. Certainly, the new knowledge that is generated through university research has benefited the entire world; but this would have been true even without Bayh-Dole. The significant market in the United States drives technology uptake that has an impact all over the world, including in developing countries. Such technology "diffusion" has been in effect for centuries, perhaps millennia.

In the area of health in particular, the development of vaccines and treatments for diseases that disproportionately affect developing countries takes at least as much time and resources as for diseases with a more lucrative market. The Bayh-Dole Act provides certainty of title, encourages use of the patent system as a means of inducing commercial investment, and allows exclusive licensing, all of which are critical to encourage pharmaceutical and biotech companies to make the investment necessary to develop a safe, viable, and effective product that can be distributed in developing countries. It is important to note also that there is nothing in Bayh-Dole that precludes funding recipients from licensing such technologies to companies outside the U.S., including companies in developing countries that are perhaps more focused on these diseases.

While individual cases and technologies make it clear that university research and technology transfer has had positive impact in developing countries, I am not aware of any empirical data to that effect, nor any comprehensive studies that have been conducted for this purpose.

Even apart from a Bayh-Dole context, it is important to note that the academic community has become more aware in recent years that it can have a unique impact, albeit relatively small, in developing countries, particularly in the areas of health and nutrition. In fact, this was one of the

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emerging issues specifically identified in a March 2007 white paper developed jointly by several academic organizations, including the University of California (UC) campuses, entitled "In the Public Interest: Nine Points to Consider in Licensing University Technology" (available at http://www.autm.net/aboutTT/Points_to_Consider.pdf).

The University of California itself has a number of research projects and licensing arrangements that are specifically intended to benefit developing countries, including the following examples:

- At UC Riverside, a USAID-funded program has for ten years been actively developing improved cowpea varieties for sub-optimal African growing conditions and has continued to provide training and resources for local implementation of improved varieties.
- The UC Riverside Center for Disease-Vector Biology utilizes federal and non-federal funds for research aimed at controlling the development of the pathogen responsible for malaria, as well as other pathogens.
- The UC Berkeley campus' socially responsible licensing program is arranging for a biofortified sorghum to be more accessible in African nations.
- The UC Los Angeles campus is working with a non-profit foundation to develop a tuberculosis vaccine.
- The UC-managed Lawrence Berkeley National Laboratory is implementing programs for a sustainable, low-cost, efficient cookstove in the Darfur refugee camps and a water purification unit that can quickly, safely and cheaply disinfect water of the viruses and bacteria that cause cholera, typhoid, dysentery, and other deadly diseases.
- The UC Davis campus is the home of the Public Intellectual Property Resource for Agriculture (PIPRA) which is a foundation-supported initiative where universities, foundations and non-profit research institutions make agricultural technologies more easily available for development and distribution of subsistence crops for humanitarian purposes in the developing world and of specialty crops in the developed world.

Universities across the nation are similarly engaged in various research and licensing programs, many of them federally funded, that benefit the living standards of developing nations. Universities are also providing local training and other resources to encourage and develop sustainable programs to improve quality of life. However, again, I am not aware of any studies that specifically evaluate the direct impact of any of these activities on the economy or living standards of developing countries.

Question #2: Are there shortcomings of Bayh-Dole that have become apparent with time?

The legislation was actually very well crafted, allowing for tremendous flexibility to adapt to new and emerging technologies and markets, creative approaches to commercialization, and even a changing economic environment. The university/non-profit community has indeed adapted its practices over the years as the need has arisen and as creative approaches to encourage development and use have evolved. For example, rather than providing a company an

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unlimited exclusive license to a patent, universities will often limit the license to just the field of use being diligently pursued by the licensee, leaving other fields free to be licensed to other companies. Universities have also become more sophisticated in their treatment of research tools (see Question #4, below).

Interestingly, one of the initial concerns with Bayh-Dole has not, in fact, materialized. In the early days of the legislation, a number of companies were wary of the government's march-in rights. As late as the early 1990's, the University of California was still dealing with companies that refused to develop any federally-funded inventions. However, as the government has shown a considered and even-handed approach to the exercise of these rights, industry's reservations seem to have dissipated. This experience made clear that any changes in the Bayh-Dole law that increased the potential for march-in would significantly decrease the ability of universities to license their inventions to companies as it would increase the risk for companies investing in what are typically very early stage inventions.

Question #3: There is still room for improvement of Bayh-Dole, despite its apparent success. What top three reforms would you suggest?

Actually, from our perspective, it is not clear that there is much room for improvement in the legislation itself. The flexibility that was built into Bayh-Dole already permits funding recipients to adapt their practices to meet changing needs and address emerging issues. One example is in the area of research tools where new practices have emerged that preserve the ability for non-profit research institutions to practice one another's inventions for research and educational purposes, even outside of a federal funding context (see also Question #4, below). In general, I would caution against any changes that make the legislation more proscriptive, reducing its flexibility and limiting the ability of funding recipients to meet future challenges of which we are yet unaware.

Question #4: Currently, Bayh-Dole provides an effective research exemption for federal government entities to practice the invention in the form of non-exclusive licenses to the government; however, these licenses do not extend to universities or non-profit research institutions. This can give rise to the perverse situation where a university invention, if licensed exclusively, may be unavailable for use in fundamental, non-commercial research by the very laboratory where it was made. This creates an atmosphere of uncertainty and confusion that negatively impacts public research. What, if any, are the downsides to amending the Act to create a research exemption to use publicly-funded research results for noncommercial research in academic and nonprofit research environments.

In its exclusive license agreements, the University of California routinely reserves not only the right for the University to continue to practice its own inventions for research and education use, but for other non-profit research institutions to do so as well. In fact, this is a growing practice within the academic community and was specifically discussed in the "Nine Points to Consider" white paper reference above.

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The Bayh-Dole Act has been amended once already to make it clear that the purposes of the Act were intended to be accomplished "without unduly encumbering future research and discovery." (35 U.S.C. 200). A further amendment to create an explicit research exemption for the use of publicly-funded inventions in the noncommercial research of academic and nonprofit research institutions is not necessary given the trend of current practice, but neither is it likely to have significantly negative repercussions.

Question #5: Perhaps one unintended consequence of Bayh-Dole was to establish incentives for universities to develop independent technology transfer programs and to manage IP in a highly individualized and even competitive manner with respect to other universities. The resulting fragmentation of IP rights has, in some cases slowed down or prevented the pursuit of projects that have limited profitability but high social or humanitarian value. The development of effective treatments for neglected diseases is an example that come to mind. Can you see any framework that would allow and embrace the development of collaborative IP management strategies across multiple publicly-funded research institutions?

The establishment of independent technology transfer offices at universities has been enormously helpful to foster university-industry relations and provides a business development perspective that supports the research enterprise. Technology transfer offices provide a common interface for industry to discuss intellectual property desires and issues in sponsored research, material transfer, collaboration, and licensing arrangements. Having technology transfer offices in place at many universities throughout the nation, in part fostered by the enactment of the Bayh-Dole Act, has been tremendously successful in helping to ensure that early stage inventions and technologies developed at universities have a chance to reach the marketplace for the benefit of the public.

While concern has been expressed that the technology transfer that was stimulated by Bayh-Dole would result in patents being held that would get in the way of research, there has been no evidence that this has actually occurred. In fact, recent studies have concluded that patenting does not seem to have limited research activity in any significant way (Walsh, et. al.).

The overarching question of how to encourage publicly-funded research institutions to manage inventions in a collaborative manner is a difficult one and should be treated on a flexible basis as there do not seem to be any one size fits all solutions that would be appropriate in terms of mandating intellectual property management. In addition, the ability of the federal government to influence any particular approach is realistically limited to inventions arising from federally-funded research. But in many cases, federal funds are only part of a laboratory's overall funding, so any federally-mandated controls related to intellectual property management could result in a different kind of fragmentation, making it difficult for a given laboratory to manage its (probably closely related) inventions in a cohesive manner. Such mandates could also lead to problems in administering and managing intellectual property which could have the unintended consequence of making it more difficult to engage in technology transfer efforts.

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An approach used recently by some funding agencies is to require development of intellectual property management plans at the proposal stage in certain circumstances where the research is intended to span multiple institutions and to achieve a particular goal. If nothing else, this forces collaborators to address the issue before the research even begins.

There are pros and cons to other frameworks that have been considered. One example is patent "pooling," or the gathering of patents arising from a common base (perhaps from a given project) for management by one entity. While this could be accomplished through licensing, it could still have the effect of fragmenting the invention portfolio out of each of the respective laboratories, which may prove detrimental. Further, since the nature of future inventions cannot be predicted, this approach could sweep in unanticipated inventions that are only peripherally related to the "pool" and might best be managed in a more productive way. We do not recommend mandated patent pooling models or particular intellectual property management models and believe that any such approach should be voluntary and implemented carefully on a program by program basis, taking into account the nature of the research, the likely resulting inventions, and the existing portfolios of the different laboratories. In cases where the public benefit is clearly supported by pooling, universities have shown themselves more than willing to participate, and have even led the way in the creation of such pools. An example is the UC Davis-based Public Intellectual Property Resource for Agriculture, mentioned in Question #1 above. However, the approach that may work well in one area may not work well in another area, so the current system that contains the needed flexibility to approach intellectual property management given the particular circumstances has worked well to foster innovation and the transfer of technology for the public benefit.

To address the issue of inventions as a potential barrier to future research, NIH has created a Policy, "Principles and Guidelines for Sharing of Biomedical Resources," that is now a condition of most NIH awards and seems to have had a positive effect on the sharing of research tools. Under this Policy, NIH expects its grantees to make NIH-funded inventions available to other researchers, especially NIH-funded researchers, with minimal barriers. These principles could be implemented by other agencies as well.

In terms of farther reaching fixes, Congress could consider implementation of a broad research exemption for use of federally-funded inventions in federally-funded research. This could perhaps be taken even further to provide such an exemption for all research conducted by non-profit research and academic institutions. Such a research exemption would need to be carefully constructed to ensure that it does not create unintended negative consequences on innovation. The University of California would be glad to work with the Committee on developing appropriate language to address this issue.

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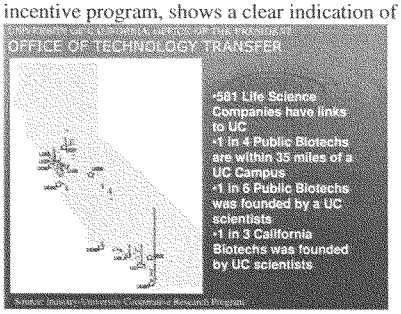
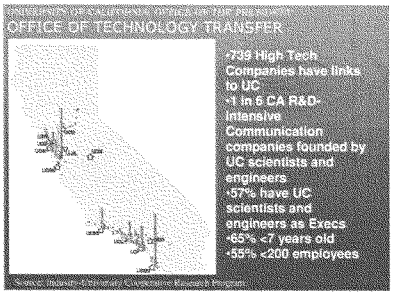
WRITTEN QUESTIONS OF SENATOR GRASSLEY FOR JUDICIARY COMMITTEE HEARING, "THE ROLE OF FEDERALLY-FUNDED UNIVERSITY RESEARCH IN THE PATENT SYSTEM", OCTOBER 24, 2007

Questions for Dr. Louis

1) What kind of impact has the Bayh-Dole Act had on job creation and the economy of your state?

For federal awards to non-profit institutions, the Bayh-Dole Act includes a "preference for small business" requirement for licensing under 35 U.S.C. 202(c)(7)(D). Small businesses are recognized as being a critical part of the U.S. economy, representing over 99% of all employer firms, employing about half of all private sector employees, and generating 60-80% of net new jobs annually over the past decade (source: U.S. Small Business Administration). Bayh-Dole's preference for small business then, is encouraging and nourishing this vital sector, providing jobs and contributing directly to the economy of the state. The University of California (UC) Industry-University Cooperative Research Program (IUCRP) found that a significant percentage of California high tech and biotechnology companies are located close to and often maintain ties with the UC campuses. Survey information from the University-managed business research-incentive program, shows a clear indication of success.





Looking back over the last couple of decades at the 333 start up companies identified in UC's database, 84.7% were founded in California. Of the 282 companies started in California, 86.2% continued to be viable (i.e. still active as of October 2007), and 95.9% of them remained in California. The establishment of start up companies in California continues to contribute to the state's economy for a sustained period of time. Looking at start up companies over a longer period, emanating from UC across fiscal years 1986-2006, generally more than 80% of them remained active, contributing to both the economy of the State of California and the nation at large. Given that start ups across the board have an average survival rate of only 50% or so after five years, this would seem to indicate that university-based start ups have better than average staying power.

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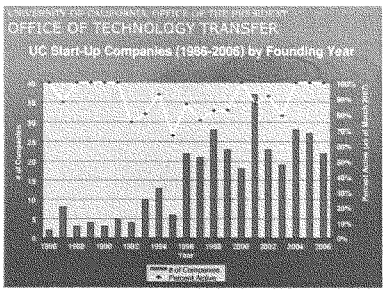

Beyond the technology transfer process stimulated by the Bayh-Dole Act, federal funding in general has contributed enormously to the body of knowledge developed in the universities. Publication of new discoveries and education and training of students, both undergraduate and graduate, who are ready for industry jobs, often locally, boost the knowledge base in the industrial sector and spawn both formal and informal research collaborations. While difficult to measure, this knowledge transfer contributes significantly to highly relevant technical knowledge of regional employees, provides jobs, and thus stimulates the economy of the state.

It is worth pointing out that the Bayh-Dole Act also governs federal funding awards to small businesses themselves. Allowing small businesses to own their federally-funded inventions and incorporate them into their business property adds an additional facilitator for commercialization of a product. In fact, without this certainty of being able to own their own inventions, it is unlikely that many small businesses would use federal funds to support their research efforts.

2) How do you think that we can improve the tracking of the federal contribution to a patented invention, given the nature of federal research and development funding and the way that universities perform research and development in their institutions?

The federal contribution to a patented invention is acknowledged in both the grant reporting process and in the patent itself, through various reporting requirements from the grantee to the awarding federal agency. The Principal Investigator reports through a Final Invention Statement and Certification Form, such as Form HHS 568, and the university technology transfer office also discloses the inventions to the Federal agency under the requirements of the Bayh-Dole Act.

The Federal granting agencies and the universities are moving rapidly to install electronic research administration databases which would allow them to identify more precise and timely information about funding that is related to inventions. In particular, the iEdison system created by the NIH has worked very well and we would encourage the broad use of this system across all federal agencies.

3) What are your thoughts on what has been said about march-in-rights by some of the other witnesses?

While most witnesses were reluctant to call for any major changes to application of the law in this area, one did argue that the government should use march-in rights to ensure affordability of drugs created in part through federally-funded research. Besides the fact that intellectual property law and policy seems like a decidedly inappropriate means to address drug pricing, it is clear that such a goal was *not* the intent of the legislation. The authors of the Bayh-Dole Act, Senators Bayh and Dole, exhibited extraordinary vision in crafting this legislative document that has contributed significantly to the national and state economies and has propelled our nation into the forefront of innovation. But in a May 25, 2004 Statement to the NIH in response to recent march-in petitions, Senator Bayh emphasized that the intent of the Bayh-Dole Act was to "insure that every effort is made to bring a product to market. If there is evidence that this is not being done, the federal agency can "march in" and require that other companies be licensed. If the developer cannot satisfy health and safety requirements of the American taxpayer, agencies may march-in." In a commentary published in the Washington Post (April 2002, Senators Bayh and Dole stated that "Bayh-Dole did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. This omission was intentional; the primary purpose of the act was to entice the private sector to seek public-private research collaboration rather than focusing on its own proprietary research."

Bayh-Dole encourages academic innovation to be coupled with small business entrepreneurship to bring products to market. While small businesses are flexible and can initiate new projects quickly they have limited capital from which to build their businesses and transform their start ups into a thriving enterprise. Building a business is risky and there is no guarantee of even recouping the initial investment capital. Any weakening of the strength of a patent, such as increasing the opportunities for "march-in" would have a chilling effect on the willingness of industry to invest in the very early stage technologies that characterize most university inventions.

This chilling effect is not entirely hypothetical. Indeed, in 1989, when NIH placed a pricing clause in its Cooperative Research and Development Agreements (CRADAs), industry participation in CRADAs began to evaporate. After some investigation, NIH ultimately decided to remove the clause in the mid-1990's and found that industry collaborations increased significantly thereafter.

Industry partners are critical to the commercialization of a university invention. While universities serve as an innovation engine producing new discoveries that can lead to the next generation of products, universities are primarily academic research and educational institutions. Universities must entrust our industry partners to develop, manufacture and distribute commercial products as they have the expertise to accomplish those tasks. Our industry partners, often pharmaceutical or biotech companies in the life sciences area, need to invest significant effort and resources to ensure that a technology is safe and effective by taking the product through clinical trial studies. Without that investment by a pharmaceutical or biotech company, the taxpayer will never benefit from an end product or have access to a treatment that is effective

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and safe for a patient. If a cure for a disease never becomes available at all, then the price is irrelevant.

While we appreciate the dilemma of accessibility and affordability of essential medicines, we fear that the restrictive practice of adding pricing controls to the march-in rights provision could unravel all the positive impact that the Bayh-Dole Act has had on the explosion of innovation in the United States and on the economy of our nation and states, and is probably not the best means of addressing the problem.

4) How does the taxpayer benefit from these partnerships if industry and non-profits/universities keep the royalty revenues from the inventions funded by the federal government?

The taxpayer benefits from federally-funded research in many ways. The most important benefit is the generation and sharing of new knowledge from which further discoveries are made. Research results are published in peer-reviewed journal articles, scientific lay magazines, and the common press, which makes the research results widely available to the public. Those research results are validated and advanced by other researchers. Another important benefit of the open accessibility of government supported research results is that industrial partners seek to sponsor and collaborate in research at universities which complements the federal awards. This leverage of taxpayer dollars helps to accelerate the scientific research for the benefit of mankind ensuring that the innovative research that is produced in universities is translated by industry partners into technologies and products that benefit society.

In those cases where research results can be translated into an actual product, the availability of the product on the market is a significant benefit to the taxpayer. Without the substantive investment of time, effort and resources by the industrial partner, it is unlikely that the public would see a useable and safe product at all.

In exchange for licensing federally-funded patentable inventions to a commercial partner, universities typically require some financial consideration (e.g. royalties) for their intellectual contribution to the technology. Under the Bayh-Dole Act, royalty revenues retained by the university can contribute to the cost of managing the technology transfer program (which in many cases wouldn't exist otherwise) and the remainder *must* be reinvested in research and education at the institution, both of which benefit the taxpayer. It is also important to understand that universities focus less on the financial returns than on the diligence requirements (which may include some consideration at certain milestones as an inducement to continue diligent development of the technology) of a license. These diligence requirements help to ensure that the technology is ultimately developed into an actual product, which is a tangible benefit to the taxpayer. The royalty revenues from licensing activity are actually very small compared to an institution's overall budget (just over half of one per cent at UC) and in most cases do not even cover the expenses of the technology transfer operation, including university investment in patents that are ultimately unsuccessful.

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The taxpayer also benefits from the kinds of economic benefits and the creation of jobs discussed in response to Question #1, above.

5) Some contend that the Bayh-Dole Act has made collaboration with U.S. universities more difficult because they claim that it's harder to finalize intellectual property contracts with them. Do you agree with this assessment? Is it your opinion that U.S. companies are increasingly turning to foreign universities for research collaboration because it is easier to deal with them? How do the intellectual property and business practices at U.S. universities compare to universities in other developed and developing countries?

We disagree with the assessment that the Bayh-Dole Act has made university-industry collaborations more difficult. In fact, the Bayh-Dole Act has encouraged and enabled many more university-industry partnerships since its passage. Furthermore, the Bayh-Dole Act was designed to be flexible enough to accommodate and facilitate an extremely broad range of relationships with industry.

The Bayh-Dole Act applies only to funding awarded by federal agencies. It does not govern industry sponsored agreements. With greater access to invention property rights, universities and their staff have become more experienced and sophisticated in their negotiations with industry. Universities now have acquired experienced staff with technical and business understandings, who comprehend the complexities of intellectual property management. Often industry comes to the university with proposals for research which they previously would have done in-house. However, often they have closed or consolidated their research departments and it is more cost-effective to seek the specialized technical understanding and facilities in a contract to an academic institution. The issue with some companies is that they are expecting universities to automatically give up the interests of their faculty in such contracted work, as industry would expect from a commercial contract lab. This is a position that universities resist vigorously, as it often conflicts with their fundamental academic principles, including their ability for uncensored publication and to conduct follow-on research.

While industry may have identified the problem that needs to be researched and solved, the university does not act as merely a contract research laboratory for industry. The scope of an industry-sponsored project usually is conducted within the context of an investigator's much larger, existing research program that is funded by a variety of sponsors. The university and its researchers must enter into the university-industry relationship with a clear understanding of the rights and obligations of each of the various sponsors of that research laboratory. The Bayh-Dole requirements do not apply to industrial collaborations except in the case where the project includes federal government funds, such as government-university-industry research centers.

The issues that most often arise in negotiating terms of industrial research collaborations are ownership of university-developed inventions, unfettered access to university research results, financial consideration, and diligent development requirements. It is extremely important that universities retain ownership of inventions they make for many reasons. At a public institution like UC, for example, inventions and patents are public assets that UC must manage prudently and for the public benefit. UC policies and practices require retention of invention ownership for

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the integrity of the research program and invention portfolio, to meet sponsor obligations and to ensure that the invention is utilized for the public benefit. Since UC has invested significant resources in establishing the infrastructure of the research laboratory that gives rise to an invention, it is appropriate for the University to receive some form of consideration in exchange for commercial rights to utilize the public asset. The type and amount of consideration may differ significantly depending upon the nature of the company, the field of use, the contributions of the commercial partner, the business model and approach toward commercialization, among other factors.

In licensing arrangements with industry, the terms of the Bayh-Dole Act still provide negotiating flexibility for universities in order to encourage workable industrial partnerships. The Bayh-Dole Act was well-crafted and anticipated the need to address the varying business models of large high-tech companies, small businesses, and biotech and pharmaceutical companies. In a licensing arrangement, the university develops terms in coordination with the industrial partner, balancing some financial consideration for participating in the patenting and licensing process with strong diligence requirements to ensure that the technology will be developed into a commercial product. Because each one of these licenses are negotiated case-by-case based on a variety of factors, such as the stage of development of the technology, the resources that must be invested into developing and commercializing the product, the other components necessary to be acquired in order to manufacture the product, the field of technology, the size of the anticipated market, among others, the negotiations are complex and time-consuming. UC has generally not encountered difficulty related to Bayh-Dole requirements in its negotiation of licensing terms for inventions arising from federal-funding.

On the specific allegation that industry is turning to foreign universities, outside of anecdotes from a very few companies, we are not aware of any concrete evidence that U.S. companies are increasingly working with foreign universities, but note that business models are adjusting to the economies and access of a more global economy and knowledge-based environment. Just as U.S. companies are off-shoring manufacturing facilities, it is not unlikely that they would also collaborate with foreign universities. From a technical perspective the competitive environment and timeliness of product introduction would make it prudent that companies seek research collaborations wherever they can locate the necessary expertise, whether within or outside the United States.

In fact, industry sponsorship of UC research has continued to climb. Interestingly, the number of research agreements into which UC has entered with foreign sponsors has also climbed, more than doubling since 2000, indicating that foreign entities do not see Bayh-Dole as a disincentive for establishing collaborations.

It is also worth noting that the Bayh-Dole Act has been such an enormous success for the U.S. economy that many foreign countries are seeking to introduce similar laws. As universities in other countries become more sophisticated in their industrial relationships, they will also learn the importance to maintaining ownership of inventions that they make and imposing diligence requirements to ensure appropriate development of technologies.

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6) What kind of interest and engagement have you had from students in technology transfer activity? What programs does the University of California, Riverside have to encourage technology entrepreneurship among young people? What percentage of retained patent revenues goes into student stipends and other forms of financial support?

UC Riverside maintains a keen interest in encouraging and fostering technology entrepreneurship. At the Richard J. Heckmann International Center for Entrepreneurial Management at its Palm Desert campus, UC Riverside has established a business management program that specifically addresses training in entrepreneurship. This new program is offering an MBA degree with a focus on entrepreneurial management. The Heckmann Center serves as a catalyst for economic diversification of the Coachella Valley region by forging close ties to the community, providing relevant research, offering innovative graduate and executive programs that attract and retain world class talent to the region, and extending the resources of the university through research, education, and public service.

Last year, the UC Riverside Bourns College of Engineering coordinated a course (led by Lecturer Christine Pence) with the Gary Anderson Graduate School of Management that placed business and technology undergraduate students in teams to meet with companies to learn about best practices for encouraging and managing innovation and for preparing engineers to be innovators. The students explored implementation of inventiveness in several local businesses. This activity was one aspect of a current project sponsored by the U.S. Department of Labor, WIRED (Workforce Innovation for Regional Economic Development). Also part of this project, known as the *California Innovation Corridor*, UC Riverside brings together graduate students from the engineering and business schools to increase their exposure and understanding of the concepts of their two cultures. Spreading the understanding beyond the boundaries of the individual graduate schools will enable the students to function more efficiently as an entrepreneurial team in the business environment. The *California Innovation Corridor* represents one mechanism for importing entrepreneurship concepts into the general undergraduate engineering curriculum at UC Riverside. At the completion of this project in 2009, we expect to have achieved greater integration of business concepts into the engineering curriculum and design experiences at both the graduate and undergraduate levels.

UC's Patent Policy outlines the distribution of licensing revenues. As required under the Bayh-Dole Act, net revenues (after inventor share and recovery of patent and licensing expenses) are returned to research and educational activities on the campus that would support students at various levels. Specifically, UC Policy requires that a portion of net revenues is devoted to research-related purposes on the inventor's campus, with any remainder being used to support research and education across the University of California system. In the past several years, due to expiration and retirement of several income-producing patents, the Riverside campus patent income has not kept pace with the related expenses, which is not uncommon among university technology transfer offices. As newer licensed patents hopefully generate income in excess of expenses, any net revenues will be used to support campus research and educational activities.

7) I'm told that it's very expensive to develop intellectual property generally, and to secure patents, specifically. I'm not sure I fully understand – and expect many do not realize – that

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non-profit organizations such as universities need to do a great deal of diligence before deciding it is worth the cost of investing in patent development. I understand patent prosecution can be an expensive proposition too. Where does a university get funds to support these labor, expertise and cost intensive activities?

When an invention is disclosed to a university technology transfer office, it must make a fairly quick assessment of the commercial potential. Evaluation of a disclosed invention involves determining the feasibility of bringing a product to market, the best way to disseminate or license in order to maximize utilization of the invention, the need for and likelihood of patent protection, the sufficiency of existing data to support a patent application, the likely fields of use for the technology, and knowledge of the direction of an inventor's research program, among other factors. Critical to approaching appropriate industrial partners is the expertise of a university business development manager who is familiar with the existing portfolio that may surround the disclosed invention, knowledge of industry commercial needs and growth potential, appropriate diligent requirements associated with the stage of development of the invention, and the ability to secure patent protection. These skills and expertise are not usually inherent in faculty researchers.

Development of federally-funded inventions into an actual product can be a costly endeavor during the patenting and development process. While it is crucial to establish clear title in the invention, which Bayh-Dole does, it is also important to many industries that the technology has strong patent protection. This protection provides security for the company to receive a return on its substantive investment toward the development of the invention. The preparation, filing, and prosecution of a U.S. patent application requires the investment of many thousands of dollars ($15,000-25,000) for a fully drawn filing with appropriate attorney-drafted patent application. The costs for foreign filing and prosecution are in addition to this and can easily reach the range of $250,000 per invention for worldwide patent protection.

Typically, universities and non-profits try to identify a prospective licensee who would be interested enough in a technology to cover the patent costs while it is examining its interest in commercialization. In many cases, the technology is at such a premature stage of development that additional research and data may be necessary to interest a commercial partner, support a patent application, or to demonstrate a stronger feasibility for commercial potential. When an experienced licensing office sees tremendous potential in a technology that is so early stage, it may choose to file a patent application "at risk" with the expectation that they can, with this protected property position, increase the incentives to develop the commitment of a prospective licensee. Clearly, given the costs of securing patent protection, and the fact that licensing offices are often under-resourced already, the decision to file "at risk" is not one that is made lightly.

When the technology is so early stage that commercial interest is not evident, additional research funding may be secured to fund the gap between discovery and commercial feasibility to bring the invention to the point of being of viable commercial interest. Retention of university technology management individuals with the appropriate kind of experience and specialized expertise is often based on the inherent technical interest in the inventive products that arise in an academic setting. Such specialists stay in the non-profits university setting, even while the financial incentives to move into much more highly compensated business community is strong.

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Funding of the technology transfer programs of the university, including patents that are filed "at risk," is derived from campus general funds and licensing revenues, if any, net of inventor share and patenting expenses. The reason universities see value in this use of their funds is that university technology transfer offices provide broad services in support of university researchers that extend beyond just patenting inventions disclosed to the office. These include the University's capability to retain entrepreneurial faculty and attract outstanding graduate students; its reputation for innovation; the enhancement of university research through interaction with the private sector; and its reputation for providing highly trained students for the industrial workforce. The benefits of technology transfer extend throughout and beyond the university community, helping university research, the researchers, industry, local and national economies, and society. Technology transfer benefits these areas by:

- Stimulating the economy
- Increasing competitiveness within the private sector
- Gaining visibility within the technical community
- Attraction and retention of talented faculty
- Promoting innovation and creativity with university technology
- Attraction of corporate research support
- Allowing the use of the university's vast technical resources

The benefits to those that participate in technology transfer activities include:

- Meeting expectations of research sponsors
- Validation of innovative applications
- Increased visibility of innovators' laboratory
- Creation of professional networking opportunities
- Benefit to the public through new products and economic development
- Generation of royalty revenue for supporting further research

8) How do royalty revenues from federally funded research at your institutions attract and retain world class faculty? How does that revenue help that same faculty compete more successfully for other research support?

Similar to other universities across the nation, the University of California maintains an established patent policy with a royalty distribution formula. As required under the Bayh-Dole Act, the UC Patent Policy provides an inventor share to reward inventors for participating in the patenting and technology transfer process which can be time-consuming. However, the royalty distribution formula is sufficiently similar among U.S. academic institutions that it is likely not a deciding factor for a prospective faculty member. A more important consideration is that faculty understand that the University of California has a successful track record and maintains experienced staff and systems to properly manage their federally-funded inventions, industrial relationships, and research collaborations.

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A faculty member wants to be able to rely on the fact that there is an experienced and professional team that will capably make the various business decisions necessary to manage the patent property. Faculty may want to be involved in consulting for companies interested in their technology, or they may exercise their entrepreneurial spirit by starting up a company based on that technology. Most faculty inventors, though, choose to have minimal involvement and focus instead on their research program and teaching activities at the University.

UC Riverside is undergoing a rapid expansion of our enlarged research mission which includes the hiring of well-established and experienced senior faculty and the establishment of a medical school. Many of these individuals are in the advanced stage of their career, where they have acquired technical understanding and credibility in their field to have had the opportunity and time to pursue commercial applications and development of their projects. In these senior faculty recruitments, the researcher always asks for time to interview with the campus technology development officials during their campus visit to ensure that they can continue their desire to ensure commercialization of their research results. Many of these faculty bring strong consulting experience and industry contacts which can be cultured into further support of their research. They also have a clear understanding of the challenges in an industrial environment, can direct the appropriate training of students, and can open up employment connections in the most advanced and growing technological areas. Assurance of a knowledgeable and experienced technology transfer staff and stable support systems within the University contributes to attracting and retaining faculty members.

In short, the royalty revenues themselves do not generally attract faculty to the institution, but the strength and experience of the technology transfer program and staff may very well be a factor.

The question is also asked whether licensing revenues help faculty compete more successfully for other research support. The short answer is no – licensing revenues generally play no role whatsoever in a faculty member's ability to compete for research funds. Their innovation, the soundness of their science, and the resources (equipment, personnel, etc.) available to them are much more important in research funding decisions.

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Arti K. Rai, Professor, Duke Law School

Hearing Before the Senate Judiciary Committee
"The Role of Federally-Funded University Research in the Patent System: A Review of Bayh-Dole and Royalty Returns"

October 24, 2007

Responses to Senator Questions

Questions from Senator Patrick Leahy

1) Under the Bayh-Dole Act, the Government appears to act as an investor in inventions. Dr. Hoffman argues that the Government's attempt to share in the profits of commercially successful inventions reduces the incentives for innovation. Can you please comment on whether the current recoupment provision affects the incentive to innovate?

The current recoupment provision could have some negative effect on the incentives GOCOs have to develop inventions. Essentially, the provision functions as a tax on development-related activities. However, because recoupment obligations only kick in when royalties exceed 5% of the GOCO's annual budget, it is highly unlikely that the recoupment provision plays a significant role for most GOCOs. The Iowa State/Ames situation appears to be an unusual one.

2)Mr. Weissman indicated that Congress needs to look carefully at whether to permit exclusive licensing under Bayh-Dole when the Government invests in research concerning new energy technologies. In your view, what are some of the issues Congress should consider or be aware of regarding federal funding in this field?

Like all basic research, basic research in energy is likely to produce "platform" inventions that are useful to a variety of different follow-on innovators. Non-exclusive licensing of such platform inventions would allow follow-on innovators to produce a variety of different, competing applications of the platform technology. By contrast, if a platform were licensed exclusively to one company, the company might have a financial incentive to use the platform technology only for applications that did not compete with markets on which the firm wished to focus.

This concern is a particularly salient one in light of the sponsored research agreement to generate energy alternatives recently negotiated between British Petroleum (BP) and the University of California. Under the terms of this $500 million agreement, BP appears to have the right to negotiate an exclusive license with respect to any technology developed by UC researchers. Although this agreement does not of course involve federal funding, it does highlight the troubling possibility that universities could license platforms for creating clean energy to a

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single firm that might not be inclined to explore all possibilities associated with the platform.

3) Under what circumstances do you view it as appropriate for the Government to exercise the rights it retains with respect to inventions made with federal funds?

The use of march-in rights is appropriate where the patented invention is question is a "platform" technology, but it has nonetheless been licensed exclusively. For example, in the case of embryonic stem cell technology, the University of Wisconsin had initially licensed most of the rights under its patent on embryonic stem cells exclusively to a single small biotechnology company, Geron. When proprietary rights over stem cells (both patent rights and tangible property rights over the physical cell lines) became the subject of intense discussion after President George W. Bush's decision to restrict federal funding to research on those stem cell lines that existed before August 2001, the threat of march-in influenced Wisconsin's decision to scale back the scope of the exclusive license given to Geron. *See generally* Rebecca S. Eisenberg and Arti K. Rai, *Proprietary Considerati*ons in 2 HANDBOOK OF STEM CELLS: EMBRYONIC STEM CELLS 793-798 (Robert P. Lanza, ed., Elsevier Academic 2004).

Questions from Senator Orrin Hatch

1)Professor Rai, thank you for your comments. I was particularly interested in what you said about software patents and software-related research. One of your interesting observations is that the Bayh-Dole Act should not be applied as a "one-size-fits-all" proposition for inventions. You draw a distinction between patentable discoveries that need further development to be useful or commercial versus research discoveries that can be put to use immediately.

What changes would you make to bring research discoveries that can be put to use immediately more in line with the intent of the Bayh-Dole Act?

The Bayh-Dole Act currently requires that federal agencies prove "exceptional circumstances" before they can declare that patents and exclusive licenses are the wrong approach towards commercialization in a particular area of federally funded research. It's worth looking into whether such a high bar is necessary, particularly because it appears agencies sometimes ignore this requirement in any event. *See* Arti K. Rai and Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMPORARY PROBLEMS 289 (2003). For example, if the adjective "exceptional" were deleted, agencies that sponsored research that was immediately useable could, without fear of violating Bayh-Dole, state that such research represented a "circumstance" where the best commercialization option was either no patents or, at a minimum, non-exclusive licensing.

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2) How significant has Bayh-Dole been to the elevation of the U.S. economy and to economies and living standards of third world nations?

Because so many different factors contributed to the revitalization of the U.S. economy after 1980, the specific effect of Bayh-Dole is extremely difficult to isolate. Indeed, I am not aware of any economic study that successfully isolates its effect. The most comprehensive collection of empirical data on Bayh-Dole suggests that it probably accelerated the commercialization of university research to some extent but that much of this commercialization would have happened anyway. *See generally* DAVID C. MOWERY, RICHARD R. NELSON, BHAVEN N. SAMPAT, AND ARVIDS A. ZIEDONIS, IVORY TOWER AND INDUSTRIAL INNOVATION: UNIVERSITY-INDUSTRY TECHNOLOGY BEFORE AND AFTER THE BAYH-DOLE ACT IN THE UNITED STATES (2004).

3) Are there shortcomings of Bayh-Dole that have become apparent with time?

The shortcomings of Bayh-Dole relate to its "one size fits all" approach and to its relatively minimal (and minimally enforced) reporting requirements.

4) There is still room for improvement of Bayh-Dole, despite its apparent success. What top three reforms would you suggest?

1) As noted earlier, lowering the bar (currently set at "exceptional circumstances") that an agency must clear before declaring that particular research should either be free from patents or that patents in the area should be nonexclusively licensed.

Relatedly, where the research in question involves many different universities, agencies should have discretion to direct universities to set up comprehensive IP management plans. *See* Arti K. Rai, *Open and Collaborative Research: A New Model for Biomedicine*, in ROBERT W. HAHN, ED., INTELLECTUAL PROPERTY RIGHTS IN FRONTIER INDUSTRIES 131, 149 (2005) (discussing problems universities encounter in managing IP in multi-university collaborations).

2) Allowing march-in rights to become operational before all appeals procedures have been exhausted.

3) Strictly enforced reporting requirements – in particular, universities should be required to report the inventions on which they gave licenses, what types of licenses those were (e.g. exclusive, non-exclusive, exclusive by particular field of use), and what development requirements are in the license, and what progress the licensee is making towards development.

5) Currently, Bayh-Dole provides an effective research exemption for federal government entities to practice the invention in the form of non-exclusive licenses to the government; however, these licenses do not extend to universities or non-profit research institutions. This can give rise to the perverse situation where a university invention, if licensed

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exclusively, may be unavailable for use in fundamental, non-commercial research by the very laboratory where it was made. This creates an atmosphere of uncertainty and confusion that negatively impacts public research. What, if any, are the downsides to amending the Act to create a research exemption to use publicly-funded research for noncommercial research in academic and nonprofit research environments.

I do not foresee much, if anything, in the way of downsides. Indeed, such an amendment would be a good idea. The reason it would be fourth on my list of reforms (after the three noted above) is that at least some universities are already reserving noncommercial research rights for all nonprofits when they license technology. For example, Stanford University has declared that it explicitly reserves such rights. Universities should be encouraged to reserve not only noncommercial research rights but also rights to do research on humanitarian uses of the technology (e.g. for low-income countries).

6)Perhaps one unintended consequence of Bayh-Dole was to establish incentives for universities to develop independent technology transfer programs and to manage IP in a highly individualized and even competitive manner with respect to other universities. The resulting fragmentation of IP rights has in some cases slowed down or prevented the pursuit of projects that have limited profitability but high social or humanitarian value. The development of effective treatments for neglected diseases is an example that comes to mind. Can you see any framework that would allow and embrace the development of collaborative IP management strategies across multiple publicly-funded research institutions?

In theory, it would appear that some type of multi-institutional "patent clearinghouse" organization could be developed. For example, in the context of fragmented IP rights over research inputs that feed into agricultural products for low-income countries, universities have established the Public-Sector Intellectual Property Resource for Agriculture ("PIPRA") (www.pipra.org) PIPRA has a searchable database of agricultural technology that universities are willing to make available. However, to the extent that IPR ownership over medical research inputs is even more dispersed than IPR ownership over agricultural inputs (ownership of agricultural inputs is largely confined to land grant universities), this approach may be more difficult to implement in the context of medical research.

Questions from Senator Charles Grassley

1)Do you know of any documented situations, or do you have any examples where you believe that a university has not acted to commercialize a patent with value that should have triggered march-in rights? If so, why do you think that this was not pursued?

The Cellpro case (involving antibody-based stem cell separation technology patented by Johns Hopkins) is a famous case in which march-in rights were not pursued, even in the face of a documented commercialization delay, and a lawsuit brought by Johns Hopkins against a competitor that had commercialized earlier

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than the Hopkins licensee. One reason march-in rights may not have been pursued is because they are so untimely – as noted earlier, they do not become effective until all appeals are exhausted.

2) Why are some universities better than others in negotiating partnerships with industry? What do you think are the characteristics for successful institutions?

Successful universities recognize that partnerships with industry need to be sensitive to the type of technology being commercialized. Life sciences technology typically follows a different commercialization path than information technology; even within life sciences, upstream research platforms are quite different from more downstream products. Successful universities also tend to focus more on industry-sponsored research than licensing revenue as a long-term source of research money. Indeed, several of these successful universities are now beginning to merge their sponsored research offices with their technology transfer offices.

3) Since a patent is not necessarily indicative of the value of an invention, what would you consider to be the type of circumstance, not included in current law, that would preclude federal agencies from providing a contractor with title to an invention?

4) How do you think that we can improve the tracking of the federal contribution to a patented invention, given the nature of federal research and development funding and the way that universities perform research and development in their institutions?

Under current law, patent applications on inventions that were supported at least in part through federal funding are supposed to include a disclosure of the federal support. This requirement seems appropriate and not unduly onerous. However, it appears that many applications are currently missing such a disclosure. If failure to disclose were considered a type of inequitable conduct under the patent statute, we would almost certainly observe greater compliance with the disclosure requirement.

5) Some contend that the Bayh-Dole Act has made collaboration with U.S. universities more difficult because they claim that it's harder to finalize intellectual property contracts with them. Do you agree with this assessment? Is it your opinion that U.S. companies are increasingly turning to foreign universities for research collaboration because it is easier to deal with them. How do the intellectual property and business practices at U.S. universities compare to universities in other developed and developing countries?

There appears to be some evidence of this phenomenon. The best non-anecdotal evidence of which I am aware is Jerry and Thursby and Marie Thursby, *Where is the New Science in Corporate R&D?* 314 *Science* 1547-1548 (2006). This study does indicate some movement of U.S. companies overseas.

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Replies to written questions, following the October 24, 2007 Senate Judiciary Committee Hearing, "The Role of Federally Funded University Research in the Patent System: A Review of Bayh-Dole and Royalty Returns"

Robert Weissman[1]

ANSWERS TO QUESTIONS FROM SENATOR GRASSLEY

1. How can you determine what the cost of the federal contribution is for a particular drug when basic research, development and testing not necessarily related to government funding is also involved? How does one account for the time and government money put into research, development and testing of drugs that do not make it to the market?

There is not much difficulty in assessing the amount of the federal contribution to a drug's research, development and testing. The amount of federal grants is known, and the allocation among various projects is already accounted for.

Determining the relative contribution of federal and private funding for a drug's R&D -- often an important assessment for drawing conclusions about whether a product is priced reasonably, or whether march-in authority should be exercised, among other matters -- requires knowing not just the federal contribution, but the private contribution. Only the private contributors know what they have spent. If it chose, the government could leverage its investment in drugs to obtain this information, conditioning federal contributions on relevant disclosures. Or, it could establish a policy of making certain presumptions about private expenditure in cases where private funders refused to make disclosures.

In the case of agricultural chemicals, companies disputing how costs for regulatory testing will be shared make these kinds of disclosures. Under FIFRA (Section 3(c)(2)(B), 7 U.S.C. 136a(c) (2) (B), of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. §§136-136y), pesticides and other agrichemicals receive a 10-year period of marketing exclusivity. For the 10-year period afterwards, generic competitors may enter the market, but must pay a share of the costs of regulatory testing conducted by the originator company. When a generic firm enters the market, the parties first seek to reach voluntary agreement over levels of compensation to be paid by the generic entrant. Disputes over the amount of compensation are handled by arbitrators. Under the body of arbitration rulings that has developed, the debate over compensation presumes carefully documented disclosure of originators' specific costs. Arbitrators generally look skeptically on cost estimates submitted by originators, as opposed to genuinely documented costs. Arbitrators typically will reduce estimates, or substitute their own estimation of reasonable costs if no documentation exists.

[1] Director, Essential Action, P.O. Box 19405, Washington, DC 20036, <www.essentialaction.org/access>.

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The point of relating the agricultural chemical story is to illustrate the feasibility of a system for allocating costs. In the Bayh-Dole context, where less precision may be needed, the system could operate even more simply than it does in the well-functioning FIFRA context.

As the question implies, it is vitally important to account for the government investment in products that do not reach market -- particularly since industry claims about its own contributions to the cost of R&D rely so heavily on inclusion of the risk of failure. The easiest way to do this is to apply the same formula used by the industry to adjust for risk of failure. It is notable that, in the march-in case over ritonavir, Abbott applied a risk adjustment for its investment in R&D, but failed to apply a risk adjustment (let alone an adjustment for cost of capital) to the government investment.[2] (There are arguments as to why cost of capital should not be included in evaluating government costs, but these do not clearly apply where the evaluation is the relative government and private sector investment.)

2. How do you think that we can improve the tracking of the federal contribution to a patented invention, given the nature of federal research and development funding and the way that universities perform research and development in their institutions?

It may be that the government already maintains good information on federal contributions to patented inventions, at least in the area of pharmaceuticals. As I mentioned in my testimony, NIH does collect detailed information on utilization of inventions developed with federal support, but this information is not made public,[3] due to confidentiality provisions in Bayh-Dole.[4] This confidentiality apparently extends even to listing drugs on the market for which the government maintains Bayh-Dole rights, even when much of the information is attainable from other public sources. The NIH publishes a list of FDA-approved drugs where the contractor has consented to release of the information,[5] but this is very limited. There is no legitimate public policy rationale for the confidentiality provision, at least as it is applied in this context, and it should be repealed.

It is possible that the NIH database -- Interagency Edison -- also contains good information on federal funding of patented products, for which NIH does not have Bayh-Dole rights. This is significant information, because of the importance of more closely scrutinizing federal support for inventions where no Bayh-Dole rights vest -- and of developing appropriate policy tools to ensure the publicly funded inventions are priced reasonably, made broadly accessible, and not encumbered by patent or other monopoly protections that improperly impede research or other public objectives.

[2] See Statement of James Love, Essential Invention, NIH Meeting on Ritonavir March-in Request, May 25, 2004, pp. 4-5, available at: <http://www.essentialinventions.org/legal/norvir/may25nihjamie.pdf>.
[3] See Interagency Edison, available at: <https://s-edison.info.nih.gov/iEdison/index.jsp>.
[4] 35 USC Sec. 202 (c) (5).
[5] Report of FDA Approved Commercial Products Involving NIH Extramural Support, available at: <https://s-edison.info.nih.gov/iEdison/commercial_report.jsp>

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Whatever information the Interagency Edison database holds, the principles of effective data gathering are clear. Funding agencies cannot collect this information on their own; the sources are too diffuse and many are presently confidential. Information must be provided by grant recipients, and grant recipient licensees. Requirements for information disclosure -- i.e., which entities are contributing, and how much, along the R&D chain -- should be built into federal grant agreements. Information should be reported back to a centralized source at the funding agency, compiled and made public.[6]

3. Some contend that the Bayh-Dole Act has made collaboration with U.S. universities more difficult because they claim that it's harder to finalize intellectual property contracts with them. Do you agree with this assessment? Is it your opinion that U.S. companies are increasingly turning to foreign universities for research collaboration because it is easier to deal with them? How do the intellectual property and business practices at U.S. universities compare to universities in other developed and developing countries?

The impact of Bayh-Dole on university-industry collaboration varies by sector. In the information technology sector, companies find the university emphasis on patenting -- sometimes veering on obsession -- to be a serious deterrent to collaboration. There is anecdotal evidence that these companies are looking to collaborate in other countries. At least, they are less likely to collaborate in the United States.

University patent practices on research tools has interfered with, or exacted a tax on research in some cases; and heavy university patenting may be contributing to patent thickets making biomedical inventions harder to commercialize. Whether excessive university patenting in these areas harms collaboration or not, they do seem to impede, or impose unnecessary costs on, commercialization.

As for other countries, unfortunately the trend appears to be for many countries to uncritically adopt a U.S.-style Bayh-Dole approach. I believe this is based on the successful publicity campaign around Bayh-Dole, not a careful review of its impact, rationale or appropriateness for other national contexts.

4. Since a patent is not necessarily indicative of the value of an invention, what would you consider to be the type of circumstance, not included in current law, that would preclude federal agencies from providing a contractor with title to an invention?

So long as Bayh-Dole is the operative framework, refusal to grant title to contractor must be reserved only for "exceptional" cases. The statute suggests by its language and overall purpose that the definition of "exceptional" probably is not "very valuable." Rather, appropriate exceptions probably should be found on the basis of a kind of invention, where there is a public policy basis for not having it patented, or for it not being widely distributed. National security and intelligence-related inventions are referenced in the statute, and are obvious such examples. Depending on circumstances, weapons-related patents may be another, as might inventions that do harm (for example, create, enable or deepen addictions). It would be reasonable to consider whether research tools not

[6] Please note: This response duplicates an answer to a similar question from Senator Hatch.

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requiring significant follow-on investment should be considered exceptional. In this case, rather than the government restricting access, it might make the invention available freely.

With Bayh-Dole as the operative framework, the key available mechanisms to ensure availability of important inventions, and to avoid profiteering, are to enforce the reasonable pricing obligations, exercise the march-in authority, and employ the automatic government license in government-funded inventions.

5. Why are some universities better than others in negotiating partnerships with industry? What do you think are the characteristics for successful institutions?

There are many factors that help or hinder university-industry partnerships. Large research universities clearly have the economies of scale to facilitate partnership development and maintenance.

Fostering partnerships should not be an end-goal, however, especially because partnerships may compromise university independence and autonomy. Even the most careful partnership arrangements almost inevitably create institutional conflicts of interest that may undermine public interest objectives. For example, industry partners commonly desire monopolies, and partnership arrangements may tether university financial interests with those of would-be monopolists. This will often be harmful for the public. University partnerships may also reduce the pool of critics of new technologies or organizational arrangements, as "independent" academics are drawn into financial relationship with industries. This is clearly the case in the pharmaceutical sector, where a great many academics have conflicts that render them unable to offer disinterested analysis of new drugs or industry practices.

Underlying the idea of university-industry collaboration is the genuinely public interest objective of fostering innovation. In many cases, some degree of separation between industry and universities -- not an absolute barrier, but more clearly delineated distinct roles -- may best foster innovation.

QUESTIONS FROM SENATOR HATCH

1. How significant has Bayh-Dole been to the elevation of the U.S. economy and to economies and living standards of third world nations?

U.S. government-funded research has made an enormous contribution to the U.S. economy and significantly improved lives overseas. But the key contribution has been that research investment, not the Bayh-Dole legal mechanism intended to facilitate commercialization. Bayh-Dole has had virtually no impact in elevating the U.S. economy or the living standards in developing countries.

Answering the question requires examining the counterfactual: What if there had been no Bayh-Dole? Contrary to the claims made by Bayh-Dole proponents at the time, many

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federally funded inventions were commercialized before Bayh-Dole; and many would have come in the absence of Bayh-Dole. Other proposals, with stronger built-in safeguards and presumptions, were made at the time; and there are many other potential ways to license government-funded inventions that would be more sensitive to competing interests, including enhancement of the public domain and fair and reasonable pricing of government-funded inventions.

As for effect on developing countries, although federal investment has led to numerous inventions of great import for people in developing countries (including many AIDS drugs), Bayh-Dole as implemented has not succeeded in making those products available at an affordable price. Policy interventions outside of the Bayh-Dole context have been key to offset the failure of Bayh-Dole in this area; and in some cases these external interventions have not been able to achieve what Bayh-Dole potentially could.[7]

2. Are there shortcomings of Bayh-Dole that have become apparent with time?

As I suggested in my testimony, many shortcomings with Bayh-Dole are now apparent. A key concern is the pricing of federally supported inventions. Bayh-Dole's authorization for exclusive licensing arrangements created the conditions in which pricing problems were likely to emerge. Safeguards were included in the statute at least to mitigate these concerns, but the safeguards have failed, due both to funding agency uncertainty about when the safeguards should be employed and political reluctance to activate them.

3. There is still room for improvement of Bayh-Dole, despite its apparent success. What top three reforms would you suggest?

1. Establish clear guidelines and standards for the exercise of Bayh-Dole safeguards: march-in authority, federal licenses to federally funded inventions, licensing of U.S.-sponsored inventions for use in the developing world. I discuss each of these issues in my testimony. Licensing of U.S.-sponsored inventions for use in the developing world should be the easiest to handle from a policy perspective; using existing Bayh-Dole rights, the U.S. government should enter into international agreements enabling the presumptive non-exclusive use of all government-funded inventions in the developing world.

2. Improved and transparent reporting mechanisms. This is also discussed in my testimony. It may be that the government maintains good information on federal contributions to patented inventions, at least in the area of pharmaceuticals. NIH does collect detailed information on utilization of inventions developed with federal support, but this information is not made public,[8] due to confidentiality provisions in Bayh-Dole.[9] This confidentiality apparently extends even to listing drugs on the market for which the government maintains Bayh-Dole rights, even when much of the information is attainable

[7] An important such example involves the AIDS drug ritonavir. This case is discussed in detail in my testimony. At the time of writing Abbott retains global pricing power over ritonavir, including in the world's poorest countries. Exercise of march-in authority or existing U.S. government license rights could lower the product's price significantly.
[8] See Interagency Edison, available at: <https://s-edison.info.nih.gov/iEdison/index.jsp>.
[9] 35 USC Sec. 202 (c) (5).

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from other public sources. The NIH publishes a list of FDA-approved drugs where the contractor has consented to release of the information,[10] but this is very limited. There is no legitimate public policy rationale for the confidentiality provision, at least as it is applied in this context, and it should be repealed.

It is possible that the NIH database -- Interagency Edison -- contains good information on federal funding of patented products, for which NIH does not have Bayh-Dole rights. This is significant information, because of the importance of more closely scrutinizing federal support for inventions where no Bayh-Dole rights vest -- and of developing appropriate policy tools to ensure the publicly funded inventions are priced reasonably, made broadly accessible, and not encumbered by patent or other monopoly protections that improperly impede research or other public objectives.

Whatever information the Interagency Edison database holds, the principles of effective data gathering are clear. Funding agencies cannot collect this information on their own; the sources are too diffuse and many are presently confidential. Information must be provided by grant recipients, and grant recipient licensees. Requirements for information disclosure -- i.e., which entities are contributing, and how much, along the R&D chain -- should be built into federal grant agreements. Information should be reported back to a centralized source at the funding agency, compiled and made public.[11]

3. Establishing government rights in sponsored research not giving rise to patentable inventions. Government sponsorship monies that do not directly lead to conception of an invention confer no Bayh-Dole rights at all. This includes cases where federal funding supports a university's pre-clinical investigations with considerable funding, but not the funding leading directly to conception of an invention. It also includes government funding of clinical trials for inventions patented by private parties, a growing area of NIH funding. It is not logical for the government to have zero rights in these cases. The core reform principle in this area should be that there must be some reciprocity in the form of price restraints for government support for R&D that directly helps products get to market, especially when the government is making high-risk investments.

4. Currently, Bayh-Dole provides an effective research exemption for federal government entities to practice the invention in the form of non-exclusive licenses to the government; however these licenses do not extend to universities or non-profit research institutions. This can give rise to the perverse situation where a university invention, if licensed exclusively, may be unavailable for use in fundamental, non-commercial research by the very laboratory where it was made. This creates an atmosphere of uncertainty and confusion that negatively impacts public research. What, if any, are the downsides to amending the Act to create a research exemption to use publicly-funded research results for noncommercial research in academic and nonprofit research environments.

[10] Report of FDA Approved Commercial Products Involving NIH Extramural Support, available at: <https://s-edison.info.nih.gov/iEdison/commercial_report.jsp>

[11] Please note: This response duplicates an answer to a similar question from Senator Grassley.

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Creating a clearly established research exemption to use publicly funded research without royalty payments would be a very positive step. I see no downside to such efforts.

5. Perhaps one unintended consequence of Bayh-Dole was to establish incentives for universities to develop independent technology transfer programs and to manage IP in a highly individualized and even competitive manner with respect to other universities. The resulting fragmentation of IP rights has, in some cases slowed down or prevented the pursuit of projects that have limited profitability but high social or humanitarian value. The development of effective treatments for neglected diseases is an example that comes to mind. Can you see any framework that would allow and embrace the development of collaborative IP management strategies across multiple publicly-funded research institutions?

Collaborative IP management schemes are available if universities and research institutions choose to pursue them. Unfortunately, as the question suggests, Bayh-Dole has created institutional arrangements that work against such collaboration.

Universities have made a modest step in the direction of collaboration through the PIPRA (Public Intellectual Property Resource for Agriculture) project, which at least illustrates some mechanisms that could be developed to facilitate more collaboration.

Probably the single best way to facilitate collaboration is to dedicate patents to the public domain, or make them available on a nonexclusive basis with zero or very low royalties conditioned on licensees adopting similar policies. Even nonexclusive licensing with a commercial level royalty rate would facilitate collaboration.

If inventions were licensed on these terms to a patent pool, then the pool could be a centralized place for researchers to gain rights to use and build on technologies.[12] If the pool was funded and staffed modestly, it could affirmatively seek to aggregate patents and related rights to facilitate new innovation. Such innovation might include entirely new inventions, or combinations of existing inventions not now commercially viable because of patent barriers.

Combination inventions are often very important in the pharmaceutical field. The case of ritonavir, an AIDS drug in which the government maintains Bayh-Dole rights, is illustrative. Abbott controls the patent rights for ritonavir, which is an effective booster for other AIDS medications. Abbott charges an extremely high price for ritonavir if it used in combination with other products, as compared to use in combination with its drug lopinavir. As a result, other combination products are not commercially viable. If the ritonavir patents were licensed to a pool, these other products would be on the market, and the world would have better and more diverse AIDS treatments available.

[12] For more on this topic, see the web page on patent pools maintained by Knowledge Ecology International, available at: <http://www.keionline.org/index.php?option=com_content&task=view&id=63&Itemid=1>.

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SUBMISSIONS FOR THE RECORD

THE STATEMENT OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION ON

The Role of Federally-Funded University Research in the Patent System

BEFORE THE SENATE COMMITTEE ON THE JUDICIARY

Submitted
OCTOBER 24, 2007

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The Biotechnology Industry Organization (BIO) appreciates this opportunity to provide the perspective of its members on the role of federally-funded university research in the patent system. BIO represents over 1,100 companies, universities and research institutions using biotechnology to research and develop cutting edge healthcare, agricultural, industrial and environmental products and applications.

From the perspective of the biotechnology industry, it has been the strength and predictability of the U.S. patent system that has led to the translation of publicly-funded research into useful, commercial products. This unparalleled patent system in conjunction with the Bayh-Dole Act has served as a basic tool for economic development and job creation in the United States.

The biotechnology industry pin-points its origin to two seminal events: The passage of the Bayh-Dole Act and the landmark Supreme Court decision of *Diamond v. Chakrabary*, where the Court opened the door for the patenting of key biotechnology inventions including biological materials and living organisms. Both of these events occurred in 1980. By allowing universities and research institutions to patent and retain title to their inventions, and allowing flexibility in licensing without excessive government intervention, the U.S. patent system in conjunction with the Bayh-Dole Act provided the necessary impetus for public institutions to transfer technology, and provided the inclination for the private sector to develop publicly-sponsored research. The result of these two events include, among other things, the existence of hundreds of innovative therapeutics, diagnostics and tools, industrial processes and agricultural products for the benefit of society, as well as hundreds of thousands of new, high-paying American jobs.

The biotechnology industry is one of the most research and development (R&D)-intensive and capital-focused industries in the world. The industry is primarily made up of small companies that are unprofitable and that lose billions of dollars annually. Yet it holds the promise for a cutting-edge cure for Alzheimer's, drought resistant crops, or the next alternative energy source. With over 1,400 companies, many of which spun out of university research, the U.S. leads the world in biotechnology R&D. In 2005, the U.S. biotech industry spent $20 billion on research and development, and since its inception roughly three decades ago, has put into the hands of the public hundreds of new therapies and vaccines and medical diagnostic tests based on biotechnology. In addition, there are more than 400 biotech drug products and vaccines currently in clinical trials targeting more than 200 diseases, including various cancers, Alzheimer's disease, heart disease, diabetes, multiple sclerosis, AIDS and arthritis. The industry has already developed dozens of insect-resistant crops and environmentally-friendly industrial applications.

All of these accomplishments have occurred despite the decades-long development time, massive investment needs, and complex regulatory processes the industry must overcome

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to bring its products and applications to market. The Milken Institute, in a 2006 report entitled "Mind-to-Market: A Global Analysis of University Biotechnology Technology Transfer and Commercialization,"[1] identified five key factors that contribute to the successful commercialization of university biotechnology research: a consistent and transparent national innovation policy that recognizes intellectual property protection and promotes entrepreneurial capitalism; the availability of funding and venture capital; biotechnology clusters not restricted by geographic borders; robust university technology transfer mechanisms; and patents and licensing.

The U.S. system of commercializing scientific discoveries has made it the world leader in the area of biotechnology in large measure because it takes into account the factors identified by the Milken Report. However, this was not always the case. Indeed, rapid commercialization of scientific discovery did not fully come about until the enactment of the Bayh-Dole Act in 1980. Prior to enactment of this legislation, publicly-funded research was owned by the government and offered for licensing on a non-exclusive basis or simply dedicated to the public. There was little incentive for business to undertake the financial risk to take these inventions and develop them into commercial products. Prior to Bayh-Dole, only 4% of the patents that resulted from federally funded research were commercialized. Since Bayh-Dole, not only has the volume of invention resulting from federally-funded research increased enormously, but also the percentage of those inventions being commercialized has increased ten-fold to around 50%. For instance, in 2005, 17,382 inventions were disclosed, 10,270 new patent applications were filed (59%) and 4,932 licenses and options were granted (48% of new patent applications filed). The total pipeline of active licenses from all the years up to and including 2005 was over 28,000.[2]

The U.S. system of transferring federally-funded research to private companies for research and development as set forth in the Bayh-Dole Act has been so successful that it has become a template for innovation and economic development for other enterprising countries such as India and China. The Milken Report shows that, while universities in the United States have clearly set the standard in commercializing research, other countries, particularly in Europe and Asia, have recognized the role of universities in spurring the biotechnology industry. The study suggests that, in order for the U.S. to maintain its leadership in innovation, it must continue to fund research and university technology transfer offices, encourage the transfer of innovative research to the private sector, and ensure strong intellectual property protection.

BIO urges this Committee to consider the immense value derived from this well-crafted system of strong patent protections and the resulting technology transfer over the past 25 years, and to ensure that the ability of this system to provide future benefit to the

[1] Mind to Market Study. http://www.milkeninstitute.org/publications/publications.taf?function=detail&ID=576&cat=ResRep
[2] AUTM U.S. Licensing Survey, FY 2005; www.autm.net

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American public and the world community is fully preserved. In its oversight capacity, this Committee should carefully consider how pioneering policies like strong patent laws and the Bayh-Dole Act have helped to create the biotechnology industry and U.S. leadership in this area, as well as the broader economic and societal benefits.

The Role of Patents in Biotechnology

In BIO's view, efficient transfer of federally-funded research is intricately linked to strong IP protections and free market incentives. In the context of the Bayh-Dole Act, patents serve as the legal instrument used in the transfer of technology, information and know-how. Commercializing an invention in the biotech sector is a lengthy process requiring significant amounts of capital, often in the hundreds of millions of dollars. While government funding and research is critical in biotech R&D, substantial additional financing from the public and private capital markets is required to actually take the product from the idea stage to one that can be used by the public.

Let's take as an example a typical healthcare-related biotech discovery. A researcher, typically in a publicly-funded laboratory, discovers a gene whose presence is only found in a particular type of cancer. The researcher also determines that the presence of this gene signals the presence of a quantifiable amount of a particular protein. Translating this initial discovery into a therapeutic application can take decades and hundreds of millions of dollars. However, it is at this early stage when the promise of a therapy is on the horizon that the researcher can seek patent protection on the various aspects of the discovery. By way of a patent, the researcher can generate interest in the further development of this potential new product by, for example, out-licensing the invention, or forming a spin-off company focusing on the R&D of this early-stage discovery. In both cases, the patent is the asset that creates a forward trajectory for the project. In the former case, an interested company partner would, among other things, review the strength and scope of the IP protecting the early-stage discovery to determine the worth of the investment. In the latter case, the IP generates the interest of institutional investors, venture capitalists, or other partners encouraging the creation of an early-stage company. In any event, the early-stage, publicly-funded discovery is now on its way to development. Of course, the road to development from this point is long and torturous, and often fraught with set backs, but the transfer of technology is complete and the wheels are set in motion.

From this point on, patents play a significant role in the investment of capital in the biotechnology markets. Investors measure opportunities in the biopharmaceutical and pharmaceutical sector through potential sales of the drug/product, the market exclusivity prospect through patent protection, other forms of marketing exclusivity (such as orphan drug exclusivity), or other means to gauge the strength and predictability of patent protection.

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The ancillary benefits of this ecosystem to the economy in the form of jobs, tax revenue and new companies should not be overlooked. According to the Association for University Technology Managers' (AUTM) annual report[3], the Bayh-Dole Act continues to create hundreds of companies and tens of thousands of new jobs annually. Virtually every state has a biotechnology center or initiative. In its policy statement on July 24, 2007, the National Governors Association recognized the import of strong IP and university technology transfer fostered by Bayh-Dole as catalysts for innovation and R&D.

If the major policy objective of the Bayh-Dole Act is to use the patent system to promote the commercialization and utilization of inventions arising from federally-supported research or development, then the biotechnology sector is an exemplary measure of its success. The Bayh-Dole Act provides one of the key environments for biotechnology companies to take the risk of investing in biotechnology R&D. It provides the lure of market exclusivity as the incentive for companies to work in cooperation with public institutions. There is little misunderstanding of the primary obligation that companies have under Bayh-Dole to *commercialize* the licensed technology. This point is solidified by the statute's provision that failure to commercialize a licensed federally-funded invention can be the basis for government march-in rights.

BIO believes that the patent system and the Bayh-Dole Act are working quite well. However, there are potential threats to this finely-tuned system. As an example, the Congress is currently considering patent reform legislation that, in its current form, could negatively impact commercialization of publicly-funded research by undermining the strength, value, and predictability of patent protection. This would, in turn, make it much less likely that companies and venture capital companies would invest in risky, cutting-edge research, resulting in publicly-funded research sitting on laboratory shelves. BIO recently testified before this Committee about its views on patent reform, and the university technology transfer community has weighed in with similar concerns.[4]

There also are potential opportunities to enhance the technology transfer system. BIO believes that consistent and transparent implementation of the Bayh-Dole Act, together with a cataloguing of "best practices" and successful partnerships, would provide more efficient transfer of technology. Congress should consider funding studies that would aid in the identification and compilation of such best practices and identify how best to support the technology transfer offices in their overall mission.

In this spirit, BIO cautions against policies that would weaken market incentives through excessive government intervention. We can point to lessons learned in the 1990s in studying the Bayh-Dole Act. Concerns that healthcare reform proposals from the early 1990s could have led to price controls caused serious perturbations in the market for biotechnology investment. The impact of potential price controls on the biotechnology

[3] See AUTM 2005 Survey, *supra*.
[4] BIO's Patent reform statement; http://bio.org/ip/domestic/20070606.asp

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industry was immediate and powerful. The capital markets crashed and investment in biotech research nearly dried up.

A similar result occurred in 1999 when President Clinton and Prime Minister Blair were cited in the press as supporting the notion that certain classes of patented genetic information should be freely available to all at the time the human genome was "unraveled." Despite a clear correction by the President the next day, it took six months for the biotechnology capital markets to recover.

In both cases, a threat to free-market protection and undermining intellectual property rights drove investors away from biotechnology research. The Bayh-Dole Act was designed to facilitate the transfer of publicly-funded research to the private sector for further development and commercialization. The careful balance set forth in the Act has been hugely successful. We have learned from history that excessive government intervention can disincentivize biotechnology companies from undertaking the huge risks to bring innovative products and services to all Americans.

CONCLUSION

The U.S. system of protecting innovation and technology transfer has worked well over these 25 years. The Senate Judiciary Committee is to be commended for undertaking this examination of this system, which the world aspires to emulate. BIO appreciates the opportunity to provide insight into the impact of how this system has given birth to the biotech industry and to describe the nature of the industry and its contributions to the improvement of the human condition. BIO's members are strong supporters of the current system of technology transfer as governed by the Bayh-Dole Act, which has opened the door to the creation of many biotechnology companies that have developed important advances and cutting-edge solutions to some of the world's most intractable problems. We caution against policies that would weaken market incentives through excessive government intervention. We urge Congress to continue its far-sighted approach to innovation as it continues oversight of this very important issue.

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Written Statement of Carl E. Gulbrandsen

on behalf of the

Wisconsin Alumni Research Foundation

Before the

Senate Committee on the Judiciary

on

"The Success and Importance of the Bayh-Dole Act in Realizing the Promise of Federally Funded Research"

October 24, 2007

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WRITTEN STATEMENT

Mr. Chairman, and Members of the Committee, including the two esteemed Senators from my home State of Wisconsin, I am grateful for the opportunity to submit a written statement in the record of the Committee's October 24th hearing on "The Role of Federally-Funded University Research in the Patent System." Thank you for holding this oversight hearing on an extremely important subject. Thank you also for an important piece of legislation (the CREATE Act) processed into law during the 108th Congress under your leadership, that of Senator Hatch and several Committee cosponsors, including Senators Kohl, Feingold, Grassley and Schumer. In the 21st Century, science depends on collaborative research, and the CREATE Act has already stimulated numerous inventive activities. Scientific progress also depends on federal funding, a strong patent law system, and technology transfer to the marketplace.

My name is Carl E. Gulbrandsen. I am the Managing Director of the Wisconsin Alumni Research Foundation, known as WARF. WARF is the patent management and licensing organization for the University of Wisconsin-Madison ("UW-Madison"). I am making my statement today on behalf of WARF.

In addition to serving as Managing Director of WARF, in 2005 I was appointed by the Secretary of Commerce to the Patent Public Advisory Committee ("PPAC") of the United States Patent and Trademark Office ("USPTO"). PPAC was created by Congress to review the policies, goals, performance, budget and user fees of the USPTO with regard to patents. 35 U.S.C. § 5. In addition, I previously served as Vice President of the Public Policy Committee of the Association of University Technology Managers ("AUTM"). I am a patent lawyer admitted to practice before the USPTO. Prior to joining WARF, I had over 20 years experience in the private practice of law where I specialized in patent prosecution and litigation representing

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individual patent owners and small businesses. I also served as the in-house general counsel of Lunar Corporation, a medical device company, and Bone Care International a pharmaceutical company. Lunar was acquired by General Electric Medical (now GE Healthcare) and Bone Care International, was acquired by Genzyme Corporation. Lunar and Bone Care were based on technologies arising out of research at UW-Madison. The products they manufactured improved lives. In the case of Bone Care, the core technology had been funded by the federal government and it is unlikely that either Bone Care or the products it manufactured would have been possible were it not for a chapter (commonly known as the Bayh-Dole Act) in the U.S. Patent Act. Finally, I have served as an adjunct faculty member teaching patent law at the University of Wisconsin ("UW") Law School and, in 2006, I presented the Kastenmeier Lecture at the UW Law School alongside the Honorable Birch Bayh and two esteemed Wisconsin scientist-inventors (Prof. Hector F. DeLuca and Prof. T. Rock Mackie) on the very subject that the Committee is considering today.

I. Background about WARF

WARF was founded in 1925 and is one of the first organizations to engage in university technology transfer. It exists to support scientific research at the UW-Madison and carries out this mission by patenting university technology and licensing it to the private sector for the benefit of the university, the inventors and the public. Through its subsidiary, the WiSys Technology Foundation, WARF also supports research and educational programs at the other campuses of the UW system. Licensing income is returned to the university to fund further scientific research. Over the past 80 years, WARF has contributed approximately $900 million to UW-Madison to fund basic scientific research.

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WARF's technology transfer successes have had a significant impact on advances in scientific research and have had profound and positive effects on the welfare, health and safety of people in the State of Wisconsin, this country and worldwide. Historically included among UW-Madison inventions patented and licensed by WARF are: Professor Harry Steenbock's invention on the in situ generation of Vitamin D in foodstuffs and medicines, which essentially eradicated rickets as a childhood disease; Professor Edwin B. Hantin's copper-iron complexes, which improved the physiological assimilation of iron in humans; and Professor Karl-Paul Link's discovery of Coumadin®, the most widely used blood-thinner for treatment of cardiovascular disease, and its counterpart Warfarin, still the most widely used rodenticide worldwide. WARF's successes are not just historical. Today, American society benefits from Professor Charles Mistretta's digital vascular imaging technology, which enables accurate diagnosis of blockage of the vessels of the heart; Professor Hector DeLuca's Vitamin-D derivatives, which are widely used to treat osteoporosis, renal disease and other diseases; Professor Rock Mackie's Tomotherapy technology for image-guided delivery of radiation therapy from all angles to treat cancer patients; Professor Yoshihiro Kawaoka's reverse genetics system to create influenza vaccines (including a vaccine against the avian H5 virus); and Dr. James Thomson's isolation of human embryonic stem cells.

The UW-Madison consistently ranks in the top ten universities, in terms of the amount of federally-funded research conducted and the patents granted by the USPTO covering discoveries arising out of that research. As recognition of its excellence in technology transfer, in March 2005 WARF received the 2003 National Medal of Technology, the highest award that can be conferred by the President of the United States to individuals and organizations making significant and lasting contributions to the country's economic, environmental and social well-

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being through the development and commercialization of technology. WARF is the first university technology transfer office to receive this prestigious award, and I was proud to accept this honor personally from President Bush in the White House. Mr. Chairman, the honor bestowed upon WARF by the President is recognition by our government of the importance of university research and technology transfer to the economic health and well-being of our country. It is from this viewpoint that this statement is written.

II. Universities: The Drivers of Basic Research in the United States

The fact that the U.S. has the world's most successful innovation pipeline is unrefuted. With due consideration for the "flattening" of the globe, which requires the United States to run faster to stay in place, we have two choices. The first is to put up walls of self-protection; the second is to march forward. In his bestselling book, Thomas Friedman recommends moving forward. Friedman, Thomas L., THE WORLD IS FLAT: A BRIEF HISTORY OF THE 21ST CENTURY 330-31 (3.0 expanded ed. 2007).

"How so?" Friedman asks. His answer is relevant to the topic of this hearing:

> . . .America has a myriad of institutional strengths. It starts with America's research universities, which spin off a steady stream of competitive experiments, innovations, and scientific breakthroughs – from mathematics to biology to physics to chemistry. It is a truism, but the more educated you are, the more options you will have in a flat world. "Our university system is the best," said Bill Gates. "We fund our universities to do a lot of research and that is an amazing thing. High-IQ people come here, and we allow them to innovate and turn [their innovations] into products. We reward risk taking. Our university system is competitive and experimental. They can try out different approaches. There are one hundred universities making contributions to robotics. And each one is saying that the other is doing it all wrong, or my piece actually fits together with theirs. It is a chaotic system, but it is a great engine of innovation in the world, and with federal tax money, with some philanthropy on top of that, [it will continue to flourish]. . . ."

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Friedman, *id.* at 244.

What makes the United States unique is our universities, and not just the great ones. Every State in the country has one. They compete with each other for Federal grants, students and faculty. We have almost one-half the universities in the world. California has about 130 colleges and universities; only 14 countries in the world have more.

Is it any wonder that American universities excel in innovating, inventing, licensing and receiving patent royalties? The roots of excellence are found in federal funding of research, strong intellectual property laws, political stability, and emphasis on the constitutional principle of publication.

Let us look further at America's research universities. A society's efforts to increase its stock of knowledge is often referred to as research and development ("R&D"). When discussing R&D, we need to distinguish between basic and applied research. Innovation starts with basic research. Today, basic research (the "R") is performed primarily in institutions of higher education. Universities and colleges perform about 60 percent of all basic research; private industry performs about 18 percent. The universities' share of basic research has almost doubled since World War II and is attributable, in large part, to federal policies, including federal funding and the Bayh-Dole Act.

In contrast, today, private industry performs about 90 percent of development (the "D"). We call this "applied research." The private sector engages disproportionately in applied research, contributing 70 percent of development research costs designed to develop and bring products to the marketplace.

In short, a majority of the "R" in our country's "R&D" is done at universities; and almost all the "D" is done in the private sector. This "reflects an efficient and understandable division

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of labor." *See* Hill, Kent, "Universities in the National Innovation System" (March 2006), available at <http://www.wpcarey.asu.edu/seidman/reports/innovation.pdf>.

The symbiotic relationship between research and education is longstanding in the United States. It is embedded in the Morrill Act, which established land-grant universities. In Wisconsin, we call the positive relationship -- that exists between the University of Wisconsin and the State, and the affirmative responsibility of the former to contribute to the latter -- the "Wisconsin Idea". Deeply rooted in our state's progressive history, the "Wisconsin Idea" permeates state government leadership and university administration. Dr. Hill enumerates why the link works so well not only in Wisconsin but nationwide today:

- Students assist with helping to transfer research findings to industry;
- Research universities excel at training future researchers;
- The academic merit system promotes rapid distribution and publication of research findings;
- Academics are allowed and encouraged to be entrepreneurial; and
- Researchers can afford to take research risks.

I encourage each and every Member of the Committee to visit the technology transfer offices and research vice-presidents of your home state universities. With utmost confidence, I can say that you will find that university research creates jobs, attracts venture capital, contributes to the tax rolls of the states, and contributes to a better society.

A recent report of the Federal Reserve Bank of Cleveland -- one of twelve regional Reserve Banks of the United States that comprise the Federal Reserve System -- examines what underlies differences in the evolution of States' income growth, *See* ALTERED STATES: A PERSPECTIVE ON 75 YEARS OF STATE INCOME GROWTH, 2005 Annual Report of the Federal

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Reserve Bank of Cleveland at 7 (2006). The study, which covered the years 1930 through 2004, concludes that innovation and workload skills make the difference. A quantifiable correlation exists between knowledge building -- through research and education -- and the states with the highest per capital incomes. In the above-average category are the States of Massachusetts, Maryland, New York, Delaware, California, Illinois, Rhode Island, Pennsylvania, Wisconsin and Vermont.

In 1980, under the leadership of the Senate Judiciary Committee (particularly Senators Birch Bayh and Bob Dole), Congress enacted the Patent and Trademark Law Amendments Act (the Bayh-Dole Act). *See* 35 U.S.C. §§ 200-212. Mr. Chairman, although the Act is named after Senators Bayh and Dole, you and other Senators played a positive role in the Act's enactment. So did Representative Bob Kastenmeier (of Wisconsin) on the House side. Howard Bremer, WARF's patent counsel at the time, was a key private-sector player. Congress drafted into law the cardinal principle that the public benefits from a policy that permits non-profits (including universities) and small businesses to retain ownership of technology invented with federal funding and to become participants in the commercialization process. After passage of the Bayh-Dole Act, universities and colleges developed and strengthened the internal expertise needed to engage effectively in the patenting and licensing of inventions.

The Act is predicated on the conviction that universities must be able to pursue their mission of creating and disseminating knowledge in an open environment and, concurrently, protect their inventions through strong intellectual property laws. As patent owners, universities depend on a high-quality patent system that promotes certainty and confidence, and permits the enforcement of exclusive rights. If that system is strong and robust, technology transfer occurs and the public is benefited. If the system is weakened, the public benefit may be reduced.

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The Bayh-Dole Act has been, and continues to be, an essential component of U. S. global leadership in technology. At WARF, we receive numerous visitors each year from around the world. Invariably, our foreign visitors ask about Bayh-Dole and express the wish that their own countries would adopt such forward-thinking legislation. In fact, Japan's recent changes to its patent law were modeled on that of the U. S. Bayh-Dole Act. The Senate Judiciary Committee should be proud of the role it played in passing such successful, landmark legislation.

The genius of the Bayh-Dole Act is that it is self-regulating and requires little to no expenditure of federal dollars for administration. To the extent that deficiencies arise, universities and their partners (including federal agencies) shoulder responsibility to optimize the technology transfer process in the public interest. In this regard, several academic organizations (WARF, Stanford, University of California, California Institute of Technology, Cornell, Harvard, MIT, University of Illinois (Chicago and Urbana-Champaign), University of Washington, Yale and the Association of America Medical Colleges ("AAMC")) recently developed a white paper on best practices in licensing. *See* "In the Public Interest: Nine Points to Consider in Licensing University Technology" (March 6, 2007), available at <http://www.autm.net>. Among its points, the white paper underlines that university licenses should strive to minimize the licensing of "future improvements," ensure broad access to research tools, be mindful of the implications of working with patent aggregators, and consider including provisions that address unmet needs, such as those of neglected patient populations or geographic areas, while paying particular attention to the developing world. In the months following publication of the principles, additional universities and associations (including AUTM and the Council on Governmental Relations) signed on to the document.

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However, despite the undisputed successes of the Act, there are continued attempts to alter the Act either directly or indirectly. At the hearing, several avowed critics of the Act have been asked to testify. After reviewing all the testimony, WARF trusts that this Committee in its wisdom will preserve one of its most important legacies and oppose (or hold further hearings on) any legislation that compromises the demonstrated success of Bayh-Dole and its pivotal role in improving the welfare, health and safety of people in this country and worldwide.

Because the Bayh-Dole Act promotes scientific and commercial collaboration, and economic development, while also empowering local communities, its true beneficiaries are this country's Governors. Bayh-Dole provides a decentralized model that is responsive to the needs and aspirations of our citizens. In the apt words of the Honorable Jim Doyle, Governor of the State of Wisconsin,

> "I look at Bayh-Dole and see good public policy that not only supports important research, but ensures that the research is done collaboratively by the best people all around the country. I see an amazing economic engine that has created a new energy and synergy between research, commercialization and local economic development."

Other Governors agree and are reliant of their universities to be economic engines and to start companies.

The importance of local control cannot be over-emphasized. The drafters of the Bayh-Dole Act created a delicate equilibrium between federal and state (and local) control. Under the Act, the federal government retains "march in" rights *ex post* to compel licensing of university patents on inventions made in the course of prior federally-funded research and agencies may utilize a "declaration of exceptional circumstances" (but neither of these tools can be exercised without adherence to administrative procedures designed to protect the interests of inventors and investors and to prevent misuses). Venture capital and investors can rely on patented technology

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not being licensed out from under them. If the current legislative balance is changed and shifted to federal agencies (for example, the NIH) to exercise greater discretion to intervene in licensing practices, as some would suggest (*see, e.g.*, Arti K. Rai and Rebecca S. Eisenberg, Bayh-Dole Reform and the Progress of Biomedicine, 66 Law & Contemp. Probs. 289 (Winter/Spring 2003)), disruptions to the innovation pipeline could occur. The ability of universities to stimulate start-up companies, create jobs and cure patients, would be chilled as would one of the driving goals of the Bayh-Dole Act (which is to benefit small businesses).

III. Federal Funding, University Patenting and Patent Licensing: The Results

To understand WARF's position -- and that of many other university research and technology transfer offices -- on federally-funded research, patent law and universities, an understanding of technology transfer, primarily through patent licensing, is necessary. We share the fundamental belief that the Founding Fathers recognized not only the need to protect the rights and property of individual Americans, but also the significance of providing incentives to stimulate the economic and cultural growth of the country. The U.S. Constitution (in Art. I, § 8, cl. 8) authorizes the Congress "[t]o promote the Progress of Science and useful Arts by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." Congress may therefore encourage the toils of inventors and authors by protecting their rights to reap fruits from their labors. It did not take the federal government long to act. In his first annual message to the Congress, President George Washington reminded legislators of the importance of progress in science and the arts, observing that "there is nothing which can better deserve your patronage than the promotion of science and literature." Less than six months later, the First Congress passed the first Patent Act, which President Washington signed on April 10, 1790.

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Americans sometimes forget where we, as a country, were in 1980 prior to enactment of the Bayh-Dole Act. The U.S. was sliding precipitously towards industrial irrelevance. We were losing competitively to the Europeans and the Japanese. Only 25 U.S. universities had technology transfer offices. No uniform federal patent policy existed. Patents were sitting on the shelves of executive branch agencies. Only 5 percent of government-owned patents were used by the private sector. In 1980, only a handful of patents were granted to universities.

In comparison, today, the United States has returned to world leadership in innovation. We are the envy of our trading partners. More than 230 universities have technology transfer offices. Universities are recipients of approximately four percent of U.S. origin patents. The list of cutting-edge inventions derived from research at non-profits, including universities, is far more impressive than the mere number of patents granted to universities. This list includes, among others, the following:

- Solution for the preservation of organs for transplant: UW-Madison;
- Leustatin, a chemotherapy drug: Brigham Young University;
- Lithography system to enable the manufacturing of nano devices: University of Texas - Austin;
- Rheumatoid arthritis relief: University of California - San Diego;
- Effective Aneurysm Treatment: UCLA;
- Water-repellent cotton fabric using nanotechnology: University of Oklahoma;
- Genetic-modified soy beans resistant to aphids: University of Illinois;
- Synthetic penicillin: Massachusetts Institute of Technology ("MIT");
- Salmonella detection medium: University of Maryland - College Park; and
- The Prostate-Specific Antigen ("PSA") Test: Roswell Park Cancer Institute (Buffalo, NY).

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Indisputably, university inventions have contributed to a "better world." For an enumeration of more university innovations, *see* AUTM Licensing Survey: FY 2005. *See* also *The Better World Report* (Part Two), TECHNOLOGY TRANSFER WORKS: 100 INNOVATIONS FROM ACADEMIC RESEARCH TO REAL-WORLD APPLICATION (2007 edition) (http://www.betterworldproject.net). These inventions, and many others, affect Americans in their daily lives, whether as hospital patients, farmers, employees in large and small businesses, scientists, students and entrepreneurs. The inventions stimulate the creation of start-up companies and new jobs, many of these filled by university graduates with professional degrees. For example, in 2006 the University of California formed 22 new start-up companies; 581 life science companies have links to UC; and 739 high-tech companies are linked to UC.

The Bayh-Dole Act is widely recognized as successful beyond all expectations. In 2003, the Vice Chairman of the NASDAQ (Alfred Berkeley III) estimated that 30 percent of the companies listed owe their value to the results of government-sponsored research and development. If it had not been for the Act, the fruits of federally-funded research might never have been commercialized. After 1980, the federal government had a coherent framework that provided for easier exploitable and ownership of scientific discoveries. Patent policy promoted entrepreneurship and investments. *See, e.g.*, Smith, Bruce L.R., AMERICAN SCIENCE POLICY SINCE WORLD WAR II, at 61 (The Brookings Institution 1990).

In 2005, the Bayh-Dole Act celebrated the 25th anniversary of its enactment. In the House of Representatives, under the leadership of the Committees on the Judiciary and Science, H. Con. Res. 319 was introduced with bipartisan sponsorship by Representatives Sensenbrenner, Conyers, Boehlert, Gordon, Berman and Smith (of Texas), among many others, expressing the

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sense of the Congress that the Act was successful. In 2006, with passage of the resolution (as section 201 of S. 1785), the House unanimously took the position that the Act has made:

> . . .substantial contributions to the advancement of scientific and technological knowledge, fostered dramatic improvements in pubic health and safety, strengthened the higher education system in the United States, served as a catalyst for the development of new domestic industries that have created tens of thousands of new jobs for American citizens, strengthened States and local communities across the country, and benefitted the economic and trade policies of the United States. . . .

152 CONG. REC. H8814 (daily ed., Dec. 6, 2006). The House also reaffirmed its commitment to the policies and objectives of the Act. During floor debate, Representative David Wu captured the essence of Bayh-Dole by stating that it "is a major reason why both research universities and small high-tech companies with university roots are such major drivers in today's America economy." *Id.* at H8816.

Although the concurrent resolution did not pass the Senate (for reasons presumably not associated with the resolution), it is not too late for the Senate to commemorate a successful law that owes its genesis to this Committee. Success should not be feared; from a political perspective, it should be applauded. *See* Remington, Michael J., "The Bayh-Dole Act at Twenty-Five Years: Looking Back, Taking Stock, Acting for the Future," AUTM Journal 29 (Summer 2005).

Conclusion

A recent report of the Congressional Research Service concluded that "the Bayh-Dole Act appears to have met its expressed goals of using 'the patent system to promote the utilization of inventions arising from federally-supported research or development; ... and to promote collaboration between commercial concerns and nonprofit organizations, including universities....' " Wendy H. Schacht, CRS REPORT FOR CONGRESS, The Bayh-Dole Act:

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Selected Issues in Patent Policy and the Commercialization of Technology (updated Dec. 8, 2006) at 8 (internal quote from 35 U.S.C. § 200). If Bayh-Dole is not broken, it does not need fixing.

In closing, as regards federally-funded research and the patent law system, I leave you with three cautionary recommendations:

- Remember that the Bayh-Dole Act has achieved its statutory objectives and has returned the United States to a position of worldwide leader in innovation;
- Unless a strong and compelling showing is made that legislative change is necessary, maintain the Act as it is presently enacted; and
- Specifically, through our patent law, continue to protect university ownership of patents and technology transfer from erosion by amendments (either direct or indirect) that compromise demonstrated successes.

Mr. Chairman, WARF is grateful to you for holding this important hearing.

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Senate Judiciary Committee
Hearing on "The Role of Federally-Funded University Research in the Patent System"

Statement of Senator Tom Harkin
October 24, 2007

Mr. Chairman, thank you for holding this important hearing on the role of federally funded university research in the patent system.

In conjunction with this hearing, I appreciate that you are addressing a provision of patent law which negatively impacts just one Federally Funded Research and Development Center in the entire country – Iowa State University. That provision limits the earnings from royalties on federal licenses that can be retained by operators of government-owned, contractor operated laboratories to 5% of their annual budget. After reaching the limit, the contractor is required to return 75% of the remaining royalties to the federal government.

I am deeply troubled by the fact that the law, as written, in effect serves to punish small successful laboratories that do a good job as stewards of taxpayer money and keep their operating costs low. Because of the way the law is currently written, even though Ames Laboratory's budget is significantly smaller than other laboratories, it is the only laboratory that has paid back to the treasury.

I am proud of the achievements of Ames Laboratory at Iowa State University. Working in conjunction with the Department of Energy, Ames Laboratory has made significant contributions towards addressing national problems.

Animal Science professor Steve Nissen, for example, developed NMB, a food supplement which cancer and AIDS patients use to fight muscle wasting. Horticulture professor Nick Christians discovered a corn gluten used in a variety of fertilizer products important for organic farming.

Iver Anderson, a senior metallurgist at Ames Laboratory and an Iowa State University adjunct professor, developed a lead-free solder. Solder is the shiny metallic "glue" that holds electronic components on computer and other circuit boards, and bonds other electrical connections. By some estimates, about 3,000 tons of electronic waste is discarded daily in the United States, creating a huge threat to the environment. Because of the research and development done at Ames Laboratory, we are now able to remove the lead from solder used in these components and thus reduce the harm to the environment.

These achievements have been made at one of the smallest contractor-operated federal laboratories in the country. The average budget of nonprofit Department of Energy laboratories is $505 million. The NASA Jet Propulsion Laboratory at California Institute

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of Technology has a budget of $1.7 billion, and the Lawrence Livermore National Laboratory at the University of California has a budget of $1.6 billion. In contrast, Ames Laboratory's annual budget ranges from only approximately $26 million to $34 million per year.

Despite this large disparity, it is the smaller institution – Ames – which sends approximately $1 million a year to the federal government. The others return nothing, precisely because their budgets are so large that it is extremely unlikely that they will ever hit the 5% cap on royalty revenues.

In other words, current law has the unintended consequence of disproportionately effecting small laboratories like Ames Laboratory, where the successful development of intellectual property is disproportionate to its budget. Because Ames Laboratory has managed to keep its operating costs low, it is much easier for it to reach the threshold where its royalties generated exceed five percent of its annual budget.

Tellingly, Ames Laboratory's partner in the development of lead-free solder – Sandia National Laboratory – has not had to return any of their royalties to the federal government. This is because Sandia has a budget of approximately $2.27 billion and thus has not reached the 5% threshold.

Mr. Chairman, federal law is designed to foster innovation and to encourage laboratories to commercialize research and development by patenting and licensing intellectual property. The laboratories are required to use their share of income for research and development, technology transfer and educational purposes, and I am proud of Iowa State's achievements in this area. I do not believe that federal law should include a provision that has a disparate impact on small, successful non-profit laboratories like Ames Laboratory at Iowa State University. That is why I fully support modifying the percentage of patent royalties that can be retained.

I appreciate your consideration in supporting a modification to present law, and I look forward to working with you in the future on this issue.

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Testimony of

Elizabeth Hoffman
Executive Vice President and Provost
Professor of Economics
Iowa State University

Before the

Senate Committee on the Judiciary

October 24, 2007

The Role of Federally-Funded University Research in the Patent System: A Review of Bayh-Dole and Royalty Returns

TESTIMONY OF DR. ELIZABETH HOFFMAN

Introduction

Good Morning Mr. Chairman and Distinguished Members of the Committee. I am Elizabeth Hoffman, Executive Vice President and Provost of Iowa State University. I am here first to convey our emphatic support for the Bayh-Dole Act. I am here also to propose a limited, technical fix that would eliminate a restriction that we believe has an unintended, inequitable, negative impact on ***small*** government owned, contractor operated laboratories; namely, the current limit imposed on retaining royalties resulting from technology transfer activities.

I am proud to be the chief academic and budget officer of the nation's first land grant university, which continues its tradition of putting ideas to work for the benefit of society. The motto on Iowa State University's seal is "Science with Practice." We believe the Ames Laboratory, which is operated by ISU for the United States' Department of Energy, is a model of that motto and a unique example of the positive social and economic impact of Bayh-Dole. By virtue of the number of licenses and options on technologies developed at Iowa State University, we have been called a "powerhouse" in the area of technology transfer.[1] As you will see, the work at Ames Laboratory is a major reason we are such a powerhouse of innovation.

Bayh-Dole Works

Let me first speak generally to the success of Bayh-Dole. Those who have looked at its impact agree that it has fulfilled its promise of stimulating economic development and facilitated the more rapid and efficient translation of innovative ideas and technology to the public good.

Prior to 1980, most inventions resulting from federal funding were placed in the public domain or held in the federal patent portfolio. Few of those inventions were commercialized, and the technical and financial potential of those inventions often went unrealized. Less than 5% of federal patents were licensed, compared with 25 to 30 percent of technologies for which federal agencies released ownership of the pertinent intellectual property to the inventing organizations.[2] Vexed by this lack of commercialization arising from federally sponsored research, Congress adopted the Bayh-Dole Act in 1980,[3] with the belief that the intellectual property arising from research could be more effectively brought to practice by allowing small business and non-profit contractors to elect ownership and to retain royalties. The underlying idea, of course, was that with ownership would come the motivation and the resources to develop ideas more effectively.

While presenting small businesses and non-profit research organizations an opportunity to realize financial returns for intellectual property, the authors of Bayh-Dole also were careful to protect the tax-payers interest in innovations enabled with federal dollars. In return for the right

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[1] Innovation Associates: *Technology Transfer and Commercialization Partnerships*, p. 77 (October 2007, available at http://www.innovationassoc.com/). In 2005, among the nation's universities, Iowa State University was second only to the University of California system in the number of licenses and options of its technology.
[2] Government Accounting Office, *Technology Transfer: Administration of the Bayh-Dole Act by Research Universities*, p. 3 (May, 1998, available at http://www.gao.gov/archive/1998/rc98126.pdf).
[3] Pub.L. 96-517.

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to elect title to a federally-funded invention, for example, the law grants to the federal government a royalty-free right to practice the invention. It also grants to the federal government march-in rights under specified conditions.[4] Additionally, the law places very specific conditions on the management of inventions, including an imperative for diligent prosecution of licensing; preference for licensing to small business; and payment of part of the royalties to the inventor.[5]

By all measures, Bayh-Dole has been a success. In December 2002, *The Economist* called Bayh-Dole "Possibly the most inspired piece of legislation to be enacted in America in the last half-century," adding "More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance."[6]

Bayh-Dole works because it recognizes that the hard work of bringing ideas to practice requires incentives *and* seed funding. By allowing institutions to retain ownership, institutions invest in the expertise needed to evaluate whether a viable product will result, and whether the market will value it. By providing incentives, Bayh-Dole assures that inventors and their sponsoring organizations continue working to bring their invention to public benefit, even after the original innovation in the laboratory and demonstration of concept.

As evidence of Bayh-Dole's effectiveness, consider that in 1980, only 250 patents were granted to universities. By 2004, this annual number had risen to 3,800.[7] Spurred by Bayh-Dole, the nation's universities have geared up: according to the Association of University Technology Managers (AUTM), over the past nine years approximately 3,600 new products have been introduced as a direct result of university research in a broad array of fields including medicine, public safety, food and agriculture, new materials, semiconductor devices, education, and communications. Five hundred and twenty seven new products were introduced in 2005 alone. Since 1980, more than 5,000 companies have been started based on university research, contributing to the creation of more than 260,000 new jobs.[8]

Bayh-Dole—The Experience at Iowa State University

The effectiveness of Bayh-Dole incentives can be seen in the upward trend in technology disclosures at Iowa State University. Prior to the adoption of Bayh-Dole in 1980, our researchers generated an annual average of 46 technology disclosures throughout the decade of the 1970's. In the 1980's, they generated an annual average of 61. The 1990's saw a further increase in disclosure activity, as scientists and engineers at ISU generated an average of 134 disclosures per year. Since 2000, we have leveled off at an annual average of 118 disclosures. In 2005, Iowa

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[4] 35 U.S.C. §203.
[5] 35 U.S.C. §202.
[6] "Innovation's Golden Goose," *The Economist,* December 14, 2002 Technology Quarterly Section, p. 3.
[7] Stevens, A.J., Toneguzzo, F. and Bostrom, D (eds.) *AUTM U.S. Licensing Survey: FY 2004* (2005, available at: http://www.autm.net/events/File/04AUTMSurveySum-USpublic.pdf).
[8] See joint letter to the Honorable David Wu and the Honorable Phil Gingrey, M.D., from the Presidents of the Association of American Universities, the Association of American Medical Colleges, the National Association of State Universities and Land Grant Colleges and the Council on Government Relations August 8, 2007. (Available at: http://206.151.87.67/docs/Bayh-DoleStatement.pdf).

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State University was second in the nation - behind the University of California System - in licenses and options with 218, and we were sixth nationally in the total number of active licenses, with 745.[9]

For those who ask about the positive social benefit of this nationwide increase in technology disclosures at colleges and universities, it is essential to bear in mind that the objective – of academic institutions, in particular - is to bring useful ideas and innovations to the marketplace and the public good. Over the last eight years, ISU has licensed 322 different technologies. One half of these were the outgrowth of federal funding. And these technologies have benefited the many, rather than the wealthy. Approximately 92% of our licenses for federally funded technologies have been to small businesses. In the past 8 years alone, fully 20 new companies have been started on the basis of 41 licensed technologies; and 16 of those companies are still in existence, contributing to the economy of our state and the nation.

An Example: Lead-Free Solder

Now, I would like to turn from a broad examination of the positive impact of Bayh-Dole, to look more closely at the Ames Laboratory. No better illustration of the success of Bayh-Dole can be found than the example of lead-free solder, a result of federal support that has been developed jointly at the Ames Laboratory and Sandia National Laboratory. The research team that created this remarkable and remarkably marketable innovation was led by Ames metallurgist Iver Anderson.

Dr. Anderson's solder provides excellent properties over other solders, including a lower melting temperature and greater strength. It is used in the electronics industry within the circuitry of their products, for example, binding components to circuit boards for computers, cell phones, and other electronic devices and appliances. By some estimates, about 3,000 tons of electronic waste is discarded daily just in the U.S., and this waste contains lead from solder. By removing the lead, we protect the environment and avoid a serious health threat.

The so-called "Iver Patent" for this lead-free solder is licensed by ISU to 28 companies under very reasonable financial terms, and over 60 companies use the patent. Those companies are both small and large, domestic and international, and include a firm in Iowa whose small business has prospered from commercializing this solder.

What is important here, in evaluating the efficacy and wisdom of Bayh-Dole, is to recognize that *if* this technology had not been protected by a patent and vigorously defended – if Bayh-Dole did not exist - it is very likely that foreign companies would dominate the solder market with respect to our lead free alloy in the United States. The fact that the patent is available for license under reasonable terms was an important consideration for the industry in recommending that our patented alloy become the industry standard for electronic soldering. And as a result, the Iver patent – and the Ames Laboratory itself – have directly served the economic interests of our nation. In a word, at the Ames Laboratory and at Iowa State University, Bayh-Dole has made us

[9] Innovation Associates: *Technology Transfer and Commercialization Partnerships*, p. 79 (October 2007, available at http://www.innovationassoc.com/)

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better at our essential public mission: delivering the fruits of education and research to the public for the betterment of humanity.

A Proposed Modification—Relief for Small GOCO Laboratories

As you see, Bayh-Dole has fulfilled its promise in growing this country's technology-based economy for over 25 years. By asking the owners of federally sponsored technology to favor small businesses, it has contributed both to local economies and spurred stability in the U.S. economy by stimulating development of diverse products and approaches to problem solving. Bayh-Dole provides effective incentives to find solutions to pressing problems, and we see no reason for fundamental change in Bayh-Dole. The principles, practice, and impact of this legislation are sound.

I do, however, want to discuss with you today one technical concern we have that we believe can have an unfair impact on small government owned, contractor operated (GOCO) federal laboratories, and that has had such a inequitable impact on the Ames Laboratory at Iowa State University.

Specifically, as many of you may know, as modified in 1984 Bayh-Dole limits the earnings from royalties on federal licenses that can be retained by operators of government-owned, contractor operated laboratories to 5% of their annual budget. After reaching the limit, the contractor is required to return 75% of the remaining royalties to the federal government. This provision requires that all royalties retained by the contractor (both the 5% of budget and the 25% of the remaining 95% of royalty revenues) must be expended for research, educational and technology transfer purposes.[10]

As indicated previously, Iowa State University operates Ames Laboratory for the Department of Energy.[11] As a small laboratory - our budget in 2006 was $26 million - Ames Laboratory is the only federal laboratory to have reached the 5% royalty limit. Simply stated, this is because the Ames Laboratory has been disproportionately successful – compared to much larger national laboratories -- in developing and licensing technology. In other words, because we receive relatively limited funding from the government, and have such a successful patent portfolio, the Ames Laboratory alone in the nation has come up against the 5% royalty cap. Last fiscal year we returned nearly $1 million to the federal government, and this fiscal year, we anticipate returning about the same amount. Remember please, these are funds would, by law and in keeping with our non-profit, public interest mission, otherwise be used exclusively for research and educational purposes.

My contention today, which I respectfully offer for your consideration, is that the authors of Bayh-Dole and subsequent modifying legislation did not intend to incorporate a provision that

[10] 35 U.S.C §202(c)(7)(E).

[11] The work at Ames Laboratory began over sixty years ago when it developed methods to purify uranium for the atomic energy program. Since then, it has continued its pre-eminence in materials development, but has expanded to such areas as non-destructive evaluation of materials, applied mathematics and bio-renewables. We are proud of the achievements of Ames Laboratory and its accomplishments in support of federal initiatives and in support of our technology-driven economy. Ames scientists have had the distinction of receiving 16 R&D 100 Awards from *R&D Magazine* since 1984.

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would have a disparate and deleterious impact on small, successful, non-profit GOCO laboratories. Whatever their motivations – and there may have been several – I cannot believe the founders of this pivotal and uniquely American system of innovation intended to punish or to tax small, successful, non-profit institutions. Bearing in mind, again, that the royalties in question are, by law, necessarily re-invested in the research and education missions and activities of these non-profit contractors – which in the case of the Ames Laboratory is a public university – we ask you to re-examine this technical clause and to modify the limitation in accord with the founding principle of and subsequent clarifying modifications to Bayh-Dole.

History of the 5% Limitation

As originally enacted, Bayh-Dole included a provision granting federal agencies discretion to retain title to inventions of GOCO contractors. Though President Reagan in 1983 issued a federal policy statement requiring federal agencies to exercise their discretion in favor of granting all contractors ownership and the right to retain royalties,[12] it was not until the Trademark Clarification Act of 1984[13] that the law was amended to require that GOCO laboratories have the right to retain title to these inventions. At the same time the 5% limitation at issue today was added.

It reads:

> (7) In the case of a nonprofit organization . . .
>
> > (E) with respect to a funding agreement for the operation of a Government-owned-contractor-operated facility, requirements (i) that after payment of patenting costs, licensing costs, payments to inventors, and other expenses incidental to the administration of subject inventions, 100 percent of the balance of any royalties or income earned and retained by the contractor during any fiscal year up to an amount equal to 5 percent of the annual budget of the facility, shall be used by the contractor for scientific research, development, and education consistent with the research and development mission and objectives of the facility, including activities that increase the licensing potential of other inventions of the facility; provided that if said balance exceeds 5 percent of the annual budget of the facility, that 75 percent of such excess shall be paid to the Treasury of the United States and the remaining 25 percent shall be used for the same purposes as described above in this clause (D); and (ii) that, to the extent it provides the most effective technology transfer, the licensing of subject inventions shall be administered by contractor employees on location at the facility.[14]

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[12] Presidential Memorandum to the Heads of Executive Departments and Agencies, Subject: Government Patent Policy, 1983 Published Papers 248 (February 18, 1983). The law at that time contained narrow exceptions related to naval nuclear propulsion and weapons contracts. 35 U.S.C. §202(a)(iv).

[13] Title V, Pub.L. 98-620, §501(3). For a history of Bayh-Dole in the context of DOE GOCO contractors, see: Edward C. Walterscheid, "The need for a Uniform Government Patent Policy: The D.O.E. Example," 3 *Harvard Journal of Law & Technology* 103 (1990).

[14] 35 U.S.C §202(c)(7)(E).

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In 1987, President Reagan issued Executive Order 12591 requiring federal agencies to grant title to inventions to all contractors, to the extent permitted by law.[15] As a result, the 5% limitation in Bayh-Dole has become an artifact contrary to the rest of federal technology policy.

An Unfair Impact on Small GOCO Laboratories

The purpose of the extensive attention that both Congress and the Executive Branch paid to invention ownership in the 1980's was to foster innovation by providing incentives to federal contractors. As the legislative history recounted here indicates, the trend consistently has been to increase the scope of contractor rights—including GOCO contractors' rights—to retain ownership of inventions. A single important invention at a small laboratory rapidly can result in royalties that exceed the 5% budget limitation. For small laboratories, this means an atrophied incentive for innovation. This is certainly inconsistent with the purpose of Bayh-Dole and executive policy statements.

When measured by budget, Ames Laboratory is one of the smallest of the GOCO laboratories. Its annual budget ranges from approximately $26 million to $34 million per year, in comparison to the $505 million average budget of other nonprofit Department of Energy laboratories.[16] Yet, Ames Laboratory led all other GOCO laboratories in royalty income for FY2006 (please see Appendix 1).

Beginning in fiscal year 2006, ISU returned $921,400 to the Department of Energy to be returned to the U.S. Treasury, the first time (as far as we can determine based on public data bases) that any laboratory has been required to return money to the Treasury as a direct result of successful technology transfer. With licensing income received during fiscal year 2007, ISU will return approximately the same once again. Furthermore, ISU anticipates the worldwide success of the Ames Laboratory lead-free solder technology alone likely will obligate us to return a sizeable percentage of royalty stream to the Treasury for the foreseeable future.

To bring home the inequitable impact of this technical limitation on small, successful, federally funded research centers, let me point out that Ames Laboratory's partner in the development of lead-free solder—Sandia National Laboratory— has not had to return any of their royalty stream to the government. This is precisely because Sandia has a much larger budget - $2.27 billion – than does Ames (please see Appendix 2, Table 2). In this successful partnership, then, is a case illustration of our contention that the 5% royalty cap functions as a discriminatory penalty or a tax, in effect, on small and successful, nonprofit laboratories. Surely, this was not – and is not – Congress' intent.

Proposed Change to Legislation

As we have discussed our dilemma with friends and colleagues, some have asked what we believe would be the better limitation on the percentage of royalty income retained by contractors that manage federal laboratories. Some have asked whether we believe the limitation on retaining royalties should be jettisoned entirely.

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[15] Executive Order 12,591, 3 C.F.R. 220. *See* Section 1(b)(4).
[16] See Appendix 2 for a listing of the non-profit Department of Energy Laboratory budgets.

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Madam and sirs, I do not feel it is appropriate for me to suggest whether Congress's should seek to recoup some portion of the income stream generated by federal investments in research and development. Given the lack of readily available, public information on the royalty income of all federal laboratories, I am hesitant too to argue that I know what the right limitation – if a limitation is retained in future legislation – should be.

What I am comfortable stating, unequivocally, is that any such limitation must not discriminate against only a portion of government-owned, contractor-operated, non-profit entities, to whit, small non-profits. Certainly, it should not have an inequitable impact on a single, small, and successful national laboratory. And I am comfortable asserting that any limitation on royalty income should not have an effect that is contrary to the very intention of the founding legislation this subsequent statutory restriction modified. That limitation should not have the effect of setting a bar above which success – which always has a price, in terms of human and organizational resources – is counterproductive.

Accordingly, I propose for your consideration that the royalty limitation be increased to 15% of the annual budget for GOCO contractors with annual budgets of less than $40 million. If the Committee, in its wisdom, feels those exact numbers are not the right ones – but accepts our basic argument and request for relief – we will be immensely gratified.

Thank you for your attention and for your leadership in Congress.

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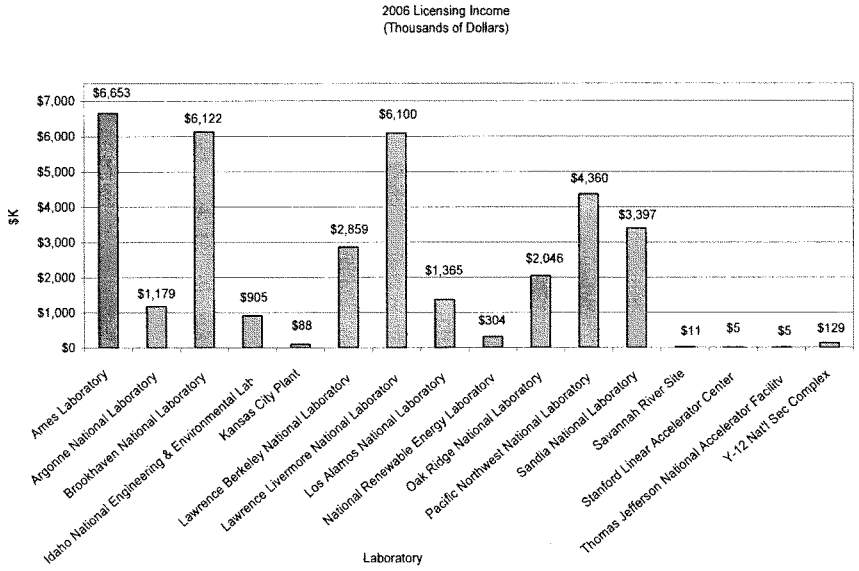
APPENDIX 1:

Royalty Income from Department of Energy Laboratories



Source: Laboratory data supplied for 2006 DOE Annual Technology Transfer Report.

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APPENDIX 2: TABLE 1
Federally Funded Research and Development Centers (FFRDCs) Operated by Universities or Other Nonprofits (Sorted by FY06 Budget)

All Dollars are in $M

Department/FFRDC (FFRDCs in yellow have technology transfer offices/licensing and <= $40M budgets)	**Contractor (Universities or Nonprofit)**	**FY06 Budget**	**Tech Transfer Activity[15]**
NASA/Jet Propulsion Laboratory	California Institute of Technology	$1,744[1]	Y
DOE/Lawrence Livermore National Laboratory	Univ. of California	$1,600[2]	Y
DOE/Oak Ridge National Laboratory	UT-Battelle, LLC	$814.9[3]	Y
DOD/Aerospace FFRDC	The Aerospace Corp.	$659[4]	Y
DOD/Software Engineering Institute	Carnegie Mellon Univ.	$442.9[7]	Y
DOE/Brookhaven National Laboratory	Brookhaven Science Associates, Inc.	$414.6[5]	Y
DOE/Ernest Orlando Lawrence Berkeley National Laboratory	Univ. of California	$400.8[6]	Y
DOE/Argonne National Laboratory	Univ. Chicago Argonne, LLC	$358.9[7]	Y
DOE/Pacific Northwest National Laboratory	Battelle Memorial Institute	$344.3[8]	Y
DOE/Fermi National Accelerator Laboratory	Universities Research Association, Inc.	$331.6[9]	Y
DOE/Stanford Linear Accelerator Center	Leland Stanford Jr., University	$315.3[10]	Y
DOD/C3I FFRDC	MITRE Corp.	272.4[11]	Y
DOE/National Renewable Energy Laboratory	Midwest Research Institute; Battelle Memorial Institute; Bechtel National, Inc.	$209.3[12]	Y
DOD/Lincoln Laboratory	MIT	$92.8[1]	Y
NSF/National Center for Atmospheric Research	University Corporation for Atmospheric Research	$83.36[13]	N
DOE/Thomas Jefferson National Accelerator Facility	Jefferson Science Associates, LLC	$81.7[14]	Y

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Department/FFRDC (FFRDCs in yellow have technology transfer offices/licensing and <= $40M budgets)	**Contractor (Universities or Nonprofit)**	**FY06 Budget**	**Tech Transfer Activity**[15]
DOD/Center for Naval Analyses	CNA Corp	$78.4[1]	N
DOE/Princeton Plasma Physics Laboratory	Princeton University	$75.3[2]	Y
DOD/Institute for Defense Analyses Studies and Analyses FFRDC	Institute for Defense Analyses	$51.1[11]	
DOD/Arroyo Center	RAND Corp.	$51.1[1]	Y
NSF/National Radio Astronomy Observatory	Associated Universities, Inc.	$50.7[5]	N
NSF/National Optical Astronomy Observatories	Assoc. of Universities for Research in Astronomy, Inc.	$36.9[5]	N
DOD/Project Air Force	RAND Corp.	$33.1[8]	N
DOD/National Defense Research Institute	RAND Corp	$31.9[9]	N
DOE/Ames Laboratory	Iowa State University, Ames, IA	$25.8[2]	Y
NSF/National Astronomy and Ionosphere Center	Cornell University	$12.16[5]	N
NRC/Center for Nuclear Waste Regulatory Analyses	Southwest Research Institute, Rockville, MD	$11.9[1]	Y
DHS/Homeland Security Institute	Analytic Services, Inc.	$8.7[6]	N
Treasury/Internal Revenue Service (IRS) FFRDC	Center for Enterprise Modernization, MITRE Corp., McLean, VA	$5.3[10]	Y
NSF/Science and Technology Policy Institute	Institute for Defense Analyses	$4.28[5]	N
DOT/Center for Advanced Aviation System Development	MITRE Corp., McLean, VA	$1.8[1]	Y
DOD/Institute for Defense Analyses Communications and Computing (NSA)	Institute for Defense Analyses	np	N
DHS/National Biodefense Analysis & Countermeasures Center (New in 2007)	Battelle National Biodefense Institute	np[14]	Y

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Footnotes:

1. NSF, Federal Funds for Research and Development: FY 2004-2006, Preliminary federal obligations FY 06.
2. USDOE Office of Science, Laboratory Plans FY 2008-2012, Total DOE Funding FY 2006
3. Lawrence Livermore Annual Report 2006, Lawrence Livermore National Laboratory
4. Reported by Chris Powers, Golden Field Office Public Liaison, Rocky Mountain News, February 6, 2007
5. NSF FY2007 Budget Request to Congress, National Science Foundation, FY 2006 funding.
6. For 2006, this is the sum of the 6 largest (of at least 12) contracts between the Department of Homeland Security and ANSER (which manages the HSI FFRDC). See OMB Watch, fedspending.org, under procurement instrument W81XWH04D0011
7. 2006 Annual Report: Intellectual Capital Shaping the Future of Software Engineering, Software Engineering Institute, Carnegie Mellon University.
8. DTIC, February 2007, RTD&E Budget Item Justification, RAND Project Air Force.
9. For 2006, this is the sum of the 6 largest (of at least 13) contracts between the Department of Defense and RAND (which manages the NDRI FFRDC). See OMB Watch, fedspending.org, under procurement instrument W74V8H06C0002.
10. For 2006, this is the sum of the 10 largest (of at least 34) contracts between the Department of Treasury/Internal Revenue Service and MITRE (which manages the CEM FFRDC). See OMB Watch, fedspending.org, under procurement instrument TIRNO99D000050 (134, 142, 144, 157, ...).
11. For 2006, this is the sum of 9 contracts between the Department of Defense and the Institute for Defense Analyses (which manages the IDASA FFRDC). See OMB Watch, fedspending.org, under procurement instrument W74V8H05C0042.
12. For 2006, this is the sum of 8 contracts between the Air Force Space and Missile Systems Center and the Aerospace Corp. (which manages the Aerospace FFRDC). See OMB Watch, fedspending.org, under procurement instrument FA880204C0001.
13. For 2006, this is the sum of the 15 largest contracts (of the 61 total contracts that year) between the Air Electronic Systems Center and MITRE Corp. (which manages the C^3I FFRDC). See OMB Watch, fedspending.org, under procurement instrument FA872106C0001.
14. The Department of Homeland Security established this new FFRDC on December 20, 2006.
15. "Yes" is indicated if they are a Member of the Federal Laboratory Consortium, or if they had technology transfer/licensing activity listed on their website.

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APPENDIX 2: TABLE 2
FFRDCs Operated by Industrial Firms (Sorted by FY06 Budget).

All Dollars are in $M

Department/FFRDC	**Contractor**	**FY06 Budget**	**Tech Transfer Activity**[5]
DHHS/National Cancer Institute at Frederick	Science Applications International Corp.; Charles River Laboratories Inc.; Data Management Services Inc.; Wilson Information Services Inc.	4,747[1]	Y
DOE/Sandia National Laboratories	Sandia Corp., Lockheed Martin Corp.	2,270[2]	Y
DOE/Idaho National Laboratory	Battelle Energy Alliance LLC	1,227[3]	Y
DOE/Savannah River National Laboratory	Westinghouse Savannah River Co.	140[4]	Y

Footnotes:
1. National Cancer Institute 2006 Fact Book.
2. Sandia National Laboratory 2007 Annual Report.
3. Idaho National Laboratory Impacts 2006,
4. Savannah River National Laboratory Factsheets, Overview, May, 2007. http://srnl.doe.gov/facts/srnl-over-may07.pdf
5. "Yes" is indicated if they are a Member of the Federal Laboratory Consortium, or if they had technology transfer/licensing activity listed on their website.

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Statement of Senator Patrick Leahy,
Chairman, Senate Judiciary Committee
Hearing on "The Role of Federally-Funded University Research
in the Patent System"
October 24, 2007

Universities conduct much of the research that advances our understanding of the world around us; since the passage of the Bayh-Dole Act in 1980, they have played an increasingly important role in the patent system and commercializing innovation.

Under Bayh-Dole, universities may take title to inventions developed with federal funds, and they can retain all the profits from licensing those inventions, without reimbursing the Government. There is one exception to this rule: when the university's work is being done in a facility that is actually owned by the federal government, the university must return a portion of the royalties from the invention, when those royalties exceed 5 percent of the facility's budget.

Iowa State University operates such a federal facility, Ames Laboratory. Through its ingenuity and successful commercialization, Ames Laboratory last year exceeded the 5 percent royalty mark and, as a result, repaid the taxpayers nearly $1 million, becoming the first such facility to do so. At the close of the last Congress, the House had hoped to raise the threshold to 15 percent, so that Iowa State would not have had to make any reimbursement. The bill was introduced on December 8th and passed December 9th. I said at the time that regardless of whether the most appropriate threshold is 5 percent or 15 percent, we should not be changing the law at the 11th hour without process.

Process is important; it illuminates and clarifies the implications of a substantive change in the law as it currently stands. This hearing will provide such process, and also gives the Committee a long-overdue opportunity to begin an examination of the successes, as well as any shortcomings, of the tech transfer provisions of Bayh-Dole in general.

American research universities are the envy of the world. Patented inventions developed at universities with federal dollars have created businesses and jobs, and boosted local economies. Perhaps most importantly, medicines developed based on this research have saved lives. Federal taxpayers fund more than 60 percent of research at universities, however, and it is proper to ask whether the taxpayer is receiving an adequate return.

At the end of the 109th Congress, I introduced the Public Research in the Public Interest Act to ensure that medical product innovations created with federal funds were available in developing countries at the lowest possible cost. I anticipate that legislation, and this hearing, will spark a responsible debate in this Congress about the rights that taxpayers should retain in inventions for which they act as venture capitalists.

I look forward to the testimony of our witnesses today.

# # # # #

43657.084

Congress of the United States
House of Representatives
Washington, DC 20515

October 23, 2007

The Honorable Patrick Leahy
Chairman
Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Arlen Specter
Ranking Member
Senate Committee on the Judiciary
152 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Leahy & Ranking Member Specter:

It is my understanding that on October 24, 2007, the United States Senate Committee on the Judiciary will conduct a hearing titled: "The Role of Federally-Funded University Research in the Patent System." I write today to express my strong support for increasing the limitation on the percentage of patent royalty income retained by small government-owned, contractor-operated facilities and their affiliated universities and non-profit organizations.

As you know, current law permits these contractors to retain royalty revenues up to 5 percent of the annual budget of the facility earned during a fiscal year. Unfortunately, this restriction on royalty retention can have an unbalanced and unfair impact on small laboratories, precisely because the cap is defined as a percentage of their operating budget.

During the 109th Congress, on December 8, 2006, the United States House of Representatives overwhelmingly approved with bipartisan support H.R. 6427. This legislation sought to amend the Bayh-Dole Act of 1980 to raise, from 5 percent to 15 percent of an annual budget, the percentage of patent royalties collected by small government-owned, contractor-operated facilities with annual budgets of $40 million or less. Enacting this modest adjustment is needed to infuse a larger investment into research and other educational activities that will have a positive impact on the day-to-day operations of these facilities. In my opinion, providing a slight increase in the ceiling to 15 percent will remedy an unintended and inequitable effect of current restrictions on small budget facilities. It also will ensure smaller contracts have the necessary funding to continue their successful pursuit of revolutionary inventions that benefit all Americans.

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Finally, I have included a copy of the Congressional Record for the House on December 8, 2006. In it you will find additional support for this modification articulated by members of the U.S. House of Representatives, including House Judiciary Chairman John Conyers.

Thank you for your consideration of this matter. Please feel free to contact me at your convenience for any reason regarding this matter.

Sincerely,

Tom Latham
Member of Congress

Enclosure

43657.086

Testimony of

Dr. Charles F. Louis

Vice Chancellor for Research

University of California, Riverside

Riverside, CA

Before the

United States Senate Committee on the Judiciary

Full Committee Hearing

On

"The Role of Federally Funded University Research in the Patent System"

226 Dirksen Senate Office Building

October 24, 2007

Introduction

Good afternoon, Chairman Leahy, Ranking Member Specter, Senator Feinstein from my home state, and Committee members. Thank you for the opportunity to appear before you today to address the very important issue of the "Role of Federally Funded University Research in the Patent System." First, I should introduce myself and my institution. My name is Charles Louis and I serve as the Vice Chancellor for Research at the University of California at Riverside (UC Riverside). I also hold a concurrent faculty appointment of Professor of Cell Biology and Neuroscience.

After a long career as an academic scientist, most of this being spent in the United States, may I first profoundly thank the U.S. Congress for the sustained support you have provided by ensuring the allocation of federal funding for the support of basic research in our nation's universities – which has contributed to the release of new products into the economy, creation of new jobs, and regional economy of cities across the nation. The benefits of this federal funding are well recognized by our economic competitors around the world who hold the U.S. system of federal research support as a model, and I strongly encourage you to continue supporting this worthy and vital cornerstone of our U.S. economy that is the subject of today's hearings.

As Vice Chancellor for Research, I am responsible for advancing the research mission of the university that includes significant responsibilities as the Institutional Official managing Sponsored Programs, Research Integrity and Compliance, and the Office of Technology Commercialization, which oversees patenting and technology commercialization efforts for the Riverside campus. I also have oversight of campus research centers and institutes as well as the support and administration of new interdisciplinary and federal initiatives by UC Riverside. Currently, I am helping to oversee the planning for a new medical school to be housed at UC Riverside.

I maintain an active role as a researcher with over 25 years of continuous NIH funding that has allowed me to train a large group of graduate students and postdoctoral fellows. My research on muscle and the lens of the eye has brought new understanding as to how altered regulation of intracellular calcium concentration results in significant diseases of the heart and skeletal muscle, as well as lens cataract formation. As a user of the patent system, I am an inventor of a patent with colleagues at the University of Iowa and University of Minnesota entitled "Diagnosing Malignant Hyperthermia Susceptibility by Detection of Abnormal Proteolytic Enzyme Digestion Fragments of the Ryanodine Receptor."

Staying abreast of national issues, I serve as a member of the Board of Council of Research Policy and Graduate Education of the National Association of State Universities and Land Grant Colleges (NASULGC) and remain active in the Association of University Technology Managers (AUTM). Prior to joining UC Riverside in 2004, I served as Vice President for Research at Georgia State University and previously held faculty and/or administrative appointments at the University of Minnesota, University of Connecticut Health Center and Leeds University in England.

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I would also like to thank the U.S. Senate and this Committee in particular for its hard work in passing the Bayh-Dole Act almost 30 years ago, which first allowed universities to take title in federally-funded inventions and translate them into good and useful products for the public. It is a privilege to be able to thank so many of the original sponsors of this law in person, including yourself, Mr. Chairman.

UC particularly appreciates passage by the House of Representatives last year of a Sense of the Congress to honor the 25th Anniversary of the Bayh-Dole Act (H.Con. Res 319, 109th Congress). This resolution was an important recognition by Congress of the "successful and substantial contributions" of the Bayh-Dole Act. The House Resolution importantly notes that "the Bayh-Dole Act fundamentally changed the Federal Government's patent policies by enabling inventors or their employers to retain patent rights in inventions through the commitment of the risk capital necessary to develop such inventions to the point of commercial application."

According to the Economist (Dec. 12, 2002), the Bayh-Dole Act is "perhaps the most inspired piece of legislation to be enacted in America over the past half-century." The piece goes on to state that "[m]ore than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance." Senator Leahy, you accurately reflected the importance of the Bayh-Dole Act during the consideration of the CREATE Act in 2004, when you stated:

> In 1980, Congress passed the Bayh-Dole Act, which encouraged private entities and not-for-profits such as universities to form collaborative partnerships that aid innovation. It worked, and as a result the Bayh-Dole Act has contributed billions of dollars to the United States economy and has produced hundreds of thousands of jobs.

A university's ability to ensure that its federally-funded technologies are successfully translated into useable products is predicated on having a strong, reliable and predictable patent system and laws like Bayh-Dole that encourage industrial partners and private equity funding sources to invest resources and commit to moving a laboratory-based discovery through the arduous and often risky development and commercialization process, and the Senate's commitment to that system is greatly appreciated.

Universities Use Federally-Funded Research to Develop Ideas That Have the Potential to Become Useful Products

The University of California ("UC") is comprised of ten campuses, including five medical schools, and participates in the management of three national laboratories, with over 170,000 faculty and staff and serving 200,000 undergraduate and graduate students. Over 17,000 students are enrolled at UC Riverside. In fiscal year 2006, investment by the federal government in basic research at UC was over $2.6 billion dollars, and at UC Riverside alone totaled over $52 million dollars. Through this federal investment, UC Riverside is conducting leading edge research in areas that include nanotechnology, genomics and gene silencing, invasive species and

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vector borne disease, ecology and sustainability, environment and energy, bioengineering, and biomedicine that will significantly increase with the new medical school plan for the campus.

The University's many scientists and engineers conduct basic and applied research, collaborate with other research partners, publish important research results that build on the nation's scientific knowledge base, and educate and train students at all levels. In the process, we also make discoveries that may be patentable and have the potential to be developed into products that will ultimately benefit the general public. Our innovations in those areas have resulted in UC being awarded the highest number of patents by any American university for the last twelve years.

UC Riverside, as part of the country's larger academic community, contributes to what is ultimately one of the primary forces of economic development for our nation: our institutions of higher education and research. Federal investment in basic research conducted by our nation's universities has a payoff not only in the creation of new knowledge, but in the form of a highly skilled workforce, the creation of jobs, economic growth, enhancement of the tax base, the introduction of new products that can be used by the public, and technological advancement. The United States and its universities are the envy of the world in terms of the grand scale of potential and advancement that are made possible by the commitment of the federal government to funding basic research at U.S. universities.

The innovations that stem from university research reach beyond the borders of individual states and the U.S. to affect the lives of humanity around the globe. By way of example, UC Berkeley is collaborating with a for-profit company and a non-profit pharmaceutical organization on an affordable malaria drug with the goal of reducing the price tenfold.

At the Riverside campus, with federal support through the USAID-sponsored Collaborative Research Support Program, and now support from the Consultative Group for International Agriculture Research Generation Challenge Program, Dr. Jeff Ehlers is investigating the breeding of cowpea varieties with improved drought tolerance and resistance to pests as part of a consortium of U.S. and African scientists developing new varieties of tropical legumes. Cowpea is the most important grain legume and hay crop in Africa, widely cultivated across semi-arid, drought-prone regions of this continent. However, drought and pest attack take their toll on production, so that cowpea yields in Africa are less than one third of their potential. UC Riverside researchers are developing and applying genomic technology to develop new and improve cowpea cultivars that have tolerance to drought and improved resistance to pests and diseases coupled with superior yield potential and yield stability.

The Need for University Technology Transfer

Universities across the nation perform the vast majority of the basic research funded by the U.S. Government. Public support of basic research funding has been critical to our nation's prosperity and has driven economic growth. The basic research and development conducted at universities is often at the leading edge of the country's technological advancement. In fact, it is

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generally much further upstream than the commercial sector is willing or able to conduct its activities. Yet the basic research conducted by universities with financial assistance from the federal government has led to some of the most important discoveries and patents of our lifetime: whether life-saving medical devices or revolutionary scientific insights or innovative agricultural products, the partnership between universities and the federal government has played a vital role in significantly improving the quality of lives in the U.S. and throughout the world.

The primary objective of basic research is the creation of new knowledge, but in the conduct of such research, discoveries occasionally are made that have more practical potential, such as a molecule that shows unusual promise for the diagnosis or treatment of a disease, or a gene that makes a plant immune to particular pathogens without use of chemical pesticides. The process of university technology transfer, as set forth in the groundbreaking Bayh-Dole Act of 1980, has set forth an efficient and effective system of university patent ownership to ensure that federally-funded discoveries can be developed in partnership between universities and private industry for the public's benefit.

The Bayh-Dole Act: Translating Federally-Funded Research into a Tangible Public Benefit

A Historical Perspective on University Technology Transfer

Prior to passage of the Bayh-Dole Act in 1980, later updated in 1984, the process of university technology transfer was difficult, if not impossible, for federally-funded inventions.

The idea of university technology transfer can be said to have originated in 1945, with prominent American scientist Vannevar Bush's report to President Truman, entitled "Science: The Endless Frontier," which became the genesis of the creation of institutions like the National Science Foundation and the National Institutes of Health.

In his report, Bush drew on his involvement in the Manhattan Project in recognizing the crucial nature of university research in national defense and urged the government to increase its support of basic academic scientific research as a result. Bush believed this type of federal support would be invaluable in creating a pipeline for these cutting-edge ideas to be transmitted to the private sector for development in order to facilitate the national interest.

Accordingly, throughout the 1950s and 60s, increasing amounts of research money began to be directed towards universities and academic research centers. However, the government had not yet adopted any type of uniform patent policy concerning the ownership of such inventions or the considerations to be weighed in determining how best to develop these ideas into commercial products – instead, each individual agency promulgated its own policies and guidelines. Thus, universities seeking industry partners to assist them in the development and commercialization of their government-funded research were faced with reconciling up to 26 different agency policies before being able to proceed. As a result, only a handful of universities had any structured technology transfer programs in place. And very few of the federally-funded patents, less than

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5% in 1980, were ever licensed for development, in part due to the government's practice of issuing only non-exclusive licenses which did not provide an incentive for a company to risk investing in commercializing a technology if its competitors could reap the benefits of its development efforts.

The government recognized that this situation was not ideal. In 1963, President Kennedy issued a Policy Statement that a more uniform governmental patent policy was urgently needed. Almost 10 years later, in 1971, President Nixon issued a revised Statement of Government Patent Policy. This Statement of Governmental Patent Policy acknowledged the value of patenting and the need to facilitate the transfer of patent rights to the private sector to further the commercial development of these products, while also balancing the interests of the public in ensuring that marketplace competition was not stifled. This led to the establishment of Institutional Patent Agreements (IPA) that a couple of the federal agencies were willing to establish and allow individual universities to own the inventions funded by that agency. The certainty of title in the university provided the impetus for universities to engage in technology transfer.

The Bayh-Dole Act Allowed Universities to Take Title to Federally-Funded Inventions in Exchange for Diligent Development

In 1980, this new policy was codified into law, under the leadership of former Senators Birch Bayh (D-IN) and Robert Dole (R-KS), as the Bayh-Dole Act. The Bayh-Dole Act established a consistent and uniform policy across agencies, allowing universities to elect to retain title in inventions created by their researchers in the course of federally-funded research, on the condition that the universities diligently work with private industry to ensure that the technology is developed in a timely and beneficial manner.

Codification of this approach appropriately shifted development of the technology from distant federal agencies with little knowledge about the applicability of the invention, to the local university which possessed the most knowledge about the mechanisms of the technology and could more effectively determine what inventions to patent or not. Universities were able to maintain control over the development of their technology, harness their understanding of the science in question to ensure the most beneficial development of their inventions, and work with local industry to stimulate the regional economy.

The policy and objective of the Bayh-Dole Act remains applicable today as when the Act first passed – using patent law to:

> promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that

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the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.

The Bayh-Dole Act requires universities to give preferences to small businesses and to ensure that federally-funded inventions are manufactured in the United States. This provision have encouraged formation of start up companies and investment by local industries in university research and allowed the U.S. economy to harness the benefits of academic research.

The Bayh-Dole Act also includes several safeguards against abuse, which reflects the government's concern for a flexible policy that nonetheless balances the interests of the public with the economic interests of private industry,. For instance, universities are mandated to require their licensees make diligent progress towards commercial development, the revenue generated by university licensing must be dedicated to supporting additional science and educational research after deduction of an inventor share and recovery of costs, and the government retains the right to practice the invention by or on behalf of the government. The government also retains, under specific circumstances, the right to "march in" if the university or its licensee has not been effective in commercializing the invention in a timely manner. These safeguards, coupled with university self-generated initiatives and policies to promote technology transfer in the public interest, ensure that the balance between the public good and private initiative is carefully maintained.

Academia-Industry Partnerships Can Translate Federally-Funded Research into Useful Products to Benefit the Public

While U.S. universities have a mission of conducting cutting-edge research and furthering human knowledge, and perform that job exceedingly well with the generous assistance of the federal government, they are neither positioned nor equipped to develop their discoveries into viable commercial products that can be used by the general public. Nor is doing so consistent with their overarching mission of research and education. Universities were thus faced with a problem – how would they translate their federally-funded discoveries into a tangible public benefit?

The Bayh-Dole Act anticipated this issue, and encouraged an innovative solution: it created the possibility of university partnerships with private industry to develop federally-funded inventions for the general marketplace.

Bayh-Dole thus allowed the academic community to rely on industry to do what industry does best: commercial development of a technology into a viable product, scale-up and production of that product, and ultimately commercial sales making the product available to the public. Without this industry participation, the public may never see the product of laboratory research.

However, it is not enough simply to offer the technology to private industry without some corresponding exchange of rights by the university. Because university technologies are

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inherently embryonic and early stage, the process of commercialization is not at all a sure thing and carries a high level of risk. Industry may not recognize the commercial value of an early stage invention, unresolvable technical difficulties may arise during the development process that would affect the technology's viability, or venture capital financing may not be available. Further, when a company does step up to the challenge, it must invest a tremendous amount of its own resources and take on the risk that the commercial development may not pan out.

Thus, universities offer limited licenses to private companies in exchange for their acceptance of the risk inherent in developing early-stage technology. In exchange for a company's investment, the university provides the company with the benefit of rights under a patent with the hope that the technology can be successfully commercialized. Through a license to the underlying patent, a company is given the economic incentive of a competitive advantage to offset the risk it must take in such early-stage investment, and is encouraged to develop and commercialize a product in a timely manner and distribute it as widely as possible, in order to recoup their investments and reap the benefits of the limited patent monopoly. Universities have found that this has been an ideal way to encourage the commercialization of its inventions and induce investment in their licenses, in large part because of the benefits offered by a strong and predictable U.S. patent system in the U.S. If companies are not assured of the strength of the patent and the predictability of the patent system, it is unlikely that they would license university technology and invest in a risky development and commercialization effort. If that occurs, then the public may never see the commercialized product.

Inventions Made Possible By University Technology Transfer

After the passage of Bayh-Dole, university technology transfer skyrocketed. Now, over 230 universities have technology transfer offices, and the UC is proud to have one of the top technology transfer offices in the world, as recognized in the recent Milken Institute Report, "Mind to Market: A Global Analysis of University Biotechnology Transfer and Commercialization."

UC manages over 7,500 active inventions in its current portfolio. Eighty percent of those inventions have generated interest in either the private or public sector. Of those interest-generating inventions, over 50% have resulted in a financial investment in the development of a product. As of FY 2003, over 700 products have been developed from UC discoveries, which have benefited the U.S. economy and have had a positive profound effect on the quality of human lives. Examples of some of UC's important inventions include:

- A vaccination for the potentially-fatal Hepatitis B disease (UCSF);
- The Cohen-Boyer recombinant DNA patent held jointly by UC and Stanford University that helped to spawn the development of the biotechnology industry (UCSF);
- Phosphite fertilizer that has superior qualities for plant growth (UC Riverside);
- Lung treatments for respiratory problems associated with premature births (UCSF);
- A laser/water Atomic Force Microscope that helps scientists to better view and analyze different properties of matter at the nanoscale (UC Santa Barbara);

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- A diagnostic method for detecting feline AIDS (UC Davis);
- The minimally invasive Guglielmi Detachable Coil used to treat brain aneurysms (UCLA);
- A plasma electric generator to create power without the use of fossil fuels (UCI);
- The Cochlear Ear Implant to assist those with hearing loss (UCSF);
- Glucose monitoring techniques useful for diabetics (UCSF);
- Strawberry varieties that create an annual $1 billion-plus industry in California, provide quality fruit to consumers across the nation, and are grown throughout the world (UC Davis); and
- The Nicotine Patch that assists smoking cessation (UCLA), among many others.

Other universities throughout the nation have developed significant products that benefit society as well, such as:

- An anticoagulant that treats heart patients and prevents blood clotting (University of Wisconsin-Madison)
- The diagnosis and treatment of diseases of the blood (University of Vermont)
- An antimicrobial treatment for food (University of Arkansas)
- The Mouseopause™ mouse model to study postmenopausal conditions (University of Arizona)
- A treatment for rheumatoid arthritis (Massachusetts General Hospital)
- An ultrasonic method to determine beef quality (Kansas State University, Manhattan)
- A treatment to promote growth in premature babies (Columbia University)
- An under vehicle inspection robot for security uses (Utah State University)

According to data provided by the Association of University Technology Managers ("AUTM"), 4,338 new products were introduced between FY98 through FY06 as a result of university technology transfer efforts. Additional discoveries from academic institutions that benefit society are highlighted in a recent report from AUTM's "Better World Project," which is available at: http://www.betterworldproject.net/.

Bayh-Dole Has Also Nurtured Start-Up Businesses and the U.S. Economy Nationwide

Bayh-Dole also encourages universities to actively license federally-funded inventions to small businesses whenever possible. This has stimulated general university interest in their local community and promoting new companies and industries. According to AUTM data, 628 new spin-off companies based on university technology were created in 2005 and 554 in 2006 with 5,725 originated since 1980. UC takes this responsibility seriously -- UC ranked second only to MIT in the number of licenses entered into with new startup companies during 2003-2005, as reported by the AUTM U.S. Licensing Survey (http://www.autm.net/surveys/dsp.Detail.cfm?pid=194).

UC is proud to have contributed to the vibrant California entrepreneurial economy and believes that research results, thoughtfully and carefully distributed to private companies through

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technology transfer, has been a crucial element of California's economic success. As of March 2007, UC's licensed technologies can be linked to approximately 300 existing startup companies that are developing technology ranging from medical compounds and devices to electronics to biotechnology to semiconductors/nanotechnology. (See Figure 1.)

Over the past 20 years, on average over 80 percent of companies founded based on a license to UC technologies are still in operation, either as stand-alone entities or through a merger and acquisition. (See Figure 2.) This observation is not unique to UC, but common among university based startups. These resilient university-based startup companies create long-term jobs and lead to sustainable regional economies.

An example at UC Riverside, Dr. David Bocian has been performing research in creating electrically-addressable molecular-scale features that can function as the circuit elements in microelectronic devices like logic chips, processor chips, and memory chips. The invention of molecular-scale circuit elements will create electronic devices of greater density and smaller size that today are beyond the physical limits of semiconductor technology. The technology will lead to significant advances in memory capability, playing a key role in new generations of electronic devices, both large and small. UC Riverside has licensed this technology to a start-up company that Dr. Bocian has co-founded.

In addition, many universities through their educational mission nurture an entrepreneurial environment that stimulates the formation of local start up companies. A number of universities have programs to educate technology managers on entrepreneurship, as well as cross disciplinary programs that pair up these programs with the business school and technology transfer office through business plan competitions. Federally-funded research thus affects not only science research but other aspects of academia as well.

This type of innovation ecosystem, in which the universities, inventors, entrepreneurs and investors interact, has the potential to reinvent local economies. By way of example, such an innovation ecosystem helped the San Diego economy transition to one of the nation's leading high tech and biotechnology centers after the downsizing of the U.S. military presence there. Originally started at UC San Diego, CONNECT, a non-profit organization that is globally recognized as a public benefit organization in the San Diego region, played a key role in nurturing an entrepreneurial environment that helped the region to flourish.

In my neighborhood, Riverside County in Inland Southern California has the second fastest growing population of any U.S. county, and the goal for the City of Riverside is to grow its technology industries. Working in concert with a group of local high technology CEOs, "The CEO Forum", UC Riverside is promoting the growth of these new industries, some of which stem from the start-up companies resulting from the inventions that have derived from the federally sponsored research on our campus. For the University this is the true value of its investment in technology transfer, namely to facilitate and promote the success of these start ups – in partnership with the City and County of Riverside, and this devoted group of local high technology CEOs.

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The types of relationships and the stimulation of the regional economy exemplified by San Diego and Riverside are replicated throughout the State of California and the nation with many other universities. University research and licensing programs touch various aspects of the economy and it is extremely important that universities continue to play an instrumental role in supporting and growing the economy, creating jobs, encouraging American ingenuity and entrepreneurship, and continuing basic research and making discoveries that are transferable to companies that are able to translate them into useful products.

Policies Surrounding University Licensing Have Evolved for the Public Benefit

As the field of university technology transfer has developed, so have solutions to the policy-based concerns that many of the critics of Bayh-Dole has raised. For example, a number of universities with well-developed technology transfer practices, including Stanford University, the University of Wisconsin and Cornell University, recently collaborated on a white paper setting forth their policy aspirations for university licensing. This document, "In the Public Interest: Nine Points To Consider In Licensing University Technology" (available at: http://www.autm.net/aboutTT/Points_to_Consider.pdf) sets forth certain basic principles that university technology transfer offices may wish to consider in their licensing arrangements to further the university missions of research, education, and public service. These include not only the promotion of academic research and the diligent development of inventions by licensees, but also goals such as increasing access to medical technology for developing countries.

The university community takes very seriously its responsibilities in ensuring that federally-funded inventions are developed for the public benefit, and has continued to demonstrate its commitment to these principles as the field has grown. We discuss some of these concerns below, and explain how the university community has acted to address the situation.

Technology Transfer Does Not Impede Scientific Research

Concern that licensing necessary scientific tools would pose a possible impediment to scientific research has been addressed by policies and guidelines set forth by the NIH with input from the university community, that encourage universities to share any ensuing inventions freely among academic institutions for research purposes. This approach has now evolved into common practice such that university-developed research tools are made widely available. Studies have shown that technology transfer has had little to no effect on the ability of scientists to conduct research and publish their research results in peer-reviewed publications.

Exclusive Licensing of Technology Can Promote Innovation, If Carefully Administered

Others voice concern that the exclusive licensing of university inventions stifles competition. In many industries, the best way to induce private industry to invest the substantial time and resources in developing an early-stage invention is to provide the company with an exclusive license to the patent covering the technology. Particularly in heavily-regulated fields such as

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biotechnology and pharma, companies are unable to justify the large amounts of money and resources required to obtain FDA approval for a new drug unless they can be guaranteed some period of exclusivity if the drug is allowed, in order to recoup their costs and to protect their investment from opportunistic rival companies who might otherwise jump into the market only after someone else made the sizable monetary investment to develop the drug.

Thus, it can be that in certain circumstances, an exclusive license represents the best chance that the university has to transform the results of its federally-funded research into a product with a very real benefit to the public. The university community is sensitive to the issues that exclusive licensing can raise and makes decisions on whether to offer an exclusive license on a case-by-case basis and in light of all the circumstances around the development of the technology as some industries operate under the nonexclusive licensing business model. In addition, universities build in many safeguards into these exclusive licenses to ensure that the licensee is working diligently to develop products as Bayh-Dole requires, and monitor these licenses closely.

University Technology Transfer Is Not Primarily Profit-Driven

Finally, many outside observers make the erroneous assumption that technology licensing is primarily an income producer for universities. While UC has been fortunate to reinvest into research and education some licensing revenues from its technology transfer activities, the majority of institutions do not. However, universities recognize that technology transfer serves an important public benefit, irrespective of its effects (either positive or negative) on the university's bottom line, and recognize it as a necessary service to enhance the value of federal funding for its research.

Licensing revenues that universities receive from royalties derived from licensing federally-funded technologies, after appropriate payment is made to the inventors and recovery of expenses, is reinvested into basic research and educational services, to ensure that further research and technological advancement can continue to occur. This reinvestment of these proceeds reflects an additional benefit to the original federal funding and is consistent with the statutory mandates of Bayh-Dole.

Bayh-Dole: Looking Forward

The benefits of the Bayh-Dole Act have been enormous not only for universities and the U.S. economy, but for the general public as a whole. And yet, activities conducted under this important piece of legislation are currently facing challenges that have the potential to severely limit its continued positive impact on the public benefit and the nation's economy. In the view of the University of California, any efforts that would undermine the effectiveness and proven success of the Bayh-Dole Act would not be in the public's best interest.

The current challenges come in two primary forms. The first involves increasing the burden or the cost for universities to engage in the technology transfer process. The second include actions

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that would reduce the incentives for industry to invest in developing a university's early stage technologies.

Increasing the Cost or Burdens of Protecting Inventions Will Harm University Technology Transfer

Because of financial constraints, universities do not have the resources to file patents on everything that is discovered by their researchers and must pick and choose the ones with the potential to be commercialized. Financial constraints are an important consideration for universities in fostering technology transfer and meeting the objectives of the Bayh-Dole Act. Any shifts in the current system could make it harder for universities to afford to engage financially in technology transfer efforts and would serve to undermine the Bayh-Dole Act's effectiveness.

UC is concerned for example, that some of the proposals being considered in the current debate over patent reform legislation could, if enacted in their current form, make it more difficult and more costly for universities and others engaged in technological advancements to continue to effectively make use of the patent system, as provided by the Bayh-Dole Act, and to ensure that advancements made in research laboratories reach the public. In addition, any rules promulgated by the U.S. Patent and Trademark Office that make it more burdensome and expensive for universities to obtain patents on their inventions, such as the new claims and continuation rules, would be detrimental to university technology transfer.

The uncertainty that these changes to the patent system will create for a university's patents has the potential to negatively impact private industry's interest in investing in the technology developed at universities. If it becomes more costly for universities to file and maintain patents, fewer patents will certainly be filed, resulting in fewer technologies that make it into the hands of the public. And if it becomes too risky for private industry to invest in patents because patent rights have become less certain under the law, the public's ability to reap the benefits of the initial federal investment in these inventions will be further curtailed.

If anything, it would be best to consider ways to further the success of the Bayh-Dole Act, and to reinforce the positive public benefit that has resulted, rather than limiting its application or success.

Any Reduction in Incentives for Industry to Partner with Universities Will Harm University Technology Transfer

As discussed above, the process of technology transfer, to be successful, must include sufficient incentive for a company to invest the time and resources necessary to engage in the risky process of developing a product for market. Any legislative or regulatory actions that increase a company's risk or uncertainty, will reduce their incentive to invest in an university's inherently early stage technology. Such action would certainly undermine the current success of the Bayh-Dole Act.

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As an example, companies have expressed concern over the government's march-in rights. It was not clear how the government would exercise those rights, and there were companies that would not touch a federally funded invention, either through licensing or sponsored research. They were concerned that, after investing resources in commercial development of a technology, the government could step in and take it away. It was only years later, after it became clear that the government was not using its march-in right capriciously, that these companies were assured of an even-handed approach by the government for march-in rights and willing to take a chance on federally funded inventions.

Another impediment to industry participation in the technology transfer process is the imposition of pricing controls. When the NIH attempted to impose a reasonable pricing clause in its CRADAs in the mid-1990s, they noticed a chilling effect on their relations with industry as discussed in a July 2001 NIH report. Many companies viewed these terms as unacceptable and declined to collaborate with the NIH as a result as it is difficult to determine what is a reasonable price when early stage biomedical technologies are years and hundreds of millions of dollars from market launch and may be one innovation contributing to a new treatment. Ultimately, the NIH removed the reasonable pricing provision and since then has enjoyed a robust relationship with industry.

More currently, some of the changes that are being proposed to the patent system may serve to weaken patent protection, render it more difficult to enforce a patent if it is infringed, and reduce the certainty that the public currently has in a patent's validity. If patent protections are weakened, the incentives for industry to engage in technology transfer and for universities to participate in the patent system will likely be diminished, reducing the potential for public benefit that exists today.

Conclusion

The Bayh-Dole Act has shown itself to be a resounding success, benefiting the public through the availability of products and contributing to the U.S. economy. One of the beauties of the Bayh-Dole Act is that it lays a solid foundation for the success of technology transfer, including elements that ensure that the public interest is preserved, while at the same time providing recipients of federal funding with tremendous flexibility. Through this flexibility, we are able to address the unique needs of different industry sectors, we are able to adjust to the realities of small businesses and large companies, and we are able to adapt our practices to deal with emerging issues.

What is truly remarkable too is that these benefits have been realized and the Bayh-Dole Act has been administered without the necessity for Congress to appropriate any of the taxpayers' money for its operation. In other words, no separate appropriation of government funds was needed to establish or manage the effort. In fact, it has been estimated that the economic benefits flowing from the universities' licensing activities adds about $41 billion to the United States economy.

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It has been the University of California's experience that the current patent system and the involvement of universities in the patent system has worked extremely well to foster innovation and has led to numerous discoveries that have been brought forward for the public benefit. The Bayh-Dole Act was indeed an inspired piece of legislation, and we hope that Congress will continue to nurture its success.

Thank you again for giving me the opportunity to testify. I look forward to answering any questions you may have.

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Testimony of Dr. Charles F. Louis, UC Riverside
Senate Judiciary Committee Hearing
"The Role of Federally Funded University Research in the Patent System"
October 24, 2007

Figure 1

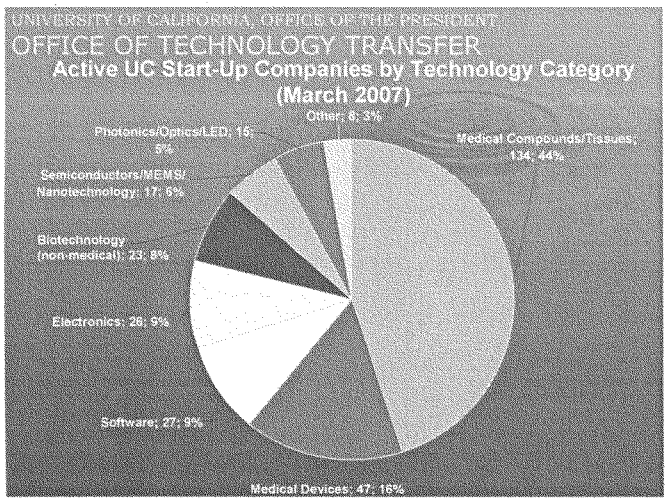
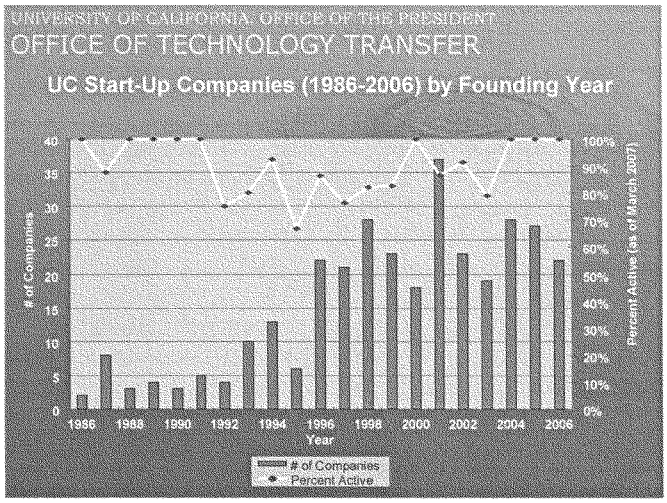


Figure 2



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Testimony of Arti K. Rai
Professor, Duke Law School

Committee on the Judiciary
United States Senate

"The Role of Federally-Funded University Research in the Patent System"

October 24, 2007

Introduction

Good afternoon Mr. Chairman and distinguished members of the committee. Thank you for the opportunity to speak on the subject of "The Role of Federally-Funded University Research in the Patent System."

I am Arti Rai, a law professor at Duke Law School and a faculty associate of the Duke Institute for Genome Sciences and Policy. For the last 10 years, I have conducted research on the interaction of federally funded research and the patent system. Currently, I am funded by the National Institutes of Health to examine intellectual property rights issues that arise in collaborative inter-university and public-private partnerships. I am also funded by the Kauffman Foundation to conduct research on technology transfer issues surrounding university-generated software. I have no consulting relationships with, and have accepted no money from, any for-profit entity.

Background on Federal Efforts in Technology Transfer

I understand that the immediate catalyst for the Committee's interest in federal technology transfer issues is the prospect of changes in the statutory provisions that govern patent royalties earned by government-owned, contractor-operated facilities (GOCOs). Under the existing provisions of the Bayh-Dole and Stevenson-Wydler Acts, GOCOs such as the Ames laboratory operated by Iowa State University must pay back to the U.S. Treasury a percentage of the royalties they earn on any patented invention. Specifically, they must pay back 75% of the net amount they earn in excess of 5% of their annual budget. Iowa State, and presumably most universities that operate government labs, would like the amount of the recoupment to be smaller.

In order to understand whether there should be "more" or "less" royalty recoupment, it is useful to understand the background of Bayh-Dole and Stevenson-Wydler. Both of these statutes aim to commercialize federally funded research through the use of patents. The theory is that if federally funded research is patented, then private

sector firms will have a powerful financial incentive to seek exclusive licenses to the research and commercialize it. (Rai & Eisenberg 2003; Rai 1999; Eisenberg 1996).

For certain types of inventions, this commercialization theory makes a lot of sense. Economic research indicates that patents on (for example) promising drugs are quite important for commercialization of such drugs. (Cohen et al. 2000). So if a university comes up with what looks like a promising drug, allowing a patent on that drug is probably necessary for commercialization. Outside of the life sciences, however, the importance of patents for commercialization is not as clear. In general, as recent debates over reform of the patent system have illustrated, patents may play a very different role in the life sciences than they do in other industries.

So commercialization through the "patent and exclusive license" model raises at least three questions. First, are all inventions best commercialized through this model? Or it is possible that one size does not fit all? Second, if one size does not fit all, who should make the decision about whether an approach based on patents and exclusive licenses is the way to go? Currently, Bayh-Dole gives a large amount of discretion to universities. Are universities well-placed to exercise that discretion in the public interest? And, third, in cases where patenting is the way to go, should some percentage of the patent licensing royalties earned by the university be paid back to the federal government?

I address each of these questions in turn.

Does One Size Fit All?

In 1980, when the Bayh-Dole and Stevenson-Wydler Acts were passed, the world of patents looked quite different than it does now. Many inventions that were patentable looked like a lot like drugs – in other words, they needed to be "scaled up" before they would be useful to anyone. Exclusive licenses to patents provide a powerful incentive to do this scaling up. Since that time, however, the scope of what can be patented has expanded a great deal. Software is now patentable. Biomedical inventions that look a lot more like scientific research tools than end product drugs are now patentable.

In the case of some of these patentable inventions, it's not entirely clear how important patents are for commercialization. Consider the case of software. Some scholars have argued have patents might help start-up software firms attract venture capital. (Mann 2005). But even these scholars note than only a minority of start-up software firms appear to have such patents. (Mann 2007). As for biomedical inventions that look like research tools – for example, embryonic stem cells, on which the University of Wisconsin has a broad patent – commercialization might be achieved through the lure of downstream patents on specific applications of these stem cells. (Rai & Eisenberg 2003).

Another argument that is sometimes made for an approach based on exclusive licenses to patents is that the prospect of sharing licensing royalties induces university

researchers to work with industry licensees and thereby transfer tacit knowledge necessary for commercialization. (Jensen and Thursby 2001). However, not all inventions involve tacit knowledge. In software, for example, development is often based on principles of modular design that require little tacit knowledge. Even outside software, absorptive capacity in industry can sometimes obviate the need for transfer of university-based tacit knowledge. In the biomedical arena, Columbia's DNA co-transformation technology was taken up by industry without an exclusive license. (Mowery et al. 2004).

In fact, there have been some recent prominent cases in which it appears that the university patent did not aid in technology transfer but instead simply allowed the university or its exclusive licensee to extract money from an entity that had already commercialized. In the recently settled case of *Eolas v. Microsoft*,[1] for example, Microsoft and various other firms did not need an exclusive license or tacit knowledge in order to commercialize the Web browser software that was the subject of the patent dispute. In this case, and others involving litigation over university software patents (Rai et al. 2007), commercialization by firms other than the university licensee was going forward, and patent rights/exclusive licenses were not necessary to facilitate "technology transfer." Rather, contrary to the spirit of Bayh-Dole, software patents in these cases primarily allowed universities to extract money from, and perhaps even to "hold up," ongoing development efforts.

Who Decides: Tweaking "Exceptional Circumstances" and March-In

Let us next move to the question of who should decide whether a federally funded invention is patented and how it should be licensed. The cases I have just discussed might suggest that the default option under the Bayh-Dole Act – giving universities broad discretion to determine when to patent and how to license – is a bad idea. But one never knows how representative litigated cases are. Universities may generally be doing a good job, with these litigated cases being the exception.

A more troubling indicator emerges from research demonstrating that the most important predictor of how many software patents a university acquires is not how much software-related research it is doing but simply how many *other patents* it has. (Rai et al. 2007). In other words, at least for patents that issued in the 1980s and 1990s (the period covered by the research), many universities with large patent operations were simply patenting a substantial percentage of whatever came in the door. They were very much using a "one size fits all" approach to their invention.

So it should come as no surprise that information technology firms are somewhat troubled by what universities are doing (Bohr 2006). These firms have argued that development opportunities and university-industry collaborations are likely to be spurred through fewer, not more, university assertions of patent rights (Johnson 2007; Thursby & Thursby 2006).

[1] Eolas Technologies Incorporated v. Microsoft Corp, 399 F.3d 1325 (Fed. Cir. 2005).

Even so, I would be reluctant to call for major changes in "who decides." In software, there is some reason to believe that universities are beginning to understand differences in technology and are using models other than the traditional ones that work for end-product biomedical inventions. (Rai et al. 2007). In the life sciences, there have been some individual cases that are troubling but not enough to merit a significant overhaul.

In terms of tweaking, it's worth studying two small changes. First, Bayh-Dole currently requires that federal agencies prove "exceptional circumstances" before they can declare that patenting is the wrong approach towards commercialization in a particular area of federally funded research. It's worth looking into whether such a high bar is necessary, particularly because it appears agencies sometimes ignore this requirement in any event. (Rai & Eisenberg 2003). Second, the so-called march-in provisions of Bayh-Dole, which allow compulsory licensing when a university patentee is not commercializing appropriately, might be worth examining. As matters currently stand, they have never been used. This may be in part because of the high procedural hurdles to their use. March-in rights can not take effect until after elaborate administrative proceedings, and subsequent court appeals, have been exhausted. (Rai & Eisenberg 2003).

At a minimum, march-in rights should not be weakened. Even though they have not been used, in some cases they appear to have served a valuable role as a threat that the government could use against a recalcitrant university patentee. (Eisenberg & Rai 2004).

Royalty Recoupment

The issue of royalty recoupment is an important and interesting one. The argument for royalty recoupment is straightforward – without recoupment, the public has to pay twice, once for the research itself and once again through the monopoly pricing that the patent affords. (Eisenberg 1996). Relatedly, one might argue that the federal government should get a return on its investment. In fact, California's recent $3 billion stem cell research initiative (Proposition 71) was promoted in part on the promise that the state would receive a large royalty stream from the licensing of technologies that emerged from the state-funded research. (Gilbert 2006)

There is little evidence, however, that the federal government would be likely to recoup significant sums from its investment in federally funded research. In fiscal years 2003 and 2004, U.S. universities had net licensing income that represented only 2.5% of their sponsored research expenditure. In FY 2004, for example, sponsored research expenditures were $37 billion while net licensing revenue was $925 million. (AUTM 2003; AUTM 2004).

In fact, there are good reasons to expect relatively low direct financial returns on the type of basic research the federal government typically funds. Economists have long noted that even though basic research generates significant economic dividends, these

dividends are too long term and diffuse for any single party to capture. Indeed, the argument for government support of basic research emerges from the insight that it is valuable economically but will not be generated by ordinary private sector financial incentives. (Arrow 1962).

Moreover, aggressive attempts to use patents to capture gains from basic research, whether by universities or by the government, may create obstacles to development and commercialization. I have already mentioned situations where universities appear to have used software patents to "hold up" commercializing firms. Additionally, particularly in the information technology industries, aggressive patenting may cause licenses to multiple university inventions to become necessary, with the result being significant transaction cost hurdles to development. (Shapiro 2000).

In the best case scenario, universities (and the government) might make some money through licensing royalties that operate as a modest tax on commercialization. The famous Cohen-Boyer patent on recombinant DNA, which made hundreds of millions for the universities involved, arguably operated in this fashion. (Eisenberg 1996). But even in that case, it is worth asking whether broad-based taxation of the income generated by the many firms that have been formed or have flourished based on public research might be a better way of recouping the public's investment.

Conclusion

In sum, there is little reason to believe we need a major overhaul of the current system of technology transfer. However, universities should be educated about the reality that one size does not fit all when it comes to technology transfer. Further, some tweaks in the "exceptional circumstances" and march-in provisions of Bayh-Dole are worth studying. Finally, given the early-stage nature of the research that the federal government funds, we should be cautious about viewing technology transfer as a mechanism for raising revenue.

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Attachment A – Rai Senate Testimony, Hearing on "The Role of Federally Funded Research in the Patent System"

ATTACHMENT A TO RAI SENATE TESTIMONY

University Software Ownership: Technology Transfer or Business as Usual?

Arti K. Rai, John Allison, Bhaven Sampat, and Colin Crossman

Working Paper

September 2007

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Attachment A – Rai Senate Testimony, Hearing on "The Role of Federally Funded Research in the Patent System"

1. INTRODUCTION

Software patents and university-owned patents represent two of the more controversial intellectual property developments of the past 25 years. Various scholars have quarreled with the breadth of software patent claims (Burk and Lemley 2003; Rai 2003). Some have also suggested that, given the allegedly poor quality of prior art documentation and patent examiner training in the area of software, many issued software patents are likely to be invalid (Lunney 2001). More generally, there is significant debate over the extent to which software patents are likely to foster innovation (Bessen and Hunt 2006). Because software products are often "complex" and may infringe many patents, some producers of end-product software are also unhappy. Large incumbent software firms like IBM and Microsoft have favored recent legislative and judicial efforts to make patents easier to challenge and injunctive relief, particularly by non-practicing patentees, more difficult to secure. The controversy over software patents has also been fueled by the rise, and arguable success, of the "open source" movement in software. Open source software developers eschew patents. Although they do rely on intellectual property in the form of copyright, they do so for purposes of enunciating licenses under which source code is made freely available.

In contrast with software patents, university patents have a long history. However, the scale of university patenting has increased substantially over the past 25 years, since the 1980 passage of the Bayh-Dole Act. While the legal question was sometimes murky prior to 1980, Bayh-Dole made it unequivocally clear that universities can patent federally funded research.

Assertive university patenting has attracted a fair amount of attention in both the scholarly and popular literature (Washburn 2005; Mowery et al. 2004). Some have gone so far as to suggest that universities may be patent "trolls" (Lemley 2006). The vast majority of analyses have focused, however, on patenting within the life sciences. (Azoulay et al. (2005); Murray and Stern (2005); Rai and Eisenberg (2003). This focus is hardly surprising, as the majority of university-owned patents (and the majority of large revenue generators) emerge from the life sciences (Rai and Eisenberg 2003; Mowery et al. 2004). Moreover, the major economic argument put forward in the legislative history of the Bayh-Dole Act – that patents on publicly funded invention promote commercialization of such invention – applies most clearly to life science areas like drug development. There, the conventional wisdom is that without the quasi-monopoly protection of a patent on the small molecule chemical, few firms would be interested in taking a potentially promising drug candidate through the expensive clinical trial and approval process.

In the case of publicly funded software, by contrast, the need for a patent and exclusive license to promote further development is less immediately apparent.[1] Although development costs are not uniformly low, they are likely to be low relative to those in the biopharmaceutical industry. Indeed, in certain cases of open source software development, firms derive revenue not from property rights over the software product itself but from a strategy that monetizes the value of support services and complementary hardware (Bonaccorsi and Rossi 2003).

Some recent events have suggested, however, that universities (or at least their exclusive licensees)[2] might in fact be interested in strong assertions of proprietary rights over software. In 2004, a district court upheld a $520.6 million jury verdict in a patent infringement suit against Microsoft brought by the

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[1] Even in the life sciences, the availability of patents on improvements as well as the presence of absorptive capacity in commercial firms may diminish the need for exclusive licensing. Mowery et al. (2004, 158) discusses the manner in which Columbia's DNA co-transformation technology was developed commercially without the need for exclusive licensing.

[2] University technology transfer officials argue that exclusive licensees generally initiate the lawsuits and that universities are brought along reluctantly. E-mail Communication from Rick Brandon, University of Michigan Office of Technology Transfer, 11/21/2006

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University of California and its exclusive licensee, Eolas Technologies.[3] The software patent in question essentially covers interactive web browsing. Eolas, a one-person startup run by one of the University of California professors listed as an inventor on the patent, filed suit on the patent on February 2, 1999, three months after it issued. And the UC/Eolas lawsuit is not unique. In a number of cases, universities and/or their exclusive licensees have sued firms (often, large incumbent firms) that commercialized the academic invention without the need for exclusivity. (Rai et al. 2007) An IBM vice-president was recently quoted as saying that "[u]niversities have made life increasingly difficult to do research because of all the contractual issues around intellectual property." (Lohr 2006)

Universities have, on occasion, had disputes not only with large software firms but also with open source software developers. In 2001, a group of university bioinformaticians petitioned the National Institutes of Health ("NIH"), asking the agency to mandate that publicly funded bioinformatics software be distributed under an open source model. At about the same time, reports emerged of individual professors facing resistance to their attempts to operate their labs under an open source model. (Benner 2002)

This paper represents the first systematic study of which we are aware of university software ownership.[4] We rely in part on a unique, hand-curated database of university software patents. Our quantitative analysis focuses on patents primarily because there is no comprehensive data on the extent to which copyright is asserted by universities.[5] This quantitative analysis is supplemented by interviews conducted with technology transfer officers (particularly at universities that own large numbers of software patents) as well as academic scientists prominent in the open source movement. Through these interviews, we draw out the policies that major university software patentees have not only with respect to patents but also with respect to software ownership more generally.

The combination of our quantitative and qualitative inquiry yields a number of interesting results. First, software patents represent a significant percentage of university patent holdings. Second, the factor that has had the biggest effect on software patenting is not R&D generally, or even computer science R&D in particular, but the overall "patent propensity" of the university – that is, the tendency of the university to seek patents. These findings are reinforced by our qualitative results. Our interviews show that some universities view software as similar to other inventions that are more "physical" in the traditional sense. This attitude is problematic, as software is likely to follow a different commercialization path than these more physical inventions.

2. UNIVERSITY SOFTWARE PATENTING: HISTORY AND METHODS OF IDENTIFYING

We began by using the USPTO's *Cassis* database to identify all patents issued in 1982, 1987, 1992, 1997, and 2002 that were assigned to institutions classified as Research or Doctoral Universities in the Carnegie Commission of Higher Education's 1972 or 1994 reports. We chose these particular years because they span a series of critical shifts in the legal regime surrounding software produced at universities.[6] Over these two decades, university patenting

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[3] On appeal, the Federal Circuit ordered a new trial concerning the validity of the patent. Eolas Technologies Incorporated v. Microsoft Corp., 399 F.3d 1325 (Fed. Cir. 2005). On August 24, 2007, immediately before the re-trial was set to begin, Microsoft and Eolas reached a confidential settlement.

[4] One study that touches on some related issues is Agrawal and Henderson (2002). Agrawal and Henderson examine the patenting practices of the MIT electrical engineering/computer science faculty. Based on their research, they conclude that patenting is a "minority activity" for most faculty members in the EE/CS department (and the mechanical engineering department).

[5] Copyright attaches as soon as the software is created. Because there is no requirement to register copyrights, it is difficult to know the total volume of university software protected by copyright. Technically speaking, it is "all" protected by copyright, but one cannot estimate how much of it exists.

[6] A methodology that sampled on year of filing would have tracked more precisely the impact of particular software cases on filing behavior. However, because we did not aim to measure the precise impact of specific cases, sampling by year of issue was sufficient for our purposes. If we assume an average patent pendency of about 2 years (which was the average pendency through the 1980s and 1990s), we can get a sense of the impact of particular decisions. Sampling on year of issuance was also an issue for our regression analyses, which assess rates of patenting against (inter alia) R&D expenditures. We addressed

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increased dramatically, from 385 issued patents in 1982 to 2946 in 2002. Patent jurisprudence in the area of software also evolved considerably during this period. Because this evolution is closely related to the manner in which we define the term "software patent," we lay it out in some detail below.

2.1 History of Software Patenting

In the 1970s, the dominant intellectual property regime for software was copyright, not patent. A 1972 Supreme Court case, *Gottschalk v. Benson*, had appeared to reject software (in that case a computerized method for converting decimal numbers to binary numbers) as patentable subject matter on the grounds that patent law did not encompass abstract scientific or mathematical principles.[7] Several years later, in the 1976 Copyright Act, Congress expressly endorsed copyright as an appropriate protection regime for software.

The IP terrain shifted in the 1980s. In the 1981 decision *Diamond v. Diehr*, the Supreme Court gave its first clear indication that certain types of software-implemented inventions were patentable. *Diehr* narrowed *Gottschalk* by upholding as patentable subject matter a rubber-curing process that used software to calculate cure time. According to the *Diehr* Court, the physical transformation of the rubber "into a different state or thing" took the invention being claimed out of the realm of abstraction. The Court allowed the patent even though software implementation represented the only novel feature of the invention.

Through the 1980s, the Court of Appeals for the Federal Circuit followed a test similar to that enunciated in *Diehr*. Under this test, if an invention's claims involved nothing more than an algorithm or series of algorithms, then the invention could not be patented. However, if the claims involved a mathematical algorithm that was "applied to, or limited by, physical elements or process steps," such claims would constitute patentable subject matter. The overall message to patent attorneys was that software could be patented, but it had to be claimed as something else.

As the patent option was becoming more attractive, copyright was becoming much less so. In the early 1990s, a series of decisions from regional appellate courts[8] made it clear that copyright covered primarily the literal source code of the program. Courts saw broader coverage as running contrary to the principle that copyright is supposed to cover only expression, not ideas or utilitarian functions.

Greater changes lay in store. In the 1994 case of *In re Alappat*, the Federal Circuit effectively eliminated the physicality limitation by holding that the patentable subject matter requirement could be met by showing that the software created a new machine – a "special purpose" computer – when it was executed. Presumably all software would produce such a special purpose computer and hence be patentable. Four years later the Federal Circuit's 1998 decision in *State Street v. Signature Financial Group* explicitly rejected any special subject matter test for software, arguing that software (like all invention) is patentable so long as it produced a "useful" result. After *State Street*, there was no need for even the fig leaf of a "physical" machine or process.

2.2 Identifying University Software Patents

Given this history, it is perhaps not surprising that identifying "software" patents is very difficult. To our knowledge, there have been only a few significant efforts to identify a large data set of software patents.[9] An initial paper by Graham and Mowery (2003), which does not attempt to define the term

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this issue by experimenting with R&D "stocks" from a variety of different time periods prior to patent issuance. All time frames yielded qualitatively similar results.

[7] Although *Gottschalk* is generally considered a subject matter case, the Court may also have been concerned with breadth – the patent in question was not restricted to any particular implementation of the algorithm. In general, "pure" software patents of the type at issue in *Gottschalk* are likely to be broader than patents covering software embedded in a particular machine. Indeed, the advent of pure software patents is one reason for complaints of undue patent breadth in this arena.

[8] While all patent appeals go to the Federal Circuit, appeals from copyright cases go through the ordinary process of appeal to the regional courts of appeal.

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"software patent," relies upon certain International Patent Classifications (IPCs),[10] limited to patents in those classes owned by large software firms. A more recent paper by Graham and Mowery (2005) uses particular U.S. patent classes,[11] once again limited to patents in those classes owned by large software firms. The Graham and Mowery approach is not likely to be significantly overinclusive, so long as it is limited to patents owned by packaged software firms. However, their approach is underinclusive, because large numbers of software patents are owned by other kinds of firms and software patents are found in many other classifications.

Another significant effort to identify a large set of software patents, by Bessen and Hunt (2006), defines "software patent" to include patents on inventions in which the data processing algorithms are carried out by code either stored on a magnetic storage medium or embedded in chips ("firmware"). Rejecting the use of patent classifications,[12] Bessen and Hunt study a random sample of patents and classify them according to their definition. Using characteristics of patents Bessen and Hunt find to fit their definition, they then develop a keyword search algorithm to identify software patents.[13]

Although the Bessen and Hunt definition of software patent is reasonable, there are so many pitfalls associated with using automated keyword searches to identify a large set of patents, . The use of language in the titles, abstracts, written descriptions, and claims of patents, even in those dealing with the same area of technology, can be highly idiosyncratic among different patent owners. Moreover, software is a critical part of inventions in so many far-flung fields that reliance on particular search terms produces a data set characterized by substantial percentages of both Type I and Type II errors.[14]

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[9] We exclude from our discussion a recent paper by Cockburn and MacGarvie (2006), which focuses on patents held by firms in 27 specific software markets.

[10] GM use IPC classes G06F (subclasses 3,4,7,9,11,12,13, and 15), G06K (subclasses 9 and 15) and H04L (subclass 9).

[11] The U.S. patent classes are 343, 358, 382, 704, 707, 709, 710, 711, 713, 714, 715, and 717.

[12] Bessen & Hunt (2006, 10-11). The Bessen & Hunt definition of a software patent appears to include patents on inventions that "use" software as part of the invention, but excludes those that "use" off-the-shelf software:

> Our concept of software patent involves a logic algorithm for processing data that is implemented via stored instructions; that is, the logic is not "hard-wired." These instructions could reside on a disk or other storage medium or they could be stored in "firmware," that is, a read-only memory, as is typical of embedded software. But we want to exclude inventions that involve only off-the-shelf software—that is, the software must be at least novel in the sense of needing to be custom-coded, if not actually meeting the patent office standard for novelty.
> *Id.* at 8.

[13] The keyword search algorithm initially identifies a set of patents that use the words "software," "computer," or "program" in the claims or specification. Patents within the set that contain the words "semiconductor," "chip," "circuit," "circuitry," or "bus" are then excluded as are patents that contain the words "antigen," "antigenic" or "chromatography."

[14] Bessen and Hunt (BH) also identify substantial degrees of over- and underinclusiveness in the data set generated by their keyword search. *Id.* at 9. Table 1 uses university patents issued in 2002 to compare the BH approach with our own approach. The two approaches yield an approximately similar number of total patents (396 patents using our approach vs. 415 using the BH approach). However, 51% of the patents our approach identifies as software are not

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Our definition of a software patent is *a patent in which at least one claim element consists of data processing, regardless of whether the code carrying out that data processing is on a magnetic storage medium or embedded in a chip.*[15] Not only is it possible to apply the definition consistently, but it also captures the realities of claim drafting. It is common for all or most of the elements in a patent claim to cover the prior art, with only one or perhaps two elements covering the purportedly novel and nonobvious advance. One finds large numbers of patents owned by computer hardware makers, for example, the claims of which initially read as though they cover something like a generic router, printer, magnetic resonance imaging machine, or other hardware, when in fact the only purported novelty is in one element consisting of a function carried out by an algorithm. Some of this may be a consequence of the fact that, prior to *Alappat*, software had to be claimed not as a new algorithm *per se* but instead as part of a piece of hardware that allegedly did something different because of the new algorithm.

In a large set of patents it is impossible as a practical matter to target perfectly those patents in which only the software element (as contrasted with other elements of the claimed invention) is novel and non-obvious. But the fact that, under our definition, data processing must be identified in a claim element does suggest that software was seen by the claim drafter as important for novelty and non-obviousness. Otherwise the drafter would not have narrowed the claim by including the data processing limitation.

For this reason, our data set is quite likely to include those patents – and only those patents – in which data processing is central.

In addition to identifying which patents out of the more than 7,600 university-owned patents in our sample are software patents, we also identified a subset of those that may be called "pure software patents." These are *patents in which the claims consist only of data processing*. That is, the entire invention consists of algorithms, and it is not limited to any particular physical embodiment. (These sorts of patents theoretically could have issued with any frequency only after the Federal Circuit's 1994 decision in *In re Alappat*.)[16]

3 UNIVERSITY SOFTWARE PATENTING: QUANTITATIVE TRENDS AND DETERMINANTS

3.1 Descriptive Statistics

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identified as such by the BH algorithm. Moreover, we classify as non-software 53% of the patents that BH classify as software. Similarly, one recent study that used software experts to read a sample of the BH patents asserts that more than 50% represented Type II errors. Layne-Farrar (2005).

A recent working paper by Bronywn Hall and Megan MacGarvie (HM) (2006) identifies patents that fall within the PTO subclasses to which patents owned by fifteen large software firms are assigned. HM then take the union of their approach and the first Graham/Mowery approach and intersect it with the Bessen and Hunt approach.

[15] Allison also uses this definition in a collaboration with Ronald Mann and Abe Dunn (2007) that has involved reading every patent issued from Jan. 1, 1998 to Dec. 31, 2002 to the almost 1,000 firms that appeared in Software Magazine's annual "Software 500" list at least once during that five-year period. This list ranks firms according to their gross revenues in software and services, and includes many firms that are primarily manufacturers in addition to firms that produce only software.

[16] To get a sense of possible Type I and Type errors, we assessed how the two Graham and Mowery approaches classified the 2,942 university patents issued in 2002. As shown in Tables 2 and 3, very few of the patents classified by us as non-software were classified as software by either the GM-IPC approach or the GM-PTO approach. However, the GM-IPC approach did not classify as software 86% of the patents we classified as software. Similarly, the GM-PTO approach did not classify as software 82% of the patents we classified as software. The Bessen-Hunt approach yields approximately the same number of total patents as does ours (396 patents using our approach vs. 415 using the BH approach). However, 51% of the patents our approach identifies as software are not identified as such by the BH algorithm. Moreover, we classify as non-software 53% of the patents that BH classify as software. Similarly, one recent study that used software experts to read a sample of the BH patents asserts that more than 50% represented Type II errors. Layne-Farrar (2005).

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Figure 1 shows that university software patenting increased more than ten-fold over the 1982-2002 period, from 37 patents in 1982 to 396 patents in 2002. Over this period, the "pure software" proportion of university software patents also increased dramatically, from 13 percent to 32 percent of all university software patents. The latter change is hardly surprising. While the patentability of pure software was unclear in the 1980s, its status became much more secure in the 1990s. Over these two decades, university software patenting also grew at a faster rate than university patenting overall. As a consequence, the software share of university patents rose from 9 percent in 1982 to 13 percent in 2002, as seen in Figure 2.

Table 1 lists the 15 universities receiving the most software patents in 2002.[17] Together, these 15 institutions accounted for 60 percent of all university software patents issued in that year. The top five institutions alone (MIT, the University of California, Stanford, Caltech, and the University of Texas) account for over a third (34.2 percent) of all university software patents. The top five software patentees also represent the top five university patentees overall in 2002. However, moving farther down the list of the top fifteen, we see that a number of the top software patentees are not among the top university patentees overall. The University of Washington (6th in software patenting/15th in overall patenting), Georgia Tech (8th/20th), Carnegie Mellon (9th/51st), the University of Rochester (12th/50th) and the University of Illinois (14th/28th) particularly stand out as institutions substantially more prominent in software patenting than overall patenting.

With respect to the patenting of "pure" software, Table 1 shows that the top three patenting institutions overall also rank among the top recipients of pure software patents (1st, 2nd, and 4th). In contrast, although Caltech and the University of Texas rank high in overall software patenting (4th and 5th respectively), they rank relatively low in the patenting of pure software (23rd and 41st respectively). The University of Washington, Georgia Tech, Carnegie Mellon, the University of Rochester, and the University of Illinois – mentioned earlier as standing out in software patenting relative to overall patenting – also stand out with respect to numbers of pure software patents (6th, 3rd, 13th, 14th, and 11th respectively).

As these examples suggest, several factors may affect university software patenting. First, the amount of software-related research and development, and thus the output of software, may matter. Second, the size of the overall research enterprise may matter, since software can be developed in many parts of the university. Third, an individual university's overall propensity to patent, i.e., the share of research outputs it patents (either because its researchers are prone to file invention disclosure statements and push for patents on those disclosures, or because technology transfer officers are prone to seek patents), may also affect software patenting.[18] Although there are undoubtedly other factors that affect software patenting – for example, attentiveness to the specific question of how software patenting is viewed in the technology licensing office or among faculty[19] – these are difficult to measure. Despite the difficulty, we examine some of these factors in our qualitative analyses.

3.2 Patent Production Functions

To examine the relative importance of 1) software-related R&D, 2) overall R&D, and 3) university propensity to patent, we estimated simple "patent production functions" relating software patent counts in 2002, 1997, 1992, 1987, and 1982 to characteristics of each of the 202 Carnegie universities in our

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[17] To be sure, the 2002 data may be somewhat unusual in that it reflects patent filings that occurred during the "dot-com" bubble of the late 1990s. However, with a few exceptions, these universities also received the largest number of software patents over the course of the sampling. Additionally, our impressions from anecdotal evidence lead us to doubt that the 'dot-com' bubble led universities to acquire very many of the patents on software-implemented business models that issued in rapidly increasing numbers in the late 1990's. As noted further below, we are currently investigating more systematically the question of whether university software patent filing patterns changed after the burst of the dot-com bubble.

[18] In our quantitative discussion, we cannot distinguish between motivations of university technology transfer offices and motivations of university scientists. In any event, these motivations may be related. For example, Azoulay et al. (2005) find that in a study of 3884 life science researchers, the overall "patent stock" of the university where the researcher is employed has an effect on number of patents held by the life sciences researcher.

[19] In the life sciences context, for example, one study that looked at patenting activity for 3884 researchers found that having co-authors who patent has a positive effect on patenting behavior. Azoulay et al. (2005).

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sample. Specifically, we collected data on total research expenditures and computer science research expenditures from the NSF's *Survey of R&D Expenditures at Universities and Colleges*[20], and aggregated these data to create R&D stocks for the 5 year period prior to patent issue.[21] We also collected data on the number of non-software patents each university was issued in each issue year.[22] To facilitate interpretation, we took natural logarithms of the independent variables.[23] Since the dependent variables are integer valued, we estimated negative binomial regressions relating software patents and pure software patents to research expenditures.[24]

Tables 2 through 6 show the main results from these simple cross-sectional regressions, for 2002, 1997, 1992, 1987, and 1982 respectively. In negative binomial models, coefficients on log-transformed variables can be interpreted as elasticities. Model 1 of Table 2 shows that, in 2002, both computer science R&D and overall R&D have a positive and statistically significant impact on software patenting, but that the elasticity of software patenting with respect to computer science R&D is much smaller. In particular, a 1 percent increase in computer science R&D implies a .11 percent increase in software patenting, but a 1 percent increase in non-computer science R&D implies a .84 percent increase in software patenting.

One explanation for this is that a substantial number of software patents result from non-computer science R&D, consistent with the argument, made by Graham and Mowery (2003), that software is likely to be produced across the university. Similarly, outside the university context, Bessen and Hunt (2006) argue that many software patents are held by manufacturing firms.

However, it is also likely that universities with more research simply have faculty who are more aware of patenting opportunities. Alternatively, they may have larger or more sophisticated technology transfer efforts. In either case, the net result could be higher propensities to patent for a given amount of software-related R&D. To assess this, Model 2 controls for the total number of non-software patents issued to the university in 2002. After controlling for total non-software patenting, the impact of the amount of non-computer science R&D on patenting drops dramatically, and becomes statistically insignificant. However, computer science R&D remains positive and statistically significant. Perhaps most notably, overall patenting has a large and statistically significant

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[20] This survey is conducted annually by the NSF Division of Science Resources Statistics, and includes R&D expenditures from all sources of funding. Also helpful for our purposes is the fact that this survey breaks down funding by science and engineering field and by source of funding (federal and non-federal).

[21] Similar results obtain if we aggregate computer science and engineering R&D. Because we sampled on issue years, and there was an approximately 2 year lag between patent application and issue (during the 1980s and 1990s), as well as a lag of uncertain duration between research and patent application, choosing a precise lag period was difficult. Accordingly, we experimented with various windows. All specifications (available upon request) yielded qualitatively similar results.

[22] Using non-software patents as a measure of university patent propensity could skew results to the extent there were universities for which the majority of patents were software patents. In those cases, patent propensity might appear artificially low. However, one cannot use the same variable on both sides of the regression. Fortunately, software patents did not represent a majority of patenting activity for any Carnegie university. We did attempt to find data on an additional proxy for patent propensity: the size of the technology transfer office. However, we were able to find data on size for fewer than half of the universities in our sample.

[23] In some cases, one or more of the right-hand side variables was zero, and the natural log of zero is undefined. Accordingly, we took natural logs of $1 plus R&D.

[24] We could not reject the hypothesis of overdispersion, and thus chose negative binomial models over Poisson models. However, we obtained qualitatively similar results from Poisson models with standard errors adjusted to account for overdispersion, and from log-log models estimated via ordinary least squares. These results are available from the authors on request.

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impact on software patenting, even after controlling for overall and computer science R&D. While a 1% increase in computer science R&D yields a .097% increase in software patents, a 1% increase in non-software patenting yields a .91% increase in software patenting.

Models 3 and 4 in Table 2 show similar regressions with the number of "pure" software patents as the dependent variable. Perhaps not surprisingly, the amount of computer science R&D has a much larger impact on "pure" software patenting than on software patenting overall. In the first specification (Model 3), a 1 percent increase in computer science R&D implies a .59 percent increase in pure software patents, more than five times larger than the effect on all software patents. Controlling for the amount of non-software patenting (in Model 4) reduces this effect somewhat, to .52%, but it is still much larger than the corresponding estimate for all software patents. On the other hand, Model 4 also shows that overall non-software patenting (after controlling for non-software R&D) still has a greater effect on "pure" software patenting. A 1% increase in number of non-software patents yields a .78% increase in pure software patents.

Table 3 shows qualitatively similar results for the 1997 cohort. Perhaps not surprisingly (given the uncertain status of software patents), results on the importance of computer science R&D for pure software patents in the 1982-1992 cohorts (shown in Tables 4 through 6) are more mixed. However, with the exception of the 1982 cohort, overall patent propensity remains a statistically and qualitatively significant determination of patenting for both software and pure software.

We also estimated a panel version of these regressions for the entire period, with university and year fixed effects. In this model, the estimated changes in R&D and other patenting are identified using within university variation over time. Table 7 shows the results. Notably, the year dummies are positive and their magnitude increases over time, reflecting the overall growth in university patenting over the 1982-2002 period. Model 1 shows that the main factor affecting overall software patenting is changes in non-software patenting, with a 1 percent increase in non-software patenting implying a .46 percent increase in software patenting. The corresponding [something is missing here—should it be "finding" or another word?] for pure software patenting is neither qualitatively nor statistically significant. Moreover, none of the R&D measures is statistically significant for either software or pure software. This last set of results should be interpreted with caution, however. Because the panels are short and there is limited within university variation, it is difficult to draw strong inferences.

4 UNIVERSITY OWNERSHIP POLICIES

To complement the quantitative analyses, we also interviewed technology transfer managers responsible for software at thirteen of the fifteen universities that received the most software patents in 2002. The interviews sought to identify their opinions on determinants of university software patenting.[25] We also asked them questions about non-patent mechanisms for dissemination of software inventions, including "open source"-based dissemination. Further, we conducted interviews with university professors and graduate students prominent in software development and in the open source software movement.

According to Gerald Barnett, formerly at University of Washington (now at UC Santa Cruz) university technology licensing offices (TTOs) that have a long history of patenting tend to see software, including pure software, through the lens they use for other inventions, particularly in the life sciences.[26] In the life sciences, established technology transfer offices have long generated revenue not only through exclusive licensing (the model contemplated in the legislative history of Bayh-Dole) but also through nonexclusive licensing (a model not necessarily contemplated by Bayh-Dole but one that can generate substantial revenue).

Barnett's perspective is in accord with results from our interviews with officials at some major technology transfer offices. Lita Nelsen, director of MIT's technology transfer office notes (speaking of pure software),

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25 We were able to obtain interview with officials at all technology transfer offices except the California Institute of Technology and Columbia University.

26 Interview with Gerald Barnett, October 2, 2003.

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> [I]f there are no strong feelings on the part of the authors to open source their work, we will look at it *like any other invention*: is it worth investing time and, when appropriate, patent money to try to license the software out (either as simple end use license or to a distributor or startup company to improve and distribute it.)[27]

Barnett's view is also in accord with our regression results, which indicate that overall university patenting propensity strongly influences both overall and pure software patenting. The regression results underscore what can be seen through a casual review of the descriptive statistics in Table 1. As noted earlier, the top 5 software patentees (MIT, UC, Stanford, Caltech, and University of Texas) are also the top 5 overall patentees. Notably, none of these five was in the top five in computer science R&D spending for the years 1996-1998.

However, of these five universities, two – Caltech and the University of Texas – do *not* have significant numbers of pure software patents. (Caltech and the University of Texas ranked 23rd and 41st respectively.) At the University of Texas, the reason for this dearth of pure software patents may be attributable to the view, explicitly adopted by UT technology transfer officials in response to complaints from computer science faculty, that faculty should be allowed freedom to share their work as they wish. Such freedom includes express permission to use the GNU General Public License (GPL), a "viral" open source license under which source code is open to all but those who redistribute the software must also make any modifications they have made to the source code available to others. This policy was adopted in the 1990s and would therefore have affected the number of pure software patents that issued in 2002.[28] The explanation for Caltech's small number of pure software patents is less transparent. Because we were unable to speak with the technology licensing office,[29] our knowledge of the Caltech situation is based on reports from scientists who work there. According to one prominent open source software developer at Caltech,[30] most software is for internal, in-house use and is probably not even reported to the technology transfer office. For software that is disclosed to the university, the faculty researcher decides how the software should be exploited. The technology transfer office is not only familiar with open source but is apparently eager to use the viral GPL: this license allows for the future possibility of forking, with one fork continuing to be available without charge via the GPL and the other fork converted into a non-viral license for which corporate clients might be willing to pay.

In contrast, the positions of MIT and the University of California are less explicitly favorable to open source.[31] According to MIT's director of technology transfer, MIT allows researchers to use the open source approach, and even manages their licenses, but this position is not part of official policy.[32] The University of California system has a highly complex set of positions on open source licensing. This complexity emerges in part from the quasi-federated structure of the UC system, within which policies towards copyright licensing (and hence open source licensing) are determined by the individual campus. While

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27 E-mail communication from Lita Nelsen, July 27, 2005 (emphasis added). According to Nelsen, software patents tend to be worth patenting when the primary value is in the algorithm.

28 Interview with Georgia Harper, Office of General Counsel, University of Texas, February 26,2004. Various University of Texas websites document the university's continuing support of open source under GPL or similar licenses where the faculty inventor and a software consultant determines that such distribution is in the best interests of the University and the public. http://www.utsystem.edu/ogc/intellectualproperty/swadmpol.htm; http://www.otc.utexas.edu/Industry/Software/process.jsp

29 The Caltech technology transfer staff refused requests for an interview.

30 Interview with C. Titus Brown, August 17, 2005

31 Where Stanford University fits in the picture is not clear. Stanford did not adopt an explicit policy in favor of open source until 2004. It adopted this policy in response to a number of requests received from professors. Interview with Kathy Ku. However, Stanford has long had a policy allowing professors to put their inventions into the public domain if they so desire.

32 Interview with Lita Nelsen, August 8, 2005.

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some campuses, such as Berkeley and San Diego, are familiar with the open source model, other campuses are much less familiar with it.[33] Various important campuses, including UC Berkeley, appear to be in the midst of fine-tuning their policies. As of early 2002, officials from the Berkeley office were quoted as criticizing the decision, made by Berkeley a decade earlier, in 1992, to release as open source the Unix operating system and TCP/IP networking protocol. (Benner 2002) At about the same time, UC Berkeley computational biologist Steven Brenner encountered difficulties in releasing his lab's software under an open source license.[34] By 2004, however, UC Berkeley had announced a policy that appeared to give a much stronger endorsement to the open source model. In this new policy, the Berkeley technology transfer office states that it will work with researchers who want to release their code under an open source model.[35] Although it is not clear whether researchers have the final say in cases of conflict, the new policy clearly appears to be encouraging towards open source. Berkeley has also developed, and encourages researchers to use, an "academic" license, under which source code is made available free of charge to academic and non-profit institutions, and made available for a fee for commercial use. In general, the new Berkeley policy appears to encourage the possibility of releasing software (and/or underlying source code) under different types of licenses for different purposes.

As noted earlier, five universities – University of Washington, Georgia Institute of Technology, Carnegie Mellon, the University of Rochester, and the University of Illinois -- rank substantially higher in software/pure software patenting than in overall patenting. The first three of these schools have unique characteristics that may explain their high levels of pure software patenting. At the University of Washington, a separate technology licensing office, now called the Digital Ventures office, is responsible for managing pure software (and digital products more generally). The University of Washington appears to be the only university in the U.S. with a technology licensing office specifically devoted to software. This office now has 7 full-time professionals as well as 2-4 part-time students. As for Georgia Tech, its level of computer science R&D funding relative to other R&D funding is quite high: it ranks 5th in computer science funding and only 32nd in other funding. Finally, Carnegie Mellon ranks 2nd in computer science funding and 87th in other funding. Carnegie Mellon is also home to the Software Engineering Institute (SEI), a research consortium founded by software firms. Patents from SEI are assigned to Carnegie Mellon, and the software firms in the consortium receive an automatic, royalty-free license.[36]

Notably, although the University of Washington, Georgia Tech, and Carnegie Mellon have a significant patent presence, this level of patenting may not represent a continuing pattern. Current technology transfer officials assert that they promote other models of software ownership. At the University of Washington, 90% of the revenue brought in by its Digital Ventures office in FY 2005 came from copyright licensing. The Digital Ventures web site features a large variety of unpatented software that can be secured for commercial use through an on-line license with a standard rate.[37] Like UC-Berkeley, the University of Washington also encourages "forking" in its licenses, that is, licenses in which software (object code and/or source code) is made available free of charge for certain uses and available for a fee for other uses. Officials at Georgia Tech's technology licensing office note they oversee dozens of open source-type software licenses each year and that, given the short technology life cycle in the software industry, algorithm patents (that is, pure software patents) are often not very

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33 Interview with William Decker, UCSD (noting that Berkeley and San Diego often use open source licenses but that other campuses are not). Cf. Interview with Joel Kirschbaum, UCSF (noting that although his office does not use open source, they often make executable code available to academics free of charge)

34 Interview with Steven Brenner, March 2004.

35 Office of Technology Licensing, UC Berkeley, Frequently Asked Questions, http://otl.berkeley.edu/about/faqs.php (discussing open source options available on Berkeley's software disclosure form).

36 Interview with Carl Mahler, September 2, 2005

37 http://depts.washington.edu/ventures/UW_Technology/Express_Licenses/

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valuable.[38] Finally, at Carnegie Mellon, the current technology transfer team states that it almost never patents pure software unless another entity (in their case, often SEI) is willing to pay for such patenting.[39]

Another interesting development that emerged from our interviews is a potential shift from patent to copyright protection of software developed at universities. While revenues can be generated from patented software inventions by means of non-exclusive licensing, universities may be reluctant to license non-exclusively because they must incur the immediate cost of obtaining a patent. In contrast, exclusive licensees typically pay patenting costs. Notably, however, software is unlike virtually every other university invention because patents do not have to serve as the foundation of a non-exclusive licensing scheme. Copyright protection, which attaches without cost upon creation of the software, will do the job. If software is to be commercialized, the copyright on it should be registered for practical reasons, but the cost of such registration is miniscule compared to the cost of obtaining a patent.[40] For this reason, at least some technology transfer offices say that they are beginning to shy away from seeking patents for the purpose of non-exclusive licensing. At the University of Washington, for example, the Digital Ventures office says that it takes a "hard look" at patenting and will use it only if there is a real need to provide monetary incentives for further improvement and commercialization of the technology (presumably by means of an exclusive license). The University of Washington's Digital Ventures has also convinced startups to "go without a patent."[41] Non-exclusive copyright licensing can be quite lucrative for universities. MINOS, a software package for solving large-scale optimization problems (linear and non linear programs) that is available through a non-exclusive copyright license, is one of Stanford's largest money generators.[42] Moreover, as noted earlier, in FY 2005 the UW Digital Ventures office made 90% of its revenue from copyright licensing.

However, even nonexclusive copyright licensing with relatively low fees can be problematic for non-profit researchers. Thus, universities that want to balance the goal of academic access with that of revenue generation, such as the University of Washington, are assessing which licenses and royalty structures are appropriate for which situations. The technology transfer offices at the University of Washington, the University of California-Berkeley, and Stanford have all embraced the idea of dual licenses that give relatively inexpensive access to the non-profit sector but allow for revenue generation from the commercial sector. Indeed, the highly lucrative Stanford MINOS program is available via a dual copyright license: the commercial use license costs more than ten times as much as the academic use license.

Information technology can substantially facilitate nonexclusive licensing with low transaction costs. Universities such as Stanford already make software like MINOS available through simple Web-based interfaces.[43] Seven universities are currently participating in a pilot test of the Kauffman Foundation's Web-based I-Bridge project, which aims to reduce the transaction costs associated with licensing. A significant percentage of the 739 projects available on the I-Bridge site appear to represent software – 56 included the term "software" in their title or brief description.[44] Many of these software projects are not patented and are available either free or by means of a dual license. Additionally, some large technology firms have decided to sponsor software projects at universities

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38 Interview with Kevin Wozniak.

39 Interview with Carl Mahler.

40 Copyright registration is not only required before an infringement action is filed, but timely registration also makes the recovery of substantial damages for infringement a far easier task.

41 E-mail communication from Chuck Williams, September 2, 2005

42 Interview with Kathy Ku

43 http://www.sbsi-sol-optimize.com/asp/sol_product_minos.htm

44 http://www.ibridgenetwork.org/searchresults.asp?sID=A7F8685984874659980E9D27E56A9D05&Page=1&RecsPerPage=10&Keyword=software&ignore=2&OrderBy=Rank&fbPR=&fbCOM=&Language=&ShowC=on&fbCHA= (keyword search for "software")

under an explicit "open collaboration" model. In 2005, four technology firms (IBM, Hewlett-Packard, Intel and Cisco) announced a set of "Open Collaborative Research" principles which under which certain types of sponsored research in software would be made freely available. IBM is now embarking on specific software projects at seven universities under the rubric of these principles (Lohr 2006).

The related question of using copyright to promote "open source" within the university is an interesting one. As we have noted, some universities have embraced open source, and these universities tend to have much smaller numbers of pure software patents. But even among technology transfer officials sympathetic to the goals of open source, a number of them mention difficulties that open source may create in the university setting. For example, faculty may prefer open source as a method of distribution not because of ideological commitment but because open source-related consulting revenues, unlike licensing royalties, don't have to be shared with the university.[45] Indeed, at least one prominent technology transfer officer (who preferred to remain anonymous) believes that some faculty make software open source for the purpose of attracting widespread interest but have every intention of asserting proprietary rights over the source code at some later point.[46] Additionally, software is often developed by groups, and TTOs sometimes find themselves in the middle of disputes among group members about the best open source mechanism to use (or, indeed, whether open source should be used at all).[47] TTOs are also wary that particular types of open source licenses will conflict with obligations to sponsors, including the federal government under Bayh-Dole.[48] Thus, to the extent funding agencies are interested in an open source approach because they think such an approach is likely to produce better software, they need to be aware of possible institutional impediments.

Because our quantitative data conclude with patents originally filed in the late 1990s, it may be that universities have become less aggressive in patenting software in more recent years. Indeed, as noted, technology transfer officers from universities with significant software patent holdings, such as the University of Washington and Carnegie-Mellon, state that they are quite receptive to non-patent based modes of technology transfer. Whether university patenting and licensing practices are currently different from practices in the late 1990s would be a valuable subject for further research.[49]

5 Conclusions

Our results indicate that universities have become more active patentees of software, including pure software. They have clearly availed themselves of the opportunities afforded by Bayh-Dole and Federal Circuit decisions in the 1990s. Moreover, at least for our sample (which terminates with patents filed through the late 1990s), behavior with respect to total software patents and pure software patents is strongly affected by overall patent propensity. From a private point of view, this correlation may make sense, especially if the reason for the effect is (as Mowery and Sampat (2001) suggest) the existence of economies of scale at the technology transfer office. To the extent such scale economies exist, they are likely to lower the private marginal cost of patent acquisition. From a social point of view, however, patenting based on scale economies is problematic. Ideally, we would want decisions about whether to patent publicly-funded

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[45] Memorandum from Pat Jones

[46] This technology transfer officer did not specify precisely how a faculty member would assert proprietary rights. In the context of a viral license, one mechanism for doing so would be to "fork" the license. One prong of the license would remain viral while the other, which was made available to paying customers, would not be viral in character. The software producer MySQL has adopted this strategy. See http://www.mysql.com/company/legal/licensing/commercial-license.html

[47] Interviews with Chuck Williams; Dana Bostrom; Lita Nelsen

[48] In theory, under Bayh-Dole, if the university and researcher choose not to patent, the government has the option of patenting. Whether a decision to release software under an open source license represents an unwarranted interference with the government's option remains an open question, at least in theory. In practice, however, we are unaware of any situation where a decision to release software under an open source license has interfered with an agency's desire to patent.

[49] The authors of this article are currently undertaking this research.

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academic research to be based not only on the private marginal costs of patent acquisition but on whether a patent is needed to facilitate commercialization in a specific case, which is likely to vary across inventions and fields. To put the point another way, a lack of differentiation between software and other research could be problematic. As case studies undertaken by Colyvas et al. (2001) point out, the optimal mode of university-industry technology transfer is likely to vary by industry and invention.[50] More specifically, as indicated earlier, the theory espoused in the legislative history of Bayh-Dole – that patents and exclusive licenses are necessary to create incentives for firms to develop and commercialize "embryonic" university inventions—does not apply neatly in software, where development costs often are relatively low.[51]

Another major argument often advanced in favor of patents is that the prospect of licensing royalties induces university researchers to work with industry licensees and thereby transfer tacit knowledge necessary for commercialization.[52] However, in comparison to the life sciences, software (particularly pure software) is an area of invention where knowledge is likely to be relatively codified. Object-oriented programming is based on principles of modular design, and one of the reasons that open source methods of software production have been successful is that the development task can be broken up into modular pieces that are then reassembled. So the need for transfer of tacit knowledge may not be as pervasive as it is in the life sciences.

Indeed, in some well known cases, such as the Eolas case noted earlier, it appears that the university patent allowed the university and/or its exclusive licensee to extract rents from other firms without aiding in technology transfer. In the Eolas case, it does not appear that Microsoft's commercialization was aided by the activities of UC/Eolas. Rather, Microsoft and other firms began to use the browser technology at issue in the case well before the patent issued.[53] In this case, and others involving litigation over university software patents (Rai et al. 2007), commercialization by firms other than the university licensee was going forward, and patent rights/exclusive licenses were not necessary to facilitate "technology transfer." Rather, contrary to the spirit of Bayh-Dole, software patents in these cases primarily allow universities to extract rents, and perhaps even to "hold up" development efforts. More generally, when software firms are arguing that development opportunities and university-industry collaborations are likely to be spurred through fewer, not more, university assertions of patent rights (Johnson 2007; Thursby & Thursby 2006), policies that treat patents as the default option for software are problematic.

While university software patenting grew dramatically over the period we studied, university practices with respect to software are not uniform. For example, universities that have policies friendly to open source are less likely to patent pure software. More generally, a fair number of universities – including universities with large number of software patents – may now be moving away from patenting and exclusive licensing of software.[54]

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[50] In addition to differential incentive effects, university patents and licenses have different informational effects across different industries. Of particular relevance to our study, the comprehensive Carnegie-Mellon survey, conducted on a broad range of large and small firms in the early 1990s, indicates that outside of the pharmaceutical and biotechnology industries, industrial R&D managers rate patents and licenses very low relative to other sources of information on public research (e.g. publications, conferences, informal interaction with university research, and consulting). Cohen, Nelson, and Walsh (2000). Even within the pharmaceutical industry, patents and licenses were less important than research publications and conferences.

[51] Of course, such costs may be somewhat higher in situations where the software in question is not "pure software." But even in those cases, to the extent that the novel or non-obvious element is software, development costs are probably still low relative to the biopharmaceutical industry.

[52] The evidence generally cited for this argument is survey data presented in Jensen and Thursby (2001). The Jensen and Thursby survey of 62 technology transfer offices found that TTO managers thought that inventor involvement was often important in the commercialization of inventions. Presumably patents and licensing royalties represent the most efficient contractual mechanism for inducing transfer of tacit knowledge.

[53] According to the UC Berkeley web site on the Eolas case, Microsoft and other firms were selling the technology by the time the patent issued.

[54] To investigate this proposition further, we are investigating more recent patent applications that have resulted in issued patents.

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Figure 1: University Software Patents, By Type and Year

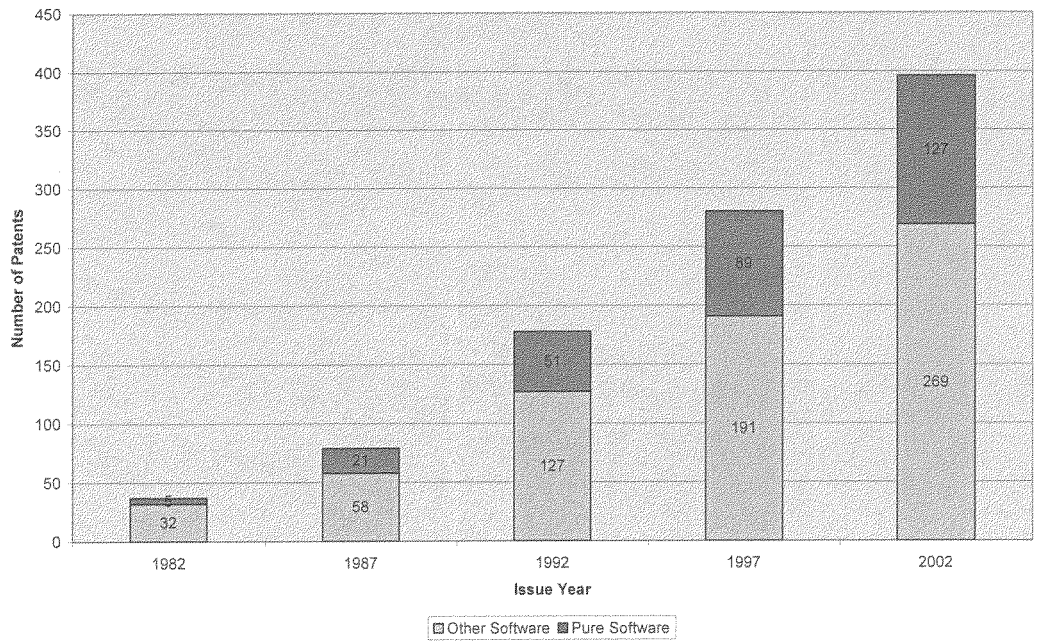

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Figure 2: University Software Patents as a Share of All University Patents

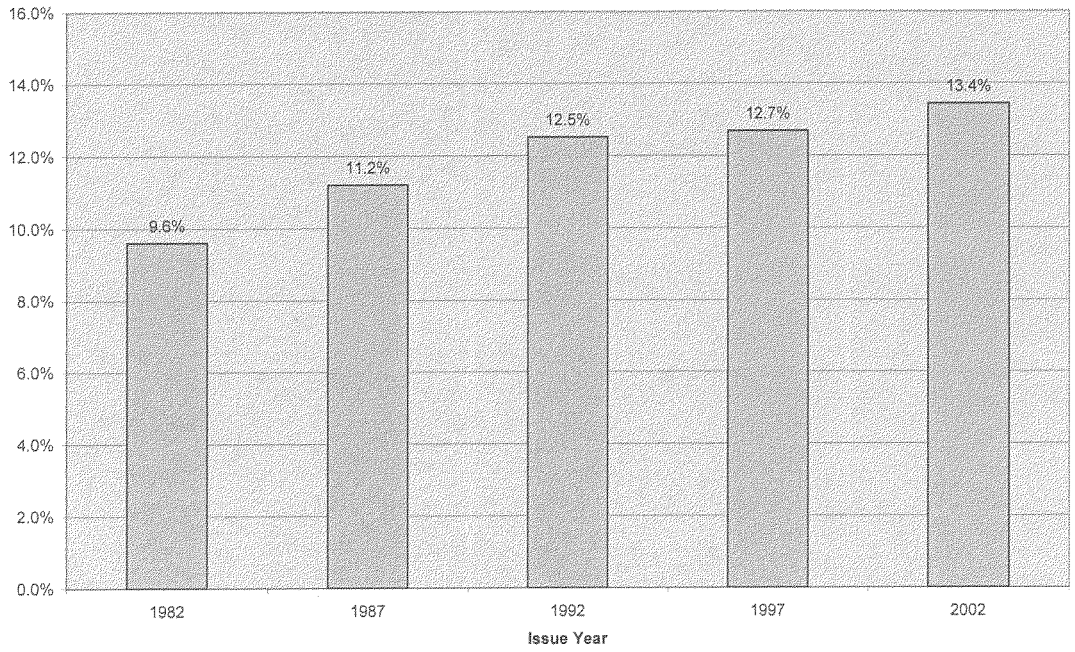

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Table 1: University Software Patenting, Overall Patenting, And Pure Software Patenting In 2002

	Rank in Patenting (Issue Year 2002)		
University	**Software**	**Overall**	**Pure Software**
Massachusetts Institute of Technology	1	2	1
University of California	2	1	2
Stanford University	3	4	4
California Institute of Technology	4	3	23
University of Texas	5	5	41
University of Washington	6	15	6
University of Wisconsin	7	7	8
Georgia Institute of Technology	8	20	3
Carnegie Mellon University	9	51	13
Johns Hopkins University	10	6	11
State University of New York	11	8	20
University of Rochester	12	50	14
University of Pennsylvania	13	13	42
University of Illinois	14	28	5
Columbia University in the City of New York	15	14	10

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Table 2: Negative Binomial Models of Determinants of Software Patents (Issue Year 2002)

	SW	SW	Pure SW	Pure SW
	(1)	(2)	(3)	(4)
ln(lagged CS R&D)	.110**	.097**	.588***	.523***
	(.049)	(.045)	(.121)	(.110)
ln(lagged Other R&D)	.839***	.073	.223	-.395**
	(.118)	(.141)	(.161)	(.163)
ln(Non Software Patents)		.910***		.781***
		(.141)		(.167)
Const.	-11.577***	-3.613**	-9.017***	-2.182
	(1.406)	(1.510)	(1.615)	(1.576)
Obs.	202	202	202	202

Robust standard errors in parentheses. *** denotes p<.001, ** denotes p<.01, and * denotes p<.05.

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Table 3: Negative Binomial Models of Determinants of Software Patents (Issue Year 1997)

	SW	SW	Pure SW	Pure SW
	(1)	(2)	(3)	(4)
ln(lagged CS R&D)	.245***	.172**	.348***	.275**
	(.076)	(.072)	(.134)	(.131)
ln(lagged Other R&D)	.986***	.308	1.005***	.271
	(.160)	(.196)	(.252)	(.320)
ln(Non Software Patents)		.832***		.813***
		(.185)		(.282)
Const.	-14.941***	-7.394***	-17.358***	-9.023**
	(1.878)	(2.179)	(2.975)	(3.587)
Obs.	202	202	202	202

Robust standard errors in parentheses. *** denotes p<.001, ** denotes p<.01, and * denotes p<.05.

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Table 4: Negative Binomial Models of Determinants of Software Patents (Issue Year 1992)

	SW	SW	Pure SW	Pure SW
	(1)	(2)	(3)	(4)
ln(lagged CS R&D)	.143*	.082	.122	.071
	(.077)	(.073)	(.110)	(.107)
ln(lagged Other R&D)	1.083***	.348*	.968***	.264
	(.192)	(.206)	(.287)	(.323)
ln(Non Software Patents)		1.027***		.955***
		(.199)		(.318)
Const.	-15.295***	-7.610***	-14.735***	-7.392**
	(2.213)	(2.221)	(3.357)	(3.446)
Obs.	202	202	202	202

Robust standard errors in parentheses. *** denotes p<.001, ** denotes p<.01, and * denotes p<.05.

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Table 5: Negative Binomial Models of Determinants of Software Patents (Issue Year 1987)

	SW	SW	Pure SW	Pure SW
	(1)	(2)	(3)	(4)
ln(lagged CS R&D)	.343***	.314***	.289	.210
	(.122)	(.092)	(.194)	(.162)
ln(lagged Other R&D)	1.013***	.291	.864**	.094
	(.236)	(.198)	(.351)	(.319)
ln(Non Software Patents)		.797***		1.035***
		(.163)		(.303)
Const.	-16.411***	-8.430***	-15.243***	-6.796**
	(2.592)	(2.117)	(3.792)	(3.261)
Obs.	202	202	202	202

Robust standard errors in parentheses. *** denotes p<.001, ** denotes p<.01, and * denotes p<.05.

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Table 6: Negative Binomial Models of Determinants of Software Patents (Issue Year 1982)

	SW	SW	Pure SW	Pure SW
	(1)	(2)	(3)	(4)
ln(lagged CS R&D)	.218*	.167	.770**	.748**
	(.128)	(.124)	(.336)	(.358)
ln(lagged Other R&D)	.612**	-.043	1.435**	.709
	(.270)	(.193)	(.635)	(.774)
ln(Non Software Patents)		1.326***		.742
		(.272)		(.501)
Const.	-10.317***	-4.045**	-27.910***	-19.811**
	(2.824)	(1.798)	(8.697)	(10.044)
Obs.	202	202	202	202

Robust standard errors in parentheses. *** denotes p<.001, ** denotes p<.01, and * denotes p<.05.

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Table 7: Negative Binomial Panel Models of Determinants of Software Patents, Issue Years 1982-2002

	SW	Pure SW
	(1)	(2)
ln(lagged CS R&D)	.037	.107
	(.046)	(.096)
ln(lagged Other R&D)	-.344	-.119
	(.277)	(.628)
ln(Non Software Patents)	.464***	.054
	(.090)	(.167)
1987 Dummy	.665***	1.363**
	(.237)	(.583)
1992 Dummy	1.354***	2.193***
	(.311)	(.754)
1997 Dummy	1.714***	2.708***
	(.379)	(.897)
2002 Dummy	2.008***	3.045***
	(.442)	(1.040)
Const.	-9.405	-15.118
	(87.124)	(418.802)
Obs.	1010	1010

All models include university fixed effects. The left-out year category is 1982. Robust standard errors in parentheses. *** denotes p<.001, ** denotes p<.01, and * denotes p<.05.

Testimony of Robert Weissman
"The Role of Federally-Funded University Research in the Patent System"
Before the
Committee on the Judiciary
U.S. Senate
October 24, 2007

Chairman Leahy and Members of the Senate Judiciary Committee, thank you for the opportunity to testify today on the important subject of federally funded research and development.

I am the director of Essential Action, a nonprofit advocacy organization that works on pharmaceutical access and other corporate accountability issues. I am also counsel to Essential Inventions, a separate nonprofit corporation that aims to promote the creation and distribution of essential inventions and other works that support public health and access to information. Information about the organizations is available at <www.essentialaction.org> and <www.essentialinventions.org>.

With colleagues, both organizations have urged federal agencies to exercise safeguards in the Bayh-Dole Act,[1] which governs the disposition of federally sponsored inventions, to address pharmaceutical pricing abuses and promote affordable access to medicines. Unfortunately, our efforts have failed.

The Bayh-Dole Act was signed into law in 1980, and effectively expanded through administrative and subsequent Congressional action over the next decade. The law aims to promote commercialization of government-funded inventions. It transfers title to government-funded inventions to universities and other contractors. Universities in turn are able to license the inventions to other parties, including on an exclusive basis.

Although federal agencies have actively embraced the Bayh-Dole mission of licensing federally funded inventions to private corporations, our experience shows that the government has abrogated its duty to ensure that pharmaceuticals incorporating federally funded inventions are reasonably priced.

The result is a public policy outrage, and a public health tragedy. U.S. taxpayers pay to fund R&D. The government turns the fruits of the research over to pharmaceutical and biotechnology companies, which then price gouge U.S. consumers and even the government itself. Thus the industry is able to execute a double swindle of the public. There is little doubt that U.S. consumers experience financial hardship as a consequence, and sometimes have been deprived of needed medicines. The Bayh-Dole licensing system has, in too many cases, distorted and concentrated markets, and facilitated abuses of market power, all with substantial deleterious consequences for pharmaceutical affordability and other public health objectives -- including promotion of the R&D enterprise. The public health consequences are most profound in the developing world, where high prices typically mean that patients go without life-saving and other essential

[1] 35 USC § 200 et. seq.

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medicines. There is a U.S. taxpayer component in the global health arena as well, because U.S. aid monies are not uncommonly used to buy drugs invented with federal research support.

Bayh-Dole created the climate in which these abuses could occur, but they were not inevitable. Government agencies could have implemented Bayh-Dole on terms that would have prevented or at least greatly limited the abuses that have occurred. With few exceptions, they have declined to do so.

In my testimony today, I will describe our initiatives and the federal government's response. The first portion of my testimony briefly reviews the history of Bayh-Dole and associated statutes. The second section recounts our efforts to employ safeguards in Bayh-Dole. The third section presents and critiques the National Institutes' of Health (NIH's) stated rationale for refusing to apply price-restraining measures to pharmaceuticals incorporating NIH-funded inventions. Finally, I conclude with recommendations for policy changes and areas for the committee to examine as it begins its investigations into disposition of federally funded inventions. These recommendations draw both on our direct experience, and the overall experience in the Bayh-Dole era.

THE EVOLUTION OF THE BAYH-DOLE ACT

Since the early 1980s, the federal government under Bayh-Dole and related laws has routinely given away the fruits of the tens of billions of dollars of research it sponsors annually, granting private corporations exclusive rights to commercialize government-financed inventions while failing to include and/or enforce reasonable pricing requirements in the licenses.

It wasn't always so. The Bayh-Dole Act represented a significant shift from previous policy. Following the creation of a major federal role in research sponsorship in World War II, the Justice Department concluded in 1947 that "where patentable inventions are made in the course of performing a Government-financed contract for research and development, the public interest requires that all rights to such inventions be assigned to the Government and not left to the private ownership of the contactor." The Justice Department recommended also that "as a basic policy all Government-owned inventions should be made fully, freely and unconditionally available to the public without charge, by public dedication or by royalty-free, non-exclusive licensing."[2]

The Justice Department offered what remains a compelling case for non-exclusive licensing: "Public control will assure free and equal availability of the inventions to American industry and science; will eliminate any competitive advantage to the contractor chosen to perform the research work; will avoid undue concentration of economic power in the hands of a few large corporations; will tend to increase and

[2] "Investigation of Government Patent Practices and Policies: A Report of the Attorney General to the President," 1947, quoted in Background Materials on Government Patent Policy: The Ownership of Inventions Resulting in Federally Funded Research and Development. Volume II: Reports of Committees, Commissions and Major Studies, House Committee on Science and Technology, August 1976, p. 22.

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diversify available research facilities within the United States to the advantage of the Government and of the national economy; and will thus strengthen our American system of free, competitive enterprise."

Even in 1947, the Justice Department position was not the uniform standpoint of the federal government. The Defense Department consistently maintained a policy of allowing contractors to gain title to government-sponsored inventions, so long as the Pentagon was able to maintain a royalty-free right to use the invention.

In the ensuing decades, government policy evolved unevenly between different agencies, with some gradual increase in exclusive rights transfers to private parties.

Beginning in the mid-1970s, big business, in collaboration with partners at major research universities, began lobbying for a major transformation in government patent policy. Based on highly questionable evidence, the business-university alliance argued that exclusive licensing was necessary to spur private sector innovation and development of government-funded inventions.

In 1980, Congress passed the Bayh-Dole Act, which authorized universities and small business contractors to take title to government-sponsored inventions. Universities were in turn permitted to exclusively license to private corporations, including big businesses. In 1983, President Reagan issued a Presidential Memorandum that instructed executive agencies to grant exclusive inventions to contractors of all sizes. In 1986, Congress passed the Federal Technology Transfer Act, which authorized federal laboratories to enter into exclusive contracts with corporations to develop and market inventions originating in the federal labs.

It is important to note that the Bayh-Dole Act was contentious at the time of passage. Other alternatives proposed at the time included a suggestion by Admiral Hyman Rickover that government inventions be licensed non-exclusively for a period of six months; and that if no party had indicated an interest in commercialization, that the patent then be open to competitive bidding for an exclusive license. A proposal by President Carter, which passed the House of Representatives prior to passage of the Bayh-Dole Act, would have limited the exclusive license granted by government to designated "fields of use." These ideas survive, at least in word, in law governing disposition of federally owned (as opposed to federally sponsored) inventions.

In the many hearings and years of debate that preceded Bayh-Dole, three intertwined concerns were preeminent. First was concern with the government getting repaid for its investment. Second was a concern that licensees would obtain windfall profits. The public had paid for the invention, cutting the investment costs of the company that would obtain control over the invention, but would the pricing fairly reflect the public subsidy? Would the monopoly patent rights enable the licensee to earn unfair superprofits? Third was the impact of the licensing arrangements on market competition and market structure. Patents provide monopolies for the covered invention, and patent protection is in perpetual tension with antitrust policies. Would the conferment of exclusive rights to

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publicly funded inventions create or deepen market concentration? Would it enable licensees to engage in anti-competitive behavior?

Regarding windfall profits, "recoupment" was the preferred remedy, but was eliminated from the Bayh-Dole text before final passage. The only recoupment provision contained in the Bayh-Dole Act relates exclusively to contractor-managed federal laboratories.[3]

Other measures were included and did remain in the statute to address potential abuses.

These include:

• The allocation to the federal government of "a nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world," including a right for the federal government to license foreign rights to use the invention to other parties.[4] At the time of the Bayh-Dole debates, the federal government's paid-up license to use subject inventions was considered the most basic governmental right. Within the government, agencies such as the Defense Department that were favorably disposed to contractors retaining title insisted that governmental interests would be protected by maintaining the paid-up license.

• The right of the government to "march-in" and issue licenses to parties other than the contractor or a university licensee, including in circumstances when the federally sponsored invention is not achieving practical application, or to meet health needs, or when public use needs are not being met.[5] The statute defines "practical application" as being achieved when an invention "is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms."[6] In the debates leading up to Bayh-Dole's passage, march-in rights were advocated as a key tool to restrain pricing or patent abuse.[7]

• The right of the government not to grant title to a university or contractor "in exceptional circumstances when it is determined by the agency that restriction or

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[3] 35 USC § 202(c)(7)(E)(1).
[4] 35 USC § 202(c)(4).
[5] 35 USC § 203.
[6] 35 USC § 201(f).
[7] See Peter S. Arno and Mickey Davis, "Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed Upon Patents Deriving in Whole or in Part From Federally Funded Research," 75 Tul. L. Rev. 631 (2001). See also David Halperin, "Bayh-Dole Act and March-In Rights," March 2001, available at: <www.essentialinventions.org/legal/norvir/halperinmarchin2001.pdf>

Here was how General Electric's general patent counsel described the role of march-in rights: "[I]f [a contractor] fails to supply the market adequately at a fair price, then there is reason for requiring it to license both the background patents and the patents stemming from the contract work. (Harry F. Manbeck, Government Patent Policy: Hearings Before the Subcommittee on Science, Research and Technology of the House Committee on Science and Technology, 96th Congress, page 48 (1979).)

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elimination of the right to retain title to any subject invention will better promote the policy and objectives of this chapter."[8]

Unfortunately, the concerns that Bayh-Dole would give rise to abusive behavior were prescient. Even more unfortunately, the government has largely failed to exercise the safeguards that Congress included in the statute, as our experience, and many others', shows.

ESSENTIAL INVENTIONS MARCH-IN REQUESTS

The Ritonavir March-In Case

In January 2004, Essential Inventions petitioned the National Institutes of Health to exercise its march-in rights for ritonavir, an HIV/AIDS drug marketed by Abbott under the brand-name Norvir. The petition and the NIH response are attached as Appendices A and B.[9]

The particular facts surrounding the Abbott's pricing of ritonavir made the march-in request particularly compelling. In December 2003, Abbott announced that it would raise the price of ritonavir, a drug that first came on the market in 1996, by 400 percent. Abbott was selective about the price increase, however. It did not apply to use of ritonavir in combination with another Abbott product, or outside of the United States. The company also said the price rise would not apply to public payers.

Abbott initially marketed ritonavir as a standalone protease inhibitor, to be used as part of a Highly Active Antiretroviral Therapy (HAART) drug "cocktail" for treating HIV/AIDS. The high doses of ritonavir for this purpose were accompanied by severe side effects, however. Over time, it turned out that ritonavir's best use was as a booster to other protease inhibitors -- a low dose of ritonavir can slow the ability of liver enzymes to break down a companion protease inhibitor, making it possible for a person on HAART to use lower doses of the companion protease inhibitor.

Abbott's 400 percent price increase raised the annual cost of using ritonavir as a standalone protease inhibitor from $9,387 to $46,935 per year.

More important was the price impact on use of ritonavir as a booster. The price jumped from $1,565 to $7,822. Abbott did not apply the price increase to all uses of ritonavir, however. The jump in the booster price applied only when ritonavir was used in conjunction with other companies' protease inhibitors. The price increase did not apply to use of ritonavir in conjunction with lopinavir, another protease inhibitor to which Abbott held patent rights. As a result, Abbott's ritonavir/lopinavir combination, sold as a two-in-one pill under the brand-name Kaletra, suddenly became much cheaper than other ritonavir-protease inhibitor combinations. Kaletra had been priced in the middle range of

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[8] 35 USC § 202(a)(2).

[9] See also James Love, "Statement at the NIH Meeting on Norvir/ritonavir March-in Request," May 25, 2005, available at: <www.essentialinventions.org/legal/norvir/may25nihjamie.pdf>.

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ritonavir-protease inhibitor combinations prior to the price increase. Afterwards, it was the cheapest, by a considerable margin. While Kaletra was priced at $8,559 a year and a single competitor was priced at $9,206, the rest ranged from more than $12,000 to more than $15,000 a year.

The anti-competitive effect of Abbott's price manipulation was clear. The price increase was a classic tying arrangement, with predictable consequences. The price differential between Kaletra and other ritonavir-protease inhibitor combinations meant that private insurers and patients in the private sector would tend to rely on Kaletra rather than alternatives.

More was at stake than simply money, though a lot of money was at stake. Not only did Abbott's pricing manipulation inevitably effect prescription decisions -- made for reasons other than the best interests of protecting patients' health -- it would affect the research agenda of other drug companies. The price rise for ritonavir changed the calculus for undertaking research into protease inhibitors that would rely on ritonavir -- any new product would be uncompetitive with Kaletra, so there was little incentive to invest in R&D.

"Looking ahead, we can foresee the continued need for new protease inhibitors that will have novel resistance profiles, that will have less toxicity, and that are more durable," explained Robert Huff, editor of Gay Men's Health Crisis Treatment News. "But how many important, useful, and desperately needed drugs will now never see the light of day -- because of Abbott's monopoly on Norvir? Abbott's unreasonable terms for Norvir will inhibit innovation, restrict research, limit medical options and hurt people with HIV."[10]

The United States government invested quite substantial resources into the development of ritonavir.[11] It funded Abbott's initial research on the drug, and thereby obtained Bayh-Dole rights in all but one of the patents Abbott claims on the project. NIH's investment in the preclinical phase at Abbott was approximately $3.5 million; if one applies the standard risk adjustments that the brand-name pharmaceutical industry typically employs when explaining the amount of investment in a product, this sum is huge. John Erickson, the principal investigator on the project at Abbott that invented ritonavir, says that early government funding played a key role in catalyzing support within the company to invest in the product's development.[12] After the Abbott team developed the precursor to

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[10] Robert Huff, "The Public Health Impact of Abbott Laboratories' Unreasonable Terms for Norvir," statement at a Public Meeting at the National Institutes of Health (NIH), May 25, 2004, available at <www.essentialinventions.org/drug/nih05252004/huff.doc>.

[11] To be clear, the level of government investment is irrelevant to whether Bayh-Dole rights attach. What matters is whether an invention was "conceived and reduced to practice" with the use of federal funds. If so, Bayh-Dole rights attach; if not, the government does not gain such rights, irrespective of how much it spends. Where such rights are in place, however, it is logical, in assessing the reasonableness of price for a federally funded invention, to examine the government and licensee's relative and absolute contributions to research and development of the invention.

[12] John Erickson, "On the Role of the U.S. Government in the Development of Norvir," statement at a Public Meeting at the National Institutes of Health (NIH), May 25, 2004, available at <www.essentialinventions.org/drug/nih05252004/erickson.doc>.

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ritonavir, federal money paid for clinical studies. At a certain point, Abbott apparently rejected additional federal funding, for fear that the government would later want to impose restraints on what it could charge for the drug.

Abbott claims that it spent more than $300 million developing ritonavir, though it provides no details to support these claims. It is very likely that this figure includes the kind of risk adjustment the company does not make in describing NIH's contribution to the early development of the product. The available evidence suggests that Abbott's clinical trial expenses were low relative to the average. The clinical trials to obtain marketing approval were small, the trial proceeded faster than usual, and FDA approval was granted in just 70 days (during a period when the average review time was more than 16 months).

As noted above, the Bayh-Dole Act specifies that march-in rights may be exercised because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention."[13] The Act defines "practical application" as including "that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms."[14] A second ground exists if "action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees."[15]

We petitioned for the exercise of Bayh-Dole march-in rights on both of these grounds. We argued that Abbott has failed to make ritonavir available on reasonable terms. Following the arbitrary escalation of price, ritonavir as a standalone protease inhibitor is priced 3-to-5 times more than other protease inhibitors not invented on a government grant. This was not, and is not, reasonable. Ritonavir is priced five times higher when used with competitors' protease inhibitors than when used in Abbott's own co-formulated pill. This was not, and is not, reasonable. Ritonavir's price jump applied to the United States, but not other markets, leaving the government-funded product five or ten times more expensive in the United States than other high-income countries. This was not, and is not, reasonable.

We also argued that the health consequences of Abbott's actions -- the distortion of prescribing decisions, and the effect on the R&D protease inhibitor pipelines -- meant that Abbott is not satisfying health and safety needs, again reason enough under the statute for NIH to exercise march-in rights.

In our petition, we asked that NIH issue an "open license" for use of ritonavir, so that any qualified manufacturer could make and sell the drug on a worldwide basis. To ensure that such actions would not undermine efforts to support R&D, we recommended that each licensee under the march-in be required to pay a 5 percent royalty to Abbott, and contribute to a fund to research new treatments for HIV/AIDS.

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[13] 35 USC § 203(a)(1).
[14] 35 USC § 201(f).
[15] 35 USC § 203(a)(2).

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Unfortunately, NIH rejected our petition.

"The record in this instance demonstrates that Abbott has met the standard for achieving practical application of the applicable patents by its manufacture, practice, and operation of ritonavir and the drug's availability and use by the public," the NIH found.

"Ritonavir has been on the market and available to patients with HIV/AIDS since 1996, when it was introduced and sold under the trade name Norvir as both a standalone protease inhibitor and a booster to increase the effectiveness of protease inhibitors marketed by other companies. Thus, the invention has reached practical application because it is being utilized and has been made widely available for use by patients with HIV/AIDS for at least eight years."

The logic of the NIH position was that Abbott met the Bayh-Dole standard of "practical application" by putting ritonavir on the market. This conclusion, however, ignored the statutory definition of "practical application," which specifies that the invention must be "available to the public on reasonable terms."

NIH dismissed our public health grounds for the petition as merely a restatement of the pricing controversy. "No evidence has been presented that march-in could alleviate any health or safety needs that are not reasonably satisfied by Abbott. Rather, the argument advanced is that the product should be available at a lower price, which is addressed below." This brief response failed to grapple not only with the way in which the price increase would impact prescription decisions -- a qualitatively different issue than whether patients or insurers are being charged too much -- but ignored altogether the unique impact of Abbott's actions on the R&D pipeline at other drug companies.

Finally, NIH said that the issue of drug pricing was one broader than the matter at hand. "The NIH agrees with the public testimony that suggested that the extraordinary remedy of march-in is not an appropriate means of controlling prices. The issue of drug pricing has global implications and, thus, is appropriately left for Congress to address legislatively." This was a bizarre conclusion. Our petition did not ask NIH to address drug pricing issues generally, but the specific case of Abbott's pricing of ritonavir, a government-funded invention. We did not ask the agency to manufacture authority for itself to wade into areas outside of its scope of expertise, but merely to exercise the safeguard implemented in the Bayh-Dole Act for the specific purpose of redressing pricing abuses and anti-competitive conduct.

It obviously was, and is, our position that NIH's decision was wrongheaded. We acknowledged at the time that NIH had discretion about whether it should act. But we believe its statutory interpretation was wrong on several grounds: the failure to consider reasonable pricing as part of the practical application standard; the refusal to consider derivative health consequences of anti-competitive conduct involving government-sponsored inventions; and the dismissal of price considerations as beyond the agency's authority under Bayh-Dole. We hope that NIH or the Secretary of HHS will revisit this

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decision, either in the specific case of ritonavir, or in other abusive cases presented.

In light of NIH's excruciatingly cramped reading of its authority and obligations under Bayh-Dole, Congress should act to give more guidance on when march-in rights should be administered. There are many reasons that NIH has been reluctant to exercise its march-in authority, but one is its historic uncertainty about how to handle matters relating to drug pricing. As I suggest below, Congress should both express the sense that NIH and other agencies should more aggressively use existing Bayh-Dole march-in authority, but also provide greater clarity to NIH and other agencies on the circumstances in which march-in rights should be exercised.

The Latanoprost March-In Case

In January 2004, Essential Inventions petitioned the National Institutes of Health to exercise its march-in rights for latanoprost, a drug for the treatment of glaucoma. The petition and the NIH response are attached as Appendices C and D.

Latanoprost was developed by Columbia University professor Laszlo Z. Bito in 1982. Dr. Bito's research in the late 1970s and early 1980s was funded with over $4 million in grants from the National Eye Institute at the National Institutes of Health. Columbia University licensed the invention to Pharmacia, which was subsequently acquired by Pfizer. Pfizer sells latanoprost under the brand name Xalatan.

Pfizer's price for latanoprost is very high. At the time of our petition, the drugstore.com price was $50 (it is now $65). A bottle lasts 4-6 weeks, making the 2004 cost of a year's supply $450-$650. The manufacturing cost of latanoprost, according to news accounts, is less than 1 percent of the sales price.[16]

The price of Xalatan in high-income countries outside of the United States is much lower than in the United States. Our petition to NIH provided evidence that the prices were two-to-five times cheaper in other high-income countries.

Our petition argued that this pricing disparity was per se evidence that Pfizer's price was not reasonable, and should therefore trigger the exercise of march-in rights. We argued that "a reasonable price for U.S. consumers, who funded the early development of latanoprost, would be a lower price than in developed economies that did not invest in the development of the drug. Pricing policies for a U.S. government funded invention cannot be reasonable when they discriminate against U.S. consumers."

We proposed the adoption of a presumptive rule that "patent owners for the subject invention should not charge U.S. consumers more than is generally charged in countries that are defined by the World Bank as high income."

NIH rejected our petition, using much the same logic as in the ritonavir decision. NIH

[16] Jeff Gerth and Sheryl Gay Stolberg, "Drug Companies Profit from Research Supported by Taxpayers," New York Times, April 23, 2000.

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again interpreted the requirement of achieving practical application of a subject invention as putting the product on the market. It ignored both the logic of the statute and its definition of practical application, which holds that a subject invention must be made available on "reasonable terms," meaning at a reasonable price:

> Pfizer has met the standard for achieving practical application of the applicable patents by its manufacture, practice and operation of latanoprost and the drug's availability and use by the public.
>
> Latanoprost has been on the market and available to glaucoma patients since 1996, when it was introduced and sold under the trade name Xalatan. Thus, the invention has reach practical application because it is being utilized and has been made widely available for use by glaucoma patients for at least eight years.

Regarding pricing issues, which the agency again treated as separate from the practical application requirement, NIH contended that "because the market dynamics for all products developed pursuant to licensing rights under the Bayh-Dole Act could be altered if prices on such products were directed in any way by NIH, the NIH believes that the extraordinary remedy of march-in is not an appropriate means of controlling prices. The issue of whether drugs should be sold in the United States for the same price as they are sold in Canada and Europe has global implications and, thus, is appropriately left for Congress to address legislatively."

REQUESTS THAT THE UNITED STATES UTILIZE ITS WORLDWIDE RIGHTS TO USE PATENTS FROM SPONSORED RESEARCH

Request that the United States Use License Rights for Pharmaceutical Procurement

In January 2007, Essential Inventions wrote to Robert Portman, then the head of the Office of Management and Budget, to suggest that the government utilize its paid-up, worldwide rights to use patents from sponsored research. This letter is attached as Appendix E.

To make the proposal specific, we requested that OMB grant Essential Inventions, and all qualified suppliers, the right to import or manufacture two AIDS drugs, d4T and ritonavir, for the purpose of supplying the federal government. The federal government directly or indirectly purchases these drugs through numerous programs, including the AIDS Drug Assistance Program (ADAP), the Department of Veterans Affairs, Medicare Part D and PEPFAR (the President's Emergency Plan for AIDS Relief).

We pointed out that d4T from Bristol-Myers Squibb is now priced at more than $3,600 per year on the Federal Supply Schedule, but generic d4T costs less than $50 per year in countries where generic competition is legal. Major savings are available for ritonavir as well. Generic ritonavir is available for as low as $190 a year, though the U.S. price would

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probably be higher.[17]

OMB staff agreed to meet with us. They did not disagree that the U.S. government had the Bayh-Dole rights we identified. They did not disagree that exercising those rights would yield enormous savings for the federal government. However, they indicated that they would not respond to our letter in writing, and that if we wanted to pursue the matter further, we should contact other agencies.

In the Congressional debates leading up to passage of Bayh-Dole, the most ardent supporters of a policy to license federally funded inventions pointed to the importance of maintaining government rights to use those inventions. This was described as a key check on pricing abuse -- the safeguard that at least the government would not be asked to pay excessive prices for the inventions it had funded. The OMB refusal to act on our recommendation, or even respond in writing, suggests that what was viewed as the most minimal safeguard has now been abandoned, at least for pharmaceutical inventions.

Request that the United States License International Organizations to Use Its Rights in Federally Sponsored Inventions

Under Bayh-Dole, the federal government not only has a paid up license to use sponsored inventions on its own behalf, it has the ability to issue licenses to international organizations or foreign governments to use those inventions.

In 1999, James Love of the Consumer Project on Technology (now Knowledge Ecology International), Ralph Nader and I wrote to the National Institutes of Health, urging that NIH exercise its Bayh-Dole rights to issue licenses to the World Health Organization (WHO) for important HIV/AIDS and other medicines in which the federal government held rights. This letter and the NIH response are attached as Appendices F and G.

We pointed out that patent barriers interfered with many countries obtaining access to generic versions of those medicines; and that even where patent barriers were not an obstacle, limited economies of scale meant most countries could not on their own obtain the full, robust price benefits that generic competition can confer. "If the WHO uses efficient procurement programs, it can obtain production of these government funded inventions at a small fraction of current world prices," we wrote. "These lower prices would lead to expanded access to essential drugs and stretch public health budgets."

We urged that NIH enter into an agreement with WHO to enable this transfer, assess for which drugs it could transfer patent rights, and take steps to ensure that all new grants and contracts reference WHO's right to use patents in which the government gained Bayh-Dole rights.

The NIH declined our request. Then-NIH director Harold Varmus acknowledged that NIH had the authority to implement our proposal, but argued:

[17] Medecins Sans Frontieres/Doctors Without Borders, "Untangling the Web of Price Reductions," July 2007.

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> This proposal, if implemented, would have powerful repercussions on the current framework for drug development arising from federally supported basic research. I am concerned that your proposal that the NIH employ its "Government use" license authorities to grant WHO standing authority to contract for the production of Government-supported inventions so as to make anti-AIDS drugs available for less cost than offered by pharmaceutical manufacturers would put the current system at risk without necessarily resulting in greater accessibility to these drugs. I am also troubled by the implications of the NIH intervening on behalf of sovereign foreign governments in a situation in which many of those governments have the authority to achieve the same result and in which U.S. intervention on this matter has not been requested.
>
> Moreover, the AIDS crisis in developing countries is a public health problem involving much broader issues than access to anti-viral drugs. The question of the supply of drug products must be considered in the context of the equally important issues of medical infrastructure, public health programs, treatment monitoring and compliance, and emergence of drug-resistant HIV strains. Unilateral action by NIH with regard to NIH-supported patent rights would consequently be ill-advised and unlikely to succeed.
>
> ... As a practical matter, it is reasonable to assume that companies will not undertake the development costs of these inventions if they believe the Government will readily allow third parties to practice the inventions.

In retrospect, some of these arguments look deeply misguided. The argument that efforts to lower the price of AIDS medicines without a comprehensive approach to addressing the problem in developing countries was disproved by history. The eventual lowering of prices helped spur donor aid and far-reaching programs that would not have been possible with high prices.

The idea that NIH would undermine developing countries' sovereign authority by helping lower the price of medicines when the countries did not act on their own ignores the complex reasons why many did not act, and also has been disproved by history. Many have taken steps on their own to lower prices for HIV/AIDS drugs, but others have not. But of those countries which have not exercised policy options to lower prices, none have complained when international developments -- including decisions by brand-name companies not to enforce patent claims -- have spurred generic competition and enabled them to benefit from lower prices. Most importantly, the NIH position ignores the reality of pharmaceutical manufacturing, in which economies of scale are vital. Individual countries may and should act on their own, but they cannot, on their own, benefit from robust generic competition. WHO or another global agency undertaking global procurement arrangements can achieve these benefits. The price reductions obtained by the Clinton Foundation for HIV/AIDS drugs are an example of this.

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The broad argument Dr. Varmus made was that licensing Bayh-Dole rights to WHO would undermine pharmaceutical companies' willingness to develop government-sponsored inventions. But this argument was misplaced as well. Developing country markets represent a small share of the world market -- roughly 15 percent at present (and less when Dr. Varmus wrote his letter).[18] Pharmaceutical companies would not stop investing in R&D if their overall market was suddenly 15 percent smaller; indeed, the global pharmaceutical market in 1999 was roughly half the size that it is presently, and it was almost 15 percent smaller in 2004 than it was in 2006. Moreover, pharmaceutical company development costs are proportionately smaller for pharmaceuticals when the United States government contributed -- often quite substantially -- to the early stage research. And, to ensure a fair return for their investment, compensation can be paid to corporate licensees -- a reasonable royalty for sales in developing countries

A standard licensing arrangement with WHO or other agencies for access to federally funded inventions remains a good idea, and is discussed further below. But in the absence of a standard agreement, surely there must be cases where the right should be exercised. Can there be a more compelling case than antiretroviral drugs? These are life-saving medications to treat one of the worst pandemics the world has experienced since the Black Plague. Prices in developing countries have plummeted for first-line and older HIV/AIDS drugs thanks to generic competition, but patent barriers are keeping prices for second-generation and second-line medicines relatively high, threatening the ability of global AIDS treatment programs -- of which the United States is the largest funder -- to expand treatment and meet the UN target of universal access to antiretrovirals by 2010.

ASSESSING THE NIH RATIONALE FOR INACTION

In two important reports, NIH has reviewed its options for assuring that federal funded inventions are made available to the public on reasonable terms, and essentially concluded that it has no role. In "A Plan to Ensure Taxpayers' Interests are Protected,[19] NIH explained why it abandoned efforts to include "reasonable pricing" provisions in Cooperative Research and Development Agreements (CRADAs), licensing federally owned inventions to third parties. In "Affordability of Inventions and Products,"[20] a July 2004 report to Congress, the agency explained why it did not seek to assure fair pricing of federally sponsored inventions.

Although some of the arguments relate to NIH's institutional capacity, many of them echo the self-interested declarations of the brand-name pharmaceutical industry.

Below I review NIH's key contentions and offer responses.

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[18] IMS Health Reports Global Pharmaceutical Market Grew 7.0 Percent in 2006, to $643 Billion," (news release), available at: <www.imshealth.com/ims/portal/front/articleC/0,2777,6599_3665_80560241,00.html>. (Global sales totaled $643 billion in 2006. Sales in Latin America, Asia (excluding Japan) and Africa totaled $99.6 billion.)

[19] National Institutes of Health, "A Plan to Ensure Taxpayers' Interests are Protected," report to Congress, July 2001, available at <www.nih.gov/news/070101wyden.htm>.

[20] National Institutes of Health, "Affordability of Inventions and Products," report to Congress, July 2004, available at: <http://ott.od.nih.gov/NewPages/211856ottrept.pdf>.

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NIH Position: The technologies developed in basic research laboratories are nascent, requiring extensive further development. Not all technologies arising from NIH-funded research lead to therapeutic drugs. The likelihood that a compound will reach the market is very low. There is a long lag time between when inventions are licensed and when they reach the market, making monitoring difficult.[21]

Response: It is true that most NIH-sponsored inventions do not lead to therapeutic drugs and those that do require more development.[22] But neither of these facts alters the reality that a company gaining exclusive license to an NIH-sponsored invention gains something of considerable value in the exchange. How valuable? The brand-name pharmaceutical industry famously likes to quote the Tufts Center for the Study of Drug Development estimate that the risk-adjusted cost of developing each new pharmaceutical product is $802 million. Risk is highest in the early phases of the development process, so relatively small dollar outlays in the preclinical phase for successful drugs constitute a very large chunk of the $802 million. The authors of the study alleging the $802 million figure place the cost of preclinical research for a successful drug at $336 million.[23] Government funding will generally not cover the entire preclinical costs of development, but it is often a large part, especially when one takes into account multiple grants beyond the one leading directly to creation of the invention.

It is true that there is a long time lag between licensing and a product getting to market, but it is not true that the delay poses particular monitoring difficulties. Where universities or federal labs or NIH are receiving royalties, they typically monitor whether milestones are met and how the sponsored invention performs if it makes it to market. Moreover, a reasonable pricing requirement, whether mandated by contractual terms or enforced by use of march-in rights, would not require much enforcing -- once the government demonstrated that it intended to enforce such obligations. Even relatively complex measures of determining fair pricing would be relatively simple to administer, once it was clear that the obligation was going to be enforced.

NIH Position: "NIH also found that the actual financial return to grantees and contractors was relatively low. Indeed, while universities and industry stressed that the current system under Bayh-Dole has been highly successful and a model now emulated by the world, they cautioned that the great majority of these patents do not generate significant revenues or even sufficient revenues to compensate the patenting expenses."[24]

Response: It is true that the great majority of patents generate little or no revenue, but

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[21] National Institutes of Health, "A Plan to Ensure Taxpayers' Interests are Protected," report to Congress, July 2001, available at <www.nih.gov/news/070101wyden.htm>.

[22] Note however that some NIH-sponsored inventions, known broadly as research tools, require little or no additional development. The particular issues surrounding research tools are briefly discussed further below.

[23] Joseph DiMasi et al., J. Health Economics 2003;22(2):151-185; see Costs and Returns for New Drug Development, Joseph A. DiMasi, FTC Roundtable on the Pharmaceutical Industry, October 10, 2006, slide 5, available at: <www.ftc.gov/be/workshops/pharmaceutical/DiMasi.pdf>.

[24] National Institutes of Health, "A Plan to Ensure Taxpayers' Interests are Protected," report to Congress, July 2001, available at <www.nih.gov/news/070101wyden.htm>.

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this is no argument for why those inventions that do have market impact should not be priced fairly. In fact, that the universe of sponsored inventions with significant market impact is small suggests that monitoring should be relatively easy. It is also worth noting that the claim that most government-funded inventions were not being commercialized was the key, misleading rationale for adoption of Bayh-Dole; after a quarter century of experience, and even with the biotech revolution, it is clear that the vast majority of government-funded patents remain uncommercialized, simply because they do not have clear commercial value -- the exact circumstance as was the case before Bayh-Dole.

NIH Position: Efforts to obtain higher royalty rates would deter companies from undertaking development of federally owned or sponsored inventions, even if the royalty or recoupment provisions only applied to blockbuster drugs.[25]

Response: NIH contends that higher royalty rates or recoupment provisions applying only to blockbusters would deter companies from developing government-sponsored inventions, and, relatedly that it abandoned the reasonable pricing requirement for CRADAs because of this deterrent effect. As a matter of simple economics and raw business calculation, it is very hard to see how a corporation would make this decision. Developing government-funded inventions would remain highly profitable even with recoupment or, much more preferably, reasonable pricing conditions. It is conceivable that some companies would refuse to accept such obligations on principle, or out of concern that it might lead to other price-related regulation. But that cannot be a reason for the federal government to sacrifice taxpayer interest. The public interest cannot so be held hostage. There is also empirical evidence of brand-name companies willingness to pay large sums -- exceeding any recoupment requirements -- where they believe they may obtain blockbusters.[26]

NIH Position: "Even in those few cases in which an NIH-invented technology is an identifiable part of a final product, the invention would typically be one of numerous components that would go into building that product. ... Just as the provider of any one component of an automobile cannot dictate the cost of the final vehicle, the provider of a single technology in the development of a therapeutic drug cannot dictate the final cost of the drug."[27]

Response: It is true that there typically are multiple patents related to any pharmaceutical product, and that where there is a government owned or sponsored patent, there may be others in which the government does not hold rights. However, it is misleading to analogize this situation to a component in an automobile; there may be several or even many patents on a drug, but nowhere near as many as there are components to a car.

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[25] National Institutes of Health, "A Plan to Ensure Taxpayers' Interests are Protected," report to Congress, July 2001, available at <www.nih.gov/news/070101wyden.htm>.

[26] See for example, Gilead Sciences and Royalty Pharma Announce $525 Million Agreement with Emory University to Purchase Royalty Interest for Emtricitabine," Gilead, Emory University, Royalty Pharma news release, July 18, 2005, available at <www.news.emory.edu/Releases/emtri>.

[27] National Institutes of Health, "Affordability of Inventions and Products," report to Congress, July 2004, page 3, available at: <http://ott.od.nih.gov/NewPages/211856ottrept.pdf>.

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Because of the government's involvement in early stage research, its patents will typically be the most, or among the most, important patents on a product. It will frequently be the case that the government patent covers a new molecule or composition -- the essence of a new drug -- and that a party with rights to that patent could work around (and frequently challenge as invalid) other claimed patents. The expert analysis we had conducted of the patent landscape in the ritonavir march-in case, for example, suggested this was the case for that drug.[28] That said, there are complexities that will emerge in some cases for products with more complicated patent landscapes, and how to address these challenges is an issue the committee should consider addressing in future hearings. An important operative principle may include reach-through mechanisms connected to Bayh-Dole rights, requiring a product that incorporates a government-sponsored invention to be fairly priced

NIH Position: Overall improvements in efficiency and time and reduction in risk to industry in bringing drugs to the marketplace should result in not only new and better drugs for the American public but also permit industry to price the drugs lower than they would otherwise."[29]

Response: It is absolutely correct that reducing risk to industry via federal funding should "permit industry to price the drugs lower than they would otherwise." This is the essence of the argument that there should be pricing restraints on government-funded inventions, or that excessive pricing should be a trigger for use of the march-in right. It is, however, demonstrably not the case that federal funding without any licensing or contractual measures, or use of policy tools such as march-in rights, will lead to lower drug prices.

NIH Position: "The cost of prescription drugs is a legitimate public concern that exists whether or not a drug was developed from a technology arising from federally funded research. NIH, however, has neither the mandate nor the authority to be the arbiter of drug Affordability."[30]

Response: It is not true that NIH does not have the mandate or authority to address drug pricing concerns. The Bayh-Dole Act gives granting federal agencies the authority to exercise march-in rights when an assignee is not achieving practical application of an invention, defined by statute as being made "available to the public on reasonable terms."

NIH Position: "Should a critical public health emergency arise, the NIH may require mandatory licensing or sublicensing if it determines that a technology is not being moved to practical application (35 U.S.C. § 203). Bayh-Dole, however, does not provide authority for the NIH to control the pricing of products resulting from inventions made by

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[28] Daniel Ravicher, statement at a Public Meeting at the National Institutes of Health (NIH), May 25, 2004, available at <www.essentialinventions.org/drug/nih05252004/ravicher.doc>.

[29] National Institutes of Health, "Affordability of Inventions and Products," report to Congress, July 2004, page 4, available at: <http://ott.od.nih.gov/NewPages/211856ottrept.pdf>.

[30] National Institutes of Health, "Affordability of Inventions and Products," report to Congress, July 2004, page 5, available at: <http://ott.od.nih.gov/NewPages/211856ottrept.pdf>.

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funding recipients."[31]

Response: There is nothing in the Bayh-Dole Act mentioning public health emergencies. The statute provides four separate grounds for march-in rights, all much broader than public health emergencies. These include to achieve practical application -- defined, again, as making the invention "available to the public on reasonable terms;" meeting public health needs not satisfied by the contractor or licensee; and satisfying requirements for public use not met by the contractor or licensee.

NIH Position: "Many companies, therefore, have indigent patient programs to supply drugs to some patients on a discounted or no cost basis, thereby making them affordable to those patients."[32]

Response: It is unfortunate to see NIH citing industry indigent patient programs as an excuse for high drug prices. Those programs do not begin to cover all who need them; many who are able to afford medicines do so as an enormous financial hardship. Even those who can absorb high prices should not be price gouged. Many medicines are of course provided by private and public insurers, meaning that even when there are not direct access problems (as there often are with the insured, because of co-payment obligations), consumers, employers and the public are bearing the financial burden.

NIH Position: "Although establishing standards for the affordability of drugs and therapies is beyond the agency's mission or authority, the NIH contributes to affordability through research that leads to the development of a wider selection of drugs or new drugs, where no drugs were available. More alternatives can translate into more choices for the public, greater market competition, affordability and, ultimately, overall return to society by the improvement of the quality of life."[33]

Response: There is no empirical basis for the claim that placing more drugs on the market will yield greater market competition and affordability. Drug prices are rising steadily; brand-name pharmaceutical and biologics companies no longer attempt to justify their pricing strategies based on R&D costs, instead saying they will charge whatever the market can bear; and available evidence suggests that new drugs in the same therapeutic class as existing patent monopoly-protected medicines are priced at or above the cost of existing drugs.

NIH Position: The public gets an enormous return on the public investment in medical R&D, because new medicines improve the quality of life and lessen the cost of illness

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[31] National Institutes of Health, "Affordability of Inventions and Products," report to Congress, July 2004, page 5, available at: <http://ott.od.nih.gov/NewPages/211856ottrept.pdf>.
[32] National Institutes of Health, "Affordability of Inventions and Products," report to Congress, July 2004, page 5, available at: <http://ott.od.nih.gov/NewPages/211856ottrept.pdf>.
[33] National Institutes of Health, "Affordability of Inventions and Products," report to Congress, July 2004, page 6, available at: <http://ott.od.nih.gov/NewPages/211856ottrept.pdf>.

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(e.g., through reduced hospital stays).[34]

Response: It is undoubtedly true that many of the drugs NIH has supported have not only had important lifesaving and quality of life effects, but have lessened the economic cost of illness. This is no argument, however, about why important medicines should be overpriced, or why the government should not demand reciprocity from corporations that profit directly from government-sponsored research. It is also an argument that proves too much. Taken to its logical conclusion, it suggests the government should directly subsidize the pharmaceutical industry with no limit. The argument can be used, and is used by the brand-name industry, to justify ever higher prices of medicines, with very little limit. People place a high value on staying alive, lessening illness and reducing pain and discomfort; that does not mean they should be charged whatever the market will bear.

RECOMMENDATIONS FOR REFORM AND FURTHER INVESTIGATION

There is obviously a rich set of issues for the Committee to explore as it continues its investigations into the role of federally funded research in the patent system. My recommendations do not seek to be comprehensive, and they draw primarily though not exclusively from experience with biomedical research. The first set of recommendations draws from Essential Invention and Essential Action's direct experience with Bayh-Dole. The subsequent recommendations stem from our examination of Bayh-Dole-related policies and practices.

1. Operationalizing March-In Authority

The NIH has adopted an interpretation of its march-in authority that is divorced from the plain language of the Bayh-Dole statute, the law's legislative history, and common sense. This must change.

Congressional statements and effective oversight might affect NIH's approach, but there is reason to be skeptical. Congress has periodically turned it attention to different aspects of Bayh-Dole related to royalty rates and reasonable pricing, but NIH has rebuffed demands that it pay attention to the affordability of the inventions it transfers to pharmaceutical and biotechnology companies. Thus, although existing statutory language should at least give the agency confidence in its authority to exercise march-in rights to address pricing abuses -- even if the authority is discretionary -- it is likely the case that legislative action will be necessary.

Reform proposals should consider both standards by which march-in rights should presumptively be exercised, and institutional roles in determining the exercise of march-

[34] National Institutes of Health, "A Plan to Ensure Taxpayers' Interests are Protected," report to Congress, July 2001, available at <www.nih.gov/news/070101wyden.htm>; National Institutes of Health, "Affordability of Inventions and Products," report to Congress, July 2004, page 5, available at: <http://ott.od.nih.gov/NewPages/211856ottrept.pdf>.

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in authority.

Ritonavir presents the easiest case for reform: a sudden, unprovoked escalation in price, with transparent anti-competitive intent and effect, and harmful public health consequences. Clear language explicitly stating that excessive pricing, abusive use of patents, and/or anti-competitive behavior are bases for the exercise of march-in rights should make clear that march-in rights should be exercised in case of behavior comparable to Abbott's price and market manipulation with ritonavir.

But the march-in authority should not be limited only to the most extreme cases. Absent a major reworking of Bayh-Dole, the march-in is the key method to ensure the public gets a return on the government investment in the form of restrained pricing. This central role does not mean march-in rights must frequently be exercised. Once background rules for pricing restraint are established, and shown to be enforceable through march-in rights, market norms will shift. Then march-ins will only need to occur occasionally if at all.

In the latanoprost case, we suggested that the standard for exercising march-in rights should be whether the medicine incorporating federal inventions is priced more than the average in other high-income countries. Setting medicine prices for U.S. consumers above the charge for consumers in other high-income countries -- in instances where the U.S. public paid for crucial research and development -- should presumptively be unreasonable. A virtue of the rich country price comparison test is that it is a simple calculation yielding a clear answer.

It would not be hard to develop other standards, however, which complement or substitute the rich country price comparison test. More elaborate formulas might inquire into the relative and absolute government and corporate investments in a medicine, based on disclosed costs from the pharmaceutical company developer. The standard could require that prices for products incorporating federally sponsored inventions be lower in price, relative to other medicines in the class or otherwise comparable. Government funded inventions should be cheaper proportionate to the private company's reduced investment costs. Drugs not incorporating this price discount would then be defined as presumptively not being made available to the public on reasonable terms.

Another possible model might be to cap returns on blockbuster drugs receiving significant government support. After a product receiving government support equivalent to 20 percent of development expenditures, say, generated revenues equal to 20 times disclosed investment costs, march-in rights could presumptively kick in. The standard could be calibrated to take into account various factors; my numbers here are illustrative only.

To ensure that the public interest in supporting R&D is advanced, march-in rules might require that licensees under march-in rights pay royalties to support R&D or perform specified R&D mandates. Royalties to the initial licensee may also be mandated.

Whatever standard is established, our experience in trying to use the march-in rights

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makes clear that a new Congressional directive is needed, with clear and presumptive standards.

It would be wise also to consider lodging march-in authority with other agencies. NIH has repeatedly denied that it has the authority conferred on it by the Bayh-Dole Act; one reason undoubtedly is that it is uncomfortable with drug pricing issues. There is no obvious reason why the agency should feel more able to develop and maintain institutional expertise in licensing of patents than in ensuring the fruits of its investments are available and affordable to the public, but that appears to be the case. In light of the NIH's expressed discomfort with pricing issues, one solution might be to establish concurrent march-in authority with another agency, perhaps the Federal Trade Commission or Department of Justice.

Establishing clear and presumptive rules for march-in rights would also make it possible to create strong rights of appeal to courts in case of agency inaction. Citizen enforcement and rights to appeal adverse agency decisions against a clear standard would be a very powerful means of ensuring Congressional objectives of obtaining a fair return on public investment were met.

It would be useful to specify that march-in rights may be exercised immediately upon grant, and not be subjected to stay on appeal.[35]

2. Using Federal Rights In Government-Funded Inventions

From a normative perspective, it is utterly shameful that the U.S. government permits pharmaceutical and biotechnology companies to gain access to government-sponsored inventions, and then price gouge consumers -- the U.S. public. But it is preposterous that the government permits those corporations to price gouge the very government that helped pay to invent and develop the drugs they are selling.

The federal government has the power to remedy this inequity. Congress should pressure the executive branch to take advantage of the fully paid-up licenses it maintains for drugs in which it holds Bayh-Dole rights. These drugs are concentrated in the areas of AIDS and cancer treatment, two areas of especially high government expenditure, so the potential savings are quite considerable.

Logically, policy in this area should be centrally managed, through an agency such as Office of Management and Budget (OMB). If OMB declines to act, individual agencies could and should take action on their own.

However, if past experience is any guide, the individual agencies are not likely to act on their own, again suggesting the need for Congressional intervention. The issues are similar to those in the Bayh-Dole context: Congress should specify clear rules for when the government should exercise its paid-up license for the purpose of accessing generic

[35] See discussion in Arti K. Rai and Rebecca S. Eisenberg, "The Public Domain: Bayh-Dole Reform and the Progress of Biomedicine," 66 Law and Contemp. Prob. 289 (2003).

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versions of medicines it purchases through various programs. Congress should also specify that paid-up licenses may be used for state programs administered with federal money. The rules that Congress establishes may parallel those for use of the march-in right, or they might perhaps more aggressively favor march-ins, on the grounds that the government as drug buyer should be able to benefit directly from its R&D investment leading to pharmaceutical inventions. Concerns about fair returns for the R&D contribution of licensees should be addressed through reasonable royalty payments.

3. Licensing U.S.-Sponsored Inventions for Use in the Developing World

The management of overseas rights in U.S. government-funded or owned intellectual property offers an enormous opportunity to advance global public health interests, at no cost to U.S. taxpayers.

As we explained in our 1999 letter, the United States already has the power to enter into agreements with international organizations to license them the rights to patents in which the government holds Bayh-Dole interests. As the recognition of the severity of global health problems grows, as the United States devotes increasing resources to addressing global health challenges -- including but not limited to HIV/AIDS -- and as discussions evolve at international organizations such as the World Health Organization over mechanisms to promote the objectives of both access to medicines and increasing innovation, it is time for the United States to manage its intellectual property assets purposefully.

If we leave aside the question of what legal rights the United States currently has, and dismiss the propagandistic claims about harms that will befall medical innovation if we promote access in developing countries, it is not hard to imagine better policies going forward. The United States should make its biomedical patent portfolio available for nonexclusive use in developing countries.

One attractive approach to this issue is embodied in the Public Research in the Public Interest Act of 2006, introduced by Senator Leahy as S.4040. The Public Research in the Public Interest Act would require university recipients of U.S. funds to license their inventions on a non-exclusive basis for use by low-income and lower-middle-income countries, and for research on neglected diseases. An attraction of the bill is its reach-through provisions, which require the developing country licensing provisions to apply to university licensees and sublicensees, to follow-on patents associated with the government-sponsored invention, and to testing data needed to obtain regulatory approval.

A similar outcome could be achieved if the U.S. government acted to use its existing rights to advance global public health objectives, by entering into agreements with international organizations to license technologies to them. There would be several benefits of licensing to a global public health patent pool, or international agency that effectively managed licenses to biomedical inventions for developing countries. The public patents could serve as "anchor tenants" for a patent pool, creating social and

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market norms to facilitate private sector licensing to the pool. A global manager of patents and related rights could also undertake or organize efficient global registration and procurement arrangements.[36] A patent pool would also be well positioned to collect and distribute royalties, making it possible to compensate companies that contributed to development of drugs with Bayh-Dole rights. A royalty system could also be calibrated to developing countries' varying income levels, so that middle-income countries could obtain lower priced drugs, while also making fair-share contributions to R&D costs.

4. Improved and Transparent Reporting Mechanisms

More effective public understanding of the extent of NIH and other agencies' Bayh-Dole rights could be achieved with better reporting of inventions where Bayh-Dole rights apply.

There are several reporting-related issues.

Patents with Bayh-Dole rights are supposed to include a reference to the supporting grant and a statement that "The Government has certain rights in this invention." Searching the U.S. Patent and Trademark Office (PTO) reveals that nearly 30,000 patents granted since 1976 list "certain rights." Although it would be a very worthy investigation to review these patents, how they have been commercialized and what returns the public has received, this is beyond the capacity of most persons or monitoring organizations, and involves a universe beyond NIH grants.

It is possible to review the registration information for every new drug, by checking the drug's listing in the FDA's Orange Book, identifying relevant patents, and then checking those patents in PTO's database. This is time consuming, though doable. This method does not work for biologics, however, which are not listed in the Orange Book, and which are an increasingly important part of the pharmaceutical landscape.

NIH does collect detailed information on utilization of inventions developed with federal support, but this information is not made public,[37] due to confidentiality provisions in Bayh-Dole.[38] This confidentiality apparently extends even to listing drugs on the market for which the government maintains Bayh-Dole rights, even when much of the information is attainable from other public sources. The NIH publishes a list of FDA-

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[36] For a detailed discussion of how patent pools could advance health interests, see Knowledge Ecology International, "The Use of Patent Pools to Expand Access to Needed Medical Technologies: KEI Comment to the World Health Organization (WHO) Intergovernmental Working Group (IGWG) on Public Health, Innovation and Intellectual Property Rights," September 30, 2007, available at <www.who.int/phi/public_hearings/second/contributions_section2/Section2_ManonRess-PatentPool.pdf>. For a working plan of a global public health patent pool, see Knowledge Ecology International, "The Essential Medical Inventions Licensing Agency: Working Plan," June 1, 2007, available at: <www.keionline.org/misc-docs/emila.pdf>.

[37] See Interagency Edison, available at: <https://s-edison.info.nih.gov/iEdison/index.jsp>.

[38] 35 USC Sec. 202 (c) (5).

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approved drugs where the contractor has consented to release of the information,[39] but this is very limited. Perusing the illustrative examples in the summary reports from the Association of University Technology Managers makes clear how much is missing. The Committee should consider revisiting the confidentiality provisions in Bayh-Dole, as well as means to centralize, organize and make public information on existing Bayh-Dole rights.

A separate issue relates to whether Bayh-Dole rights are properly acknowledged.

In filing patent applications, contractors are supposed to note both the supporting grant and that "the Government has certain rights in this invention."[40] Failure to notify the government of its Bayh-Dole rights may lead to forfeiture of the university's title in the invention.[41]

But the Bayh-Dole rights apply only to "subject inventions," defined as "any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement."[42] Grants may be made to support work in an area, but if conception of the invention occurs with non-government funding, the government has no rights. This on-off approach in an area where funds may easily be co-mingled creates incentives and opportunities to circumvent the government's retention of rights.

Even where Bayh-Dole rights should attach, the university or contractor may not report them. Although the potential penalty for failing to report is forfeiture, various government monitoring agencies have found a high percentage of non-reporting.[43] This is an area worthy of further Committee investigation.

A final transparency issue relates to university publication of its license arrangements with corporations. Some universities have helpfully published standard form contracts, but this is only a modest first step. All university and federal agency licensing arrangements should be made publicly available, perhaps in connection with new government contracting databases now under construction. Permissible redactions for purported proprietary reasons should be kept to a minimum.

5. Establishing Government Rights in Sponsored Research Not Giving Rise to Patentable Inventions

The required Bayh-Dole nexus between government sponsorship and conception of the invention creates an opportunity to game the system, so that government funds are not used for the work leading directly to conception. We have received anecdotal reports that this is not uncommon.

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[39] Report of FDA Approved Commercial Products Involving NIH Extramural Support, available at: <https://s-edison.info.nih.gov/iEdison/commercial_report.jsp>
[40] 35 USC § 201 (c)(6).
[41] 35 USC § 201 (c)(1).
[42] 35 USC §201(e).
[43] See Government Accountability Office, "Technology Transfer: Reporting Requirements for Federally Sponsored Inventions Need Revision," August 1999, GAO/RCED-99-242.

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There is a much bigger consideration, however. NIH sponsorship monies that do not directly lead to conception of an invention confer no Bayh-Dole rights at all. This includes cases where federal funding supports a university's pre-clinical investigations with considerable funding, but not the funding leading directly to conception of an invention.

It also includes cases where the NIH supports clinical testing, a growing area of investment by the agency. There is growing interest in NIH supporting clinical testing of promising inventions that are not receiving private sector take-up. These instances involve the agency venturing further away from its mission in creating health-related informational public goods. This is not to say such a role for NIH is inappropriate; there is a very strong public rationale for NIH taking on this mission. But it is a context in which the agency is acting very much like a venture capitalist, albeit primarily only in areas that other venture capitalists do not wish to tread (except possibly in conjunction with government support). The case for a government demand of reciprocity for its investment is thus very strong -- but there is no such reciprocal requirement.

Consider the case of cetuximab, the generic name of the drug that led to Martha Stewart's securities-related conviction. Patent rights to the drug are held by ImClone. It is sold under the brand-name Erbitux. The drug is marketed by Bristol-Myers in the United States and Merck outside the United States. It is a targeted colon cancer treatment and now approved also for head and neck cancer. The U.S. price for the drug is on the order of $17,000 a month.

Although there is some uncertainty about the efficacy of the drug in extending survival time, it has positive properties in the way it treats tumors and new evidence suggests it may prove to be useful and important.

At $17,000 a month, it is already proving very profitable. Approved in 2004, Erbitux became a billion-a-year seller in 2006.[44] In North America, 2006 sales amounted to approximately $652.2 million, compared to approximately $413.1 million in 2005. Outside of North America, Merck's 2006 sales totaled approximately $428.2 million, compared to approximately $265.3 million in 2005.

It does not appear that United States has Bayh-Dole rights in cetuximab.[45] Although ImClone reports in its 10-K that "we have an exclusive license from the University of California to an issued United States patent for the murine form of ERBITUX, our EGFR antibody product"[46] the licensed U.S. patent number appears to be 4,943,533, which does not list any governmental interest.

Although the U.S. government may not have contributed the funds leading to the invention of the drug, it played a key role in getting it to market. The National Cancer

[44] ImClone Systems Incorporated 2006 10-K report to SEC, page 58.
[45] It is possible that Bayh-Dole rights do apply. Cetuximab is not listed in the FDA's Orange Book.
[46] ImClone Systems Incorporated 2006 10-K report to SEC, page 27.

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Institute describes its role in the development of cetuximab as follows:

> 1980s: Erbitux (NSC 632307), known generically as cetuximab, is one of four NCDDG-developed agents approved by the FDA since the inception of the NCDDG. This agent, a chimera comprising human and mouse monoclonal antibodies against the epidermal growth factor receptor (EGFR), is based on Dr. John Mendelson's 1980s hypothesis that monoclonal antibodies against EGFR could block receptor activation, which in turn would interfere with the cell signaling that leads to increased cell proliferation, angiogenesis, invasion, and metastasis.
>
> 1990s: In 1990, the NCDDG began work on Erbitux, and in 1999, ImClone Systems of New York commenced phase III trials in collaboration with Merck KGaA of Darmstadt, Germany. In 2001, Bristol-Meyers Squibb and ImClone agreed to co-develop this agent, and the first application for FDA approval was submitted in November of that year.
>
> 2001–present: ImClone submitted its original request for FDA approval in 2001, but the FDA determined that this application could not be reviewed because of missing information. However, in August 2003, ImClone submitted the results of a large, well-run trial, the results of the two earlier studies, and the missing information requested by the FDA, and Erbitux received approval for the treatment of metastatic colorectal cancer in 2004. Combinations of Erbitux and radiation or platinum-based chemotherapeutic agents are under exploration.[47]

Given the evident substantial governmental support for development of cetuximab, shouldn't the government have some power to restrain its abusive pricing?

The committee should consider how and what governmental rights may be established in cases where the government contributes significantly to a product reaching market, but not to the research leading to the patent. The core principle should be that there must be some reciprocity in the form of price restraints for government support for R&D that directly helps products get to market, especially when the government is making high-risk investments.

6. Assessing University Corporate Entanglements in the Bayh-Dole Context

Bayh-Dole has been a central component of the evolving university-industry relationship, but it is by no means the only element. Bayh-Dole paralleled and facilitated a range of university-industry organizational relationships, notably including university creation of, and investment in, start-up companies to commercialize university inventions, and large-scale corporate-sponsored research.

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[47] Developmental Therapeutics program, National Cancer Institute, "Success Story: Erbitux," available at <http://dtp.nci.nih.gov/timeline/noflash/success_stories/s17_Erbitux.htm>.

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These organizational arrangements are fraught with danger. One concern relates to whether Bayh-Dole licenses are misallocated to firms not best positioned to advance the public interest. Such firms may not be best positioned to commercialize the inventions (a possible distortion with university-connected companies, where returns to the university may be much higher than a standard licensing arrangement) or which may use them for anti-competitive purposes (a particular concern with licenses to giant corporations with sponsorship deals) or which may not be best incentivized to make inventions available to the public on reasonable terms.

The massive size of recent corporate sponsorship arrangements intensifies the cause for concern. Consider the $500 million proposed deal between BP, University of California, Berkeley, the Lawrence Berkeley National Laboratory, and the University of Illinois at Urbana-Champaign. This deal contemplates "the largest proposed academia-industry research alliance in U.S. history,"[48] to be known as the Energy Biosciences Institute (EBI). The Institute, dedicated to "problems related to global energy production" and expected to research primarily biofuels, will encompass 24 laboratories spanning the three campuses, and will occupy state-of-the-art facilities in each, representing a significant public investment. The state of California, for example, has pledged $40 million to construct facilities specifically for the Institute's use.[49]

Now in the later stages of contract negotiations, the universities' proposal, released in March and accepted by BP, offers to lease BP private research facilities on the public UC Berkeley campus. These facilities would be off limits to UC Berkeley personnel. Within the closed facilities, BP would own all inventions developed, and researchers would have no obligation to publish research performed. Under terms of the deal, BP would retain the option to exclusively license and commercialize inventions developed in open facilities, even inventions developed entirely by university scientists, provided they are BP-funded.[50]

The agreement promises that "U.S. government rights will be reserved a) for inventions arising from U.S. federal funding at the UCB and UIUC campuses; and b) for all inventions owned by LBNL."[51]

Even stipulating good intentions by all parties involved, it is obvious that this deal will invite abuse. The inevitable co-mingling of funds will lead to uncertainty about where Bayh-Dole rights arise, and there will be every in-bred bias to manage the monies and reporting to lessen those rights. Where Bayh-Dole rights do attach, it is obvious that BP will have an inside track on exclusive licensing arrangements (as well as an ability to advocate for exclusive licensing where non-exclusive licensing may be possible). Thus will the oil goliath be positioned to leverage its investment and skim the benefits of

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[48] Discover Magazine, "Science's Worst Enemy: Corporate Funding," Jennifer Washburn, October 11, 2007, available at: http://discovermagazine.com/2007/oct/sciences-worst-enemy-private-funding.
[49] Energy Biosciences Institute proposal. Letter from Governor Arnold Schwarzenegger to The Right Honorable Lord Browne of Madingley, available at: http://www.ebiweb.org/proposal.htm.
[50] Energy Biosciences Institute proposal, pages 71-73, available at: http://www.ebiweb.org/proposal.htm.
[51] Energy Biosciences Institute proposal, page 72, available at: http://www.ebiweb.org/proposal.htm.

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public research, and perhaps exert control over the direction of energy technology development.

These type of arrangements should be subject to careful scrutiny by the Committee as it conducts subsequent hearings into Bayh-Dole and management of federally funded inventions.

7. Fresh Thinking on Federally Sponsored Research, Patenting and Development

Central to Bayh-Dole's allocation of technology rights was the decision to forfeit the government's claim to title in inventions it sponsored, and to give exclusive rights to contractors. In the case of universities, the theory was that universities would best be able to speed their commercialization, including through exclusive licensing.

There was very little evidence to support this theory at the time Bayh-Dole was passed. Proponents relied primarily on a single study, which was inconclusive and who's findings they mischaracterized.[52] Although there is now a great deal of data related to university patenting and licensing, the actual evidence that Bayh-Dole is effective at achieving its objectives -- as opposed to alternative approaches -- remains inconclusive. As the Committee proceeds with its hearings on management and disposition of federally funded inventions, it will be useful to examine Bayh-Dole with an open mind, and to consider different patenting, licensing and development arrangements, to reform or augment current policy.

A. Alternative Pharmaceutical Development Models

Pharmaceutical development is actually the strongest case for the Bayh-Dole approach, because there is no question that, after an initial invention has been achieved, quite significant resources must still be deployed to develop and test medicines before they reach the approval stage. Even in this context, however, one could imagine alternative arrangements. The government could retain title, and do the licensing itself. In theory -- although not supported by NIH experience -- a government licensor might better seek to advance public interest aims, including not just commercialization, but commercialization on reasonable terms. Or, more profoundly, the government's role in clinical testing -- already expanding steadily -- could be expanded further, so that it takes inventions closer to the point of commercial application, at which point it could negotiate for shorter terms of exclusivity, or no exclusivity at all.[53]

B. Research Tools and the Anti-Commons

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[52] See Rebecca S. Eisenberg, "Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research," 82 Va. L. Rev. 1663 (1996); Robert Weissman, "Public Finance, Private Gain: The Emerging University-Business-Government Alliance and the New U.S. Technological Order," Undergraduate thesis, Harvard University, 1989.

[53] For one far-reaching approach, see the Free Market Drug Act, introduced as H.R. 5155, 108th Congress, 2d session.

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Commerce Department regulations that require a first effort to license inventions non-exclusively properly reflect the recognition that there are multiple public benefits in competition as opposed to exclusive licensing. Non-exclusively licensed patents can remain more fundamentally a part of the information commons, promote market competition and advance antitrust objectives, and restrain pricing abuses. It is ironically the case, however, that nonexclusive licensing as practiced presently by universities may thwart these objectives.

The Association of University Technology Managers reports that roughly half of university licenses are provided on a non-exclusive basis. Many or most of these non-exclusive licenses involve research tools -- upstream inventions used in the research and development process. As Professors Arti Rai and Rebecca Eisenberg have noted, heavy patenting in this area, combined with demanding licensing terms (even where licensing is nonexclusive) has tended to create an anti-commons, where research institutions charge each other, and corporations, to use the intellectual equipment for research.[54] The situation is far worse where universities engage in exclusive licensing, but non-exclusive licensing with royalty payments has proven problematic as well. So long as this information is going to be patented, the patents should be licensed on a no-royalty basis, with no conditions attached. They should, effectively, be dedicated to the public. This will deprive universities of some income, but it will eliminate an innovation tax that provides no net income for research overall, and creates bureaucratic and time delays in the research process.

C. Nonexclusive Technology Development Models: Climate Change Technology Imperatives

The committee should look with care as well at technologies outside of the biomedical area. It is a certainty that federal investment in research to address climate change -- including in solar and alternative energy technologies and in energy efficiency technologies -- will soar in coming years. These markets are sure to boom in coming years, and the technology development process is likely to follow pathways that do not resemble drug development.[55] To address the frightening perils of climate change, we

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[54] Arti K. Rai and Rebecca S. Eisenberg, "The Public Domain: Bayh-Dole Reform and the Progress of Biomedicine," 66 Law and Contemp. Prob. 289 (2003).

[55] The post-World War II history of the tire industry illustrates how management of federally controlled patents can shape industry structure and promote competition. The need for alternative sources of rubber during the war led the government to undertake action to gain control of patents held by Standard Oil on rubber and to invest in synthetic rubber R&D. After the war, when the government disposed of its rubber patents and factories, it placed a number of limitations on disposal, including establishing competitive industry and selling facilities to some non-dominant firms (Charles Philipps, Competition in the Synthetic Rubber Industry, North Carolina Press, 1961.)

As has been the case with Bayh-Dole, this history and competitive culture shaped the industry's views on patent policy. In the period leading up to passage of Bayh-Dole, Firestone sent its chief patent counsel to testify before Congress and explain how nonexclusive licensing of synthetic rubber technology, developed under government sponsorship during World War II, prevented a monopolistic market.

"You will hear criticism of such a program [of nonexclusive licensing]," Stanley Clark

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will need robust, competitive and efficient energy and energy services markets. There should be a presumption favoring open and collaborative development models that enable market players to obtain compensation through means other than enclosing the information commons and monopoly pricing. Management of patent policy and federally funded inventions will play an important role in determining how energy markets evolve and how efficient they are.

Chairman Leahy and members of the Senate Judiciary Committee, the public investment in biomedical and many other forms of R&D is a proud story for the U.S. government. The U.S. economy is far stronger than it would otherwise be, and U.S. consumers are far better off than they otherwise would be, as a result of the long tradition of government support for R&D. The information commons is richer and the public domain more robust. But in a world where so many ideas are reduced to patents, there must be a much more proactive management of U.S. patents and license rights to advance the multiple objectives of supporting innovation, bringing products to market, ensuring fair prices and access to new technologies, promoting market competition, and enhancing the public domain and information commons.

I would like to thank you and the Committee for inviting me to testify today, and I look forward to working with you in the future to ensure that the federally funded inventions and the patent system advance these multiple objectives.

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testified. "Some have told you and will tell you that unless the research contractors are given titles to the patents which are produced at government expense, the contractors will not accept government research and development contracts. Don't you believe it. They want those government funds and the rewards and advantages that come with such contracts and they won't turn them down. What they get can be, in many instances, very rewarding even without the patents and in any event there are no risks involved, the government assumes all of those."

"Among other benefits, he explained, "the research staff and the records of the contractor constitute a body of 'know-how' which inevitably remains the property of the contractors and may be a palpable asset." (Stanley Clark, Subcommittee on Monopolies and Anti-Competitive Activities, Senate Select Committee on Small Business, December 19-21, 1977, 95th Congress, 1st Session, page 222.)

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