Testimony of
Arti K. Rai

October 24, 2007

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Professor, Duke Law School

Committee on the Judiciary
United States Senate

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

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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, 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).

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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Norman J. Latker
Statement Before NIH On
Essential Inventions Petition Regarding Norvir
May 25, 2004

Hello. I'm Norm Latker, and I'm here to address the petition sponsored by Mr. James Love of Essential Inventions, which asks NIH to end the exclusive title held by Abbott Laboratories for the AIDS drug Norvir.

I thank you for the opportunity to address this issue today.

While I am sympathetic to the efforts of Mr. Love, which I believe are motivated by a desire to enhance the quality of life for the millions of Americans living with AIDS, I must oppose his petition, which, if successful, would undermine the integrity of the Bayh-Dole Act, which I helped to draft back in the 1970s.

Although there was spirited opposition to Bayh-Dole when it was brought before Congress in 1980, a broad political consensus was ultimately built around the notion that market forces would do a far better job of disseminating government-sponsored inventions than bureaucracies ever could.

The Act has been enormously successful. As the Economist Magazine put it recently, it is "the most inspired piece of legislation to be enacted in America over the past half-century."

That may sound like hyperbole, but the impact of the Act has indeed been astounding-and overwhelmingly positive.

It has fostered a potent four-way partnership between researchers, their institutions, government and industry. That partnership has evolved into the most powerful engine of practical innovation in the world, producing innumerable advances that have extended life, improved its quality and reduced suffering for hundreds of millions of people.

Of course, the law isn't perfect. No law is. There have been changes in the three decades since Bayh-Dole's passage-changes that no one could have predicted. But overall it has stood the test of time.

While I feel I can provide some perspective on the Act, there is very little I can say with authority on the underlying issues that have prompted Mr. Love's petition.
Frankly, there are a number of things that I simply do not know.

For example, I don't know how Abbott Laboratories reached its decision to raise the price of Norvir. I don't know whether it was based on legitimate business issues, or as AIDS activists allege, on simple corporate greed.

Nor can I pretend to know what impact the price hike will have on those who need the drug to stay healthy, or on the healthcare finance system. I do not know if some people who need Norvir will now not have access to it. I don't know whether Abbott's promise to provide the drug for free to those who cannot afford it should be taken at face value. It is worth noting that Senator John McCain has called on the Federal Trade Commission to investigate Abbott Laboratories for possible abuse of its monopoly power with respect to Norvir. Attorneys General in Illinois and New York are also looking into the matter. Again, I do not know precisely what criteria these organs of government might use to determine whether corrective action is warranted.

But I do know this: the Bayh-Dole Act is not an arbiter of healthcare policy or drug pricing, and was never intended to be.

Bayh-Dole defines critically important aspects of intellectual property law, while ensuring that viable government-sponsored research does not go to waste.

It is decidedly ill-suited for any other purpose.

Simply put, the legal philosophy of Bayh-Dole is this: if the government accords broad marketplace prerogatives to the developers of government-funded inventions, such inventions are far more likely to be developed and disseminated to the public.

The law holds that intellectual property rights should be accorded in full to the innovators, rather than to the government agency that financed their research, and that developers should be free to leverage their property rights to their advantage in the market place as intended by the patent system.

There were a few conditions placed on this freedom-conditions which are now the subject of dispute. In layman's terms, the conditions provided that:

a) Reasonable efforts were required to develop the inventions to practical application, and made readily available to society;

b) The inventions should not be used in such a way that might threaten public health;

c) If an invention were subject to a federal order of some kind, the developer must comply with that order; and

d) The marketed invention should be made within the United States.

These conditions were translated into the legal language found in section 203 of the Act-what we now refer to as the "march-in" clauses, because they give the government the power to "march-in" and reassign intellectual property rights. These were conceived as extraordinary measures to be used only when there was overwhelming evidence to

show that the public resources invested into an innovation were being wasted or abused.

Obviously, Abbott Laboratories has been enormously successful in bringing the benefits of Norvir to the public at large. The drug may be expensive-perhaps intolerably expensive, given the critical importance it holds for people with AIDS. But by the criteria established by Bayh-Dole, Abbott has complied with the law.

Mr. Love would of course disagree, both with my interpretation of the march-in clauses and my belief that Abbott has not broken the law.

His petition asserts that Bayh-Dole invests NIH with the authority to determine whether the price of Norvir is too high and, if so, to terminate the exclusivity of Abbott's property rights.

The petition points out that one march-in clause, section 203a, specifies that the invention in question must be made available on "reasonable terms", which the authors interpret to mean "reasonable prices".

None of this is supported by a correct reading of the Act and its legislative history. In fact, if the drafters of Bayh-Dole had intended such an interpretation, we would have inserted specific criteria into the law to enable NIH-or any government funding agency - to assess what a reasonable price might be. No such criteria are found, because controlling patent rights on the basis of price was antithetical to what the drafters had in mind.

Nor did we envision that the law could authorize government funding agencies to compel private entities to divulge internal accounts or pricing information. If we had foreseen such a process, the Act would have contained enabling language specifically empowering it.

It must be admitted that the law is written in the arcane legalese of the period, and many sections are quite easy to misinterpret unless armed with the correct definitions. Let me provide some of those definitions now.

The Bayh-Dole Act refers to three key entities involved in the government-sponsored research and subsequent development of an invention.

1) Contractors: These are the organizations that originally used government research funds to make fundamental discoveries

2) Licensees: These are the entities that acquire a license to an invention, develop it and bring it to the marketplace. They pay royalties to the contractor. And bear risk. In the fields of human health and life sciences, these are usually drug companies.

3) Assignees: These are defined by the Act as non-profit patent management

organizations, which at the time brokered the license agreements between the contractor and the licensee. Their role has been marginalized in recent years as universities and research institutes have taken on the role themselves.

When reading the march-in clauses, it is important to understand that Section 203a only applies to contractors-that is, the original researchers -and assignees.

Section 203a does not apply to licensees.

This was not an accidental omission. That licensees are consciously excluded from 203a is obvious, because the next three sections -203b--d explicitly apply to all three entities: contractors, assignees and licensees.

Back in 1980, it was clear that most health inventions could only be practically developed under licenses with the drug industry. Bayh-Dole granted the property rights to the contractor, who would then negotiate a license agreement with the licensee. Of course, drug pricing played no role in these negotiations. Pricing a drug which has not yet been tested, approved and marketed is, of course, impossible.

As the phrase "reasonable terms" found in 203a applies to contractors, and not to licensees, it cannot mean "reasonable prices," because contractors, in the view of the drafters, would not normally be setting prices. Further, they are not required to do so under the defined contractor obligations under the Act.

The phrase clearly refers to the terms of the agreement between the contractor and the licensee.

Bayh-Dole wants government-sponsored inventions moved to the marketplace. Towards that end, it obligates the contractor to transfer the invention to the licensee without demanding exorbitant, or unreasonable, royalties.

The ultimate price of the drug to be developed had nothing at all to do with section 203a or the contractor's defined obligations under sec. 202c. Pricing was -and is-left to the discretion of the licensee. It is the licensee, after all, who bears all the risks of developing the innovations-the clinical trials, the FDA approval procedures, the vagaries of the marketplace. They do so because they know that Bayh-Dole guarantees them exclusive rights over the invention.

After explaining all that, I must now point out that Norvir has never been licensed, and that Abbott Laboratories is not a licensee. It is, in fact, a contractor who obtained title to its invention directly through a contract with NIH.

Again, when the law was written, we thought that in most cases, a contractor would be an academic, research institute or small business that would not have the resources to develop and market the invention on their own. Bayh-Dole therefore emphasizes the licensing process, as is abundantly evident throughout the Act and its implementing

regulations.

Abbott Laboratories, as it happens, had no need to license its invention. It had title to the invention and the resources to bring it to the market without any assistance. This exposes a minor ambiguity in Bayh-Dole. Obviously, "reasonable terms" in this particular case cannot mean "reasonable royalties." But neither can it mean "reasonable pricing", as a requirement of the contractor under its defined obligations. In other words, we cannot spontaneously reinterpret 203a to mean that when a contractor brings a drug to market itself, it must price the drug "reasonably". "Reasonable terms" could not mean one thing for a licensee, and another for a contractor, unless the law contained specific language defining these meanings.

The intent of 203a is obvious enough, even if it fails to specifically address the case at hand.

In closing, I'd like to return briefly to the broader issues that have prompted Mr. Love's petition.

It must be plainly understood that medical access problems in the United States stem not from the research and development regime, but from the way healthcare entitlements are ascribed and healthcare resources are distributed.

I confess that I am no fan of price controls, because I believe that they could stifle innovation and drastically reduce the amount of money the drug industry pumps into pharmaceutical research every year. Contrary to what has been published in recent weeks, only a very small portion of the government health research and development funds are channeled directly into drug research and clinical studies. Most is used to sponsor investigations into the life sciences.

It is in fact the private sector that ponies up the resources to develop, test, obtain approval for, and market new drugs. It is an undeniable responsibility of government to create and maintain incentives for these investments, because there is no way the government could manage the job on its own.

In the absence of government price controls, drug companies will seek to maximize their profits by balancing prices with the need for market penetration - and that is exactly what the drafters of Bayh-Dole expected. Pricing freedom is one reason often cited by the pharmaceutical industry for concentrating their research and development activities in the U.S. It is why the U.S. remains the world leader in medical research, and why so many drugs are made available here first.

That said, the public has an interest in affordable healthcare. I think there are many ways that might be achieved without resorting to outright price controls. State governments, for example, are themselves major purchasers of drugs, and could, through clever use of their market power, help keep prices down.

If a political consensus were to emerge that drug prices need to be controlled by the government, the only legal and appropriate means of instituting such controls would be through a full-fledged legislative process, tested by the courts and administered through empowered organs of government.

Obviously any healthcare reform effort could face resistance from vested interests, and it is tempting for some to look for shortcuts. But twisting intellectual property law into an administrative mechanism to control drug prices would have intolerable consequences for innovation, drug development and healthcare in this country.

A sober reading of the Bayh-Dole Act will leave no doubt that retail drug pricing has nothing to do with the march-in provisions of the Act.

Mr. Love's petition must therefore be denied.

Thank you again for the opportunity to be here today.

see Lincoln

When Senator Bob Dole and I introduced the what would become the Bayh-Dole Act in 1978, we did so at a press conference where several universities spoke movingly about potentially promising therapies that would never benefit the American public which sponsored the research. The reason? Our universities and non-profit organizations lacked clear ownership rights for their early stage discoveries needed to move the concept to the marketplace.

Prior to passage of the Act, tens of thousands of promising discoveries withered away because previous policies emphasized that results of federally funded R&D should be freely disseminated to further the growth of human knowledge. Many felt that it was somehow unethical for universities and other non-profit research institutions to partner with industry, that such a relationship would of necessity corrupt science. They insisted that Government-funded inventions should be freely available to all under non-exclusive licenses. These polices resulted in 28,000 Government funded patents quietly gathering dust on the shelves of federal agencies in Washington, D.C.

The steady erosion in the 1970's was another unintended consequence of this policy as the United States saw itself falling further and further behind its high technology competitors. Pressure increased to show a greater return than academic papers for the billions invested by our hardworking men and women in public sector research.

Thus, Congress overwhelmingly felt that we needed a new policy providing practical incentives to our universities and small businesses deriving practical solutions to problems such as the tragedy of illness, as well as finding new technologies and methodologies to make the U.S. economy competitive again.

The result was the passage of the Bayh-Dole Act of 1980. The past 25 years of Bayh-Dole illustrate that balancing the traditional research roles of our unparalleled universities and non-profit institutions was a significant factor in the rebirth of the U.S. economy. It is ironic with this success before us that the same criticisms that resulted in the failed policies of the past are again regaining some currency.

President Lincoln aptly stated that the patent system was intended to add "the fuel of interest to the fire of genius." Recently I saw the full quote of our greatest President. Here's what Abraham Lincoln said in his Second Lecture on Discoveries and Inventions:

> ...In anciently inhabited countries, the dust of ages—a real downright old-foggism—seems to settle upon, and smother the intellects and energies of man. It is in this view that I have mentioned the discovery of America as an event greatly favoring and facilitating useful discoveries and inventions.
>
> Next came the Patent laws. These began in England in 1624; and, in this

> Country, with the adoption of our constitution. Before then, any man might instantly use what another had invented; so that the inventor had no special advantage from his own invention. The patent system changed this; secured to the inventor, for a limited time, the exclusive use of his invention; and thereby added the fuel of interest to the fire of genius, in the discovery and production of new and useful things.

It is exactly this fire of interest that was missing in the previous patent policy system. Based upon a misguided, and arrogant, belief that extinguishing the fire of interest would better serve the public, federal agencies took inventions from their creators and gave them away freely through non-exclusive licenses. Predictably, this system failed miserably to produce results; although it probably helped our economic competitors easily search through our best science looking for good ideas.

Ironically, this is where our critics want to return us. From their perspective, innovation looks simple. They seem to believe that companies easily find hidden treasures in our non-profit sector, negotiate exclusive licenses and bottle up science while they make killings in the market.

The reality is quite different. First, university research is a long, long way from a commercial product. Because the vast majority of non-profit R&D is basic, early stage research, any resulting patent is much more like an unproven idea than a product. The companies most likely to aggressively develop such inventions are small businesses which must have strong intellectual property protection to protect their investments. It's a rule of thumb in industry that for every $1 dollar spent in discovery, at least $10 dollars will be spent in development. These larger costs are borne by the private sector. And even then, the likelihood of success is small. This is not an exercise for the timid. Yet, once we cut the fetters of bureaucratic red-tape, Lincoln's faith in the American innovative spirit rapidly emerged.

Without companies willing to take significant risks to turn university inventions into a product, the invention will lie fallow, never benefitting our health and wealth.

And what drives our public sector scientists? I firmly believe that the great motivating factor in their lives is conducting state of the art research (which is why they are in the public sector in the first place) coupled with a passion that their research find a practical application.

I well remember the testimony of Dr. Leland Clark, a professor of research pediatrics at the Children's Hospital Research Foundation in Cincinnati, Ohio. Dr Clark's professional life was finding practical solutions to improve the lives of the children and adults facing cancer and serious burns. Here's what he told the Senate Judiciary in strongly endorsing the Bayh-Dole bill:

> The point is, as part of the mental process which leads to an invention, the inventor often envisions possibilities for application which are not immediately

evident to others. The inventor's personal persistence and confidence is often the deciding factor which carries the idea forward and prevents the invention from being set aside or ignored.

Our university inventors like Dr. Clark are exactly what President Lincoln had in mind. However, while the Bayh-Dole Act provided the legal framework to turn ideas into useful products, the real work was done on campus.

There is ample evidence that AUTM and others have gathered showing how universities are now integral parts of every state's economic development plans and are significant drivers of new technological development.

Another less mentioned benefit is that the Bayh-Dole Act has strengthened science as well as the economy . A few years ago, the National Science Foundation in its annual **Science and Engineering Indicators** publication lauded the significant growth in jointly authored university/industry scientific papers was a positive step forward for American science. Before Bayh-Dole companies were rightly leery of having their best and brightest perform research with their public sector counterparts for fear of losing patent rights to the federal government. Bayh-Dole lifted this unhealthy barrier to science.

In the 2004 edition, **Science and Engineering Indicators** showed that U.S. patents frequently cite academic articles particularly in the life sciences, but also showing a strong presence in physics, engineering and technology. "This growth in citations of S&E (note: science and engineering) literature, referenced by scientific field, technology class of the patent, and nationality of the inventor and cited literature, provide an indicator of the link between research and practical application." In other words, academic research is strongly linked to technologies growing our economy.

It is no accident that the rest of the world is copying the Bayh-Dole model to energize their economies and make their universities more relevant. It is only wealthy countries that can afford the luxury of having world class centers of learning. We are blessed that many of the brightest minds in the world come to the United States for their education, and stay to work in our research institutions.

Those supporting our public sector institutions through their tax dollars support the advancement of science, but even more, they want a better life for themselves and their children.

Bayh-Dole is making this dream possible. We should be rightly proud of our achievements of the past 25 years. We should also be willing to honestly examine our behavior to insure that we are true to the mission set before us—to increase knowledge while bringing practical solutions to the world community.

I am honored to have been able to play a role in this effort. The illustrations that the Association of University Technology Managers included in this booklet aptly show that we have come a long way. Yet, I must close with a warning that the critics must be

answered. When I opened the hearings on the Bayh-Dole bill, I concluded with the following statement:

> The United States has built its prosperity on innovation. That tradition of unsurpassed innovation remains our heritage, but without continued effort it is not necessarily our destiny. There is no engraving in stone from on high that we shall remain No. 1 in international economic competition. In a number of industries we are no longer even No. 2. New incentives and polices are needed to reverse this trend.

The Bayh-Dole Act more than fulfilled our hopes and dreams. Many, many lives are the better for the success our universities and non-profit organizations have had under it. We should never forget this lesson.

Otherwise, as the great philosopher Yogi Berra once said, it will be deja view all over again.

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Drug Patent Restoration Act

by: snogreen

09/26/05 05:15 pm
Msg: 107245 of 107255

here is teh exact wording of the Drug PAtent Restoration Act. read what SCLN says about it and I will then highlight the imperative sentance:

<<Under the Drug Price Competition and Patent Term Restoration Act of 1984, or DPCPTRA, a sponsor may be granted marketing exclusivity for a period of time following FDA approval of certain drug applications, regardless of patent status, if the drug is a new chemical entity or new clinical studies were used to support the marketing application. This marketing exclusivity would prevent a third party from obtaining FDA approval for a similar or identical drug through an Abbreviated New Drug Application, or ANDA, which is the application form typically used by suppliers seeking approval of a generic drug, or 505(b)(2) application. The DPCPTRA also allows a patent owner to extend the term of the patent for a period equal to one-half the period of time elapsed between the filing of an IND and the filing of the corresponding NDA plus the period of time between the filing of the NDA and FDA approval with the maximum patent extension term being five years. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for the patent term extension.>>

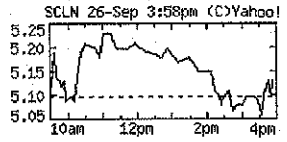
READ THIS:<<a sponsor may be granted marketing exclusivity for a period of time following FDA approval of certain drug applications, regardless of patent status, if the drug is a new chemical entity or new clinical studies were used to support the marketing application>> IF NEW CLINICAL STUDIES WERE USED FOR THE NDA, YOU CAN GET THIS> SCLN USED NEW CLINICAL STUDIES FROM THE 1994 TRIAL! all short scam lies. .....last and next?

<<This marketing exclusivity would prevent a third party from obtaining FDA approval for a similar or identical drug through an Abbreviated New Drug Application, or ANDA, which is the application form typically used by suppliers seeking approval of a generic drug, or 505(b)(2) application>> IF SCLN GETS THIS, NO OTHER COMPANY COULD TOUCH REGULAR ZADAXIN ANYWAY> THEY ARE PREVENTED FROM DOING SO BY THE FDA.

all lies, all scams, all lies, all scams, all lies, all scams.....ALL SCUM!

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DRUG PATENT ACT

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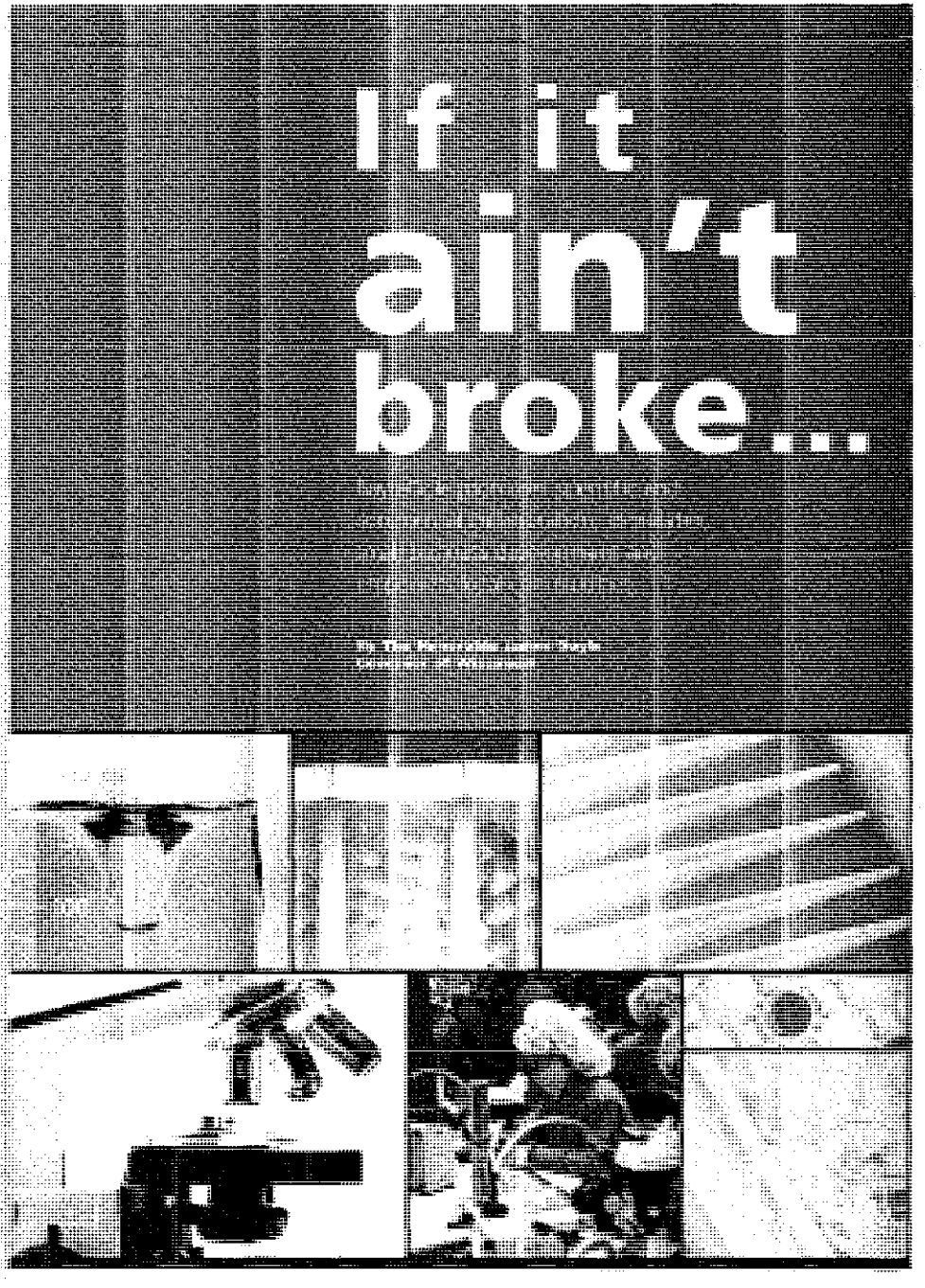
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I encourage our elected representatives in the United States Congress to proceed with great caution as they consider U.S. patent law changes that might disturb the amazing state-based economic engine that has grown by leaps and bounds in the wake of the passage of the Bayh-Dole Act of 1980.

IT DOESN'T NEED FIXING.

As Governor, one of my top priorities is creating jobs by building a strong, technology based economy. There is much a state can do to promote economic development, but we also must rely on policymakers in Washington to set sound policy.

I encourage our elected representatives in the United States Congress to proceed with great caution as they consider U.S. patent law changes that might disturb the amazing state-based economic engine that has grown by leaps and bounds in the wake of the passage of the Bayh-Dole Act of 1980.

Let's start with the business side of the equation. The "business model" Bayh-Dole replaced was a centralized model that pushed tax dollars out the door to fund research pretty effectively, but was never designed as an "investment" and as a result did practically nothing to achieve either a financial return or a quantifiable public good for the millions and millions of dollars spent.

Operating in this mode, for example, the federal government had at one point in time accumulated nearly 30,000 patents, 95 percent of which were simply gathering dust on a shelf. Five percent had been licensed to industry, but considerably less than that ever led to something a consumer could use. In 1978, seven years after the Nixon Administration had made a point of saying that the public interest required that efforts be made to encourage the expeditious development and civilian use of inventions generated by federally funded research, the National Aeronautics and Space Administration (NASA) reported that of the 31,357 contractor inventions reported to it, fewer than 5 percent had been made available for commercial development.

I believe that there are many things that only the federal government can do and many things that it does exceptionally well, but technology transfer does not appear to be one of them. It is clear that under the government business model that preceded Bayh-Dole, the intended benefits which were to flow to the public in the form of new products and new jobs never materialized.

The Bayh-Dole business model is a decentralized model focused on states, universities and small businesses that encourages research, collaboration and commercial development. Under Bayh-Dole, universities moved aggressively to patent discoveries resulting from federally funded research and, equally important, to move these discoveries to the marketplace where the public could benefit from the research it helped to pay for. Consider this startling and telling fact. In the first 20 years of Bayh-Dole's existence, more start-up companies were formed with university patents than had been created with the thousands and thousands of federal government held patents in the entire history of the United States before Bayh-Dole.

Bayh-Dole obviously spurred the academic and scientific community to collaborate more effectively, and it has clearly generated more commercial activity and greater access to products for consumers. But, one other thing makes the Bayh-Dole model the clear winner from a business point of view. It has generated a new source of revenue for universities that can offset at least a portion of the cost of the important research being funded by federal tax dollars. In 1991, as the early licenses coming on line as a result of Bayh-Dole began to generate royalties, universities earned $130 million. By 1999, that number had jumped to $675 million and just four years later in 2003, universities across the country earned more than $1 billion dollars in royalties that they could re-invest in the critical research that drives so much of our economy these days.

Most Governors will also tell you that because the Bayh-Dole model empowers universities and is more likely to stimulate small business development, it is far more responsive to the wishes and needs of our citizens.

In Wisconsin, for example, we have 13 four-year state university campuses, 13 two-year community colleges and 16 technical colleges. When it comes to research, the University of Wisconsin–Madison is our flagship and that great institution enjoys a wonderful and very productive relationship with the Wisconsin Alumni Research Foundation (WARF), one of the oldest and most admired technology transfer centers in the world. Bayh-Dole has energized a synergy between these two great institutions that has sparked new business development, more jobs and helped grow the local tax base and support the schools, roads, parks and all sorts of other community services and activities upon which our citizens depend and enjoy. Thanks to Bayh-Dole, the UW–Madison-WARF model of collaboration and cooperation is spreading to other campuses in the UW System and benefiting the people of Wisconsin in Green Bay, Milwaukee, Stevens Point and Menomonie, just to mention a few.

Most Governors will also tell you that because the Bayh-Dole model empowers universities and is more likely to stimulate small business development, it is far more responsive to the wishes and needs of our citizens.

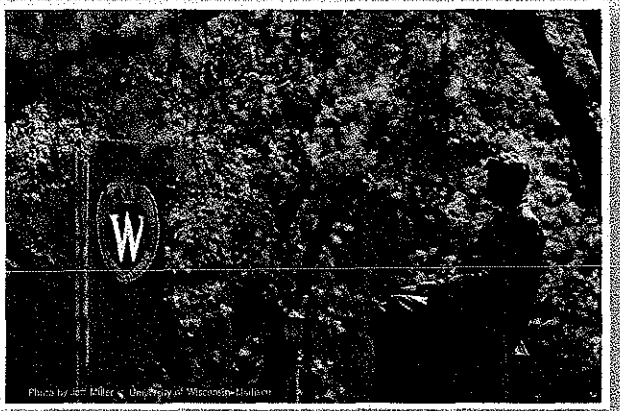
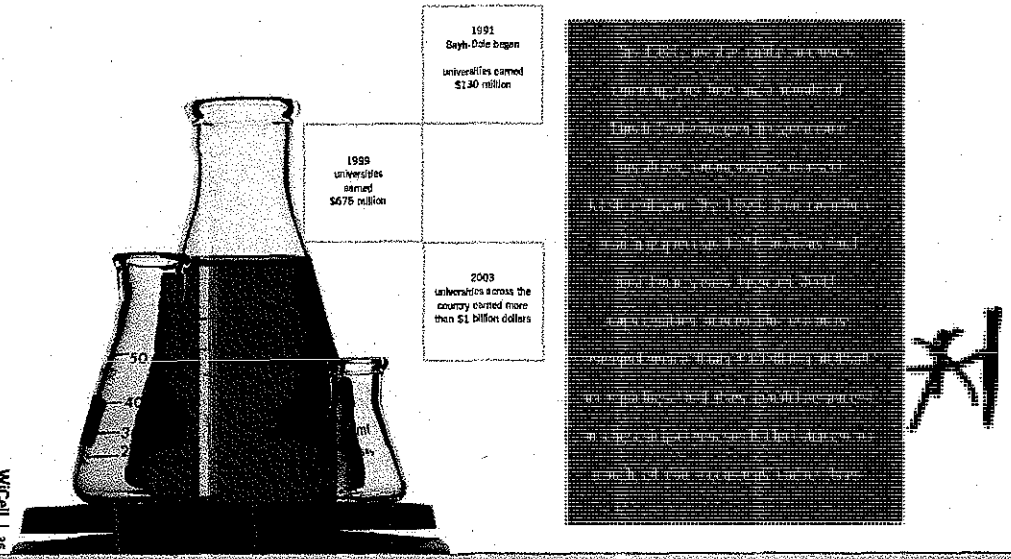


Photo by Jeff Miller, University of Wisconsin-Madison

At the UW–Madison, Abraham Lincoln statue and a "W" crest banner on Bascom Hill during spring.

In Wisconsin, for example, we have 13 four-year state university campuses, 13 two-year community colleges, and 16 technical colleges. When it comes to research, the University of Wisconsin–Madison is our flagship and that great institution enjoys a wonderful and very productive relationship with the Wisconsin Alumni Research Foundation (WARF), one of the oldest and most admired technology transfer centers in the world. Bayh-Dole has energized a synergy between these two great institutions that has sparked new business development, more jobs and helped grow the local tax base and support the schools, roads, parks and all sorts of other community services and activities upon which our citizens depend and enjoy.



And, while Wisconsin can brag that WARF is the oldest technology transfer center, Bayh-Dole has made sure we can no longer brag about WARF being one of the few technology transfer centers in the country. Consider another startling and very telling fact. When Bayh-Dole was passed there were fewer than 20 technology transfer centers focused on licensing discoveries generated by university research. Today, there are nearly 400 such centers.

Think about that. Hundreds and hundreds of centers located across the country, each one working with their local academic and scientific communities to develop small businesses in their communities that will generate jobs, strengthen the local tax base and produce products that will help consumers live better lives. Bayh-Dole made that happen, and in so doing, gave a new and very important vitality to the meaning of the concept of local control.

And so finally to that healthy dose of common sense the people of Wisconsin always want to see their elected officials factor into their decisions, 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.

Thanks to Bayh-Dole the UW–Madison-WARF model of collaboration and cooperation is spreading to other campuses in the UW System.

The Bayh-Dole state- and university-based collaborative model is the better way. It's the right way. It's not broken.

As the old saying goes, if it ain't broke ... ●

Jim Doyle is Wisconsin's 44th governor and is currently serving his second term as Wisconsin's leader. Through his "Grow Wisconsin" agenda, Governor Doyle has worked hard to put the state in the position to create jobs. From funding the BioStar initiative to expanding access to technology zone tax credits, Governor Doyle is capitalizing on Wisconsin's leadership in research, biotechnology, and stem cells, and laying the foundation for a vast expansion in high tech jobs.

[Ip-health] Norman Latker's letter to NIH

James Love james.love@cptech.org
Fri May 21 13:09:01 2004

- Previous message: [Ip-health] Speakers for NIH May 25 Norvir March-In meeting
- Next message: [Ip-health] Chicago Tribune: Abbott AIDS Drug pricing leads to review of patent
- **Messages sorted by:** [date] [thread] [subject] [author]

-------- Original Message --------
Subject: [techno-l] Abbott/Pfizer March-in Petition
Date: Fri, 23 Apr 2004 14:07:08 -0400
From: Norman Latker <NJL@browdyneimark.com>
To: <Techno-l@lists.uventures.com>

Below is the letter that I forwarded as an attachment with my earlier email.

NORMAN J. LATKER
5112 Edgemoor Lane
Bethesda, MD 20814

April 14, 2004

Dr. Mark Rohrbaugh
Dir. of the Office of Tech. Transfer
Office of Intramural Research
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852

Dear Dr. Rohrbaugh:

I would like to comment on recent petitions filed by Mr. James Love and Mr. Sean Flynn of Essential Inventions, Inc, requesting the National Institutes of Health to invoke the march-in provisions of the Bayh-Dole Act to invalidate exclusive drug patents held by Abbott Laboratories and Pfizer Inc.

While the authors of the petition might be commended for embarking on such an innovative approach to controlling drug prices, it must be clearly understood that Bayh-Dole defines critically important aspects of intellectual property law, and is decidedly ill suited for any other purpose. Any attempt to use it as a weapon in the political debate over drug prices is doomed for failure, as the enabling language required for such uses is wholly - and intentionally -absent from the legislation.

In the unlikely event that NIH were to grant the request of the petition's authors, the decision would have virtually no chance of surviving judicial review.

Nonetheless, I feel compelled to speak out in defense of Bayh-Dole, which has fostered the development of a potent four-way partnership between researchers, their institutions, government and industry. This partnership has become a powerful engine of innovation, generating more

practical advances than the rest of the world combined. Nowhere is this more true than in the fields of medical technology and pharmaceuticals.

Should the petitioners succeed in subverting one of the key precepts of Bayh-Dole - that of according broad marketplace prerogatives to the developers of government-funded inventions - this marvelous engine could stall.

The Spirit Of Bayh-Dole

I hope I can provide some perspective on the Bayh-Dole Act, large portions of which I helped to draft back in the 1970s, when I served as Patent Counsel for the Department of Health, Education and Welfare (HEW). I was also an architect of the Act's implementing regulations, to which the authors of the petitions heavily refer.

The authors have woefully misrepresented the spirit and purpose of the legislation, which was intended to enlist the marketplace to develop and distribute government-supported innovations. Judging from the petition, they appear to have been informed primarily by a recent article in the Tulane Law Review, penned by Peter S. Arno & Michael H. Davis, which unfortunately paints a highly distorted picture both of the Act itself and the legislative process leading to its passage.

Before the enactment of Bayh-Dole, an enormous amount of government-sponsored research and innovation went to waste, as there were no clear mechanisms in existence to transfer the resultant inventions to the marketplace.

Although there was spirited opposition to the bill, a powerful bipartisan consensus was built around the basic notion that market forces would do a far better job of disseminating such inventions to society than government bureaucracies ever could.

Put simply, the drafters of the act wanted to ensure that adequate incentives were in place to facilitate invention and to attract corporate investment into their development and distribution. We understood that inventions resulting from government research are conceptual in nature, and require significant investment by the private sector to bring them into practical application. This is especially the case with regard to life science inventions, the subject of the march-in requests.

Our answer to the problem was that intellectual property rights should be accorded in full to the innovators, rather than to the government agency that financed their research, and that innovators should be free to leverage their property rights to their advantage in the market place as intended by the patent system. The only conditions to be attached to this freedom were envisioned as follows:

a) Reasonable efforts were required to develop the inventions to practical application;
b) The inventions should be readily available to society;
c) The inventions should not be used in such a way that might threaten public health;
d) If an invention were subject to a federal order of some kind, the developer must comply with that order; and
e) The inventions should be manufactured within the United States.

These conditions were translated into the legal language found in section 203a of the Act, which is reproduced in the subject petitions.

The march-in clauses were conceived, as extraordinary measures to be used only when there was overwhelming evidence to show that the public resources invested into an innovation were being wasted or abused. This is clearly not the case with either Retonavir or Latanoprost, both of which have been successfully developed and are readily available to the public at large.

Control Of Drug Prices

What I find most disturbing about the subject petitions is the attempt to transform a fundamental piece of intellectual property law into an administrative mechanism to control drug prices, with no regard for the consequences.
The drafters of Bayh-Dole never envisioned that the law could authorize government funding agencies to compel private entities to divulge internal accounts or pricing information, which is why the Act lacks any functional criteria specifying how this could be done.

Nonetheless, the petition's authors hold that the government should issue multiple licenses for the drugs because the companies are charging too much for them, and quite falsely assert that the Act invests funding agencies with the authority to approve the pricing of inventions after they have been developed and distributed in the marketplace by private sector initiatives.

The assertion that funding agencies are vested with the jurisdiction to approve pricing is said to rest on the Act's definition of "practical application" which includes a requirement that the invention be made available to the public on "reasonable terms". The petitioners argue that the latter term is to be interpreted, in an ordinary context, as including a "reasonable price", and that the funding agency is therefore authorized to assess what a "reasonable" market price might be.

The Scalia Rule

That "reasonable terms" must include the notion of price, they maintain, is evidenced by a number of court decisions supporting that definition. They also cite the Scalia rule:

[First], find the ordinary meaning of the language in its textual context; and second, using established canons of construction, ask whether there is any clear indication that some permissible meaning other than the ordinary applies. If not - and especially if a good reason for the ordinary meaning appears plain - we apply the ordinary meaning.

Scalia's instruction to refer to the "textual context" of the language is indeed helpful-but not to the argument put forth by the authors of the petition. The march-in conditions and the entire body of the Bayh-Dole Act stress the overriding importance of delivering intellectual property rights to innovators and developers. Property rights are inherently invested with the ability to set prices. The Act also emphasizes the broad dissemination of the benefits of the invention to society.

In context, therefore, "reasonable terms" cannot be interpreted to mean a limitation on the developer's ability to set prices in the marketplace.

In fact the opposite is true: if the rights-holder were not given the freedom to set prices, it would not be willing to commit resources required to ensure an invention's delivery into the marketplace, thereby obviating the requirement that it be widely available. No commercial concern would invest in the commercial development of any invention knowing that their sales price could be challenged by the government after marketing.

Again, if the drafters had intended such an interpretation, we would have inserted specific criteria into the law to enable the funding agency to assess exactly what a reasonable price might be. No such criteria are found, precisely because controlling patent rights on the basis of price was antithetical to what the drafters had in mind.

The Price Of Drugs

Of course it could be argued that extremely high prices might prevent an invention from achieving widespread application, and the petition authors attempt to show that this is the case with Retonavir or Latanoprost.

However, while the authors might show that the drugs are expensive, they fail utterly to substantiate the notion that high prices have curtailed their availability, or their continued improvement by the developer. For example, the authors fail to show that the 600-800 people nationwide who do not have access to Retanovir would necessarily be granted access if the price of the drug were reduced. They also fail to mention the tens of thousands of people who do have access to the drug, and that many of these individuals receive it for free.

Price comparisons with other countries are also of dubious value. The authors argue that since the developers companies offer the same drug at lower prices in other countries, that this somehow violates the notion of reasonable terms. Not only do they fail to substantiate this logically, they also fail to point out that the average prices paid for drugs overseas are often reduced by means of direct government subsidies and/or price controls, neither of which are effected through intellectual property law.

The authors also imply that since the drug was developed in the United States, it is unfair that Europeans are getting it cheaper:

"Prices in the U.S. are generally 2-5 times the price in most European countries, despite American taxpayers funding its early development."

Even if one accepts the prices the authors provide for Latanoprost in various countries at face value - although one must wonder about the methodology used, and how representative or timely the data really are - they provide no insight into how or why drug prices come to be lower in other countries.

Note that prices are lower not only in the low income countries like Nicaragua where weak spending power could compel lower prices - but also in countries like Germany and Sweden, where per capita spending power is roughly equivalent to that in the U.S. The primary reason is that the vast majority of drug purchases in such countries are financed by governments, which use their monopoly power to keep the price of medications low.

Healthcare Policy

That is not to say that the needs of the minority who do not have access should be ignored. But it must be plainly understood that medical access problems in the United States stem from the way healthcare entitlements are ascribed and healthcare resources are distributed.

Healthcare reform has been under consideration in the Congress recently and the possibility of the policies of state-mandated price controls or broad entitlements to healthcare as they exist in European countries have been discussed. But the appropriate means to effect such policies must be through public debate, legislation and/or referenda.

Obviously any healthcare reform effort could face resistance from vested interests, and it is tempting for some to look for shortcuts. But twisting intellectual property law into a political weapon of expediency is not the answer.

In the absence of government price controls, drug companies will seek to maximize their profits by balancing prices with the need for market penetration - and that is exactly what the drafters of Bayh-Dole expected. Pricing freedom is one reason often cited by the pharmaceutical industry for concentrating their research and development activities in the U.S. It is why the U.S. remains the world leader in medical research, and why so many drugs are made available here first.

If a political consensus were to emerge that drug prices need to be controlled by the government, the only legal and appropriate means of instituting such controls would be through a full-fledged legislative process, tested by the courts and administered through empowered organs of government.

Accordingly, I feel strongly that the petitioners' request for a march-in action, motivated entirely by a desire to control drug prices and based on a misinterpretation of the law, must be denied.

Sincerely,

Norman J. Latker

- Previous message: [Ip-health] Speakers for NIH May 25 Norvir March-In meeting
- Next message: [Ip-health] Chicago Tribune: Abbott AIDS Drug pricing leads to review of patent
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BD Report

Gail's comments:

Overall, very easy to read, and interesting! Just a few comments for clarity from a lay reader:

1. p. 2., para. 1: The introduction of the role of the employers was a bit abrupt for me. I think a transition sentence or two that sets up the tension between the inventor and the employer, kind of summarizing the two quotes, would frame the discussion you embark on here.

2. Same para: I was confused by the phrase "upholding the assignment." I figured it out, but it took some effort.

3. p. 3, para. 1. expression "right in employers" is confusing (again not common usage).

4. Same sentence, "(including adoption by the federal government)..." to what legislation does this refer?

5. p. 4, top para in progress: "...inventions made by employees of private sector employers were not generally handled in this manner." I found myself wanting more information about how they were handled in industry.

6. Same para, next sentence: why do you say the Bay-Dole body of laws was "limited to" addressing Federal policies, rather than just "addressed Federal policies?"

7. p. 6, para 1 (full), line 7: suggest changing "being examples of" to "include."

8. Same sentence – too long. Need a couple of sentences there, rather than one long one, for clarity.

9. p. 7, para 1. Not sure what you mean by "change in equities" or "elimination of equities" in the next paragraph.

10. Same (para 1): You give a formal definition of the Nash equilibrium; can you also give an example to illustrate your argument?

Critics have not made their case for eliminating the equities provided under Bayh-Dole – Norman J. Latker

Proposed changes in Bayh-Dole protections for inventors would collapse the partnerships that have delivered government-funded inventions to the marketplace for 25 years with success unanticipated by even the early proponents of the law. They also would deny to inventors the reward envisioned by the Constitution, and they should be resisted on that ground alone.

Over 300 years ago, John Locke asserted that "a man has a right to what he hath mixed his labor with." A hundred years later, the drafters of our Constitution implemented this principle by granting to Congress the power to secure "for limited times to authors and inventors the exclusive right to their respective writings and discoveries" as an incentive "to promote the progress of science and useful arts."

In the *Federalist* on January 23, 1788, James Madison supported this prospective Congressional authority by noting:

> "The utility of this power will scarcely be questioned. The copyright of authors has been solemnly adjudged, in Great Britain, to be a right of common law. The right to useful inventions seems with equal reason to belong to the inventors. The public good fully coincides in both cases with the claims of individuals."

In a letter to Thomas Jefferson on October 17, 1788, Madison, probably anticipating criticism of this new authority, made a more important insight:

> "With regard to monopolies, they are justly classed among the greatest nuisances in Government, but is it clear that as encouragements to literary works and ingenious discoveries they are not too valuable to be wholly renounced? Would it not suffice to reserve in all cases a right to the public to abolish the privilege at a price to be specified in the grant of it? Monopolies are sacrifices of the many to the few. Where the power is in the few, it is natural for them to sacrifice the many to their own partialities and corruptions. Where the power, as with us, is in the many, not in the few, the danger cannot be very great that the few will be thus favored. It is much more to be dreaded that the few will be unnecessarily sacrificed to the many."

Neither the Constitution nor the respective implementing laws guarantees the employers of authors or inventors any right to ownership of their work. The failure to address the rights of employers is not surprising because in 1787 writers and inventors were in most part self-employed. As that fact changed, however, the common law addressed the relationship between employers and employees by upholding the assignment of a person's future ideas as a condition of employment.

This seemingly logical rule of law eliminated any need on the part of employers to examine whether it was equitable or desirable company or social policy to require the assignment of

future ideas solely as a condition of being employed. No further consideration was given to the fact that such future ideas were not yet conceived and therefore could not be evaluated to determine their value to society.

It seems clear, however, that given a possibility of equal footing, the law intended that employees would negotiate for a value "in what he had mixed his labor with." As time passed, it became evident that employees would not achieve such footing.
The rights of authors and inventors faded into obscurity in the 1950s and 60s as public and private organizations grew larger and research funding was concentrated in those organizations; the assumed right of ownership was adopted by the federal government.

As time passed it was determined that inventions funded by the government were not reaching the marketplace to the degree expected from the ever-increasing volume of research funded by the federal government after World War II, while employer ownership resulted in no noticeable impediment to commercial development of inventions made by employees of private-sector employers.

A number of studies at the time concluded that the government policy generally requiring non-exclusive licensing of inventions resulting from its funding was destroying the incentives intended by the constitution "to promote the progress of science and useful arts" through its grant of exclusive rights. Of course, inventions made by employees of private-sector employers were not generally handled in this manner. Thus, the Bayh-Dole body of laws was limited to addressing the federal government policies for disposition of inventions made in performance of its research.

The rationale of Bayh-Dole was simply this: if the law affords broad marketplace prerogatives to the developers of government-funded inventions, the inventions will far more likely be developed and so made available to the public. To achieve this, ownership is left with the innovators, rather than the government agency that financed the research. The innovators are then free to leverage their rights to their advantage as intended by the constitution.

The Act has been enormously effective. As the *Economist, Technology Quarterly*, concluded, the Act is "the most inspired piece of legislation to be enacted over the past half-century." In operation, Bayh-Dole fostered a potent four-way partnership among researchers, their institutions, government and industry. That partnership has created a powerful engine of practical innovation, producing many scientific advances that have extended life, improved its quality and reduced suffering for millions of people.

Universities, in particular, have been very successful in commercializing their inventions. Bayh-Dole is generally credited for contributing to the dramatic increase over the last 25 years in the number of university inventions reported, patents granted, royalty-bearing licenses negotiated, collaborative research agreements struck and start-up companies spun off. As noted by the *Economist,* since 1980, American universities have witnessed a ten-fold increase in their patents, created more than 2,200 companies to exploit their technology -- producing 260,000 new jobs -- and have contributed $40 billion annually to the American economy.

Now, after 25 years of successfully meeting its intended purpose beyond even the expectations of its proponents, a cottage industry of critics calls for amendment of Bayh-Dole primarily on the basis that the Act's limited monopoly allows marketers to set the price for goods embodying inventions for which the taxpayers have already paid. This, they correctly argue, can result in a high return to the innovator, requiring higher prices than would be expected given competition from additional marketers.

This position ignores the fact that inventions resulting from government research are mostly conceptual in nature and require significant investment by the private sector to bring them to practical application. The investment necessary to develop such an invention normally exceeds by many multiples the government funding that produced it. In such a situation, it has been demonstrated that a limited monopoly is a necessary incentive for initial investment. Most critics acknowledge this, but argue that the grant of monopoly can be limited by amending the Act to require that the government first determine whether private sector funding is necessary to deliver an identified invention to the marketplace.

In this regard, critics fail to recognize or acknowledge that exactly this kind of policy was in effect at a number of different government agencies during the 1960s and 70s prior to Bayh-Dole. After extended trial and debate, such policies were rejected as a means of maximizing delivery of government-funded inventions to the marketplace. The primary reasons for rejection were political intervention in the decision-making process, delays in processing decisions, inadequate and untrained staff and the unlikely prospect that the government would chose correctly. A bad choice by the government would result in loss of incentives to pursue commercialization of the government-owned invention both in the inventing organization and the inventor, as well as loss of inventor know-how to guide a changing invention through the development process.

The Bayh-Dole partnership should be viewed as an example of a "Nash Equilibrium," which involves a set of equities, one for each participant, such that no participant has an incentive to unilaterally change its action. The participants are in equilibrium if a change in equities for any one of the participants would lead that participant to gain less than if the current equity remained.

Clearly, the current critics of Bayh-Dole and their proposed suggestions for change have not made any case for elimination of the equities envisioned by the Constitution for inventors other than their unsubstantiated belief that elimination of monopoly where not warranted will decrease the purchase price of the goods successfully reaching the marketplace. However, experience indicates that there can be no guarantee that such goods will even reach the market absent the equities established by Bayh-Dole.

Most likely decreased purchase prices will not be achieved by pursuing the critics' suggested changes since their adoption will collapse the Bayh-Dole partnerships, ending the environment that has delivered government funded inventions to the marketplace over the last 25 years. A return to policies that have already failed without some justification as to why they will now succeed makes very little sense. But the most obvious reason for rejecting these

proposed changes is the fact that they deny to inventors the reward envisioned by the Constitution, which was Bayh-Dole's primary motivation.

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Bayh-Dole: Don't Turn Back The Clock

By Sen. Birch Bayh

The following is adapted from a speech by Birch Bayh to the Licensing Executives Society 2006 Annual Meeting, New York, New York Tuesday, Sept. 12, 2006.

After a quarter century of what by most objective standards has been an exceptional success, the Bayh-Dole law is under increasing attack today.

Most of the attacks have come from individuals who have little experience with the comprehensive nature of how the law is implemented. They do not know what Bayh-Dole does and does not do, and why certain features were incorporated in the law. Equally important, these nay-sayers have no appreciation for the factors that motivated our efforts to develop this legislation in the first place. Most unfortunate of all, these modern-day experts in technology transfer apparently do not understand the basic factors on which our nation's free enterprise system is based.

Bayh-Dole didn't just happen. The development of the legislation depended upon countless individuals with a working knowledge of university research, patent law and basic economic motivators.

Permit me to give you a behind-the-scenes view of the genesis of Bayh-Dole. This is important because the better we understand the process that led to this law, the better we are able to deal with today's critics. First, a basic premise on which we, as Americans have relied.

Historically, American economic success has depended upon our ability to develop creative and innovative minds whose ideas serve as the catalyst for business and industry. Free and open competition has resulted in generation after generation of increasingly sophisticated technology. With this innovation came new products followed by more and better paying jobs, increased family incomes and opportunities for home ownership.

Unfortunately, by the 1970s, we had begun to take our quality of life and our economic dominance for granted. America began to lose its technological advantage:

- We had lost our No. 1 competitive position in steel and auto production. In a number of industries, we weren't even No. 2.
- The number of U.S. patent issued each year had declined steadily since 1971.
- From 1973-1978, the number of patents granted to non-citizens had increased 35 percent.
- Investment in research and development over the previous 10 years had been dormant.
- American productivity was growing at much slower rate than that of our free world competitors.
- Small businesses, which had compiled a very impressive record in technology innovation and which had provided most of the new jobs, were receiving a smaller percentage of federal research and development money.

- The number of patentable inventions made under federally-supported research had been in a steady decline.

The bottom line of these alarming economic indicators was that the United States was losing its technological edge. Frankly, the problem was so enormous and complex I doubted if there was anything I could do. It seemed hopeless, and I felt like Moses in the wilderness -- doubting if the "Man Upstairs" would send down a lightening bolt.

The first step out of the wilderness began with a call to my office in the summer of 1978 from Ralph Davis, head of technology transfer at Purdue University. Like Indiana and many other universities, Purdue was making cutting edge discoveries from research funded by federal dollars. But Davis said federal government policies that prohibited universities from owning these patents and leasing them to businesses killed the incentives necessary for innovative companies to fully develop these new ideas. If a company couldn't own the patent, it would not invest in developing it.

I asked Joe Allen, a staffer on the Subcommittee on the Constitution which I chaired and which had jurisdiction in the Senate over patent issues, to check this out. He discovered that although the U.S. government owned approximately 28,000 patents, less than 4 percent were licensed to industry. The others were sitting on the shelf at the Patent and Trademark Office. All those new ideas were gathering dust. The taxpayers were getting nothing.

Next, Joe and I met in my office with Ralph Davis and two of his associates, Howard Bremer, Director of the University of Wisconsin Alumni Research Foundation, and Norman **Latker**, Patent Counsel at HEW. The collective vision of these three individuals was critical to our success. The meeting resulted in draft legislation designed to take advantage of the innovation found on campuses and the entrepreneurial skills of small businesses. I asked Sen. Bob Dole from Kansas to join in and the battle began. While Bob and I didn't always see eye to eye, we did agree that the United States could no longer afford to waste billions of dollars on university and small business research with no return on the investment.

The legislation was straightforward and easy to understand. Universities and small businesses would retain ownership of the ideas they developed through government funded research. They could license such patented ideas to industry at large for commercialization and would receive royalties. The inventors, usually professors, also received a share of the royalties if they assisted in developing the patent to market.

The Bayh-Dole bill was introduced and the legislative journey began. It was far from a cake walk.

First, Senator Russell Long, Chairman of the powerful Senate Finance Committee, told Joe Allen, "This is the worst bill I've ever seen." Senator Long believed if the taxpayers funded any of the research, the government should have total ownership of the ideas produced. But the Long theory ignored the fact that many of the resulting inventions were at a very embryonic stage of development. They required substantial expenditures before they actually became a product or applied system of benefit to the public.

Senator Long was one of the most influential members in the Senate. Among 100 equals, Russell Long was more equal than the others. He was a good friend and I had hoped to get his support. But, he'd made up his mind, he was protecting the taxpayers. The task of getting Bayh-Dole would be uphill all the way.

Now, from its inception, Bayh-Dole did provide government entities with first call on patents developed by government research when needed. However, it's also important to understand that for every dollar's worth of academic research that leads to a patent, it requires $10 to $10,000 (sometimes close to $1 million) of private capital to develop it and bring it to market. Far from getting a free lunch, companies that license ideas from universities often wind up paying over 99 percent of the innovation's final cost, without which the idea would have no value.

Nevertheless, we knew we were in for a long, tough, legislative battle.

Fortunately, we had allies on the campuses across the country and strong support among the small business community nationwide. We organized task forces composed of individuals from both groups (universities and small businesses) and directed them to talk to their individual Senators and Congressmen. They did just that. Don't let anyone tell you that determined individuals can't make a difference.

To illustrate the power of this combination of citizens, I remember one afternoon when I was at my desk on the Senate floor, and an excitable Joe Allen came bounding up to report some good news. "Senator, we just got two more sponsors. Senators Kennedy and Thurmond just signed on."

Well, getting Ted Kennedy and Strom Thurmond to agree on anything was an achievement, but I couldn't help but kid Joe by asking, "Joe, are you sure this bill makes sense?" Bayh-Dole passed the Senate by the vote of 91 to 4. Those dedicated individuals had made a difference.

The Bayh-Dole bill moved to the House of Representatives, where Rep. Bob Kastenmeier of Wisconsin was chairman of the House Judiciary Subcommittee with jurisdiction over patents and trademarks. Rep. Kastenmeier was sponsoring a Carter Administration bill that was a more traditional measure for patent law reform.

Our team went to work and through Howard Bremer's efforts, individuals at the University of Wisconsin explained to Rep. Kastenmeier the benefits to be derived from Bayh-Dole. In addition they pointed out to the Congressman the positive impact Bayh-Dole could have in his district. In a matter of days, we agreed to join Congressman Kastenmeier's legislation and Bayh-Dole in one package that quickly passed the House and was sent back to the Senate for its concurrence.

This was not the end of the story, since 1980 was an election year. With members anxious to go home and campaign, Congress recessed, planning to come back after the election for a lame duck session to take up the Budget Bill and other items including Bayh-Dole. The Senate needed to agree to changes made to the bill in the House.

When Congress reconvened for the lame-duck session, as a result of the Ronald Reagan landslide, 12 Democratic Senators had been replaced by Republicans. The people of Indiana had said, "Bayh, stop making law and start practicing it." On January 3, I would be out of a job.

But, Bayh-Dole was paramount on my mind. The lame-duck session would be short, with only a few days for us to finish our task. What would Senator Long do? Our campus and small business allies had been communicating with their Senators, but Senator Long had put a hold on our bill and if he persisted, the rules of the Senate would enable him to stop us.

On the very last day of the 1980 session, Sen. Long's legislative director cornered Joe Allen on the Senate floor and asked, "Does Senator Bayh really want that crazy patent bill?" Joe's answer was an

emphatic, "Yes!"

Later that afternoon, I got a phone call from my friend, Russell Long. After commiserating with me at length over the outcome of the election, he paused and said, "Oh, by the way, Birch, take the vote on that damn patent bill. You've earned it. We'll miss you in the Senate." Click.

Now, fast forward 25-plus years. Here is what some of the critics are saying. I purposefully omit any attribution to avoid embarrassing the authors of such short-sighted and ill-founded criticism.

1. Universities and their researchers should not be entitled to financial reward because they are not manufacturing anything. Response: Bayh-Dole is designed to create the incentive for entrepreneurs to invest in the idea and provide the development capital necessary to create a valuable product out of the idea. The marriage of intellectual property and its developmental partner is the basis of Bayh-Dole's success.

2. Bayh-Dole creates the incentive for universities and researchers to ignore their search for knowledge and to become motivated by patent royalties. Response: Such conclusions can only come from those who have no familiarity with the dedication of our universities and their faculties to spread knowledge and advance science.

3. Researchers/inventors should not share in the royalties granted universities for licensing the product of their research. Response: Bayh-Dole specifically requires a university to reach an agreement with its researcher/inventor so that he or she would continue to assist in the development of the idea until it reached the public. Prior to Bayh-Dole, the researcher/inventor would patent the invention, write a paper for publication in a reputable publication, and return to the laboratory for more research. The idea gathered dust and the public suffered.

4. Industry alliances are tainting university research away from basic toward applied research. Response: A National Science Foundation study found no evidence of such a shift.

5. Bayh-Dole has adversely affected the publication of scientific papers by academia. Response: The U.S. remains by far the leading source of science and engineering publications.

6. Here's the real zinger. There should be no exclusive licenses. They should be made available to all. This criticism is heard repeatedly. Response: Without protection, business and industry will not risk the large amount of capital necessary to get an idea to the marketplace It was this same philosophy that resulted in the 28,000 patents gathering dust that Joe Allen discovered in 1978.

Enough attention to the critics. After 25 years, a successful law should have produced tangible results. Here's what The Economist had to say in 2002: "Possibly the most inspired piece of legislation to be enacted in America over the past half century was the Bayh-Dole Act of 1980...More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance...

"The Bayh-Dole Act did two big things at a stroke. It transferred ownership of art invention or discovery from the government agency that had helped pay for it to the academic institution that had carried out the actual research. And it ensured that the researchers got a piece of the action.

"Overnight, universities across America became hot-beds of innovation, as entrepreneurial professors took their inventions (and graduate students) off campus to set up companies on their own."

Let's review some statistics from the most recent Association of University Technology Manager's survey. Under the provisions of Bayh-Dole:

- 137 non-profit institutions introduced 567 new commercial products through their licensing agreements in FY2004.

- 185 institutions have introduced 3,114 new products through licensing since 1998.

- 16,871 invention disclosures were reported, up 8.8 percent over the previous year (about 250 university inventions were disclosed in 1980, the year prior to Bayh-Dole).

- In 2004, 462 new companies were formed, based on academic research (an increase of 23.5 percent over the previous year).

- 67.8 percent of university licenses went to small businesses.

But these are just statistics. Consider the new products benefiting not just the United States, but the world: Cisplatin Citracal, a new treatment for Crohn's disease; recombinant DNA technologies; the nicotine patch; better monitoring of diabetes patients; techniques to reduce infant respiratory deaths; 3-dimensionial surgery technologies; new crops; and even the Google search engine all sprang from university research. There are many others.



So given this history, where are we now? The hard fact is that we are in danger of losing the larger philosophical war unless we explain to policy-makers and the general public why protecting intellectual property is important not only economically, but also ethically. Also, we need to understand that hidden in some of the attacks on Bayh-Dole is a veiled assault on our country's patent system.

Our patent system and Bayh-Dole provide incentives and rewards for successful risk-taking. We should be proud of this and bold in its defense. In recent months, legislation posing as "patent reform" has been introduced in Congress. If such legislation should pass, it would do irreparable harm to our economic growth and our ability to provide sophisticated solutions to the problems that face our society. We cannot remain complacent.

This is true of us as individuals and true of the United States of America. We must remember how Edward Gibbons concluded his great volume, The Decline and Fall of the Roman Empire: "All that is human must retrograde if it does not advance. Nations, like individuals, are either moving forward in life or moving backward. We are never standing still. The ethical creation of wealth is the real challenge facing the world today."

Clearly, a few dedicated citizens can have a tremendous impact on our country's policies. If Ralph Davis, Howard Bremer, **Norm Latker** and Joe Allen could harness the effort that provided us with Bayh-Dole, certainly those of us who face this challenge a generation later should be willing to stand up and be counted!

Let me repeat, if we don't do it, who will?

Birch Bayh is a former Senator from Indiana who co-authored the Bayh-Dole Act, which revitalized the nation's patent system and helped create the biotechnology industry by spawning a whole generation of scientist-entrepreneurs. Currently, Senator Bayh is a partner in the Washington, D.C. law firm of Venable LLP. Email: bbayh@venable.com

FOR "BLUE SHEET"

Over 300 years ago, John Locke asserted that, "a man has a right to what he hath mixed his labor with". A hundred years later, the drafters of our constitution implemented this principle by granting to Congress the power to secure "for limited times to authors and inventors the exclusive right to their respective writings and discoveries" as an incentive "to promote the progress of science and useful arts".

In the Federalist on January 23, 1788, James Madison supported this prospective Congressional authority by noting:

> "The utility of this power will scarcely be questioned. The copyright of authors has been solemnly adjudged, in Great Britain, to be a right of common law. The right to useful inventions seems with equal reason to belong to the inventors. The public good fully coincides in both cases with the claims of individuals."

In a letter to Thomas Jefferson on October 17, 1788, Madison, probably anticipating criticism of this new authority, made a more important insight:

> "With regard to monopolies, they are justly classed among the greatest nuisances in Government, but is it clear that as encouragements to literary works and ingenious discoveries they are not too valuable to be wholly renounced? Would it not suffice to reserve in all cases a right to the public to abolish the privilege

> at a price to be specified in the grant of it? Monopolies are sacrifices of the many to the few. Where the power is in the few, it is natural for them to sacrifice the many to their own partialities and corruptions. Where the power, as with us, is in the many, not in the few, the danger cannot be very great that the few will be thus favored. It is much more to be dreaded that the few will be unnecessarily sacrificed to the many."

Neither the Constitution nor the respective implementing laws guarantees any right to the employers of such authors or inventors. The failure to address the rights of employers is not surprising because in 1787 writers and inventors were in most part self-employed. But as that fact changed, the common law addressed the relationship between employers and employees by upholding the assignment of a person's future ideas as a condition of employment.

This seemingly logical rule of law eliminated any need on the part of employers to examine whether it was equitable or desirable company or social policy to require the assignment of future ideas solely as a condition of being employed. No further consideration was given to the fact that such future ideas were not yet made and could not be evaluated to determine their value to society.

It does seem clear, however, that given a possibility of equal footing, the law intended that employees

would negotiate for a value "in what he had mixed his labor with." But as time passed, it became evident that employees would not achieve such footing.

It was in the context of this right in employers (including adoption by the federal government) coupled with the growth of large private and public organizations and the concentration of research funding in these organizations that the rights of authors and inventors faded into obscurity in the 1950's and 60's. Interestingly, at the same time the public perception of these organizations became increasingly critical. As latter day Edisons and Westinghouses became obscure within these organizations, the public lost its ability to relate to the organizations' achievements and began focusing on their problems.

While employer ownership resulted in no noticeable impediment to commercial development of inventions made by employees of private sector employers, it was determined that inventions funded by the government were not reaching the marketplace to the degree expected from the ever increasing volume of funding of research by the Federal Government after WWII. A number of studies at the time concluded that the government policy generally requiring dedication or non-exclusive licensing of inventions resulting from its funding

destroyed the incentives intended by the constitution "to promote the progress of science and useful arts" through its grant of exclusive rights. Of course, inventions made by employees of private sector employers were not generally handled in this manner. Thus, the Bayh-Dole body of laws was limited to addressing the Federal Government policies for disposition of inventions made in performance of its research.

The rationale of Bayh-Dole was simply this: if the law affords broad marketplace prerogatives to the developers of government funded inventions, the inventions will far more likely be developed and so made available to the public. To achieve this, ownership is left with the innovators, rather than the government agency that financed the research. The innovators are then free to leverage their rights to their advantage as intended by the constitution.

The Act has been enormously effective. As the Economist, Technology Quarterly, concluded, the Act is "the most inspired piece of legislation to be enacted over the past half-century." In operation, Bayh-Dole fostered a potent four-way partnership between researchers, their institutions, government and industry. That partnership has created a powerful engine of practical innovation, producing many

scientific advances that have extended life, improved its quality and reduced suffering for millions of people.

Universities, in particular, have been very successful in commercializing their inventions. Bayh-Dole is generally credited for contributing to the dramatic increase over the last 25 years in the number of university inventions reported, patents granted, royalty-bearing licenses negotiated, collaborative research agreements and start-up companies. As noted by the Economist that since 1980, American Universities have witnessed a ten-fold increase in their patents, created more than 2,200 companies to exploit their technology producing 260,000 new jobs and have contributed $40 billion annually to the American economy.

Now after 25 years of successfully meeting its intended purpose beyond even the expectations of its proponents, a cottage industry of critics calls for its amendment primarily on the basis that the Act's limited monopoly allows marketers to set the price for goods embodying inventions for which the taxpayers have already paid for. This they correctly argue can result in a high return to the innovator requiring higher prices than would be expected given competition from additional marketers. However, this position ignores the fact that inventions resulting from government

research are mostly conceptual in nature and require significant investment by the private sector to bring them to practical application. The investment necessary to make such an invention normally exceeds by many multiples the government funding that produced them. In such a situation, it has been demonstrated that a limited monopoly is a necessary incentive for initial investment. Most critics acknowledge this, but argue that the grant of monopoly can be limited by amending the Act to require that the government first determine whether private sector funding is necessary to deliver an identified invention to the marketplace.

In this regard, critics fail to recognize or acknowledge that exactly this kind of policy was in effect at a number of different government agencies during the 1960's and 70's prior to Bayh-Dole. After extended trial and debate, such policies were rejected as a means of maximizing delivery of government funded inventions to the marketplace. The primary reasons for rejection being examples of political intervention in the decision-making process, delays in processing decisions, inadequate and untrained staffing, and the unlikely prospect that the government will chose correctly and if not, the loss of incentives to pursue commercialization of the government owned invention both in the inventing organization and the inventor, and loss of inventor know-how

to guide a changing invention through the development process, etc.

The Bayh-Dole partnership should be viewed as an example of a "Nash Equilibrium" which involves a set of equities, one for each participant such that no participant has an incentive to unilaterally change its action. The participants are in equilibrium if a change in equities for any one of the participants would lead that participant to gain less than if the current equity remained.

Clearly the current critics of Bayh-Dole and their proposed suggestions for change have not made any case for elimination of the equities envisioned by the constitution for inventors other than their unsubstantiated belief that elimination of monopoly where not warranted will decrease the purchase price of the goods successfully reaching the marketplace. However, experience indicates that there can be no guarantee that such goods will even reach the market absent the equities established by Bayh-Dole. Most likely decreased purchase prices will not be achieved by pursuing the critic's suggested changes since their adoption will collapse the Bayh-Dole partnerships ending the environment that has delivered government funded inventions to the marketplace over the last 25 years. A return to policies that have already failed

without some justification as to why they will now succeed makes very little sense. But the most obvious reason for rejecting these proposed changes is the fact that they deny to inventors the reward envisioned by the Constitution, and should be resisted on that ground alone which was Bayh-Dole's primary motivation.

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I. INTRODUCTION

Louis Pasteur stated, "There is no greater charm for the inventor than to make new discoveries, but his pleasure is heightened when he sees that they have a direct application to practical life." On December 12, 1980, the U.S. Congress attempted to facilitate the application of new discoveries to practical life when it passed "[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century."[1] The Bayh-Dole Act,[2] sponsored by two senators, Birch Bayh, a Democrat from Indiana and Bob Dole, a Republican from Kansas, governs the policies and procedures for patenting and ownership of intellectual property arising from federally funded research at universities, non-profit institutions and small businesses. In enacting this legislation, the objective of Congress was to encourage utilization of research, promote collaboration between commercial concerns and non-profit organizations, and to enhance the commercialization and public availability of the innovations.[3]

Prior to the Act, academic researchers disseminated their discoveries to their professional colleagues through a variety of formal and informal communication channels including data sharing, seminars, and journal publications. Yet, there was no simple, uniform way for universities to effectively transfer the rights to commercialize the discoveries of faculty researchers to the marketplace. Each institution followed its own policies and procedures for managing and promoting the patented inventions it financed. However, those efforts were

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

[2] 35 U.S.C. § 200-212

[3] 35 U.S.C. § 200. "It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area."

extremely limited since the vast majority of funding for scientific research at universities was provided by grants from various agencies of the federal government. For those inventions created through research supported by the federal government, ownership remained with the source of the funding. Thus, "the federal government held title to most of the patents that resulted from its funding of university research."[4] The legislative and regulatory framework at the time made it difficult for the government to grant exclusive licenses. For example, if a company requested an exclusive license to a patent, a 60 day notice was required to be placed in the Federal Register[5]. If a competing company also requested a license to the same patent, the policy was to grant only a non-exclusive license to each of the parties. Thus, most inventions were placed in the public domain and made freely available to all interested parties. As a result, these innovations languished, because "no incentive for any individual or company to take the necessary risk to underwrite product development to commercialize academic scientific breakthroughs" existed.[6] Senator Birch Bayh later remarked, "What sense does it make to spend billions of dollars each year on government-supported research and then prevent new developments from benefiting the American people because of dumb bureaucratic red tape."[7] In an effort facilitate the transfer of federally funded research results to the marketplace, the Bayh-Dole Act sought to streamline the patent process and provide specific ownership rights to the inventors.

II. HISTORICAL CONTEXT

The patent policy created by the Bayh-Dole Act is consistent with the general property rights framework espoused in The United States Constitution. Article I, Section 8 states, "The

[4] "The Bayh-Dole Act at 25," *BayhDole25, Inc.*, April 17, 2006, p. 2
[5] 37CFR404.7 US Code of Regulations on exclusive licensing of government owned inventions
[6] Id.
[7] News from Senator Birch Bayh, April 23, 1980, on approval of S.414 (Bayh-Dole).

Congress shall have Power… To Promote the Progress of Science and useful arts, by securing for limited Times to Authors and Inventors the exclusive Rights to their respective Writings and Discoveries." By providing inventors "the sole right to profit from their inventions for a limited time, the framers sought to promote scientific progress."[8] Without the constitutional protection of certain intellectual property rights, scientists would be dissuaded from disseminating their research for fear that another might claim their innovation as their own. Abraham Lincoln, the only U.S. president to hold a patent[9], stated that without patents,

> Any man might instantly use what another had invented; so that the inventor had no special advantage from his own invention. The patent system changed this; secured to the inventor for a limited time, the exclusive use of his invention; and thereby added the fuel of interest to the fire of genius.[10]

Patents spur innovation. "Without the incentive provided by the patent, the pace of innovation would slow because inventors would not be rewarded as much for the time, effort and risk that it took to develop the innovation."[11] Thus, patents, since the first patent law was enacted by the Republic of Venice in 1474, were considered necessary to protect the rights of scientist and provide impetus scientific innovation.

The protection of certain intellectual property rights was imperative not only for the progress of research but also to the commercialization of the resulting inventions. Frederick Gardner Cottrell, the inventor of the electrostatic precipitator for mitigating air pollution and creator of Research Corporation, the first foundation in the United States devoted to the advancement of science, claimed a manufacturer required "a certain amount of protection before it [would] invest in machinery or other equipment, to say nothing of the advertising necessary to

[8] "The Bayh-Dole Act at 25," *BayhDole25, Inc.*, April 17, 2006, p. 4
[9] Patent No. 6469 for a device to lift boats over shoals
[10] Abraham Lincoln, Second Lecture on Discoveries and Inventions, February 11, 1859, in Collected Works of Abraham Lincoln, Vol. 3 (New Brunswick: Rutgers University Press, 1953), p. 363
[11] Ted Buckley, The Myth of the Anticommons, 3

put the invention on the market. Thus, a number of patents given to the public absolutely freely by their inventors have never come upon the market chiefly because what is everybody's business is nobody's business."[12] Adequate protection of intellectual property is essential to attract the funding necessary for proper development and promotion of the discoveries. If a scientist could not claim exclusive rights to his invention, no manufacturer would be willing to invest the funds necessary to develop, manufacture, and distribute the invention in the marketplace.

The role of universities in the research and development enterprise changed dramatically in the aftermath of World War II. Federally funded research played a vital role in World War II. Prior to the war, government research was primarily conducted in dedicated laboratories. However, during World War II, wartime efforts came to dictate the research agendas of both universities and government scientists. In response to the growing demands of war, in June 1940, President Franklin D. Roosevelt established the National Defense Research Committee (NRDC) "to coordinate, supervise, and conduct scientific research on the problems underlying the development, production, and use of mechanisms and devices of warfare."[13] Ultimately, two major government funded initiatives, the MIT Radiation Laboratory (RadLab), a division of the NRDC which developed over 100 different radar systems, and the Manhattan Project, which created the atom bomb, made a dramatic contribution to the war effort and effectively exploited America's technological superiority to give the Allies a crucial edge necessary to win the war.[14]

After the war, government laboratories grew, "in line with the increased U.S. commitment to defense and military applications." In 1946, Vannevar Bush, the former

[12] Frederick Gardner Cottrell, "The Research Corporation, an Experiment in the Public Administration of Patent Rights," *Journal of Industrial and Engineering Chemistry* 4: 865 (1912)
[13] The Bayh-Dole Act at 25," *BayhDole25, Inc.*, April 17, 2006, p. 7
[14] Id. at 8.

chairman of the NRDC, authored a report[15] that "linked government support of basic science to the goal of stimulating the economy" [16] and established the framework for an "unprecedented and heavily subsided system in support of scientific research that propelled the American economy."[17] University research endeavors expanded, fueled by the enhanced federal funding. In 1935, the federal government provided less than a quarter of the funding for academic research and development, about $575 million dollars. By the 1960s, federal funding had increased by more than 250% and accounted for more than 60% of academic research and development funding. By the time Bayh-Dole was enacted in 1980, federal support of academic research and development encompassed 70% of total such spending.[18] Yet, the increase in federal spending, alone, did not yield the anticipated technological innovations. Without any way to effectively translate research discoveries into commercial products, American technological leadership lagged.

By the late 1970s, America had seemingly lost its technological advantage. In his statement to the National Institutes of Health, in 2004, Senator Birch Bayh outlined the key problems that had led to the erosion of America's technological superiority. America "had lost [its] number one competitive position in steel and auto production. In a number of industries [America wasn't] even number two." Bayh linked this decline in competitiveness to an overall reduced impetus to innovate, demonstrated by "the number of patents issued each year [which] had declined steadily since 1971." The drop in the number of patents was tied to the level of investment in research and development over the previous ten years, which had remained stagnate. As a result of America's loss of competitive edge, decline in innovation, and static

[15] Vannevar Bush, Science: The Endless Frontier (Washington, D.C.: U.S. Government Printing Office, 1945).
[16] Id. at 9.
[17] Yale President Richard Levin speech at Fudan University, September 23, 2005 http://opa.yale.edu/president/message.aspx?id=19
[18] Id.

funding, Bayh claimed, "American productivity was growing at a much slower rate than that of [America's] free world competitors." Moreover, not only was the level funding a problem, the funds were not supporting the most appropriate sources of innovative ideas. Although small businesses had amassed "a very impressive record in technological innovation," they received "a smaller percentage of federal research and development money." Furthermore, "The number of patentable inventions made under federally supported research had been in steady decline."[19] Thus, in an effort to stimulate innovation in the United States and reassert America's technological advantage, Senators Bayh and Dole introduced the University Small Business and Patent Act in order to streamline the patent process and provide protection for intellectual property rights.

III. THE BAYH-DOLE ACT

The Bayh-Dole Act sought to promote a technological revolution and allow the United States to reclaim its global leadership in scientific innovation. In order to accomplish this objective, the bill established a universal policy of "title in contractor" for determining patent rights, providing for the proper balance for the role of government in ownership of property rights, consistent with the principles John Locke first espoused in 1690:

> Whatsoever then he removes out of the state that nature has provided and left it in, he has with, and joined to it something that is his own, and thereby makes it his property[20].

The provision in the Bayh-Dole Act provided contractors, such as universities and small businesses, with the right to retain the title to innovations funded in part or in whole by the

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

[20] Locke, John. The Second Treatise on Civil Government. Buffalo: Prometheus, 1986.

government.[21] In addition, the act facilitated the transfer of technology from the university to the marketplace. By providing universities and small business with exclusive ownership of their innovations, they were incentivized to attract the funding necessary for development and distribution of their innovations. Furthermore, research agencies were now governed by a uniform set of rules. Potential investors and corporate partners were no longer subject to changes in agency patent policy and as a result, they were more willing to commit the funds required for the development of those federally funded innovations. Moreover, the act provided federal contractors (i.e., universities) with authority to grant exclusive patent licenses. Universities were required to file patent applications on their inventions and to accord small businesses preference when granting licenses.[22] The government retained "march-in rights" to the inventions it funded, "which allowed a federal agency to pull title back to a patent and grant a license to a responsible new applicant, if the current licensee failed to make the product available on reasonable terms."[23] Ultimately, the design of the act allowed each agency to do what it did best. The federal "government provide[d] funding for university research, much of which [was] too speculative (and expensive) to be undertaken by the private sector. Scientists decide[d], on the basis of peer review that relies on their profession expertise, exactly how government research funds should be allocated."[24] As a result, government funding was apportioned to the most relevant and pressing research projects. Additionally, the act permitted universities to own the innovations developed in their research facilities and allowed scientists to benefit from "successful commercialization of federally-financed research, through jobs created, patents

[21] See 18 U.S.C. §202

[22] The emphasis on small businesses deflected criticism that the legislation provided a giveaway of taxpayer financed intellectual prooerty to established corporations that neither needed nor deserved such subsidies." The Bayh-Dole Act at 25," *BayhDole25, Inc.*, April 17, 2006, p. 20

[23] Id.

[24] Id. at 21.

licensed and innovations developed."[25] Government, universities, scientists, and taxpayers benefitted from the act.

IV. IMPACT OF THE BAYH-DOLE ACT

Together with landmark decisions concerning patentable subject matter (e.g., Diamond v. Chakrabarty, 1980[26]), the Bayh-Dole Act led to a dramatic increase in marketable innovations. As a result of the passage of the bill, academic institutions have made technology transfer a priority. "The percentage of patented innovations licensed for commercial purposes has increased from "single figures to 30%."[27] Moreover, university funding for academic research and development has increased from 14% in 1980 to 20% in 2001. Total research and development funding has increased from $6 billion dollars in 1980 to $33 billion in 2001.[28] This surge in funding has lead to an increase in research activity. More scientists have been able to obtain the funding necessary to pursue their research. Furthermore, as a result of the Bayh-Dole Act, scientific researchers are more highly valued by universities. "The brain drain that so many other countries suffer from, wherein top scientists leave low-paying university positions to work for industry does not have an impact on U.S. universities."[29] In fact, influential researchers from countries, such as India and China have been attracted to positions at universities in the United States to escape "the relative drudgery of their academic research in environment."[30] As a result of the influx of university faculty, students have been given more opportunities to interact with and assist researchers and in some instances conduct their own projects.

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[25] Id. at 22.
[26] 447 U.S. 303 wherein the Supreme Court determined that genetically modified micro-organisms can be patented. http://caselaw.lp.findlaw.com/scripts/getcase.pl?navby=CASE&court=US&vol=447&page=303
[27] Id. at 22.
[28] AUTM, Annual Licensing Survey: FY 2003 (Survey Summary) (Northbrook, Illinois: 2004). http://www.autm.net/surveys/dsp.surveyDetail.cfm?pid=16
[29] Schwartz Technology Transfer Tactics
[30] Id.

Ultimately, this rise in faculty and student research has lead to an increase in innovation as demonstrated by the increase in patents issued to U.S. universities. In 1980, 250 patents were issued. In 2003, thirteen years after the Bayh-Dole Act was passed, 3,933 patents were issued.[31]

The tremendous number of patents issued has translated into many life-enhancing innovations in the marketplace, including the development of many important biotechnology productssuch as:

- New anti-retroviral treatments for HIV/AIDS from Emory University;
- Treatments for inflammatory diseases such as rheumatoid arthritis from New York University;
- An artificial lung surfactant for babies born with respiratory distress system was developed by the University of California;
- A new treatment for Crohn's disease and other inflammatory bowl diseases was discovered by scientists at Washington University in St. Louis;
- Non-toxic therapies for chagas disease were developed through collaboration between University of Washington and Yale University; and
- Recombinant DNA technology was developed through a partnership between researchers at Stanford University and University of California.[32]

All of these and many more discoveries have resulted from the rise in technology transfer and have had a tremendous impact on the lives of many Americans.

The rise in technology transfer as a result of the Bayh-Dole Act has not only facilitated the discovery of life-saving innovations, it has invigorated waning state economies. Thousands of new companies and jobs have been created as a result of rise in innovation. "Industry models show that $100 in research expenditures creates $222 in wealth in the local economy."[33] For

[31] Id.
[32] http://www.ucop.edu/ott.bayh.html
[33] Ted Strickland and Lee Fisher, Don't Believe the Doomsayers. Ohio's Economy is Doing Fine. The New York Times, September 6, 2008 at A9.

example, "graduates of [Massachusetts Institute of Technology have] founded over 4,000 companies nationwide and [continue] to create an additional 150 companies a year."[34] Over 1,000 of these companies are based in Massachusetts that accounts for almost "25% of all manufacturing activity in the state." The innovations of MIT researchers paired the efforts of the university's technology transfer office to patent and market the discovery yielded tremendous benefits to the state of Massachusetts.

Technology transfer endeavors had similar effects in Ohio. "Ohio State University Medical Center created 3,742 new jobs between 2001 and 2007 by targeting research grants related to cancer studies."[35] By combining higher education and federal economic development funds, Ohio was able to institute a $150 million Ohio Research Scholars program. This program plans to "bring 26 world-class scholars to state campuses, individuals whose research specialties align with [the state's] economic development priorities."[36] Thus, by utilizing the Bayh-Dole framework, Ohio has been able to revitalize the state's economy by enticing distinguished researchers to its universities and develop their discoveries in an effort to attract new industry to the state. Not only has Ohio profited from the Bayh-Dole Act, but in the future, individuals in other states will benefit from the technology developed in Ohio.

Nowhere has the impact of this act been more apparent than the biopharmaceutical industry. The patent process has been an integral part of the development of new biological and pharmaceutical products. "Each biopharmaceutical that is brought to market requires on average $1.2 billion in research and development."[37] The high costs are due both to the time and effort

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[34] BankBoston, "MIT: The Impact of Innovation." Boston, 1997. http://web.mit.edu/newsoffice/founders/Founders2.pdf
[35] Id.
[36] Id.
[37] Buckley 3

that is expended developing and testing new medicines as well as the numerous failed innovations for each success. "For every biopharmaceutical that is brought to market there are approximately 10,000 failed attempts."[38] The cost of the required human clinical trials is substantial and has risen "7.5% above the annual rate of inflation during the 1990s."[39] Furthermore, the clinical development and regulatory approval process takes an average of 97.7 months before a biopharmaceutical can be distributed to the public. Thus, patents are necessary to allow inventors and investors to recoup the cost of research and development and invest in future projects.

As a result of the impact of the Bayh-Dole Act and its twenty-fifth anniversary, on December 16, 2005, the House of Representatives passed a concurrent resolution commemorating the legislation, stating that the bill has

> made substantial contributions to the advancement of scientific and technological knowledge, fostered dramatic improvements in public safety, strengthened the higher education system in the United State, 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.[40]

In the resolution, Congress went on to reaffirm "its commitment to the policies and objectives" of this technology transfer process.

V. CRITICISM

A. THE UNIVERSITY AS CORPORATE RESEARCH LAB

Although acclaimed by Congress, the Bayh-Dole Act is not without its critics. Janet Rae-Dupree, a science and emerging technology journalist in Silicon Valley for *The New York Times*, recently wrote that the Bayh-Dole Act has "distorted the fundamental mission of universities,"

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

which she claims is discovery and education by "freely sharing techniques and results."[41] Rae-Dupree asserts that "today's universities function more like corporate research laboratories" than institutions of higher education.[42] Rather than funding educational research endeavors, "university technology transfer offices throw money into a void" in the hopes of discovering one "blockbuster invention," which would solve the university's financial problems.[43] Implicit implicit in Rae-Dupree's argument is that the money generated from royalty revenues would be better spent on research unlikely to yield commercially profitable results. Yet, "without the funds generated by academic licensing activity, many labs would suffer, less research would be done, fewer products and innovations would reach the people who need them, and massive economic benefits produced by these innovations would not accrue to the U.S. and local economies."[44] Without the financial benefits that amassed by universities through their technology transfer efforts, much of the academic research that is currently conducted would be too expensive to continue. Moreover, many of the "greatest innovations of our time" may not have been translated from academia to the marketplace. Critical medicines such as Guardasil, a vaccine to prevent cervical cancer, and treatments for HIV/AIDS such as Emitriva, as well as search engines such as Google, are a direct product of university research and the framework set in place by the Bayh-Dole Act.[45]

Rae-Dupree contends that the Bayh-Dole framework has encouraged scientists to forgo certain under-explored areas of research in favor of other more commercially viable lines of inquiry. She claims that the commercialization of research prevents experimentation that leads

[41] Janet Rae-Dupree, "When Academia Puts Profits Ahead of Wonder," *The New York Times,* September 6, 2008, at BU4.
[42] Id.
[43] Id.
[44] David Schwartz Technology Transfer Tactics
[45] David Schwartz Technology Transfer Tactics

to a greater understanding of the world, but may not have immediate market value. Yet, the vast majority of research dollar result from competitive grant applications that are subject to peer review. Thus, a researcher cannot simply select a commercially relevant subject on which to conduct research, but must convince a jury of peers of the scientific merit of engaging in a particular line of inquiry. Moreover, the metrics on which performance is judged remains the number and quality of publications in peer-reviewed scientific journals. Furthermore, U.S. universities have long relied on state, federal, and private support. Historically, much of this funding has been geared toward proposed research with practical benefit to a particular state or regional economy.[46] Finally, the pursuit of marketable innovations is inextricably tied to basic research. In fact, this supposedly neglected "basic research is the source from which all commercially oriented applied research and development flows."[47] Often the commercial viability of an innovation is unanticipated and stems from advances in basic research from ten to twenty years ago. Thus, even research geared toward commercial gain has a foundation in basic "Blue Sky" innovation. The pursuit of marketable inventions is not at the expense of basic research, because basic research is the foundation of the future commercially viable inventions.

Rae-Dupree also contends that the Bayh-Dole Act reduces academic openness and impedes the dissemination of knowledge. "Rather than freely sharing techniques and results, researchers increasingly keep new findings under wraps to maintain a competitive edge" creating an "every laboratory for itself" mentality.[48] Yet, even before the Bayh-Dole Act was enacted leading scientists were reluctant to share their research. For example, James D. Watson and Francis Crick evaded and misled other researchers, including their colleague, Rosalind Franklin,

[46] The Bayh-Dole Act at 25," *BayhDole25, Inc.*, April 17, 2006, p. 31
[47] Chinese University Forum
[48] Janet Rae-Dupree, at BU4.

so that they could be the first recognized for decoding the DNA structure. Their scientific ambitions, rather than commercial considerations, motivated their secrecy. No patent incentive influenced their behavior.[49] Furthermore, contrary to Rae-Dupree's argument, the patent process actually facilitates the dissemination of information. When a patent application is filed the information regarding the innovation is subsequently published. The patent system is based on a fundamental bargain. If the innovator fully discloses his invention, the government will grant the inventor a period of time in which he is afforded the right to exclude others from selling a product that incorporates his invention. Furthermore, "by definition, patents are published to allow others, including students, to learn what the inventor has learned and to facilitate further discovery."[50] Thus, rather than encourage secrecy and competition between scientists, the patent process actually promotes the open dissemination of information.

Rae-Dupree argues that technology transfer is detracting from the fundamental goals of the university, discovery and education. Yet, Yale University president, Richard Levin, contends that there is a third goal of universities, community service. "By serving as models of institutional citizenship, universities make a direct contribution to social betterment and inspire their students to recognize obligation to serve."[51] By contributing "directly to local economic development, neighborhood improvement, public education, health care, [and] social service" the university can model the role of a good citizen to its students. To illustrate his point, Levin uses Yale's efforts to revitalize the city of New Haven, Connecticut. When Levin became president of Yale in 1993, New Haven was "deeply troubled,"[52] plagued by poverty and crime. As part of a comprehensive strategy to strengthen the city, Yale sought to contribute to the economic

[49] James D. Watson, *The Double Helix: A Personal Account of the Discovery of the Structure of DNA* (New York: Touchstone, 2001)
[50] Email
[51] Levin speech
[52] Id.

growth of the city through an aggressive technology transfer plan. By seeking out "faculty interested in commercializing their results," utilizing students at the School of Management to craft business plans, soliciting funds from venture capitalists, and finding "real estate solutions in New Haven," Yale was able to facilitate the establishment of over thirty biotechnology companies in the greater New Haven area.[53] Ten years later, this aggressive technology transfer effort in conjunction with Yale's other community revitalization activities has transformed New Haven from an ailing city into an "an irresistible destination" according to an article featured in the *New York Times* travel section. Rather than undermining the fundamental goals of the university, technology transfer plays an integral role in the third mission of universities-community service.

In response to Rae-Dupree's article, the president of the University of Michigan, Mary Sue Coleman, wrote that the transfer of research discoveries from the university to the marketplace "is a fundamental responsibility of a university system." The process enriches the "research and learning environment via engagements with our community and business partners, and ensures that the benefits of our activities benefit the general public." Rather than hampering the research, Coleman claims the Bayh-Dole Act is essential to achieving a "robust technology transfer capacity."[54] The act facilitates the technology transfer process and contributes to the free flow of information and innovation that originates in university laboratories.

B. THE ANTI-COMMONS EFFECT

[53] Id.
[54] Email

In 1998, in response to the rise in technology transfer, Heller and Eisenberg theorized that over-patenting was threatening biotechnological innovation.[55] This theory was labeled the tragedy of the anti-commons. Heller and Eisenberg hypothesized that patent activity in the field of biotechnology has reached unsustainable levels and as a result basic, academic research would be hindered in the future by the imposition of long negotiations and expensive licenses necessary to acquire research inputs from academia.[56] The anti-commons theory predicted that transaction costs of acquiring numerous research inputs would increase exponentially as the number of patents increased. Innovations would decline because scientists would be unable to conduct scientific research without infringing on the patents of others.

Heller and Eisenberg identified two scenarios where the fragmented ownership of technology would potentially lead to increased transaction costs for future product development. First, patents on numerous "upstream" technologies, or research tools, would act like "tollbooths on the road to product development, adding to the costs and slowing the pace of downstream biomedical innovation."[57] F. M. Scherer states, "The problem is analogous to conditions on the Rhine River during the 18th Century. Over the 85-kilomenter stretch between Mainz and Koblenz in 1780, there were nine toll stations."[58] As a result of the overabundance of tolls on the river, the number of boats traveling down the river was reduced significantly. Similarly, innovation would be reduced the more transactions costs there are to obtain the research inputs necessary for a particular study. The second scenario Heller and Eisenberg posited was that the reach-through license agreements on patented upstream technologies would be used to obtain

[55] Heller, M.A. and Eisenberg, R.S. "Can Patents Deter Innovations? The Anticommons in Biomedical Research." Science Vol 280. 1 May 1998.
[56] Intellectual Property in the Community AAS Scientific Community: A descriptive analysis of a pilot survey on the effects of patenting on science
[57] Eisenberg at 699.
[58] Scherer, F.M. "The Economics of Human Gene Patents." Academic Medicine Vol. 77, No. 12 (December 2002) Part 2, p. 1363.

"rights in subsequent downstream technologies" blocking the integration of the innovation and any improvements in future research. In both these scenarios, patents would impede innovation by preventing researches access to the previous discoveries of others. Ultimately, over-patenting would lead to "fewer useful products for improving human health."[59] Although Heller and Eisenberg cited no empirical evidence in their study, the theory garnered a great deal of attention.[60]

The 2002 Federal Circuit Court of Appeal's decision in *Madey v. Duke,*[61] which confirmed the absence of an academic research exemption to patent infringement liability, provided evidence of the reality of this fear to critics. Dr. John M.J. Madey brought a claim against Duke University for patent infringement after he was terminated from his position as the director of Duke's FEL[62] research laboratory. Madey claimed that the university's subsequent work at the lab infringed on patents obtained by him prior to his employment at Duke. Duke defended the work claiming that it was protected by the experimental use exception. Although the district court granted summary judgment in favor of Duke, the Court of Appeals reversed holding that

> regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or non-profit status of the user is not determinative.[63]

The court went on to conclude that even when academic research did not appear to have a commercial objective "these projects unmistakably further the institution's legitimate business

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[59] Heller and Eisenberg
[60] Ted Buckley, The Myth of the Anticommons, 2.
[61] Madey v. Duke Univ., 307 F.3d 1351 (Fed. Cir. 2002)
[62] Free electron laser
[63] Id. at 1362.

objectives," by "educating and enlightening students and faculty participating in these projects" and "increasing the status of the institution and lure lucrative research grants, students and faculty."[64] The court effectively denied the existence of an experimental use exception to patent liability for university research and fueled concern that the increase in patents would impede university research by subjecting researchers to infringement liability. Although university research does not enjoy a research exemption, the concern about impeding basic research may be overblown since the punishment for infringing patents is up to three times the commercial damage inflicted on the patent holder. Given that in most situation a university is simply pursuing federal grant-funded research, thus significantly limiting the commercial damage and making it economically unattractive to pursue costly and time-consuming infringement litigation.

Yet, the anti-commons theory that hypothesizes that the increase in patent activity is creating a "patent thicket," which makes the pursuit of scientifically and socially worthwhile research overly burdensome, is theoretically flawed. "An implicit part of the argument is that there is a scarcity to the biological commons akin to geographical scarcity."[65] Similar to the Rhine River, "there is a single starting and ending point" and only one route to travel between the two points.[66] Yet, in the study of biotechnology there are numerous starting points and routes to obtain the same end result.

> Imagine that a shipper wants to transport good[s] from Mainz to Koblenz but is faced with having to go through nine toll stations on the river. Whereas in the 18th century, the shipper had no option but to traverse the river, in the 21st century biotechnology world, the shipper has alternate routes such as roads, raid or air.[67]

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[64] Id.
[65] Buckley at 4
[66] Id.
[67] Id at 5.

Thus, the shipper can avoid the tolls altogether by utilizing an alternative route. Similarly, researchers can invent around a patent.

To illustrate the concept of "inventing around a patent," Ted Buckley uses the discovery of statins, "medicines designed to lower blood cholesterol levels" as an example.[68] As Buckley explains, the desired endpoint of the innovation is lower cholesterol, yet unlike the Rhine River example, there are numerous different routes to this end point. Currently, there is not just one statin on the market, but five.[69] Similarly, there are presently multiple products being developed for the treatment of breast cancer and chronic myeloid leukemia. Thus, there are many different solutions to one problem or disease. The patenting of one innovation does not deter the discovery of another alternative remedy to the same ailment.

In fact, evidence of the anti-commons effect seems to be merely anecdotal.[70] A survey conducted by the American Association for the Advancement of Science found that "while patents were the most common means used by respondents to protect IP...the licensing of these patented technologies is not the primary means by which respondents within academia acquire or disseminate technology."[71] Rather academics continued to disseminate information through publishing and informal sharing as they did prior to the enactment of the Bayh-Dole legislation. In essence, academic researchers have claimed free pass through the patent toll-booths. Thus, the study concluded that the more formal and restrictive licensing process implemented by the

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[68] Buckley at 5
[69] Id.
[70] Only one empirical study of biotechnology patents has detected evidence of the anti-commons effect. However, the study used an indirect measure- the aggregate citation rates to scientific articles covered by a patent, and found the effect quantitatively modest at best. Fiona Mrray & Scott Stern, *Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis* 5 (Nat'l Bureau of Econ. Research, Working Paper No. 11465, 2005).
[71] AAAS

Bayh-Dole Act had little affect on academic researchers in the acquisition of patented technologies for research.

Likewise, The National Academy of Sciences surveyed 414 academic scientists to determine whether their research had been negatively impacted as a result of over-patenting. The survey found that only one percent of the academics experienced delays of a month or longer in commencing their research as a result of patent negotiations and transaction costs related to research inputs. None of the respondents reported abandoning their research as a result of these delays.[72] The survey found that "fears of widespread anti-commons effects that block the use of upstream discoveries have largely not materialized."[73] Rather than being bogged down by lengthy negotiations and high transactions costs, academic researchers used a variety of strategies to gain access to the research inputs. "In addition to licensing being widely available," researchers invented around, went offshore, challenged questionable patents and used technology without a license in order to accomplish their research goals.[74] Therefore, although the abundance of patents has been shown to cause research delays in a few rare cases, the survey did not detect the abandonment of research or the decline in innovation predicted by the anti-commons theorists. Instead researchers found access to patented research inputs through different avenues.

Similarly, a study conducted by David E. Adleman and Katheryn L. DeAngelis found "little evidence that the rise in biotechnology patenting is adversely affecting innovation."[75] Their analysis was based on biotechnology patents granted in the United States from January

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[72] Walsh, J.P., Cho, C. and Cohen, W.M. "View from the Bench: Patents and Material Transfers." *Science* Vol 309. 23 September 2005.
[73] Id. at 1093.
[74] Id.
[75] David E. Adelman and Katheryn L. DeAngelis, *Patent Metrics: The Mismeasure of Innovation in the Biotech Patent Debate*, Texas Law Review Vol. 85:1677.

1990 through December 2004. "The data cover[ed] the period of the most dramatic rise in biotechnology patenting, important shifts in PTO [U.S. Patent and Trademark Office] policy towards more stringent standards for obtaining patents on genetic sequences, and dramatic growth followed by a significant retrenching of the biotechnology financial markets."[76] This time period is significant, because the anti-commons effect would be most prevalent at the time when the number of patents issued and the control over intellectual property was at its highest. However, the study concluded that "the lack of concentrated control, the rising number of patent applications, and the continuous record of new market entrants provide[d] strong evidence that biotechnology patenting is not adversely affecting innovation."[77]

In his study, Buckley predicts that if contrary to the aforementioned empirical studies, the tragedy of the anti-commons did exist there would be three readily identifiable effects. First, "the amount of research and development would decline" because "companies will spend research and development dollars until the point at which it is no longer profitable to do so." Thus, if the tragedy of the anti-commons is occurring, then the cost of obtaining the licenses for the necessary research tools to conduct a study would far outweigh the potential benefits of the research and the study would be discontinued. However, according to Ernst & Young LLP's annual biotechnology industry reports, "the amount of research and development by publicly traded companies in the biotechnology arena has grown substantially" from about $9 billion in 1994 to over $20 billion in 2005.[78] In fact, since 1998 funding for research and development has increased 60%. Furthermore, venture capital funding for privately held biotechnology firms has increased substantially. "In 2005, the amount of [venture capital] funding was almost $4 billion,

[76] Id. at 1680.
[77] Id. at 1681.
[78] Ernst & Young LLP, annual biotechnology industry reports, 1993-2006.

up 300% from 1995."[79] This increase in funding demonstrates that research and development is on the rise.

Second, "fewer potential innovative therapies would be tested." Hypothetically, if the tragedy of the anti-commons was occurring, then prolonged negotiations and high transactions costs would impede research and lead to fewer innovations. However, Buckley posits "given the long lead time that it takes to research and develop an innovative therapy and bring it to market, approximately 12 years, it may be too early to see evidence of the tragedy of the anti-commons."[80] Thus, he examines the number of Investigational New Drug (IND) submissions that would hypothetically be lower if the tragedy of the anti-commons were occurring. However, the number of original INDs received increased sharply from approximately 400 in 2004 to 550 in 2005. Buckley claims that this is the time period that one would expect the number of INDs to decline as a result of over-patenting in 1998. "If there was an anti-commons problem it would take 3 - 6 years to manifest," due to the preclinical testing that must be completed before and IND can be submitted.[81] Buckley also notes that the number of biological compounds entering preclinical trials has also increased. In 2005, 37% more compounds entered preclinical trials than in 1998.[82] This increase in INDs submissions and biological compounds entering preclinical testing is inconsistent with the tragedy of anti-commons theory.

Finally, "companies and researchers would clamor for a public policy remedy."[83] Yet, "a substantial number of members of the Biotechnology Industry Organization (BIO), the trade association for the biotechnology industry...companies who depend on the ability to research

[79] Buckley 8
[80] Buckley 9
[81] Buckley 10
[82] Id.
[83] Buckley 6

and develop innovative therapies," support the current patent system implemented by the Bayh-Dole Act. "BIO's position implies that the patent system encourages innovation."[84] BIO "affirms that intellectual property rights are a prerequisite for the commercial success of these [biotechnology] companies and for future innovation in these knowledge inputs."[85] Without the ability to patent their innovations and obtain exclusive license, these companies would not be able to recoup their initial investments or raise money to fund other research and development.

Heller and Eisenberg's anti-commons theory is not only theoretically flawed, it lacks support from empirical evidence. In fact the theory has been refuted by multiple studies. As university technology transfer offices continue to take advantage of the Bayh-Dole framework innovations, patents, and funding for future research and development continue to rise.

VI. THE FUTURE OF TECHNOLOGY LICENSING

Even though there is only anecdotal evidence of the tragedy of the anti-commons, technology transfer offices at universities[86] across the country have responded to the criticism and acknowledged the importance of creating a balance between the business interests of [university] licensing partners and the mission of the university - education and discovery. Last year a group of leading research universities released a white paper entitled "In the Public Interest: Nine Points to Consider in Licensing University Technology."[87] Together with the Association of University Technology Managers (AUTM), they have called on other universities to endorse these principles in order to hold the technology transfer profession to a higher

[84] Buckley 11
[85] Buckley 12
[86] The universities participating in the July 2006 conference to brain storm critical issues in university technology transfer included California Institute of Technology, Cornell University, Harvard University, Massachusetts Institute of Technology, Stanford University, University of California, University of Illinois, Chicago, University of Illinois, Urbana-Champaign, University of Washington, Wisconsin Alum Research Foundation, Yale University, and Association of American Medical Colleges (AAMC).
[87] "In the Public Interest: Nine Points to Consider in University Licensing," March 6, 2007. http://www.autm.org/aboutTT/Points_to_Consider.pdf

standard and ensure that licensing activities are "in the public interest and for society's benefit."[88] The paper stresses the importance of considering the nature of the invention, its relevance to future research, and the level of patent protection necessary to facilitate marketplace viability when overseeing the transfer of innovation from research laboratory to the marketplace. The paper acknowledges that if the scientific field is to advance, each participant has a stake in ensuring that the necessary research tools are not compromised.

The first point stressed by the paper is that "universities should reserve the right to practice licensed inventions and to allow other non-profit and governmental organizations to do so" as well.[89] Even when licensing an innovation exclusively to a commercial entity, the university should preserve a right of use for academic and government research purposes. In order to allow future research to proceed unencumbered by patents and to permit academics to publish their research in peer-review journals, universities should reserve a right to use for academic research when licensing innovations. The university should seek to allow the technology to be utilized by other fields and encourage the free flow of information in academia.

The second point states, "exclusive licenses should be structured in a manner that encourages technology development and use."[90] Although exclusive licensing is sometimes necessary to allow commercial partners to recoup their substantial investments in the development of the product, "universities need to be mindful of the impact of granting overly broad exclusive rights and should strive to grant just those rights necessary to encourage development of the technology."[91] The paper concedes that unintended negative consequences may result from a license that encompasses all fields if the innovation is found to have

[88] Id. at 1.
[89] Id.
[90] Id.
[91] Id.

"unanticipated utility" in the future. As such, the university should be mindful of these potential unforeseen consequences and work to ensure "broad practical application of the fruits of its research programs" when structuring their license agreements. In addition, universities can promote the dissemination of research through "mandatory sublicensing" whereby exclusive licensees are required to grant sublicenses in order to address "unmet market or public health needs."[92] Exclusive licenses can be crafted to grant the licensee the exclusive right to the sale of the product, but not exclusive use, allowing the university to license the use of the technology to others for research and development. The paper stresses that even when an exclusive license is unavoidable, the license, like any medical technology, "should not hinder clinical research, professional education and training, use by public health authorities, independent validation of test results, or quality verification." Finally, after licensing, universities should "promote the development and broad dissemination of licensed technology" by monitoring and reevaluating the necessity of their existing exclusive licenses.[93]

Point three in the paper requires universities to "strive to minimize the licensing of future improvements."[94] Ideally, licenses should be strictly limited to current patent applications and existing patents. The license should not automatically grant rights to subsequent improvements of the innovations to the licensee. When an improvement license is absolutely necessary to the development of an innovation, the scope of the grant should be very narrowly taylored so as not to constrain the innovation indefinitely, across all fields of research. Furthermore, improvement

[92] Id. at 3.
[93] Id.
[94] Id. at 4.

licensees should be subject to "proper diligent development requirements" to prevent an innovation from languishing under the control of an exclusive licensee.[95]

"Universities should anticipate and help to manage technology transfer related conflicts of interest" under point four.[96] Licensing university research to start up companies established by faculty or student researchers raises potential conflict of interest issues for university technology transfer offices. The university should be cognizant of these issues and establish avenues by which these conflicts can be resolved in an "open and collegial" manner representative of university values. The paper suggests that these conflicts should be addressed and resolved by "academic and administrative officers and committees outside the technology transfer office" in an unbiased and non-punitive way.[97]

Point five encourages universities to "ensure broad access to research tools"[98] by utilizing a blend of non-exclusive and exclusive licenses as outlined in point two. Broad access is necessary for the development of improvement patents and future innovations. The scientific enterprise requires the dissemination of research that originates with the use of the research tools developed in university labs. As such, broad access should be granted for academic and government use.

Point six stresses "enforcement action should be carefully considered" before a university decides to initiate a lawsuit to prevent patent infringement.[99] When addressing whether or not to pursue litigation, the university should balance the needs of their commercial partner with the university goals of education and discovery. Additionally, the university should be "mindful of

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[95] Id.
[96] Id. at 5.
[97] Id.
[98] Id.
[99] Id. at 6.

their primary mission to use patents to promote technology development for the benefit of society."[100] If the university does choose to pursue litigation, the objective of the lawsuit should closely align with the university's initial motivation to patent the innovation, namely the "to protect the rights of existing licensees to enjoy the benefits conferred by their licenses."[101] Pursuit of "nuisance suits," non-meritorious, frivolous litigation by universities is explicitly discouraged.

Point seven instructs universities to "be mindful of export regulations."[102] "Licensing proprietary information or confidential information can affect the fundamental research exclusion (enunciated by various export regulations) enjoyed by most university research."[103] Thus, when structuring licensing agreements, universities must be cognizant of the applicable federal export control laws in order to preserve the dissemination of research in the United States.

Point eight instructs universities to "be mindful of the implications of working with patent aggregators."[104] Patent aggregators acquire and bundle the rights to various unlicensed university patents and market the portfolio of patents to third parties, potentially facilitating the commercialization of those patents through further licensing. Patent aggregators operate under one of two models: the "added value" or the "patent troll" model. Under the added value model, the patent aggregator compiles a selection of patents relevant to a particular technological invention, such as a semiconductor that incorporates a number of patented innovations from various sources. The aggregator then offers secondary licenses to the bundle of assembled of

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[100] Id.
[101] Id.
[102] Id.
[103] Id.
[104] Id. at 7.

patents to third parties. "By consolidating rights in patents that cover foundational technologies and later improvements, patent aggregators serve an important translational function in the successful development of new technologies" and potentially facilitate the commercialization of certain underutilized patented innovations.[105] Yet, the paper advises that in order for the benefits of patent aggregation to be realized, licensing agreements should contain terms that are consistent with the university's mission to disseminate research and provide useful technological innovations to society.

In contrast to the added value model, patent trolls amass rights to a multitude of patents that cut across a large segment of technology without the intention of facilitating the commercialization of any of the innovations. Under the patent troll model, the aggregator advertises the portfolio of patents to companies in the relevant field with the assumption that if the company is conducting research in the field, they must be infringing on at least one of the hundreds or thousands of patents in the bundle. In select cases, companies are forced to purchase the rights to unnecessary patents, rather than expend the resources required to do the due diligence needed to "establish their freedom to operate under each of the bundled patent." Unlike the scientist, commercial licensee, or the added value aggregator, the patent troll "extracts payment" without providing "any enhancement to the licensed technology."[106] Thus, universities should be extremely cautious of licensing patents to patent trolls. In fact, "universities would better serve the public interest by ensuring appropriate use of their technology by requiring licensees to operate under a business model that encourages

[105] Id.
[106] Id. at 8.

commercialization" rather than licensing their technology to patent trolls, which "rely primarily on threats of infringement litigation to generate revenue."[107]

Finally in point 9, AUTM urges universities to "consider including provisions that address unmet needs, such as those of neglected patient populations or geographic areas, giving particular attention to improved therapeutics, diagnostics and agricultural technologies for the developing world."[108] Around the globe, individuals suffer from preventable or curable diseases. Although technology transfer licensing practices, alone, cannot solve this problem, providing developing countries with access to medical advancements should be part of a comprehensive plan. Accordingly, "universities should strive to construct licensing arrangements in ways that ensure that these underprivileged populations have low- or no-cost access to adequate quantities of these medical innovations."[109] Through strategic technology licensing and management, universities can work to help eradicate the curable diseases that afflict these underserved populations.

This noble goal aligns perfectly with Levin's third mission of the university. As the gatekeeper to many vital drugs and therapies, the community of university technology transfer offices extends beyond their home state to encompass the impoverished populations of third world countries. As such, the universities to strive allow these individuals access to the same standard of care and service provided their students in the U.S.

Through the paper, this alliance of universities has strived to address some of the concerns of the critics and set forth a comprehensive guideline for the patent and licensing strategies of the university's technology transfer offices. The paper stresses the importance of

[107] Id.
[108] Id.
[109] Id.

balancing the interests of corporate partners with the fundamental vision of the university. In essence the nine points serve as an instructive corollary to the Bayh-Dole Act.

VII. CONCLUSION

Universities have served for centuries to teach, to generate new knowledge through research, and to serve society. Academic scientists make basic discoveries in research programs often funded by government or non-profit organizations. The university technology transfer office facilitates partnerships with companies whose resources and commercial expertise help translate these basic discoveries into useful products. And society's investment in research comes full circle, with basic discoveries brought forward to improve the health and prosperity of the broader community. The role of technology transfer will be critical for universities for the foreseeable future. New ideas and technology from university research helped to create the world we live in today, and will continue to shape the world of tomorrow. By maintaining the core values of the university while working with the private and public sectors to enable development of products, those of us in the technology transfer profession help change the world.

The debate between the supporters and critics of the Bayh-Dole Act continues as both sides formulate theories and conduct studies to document the positive and negative effects of the act. Advocates point to the increases in scientific innovation as a result of the streamline patent process, while critics complain that universities are operating as corporate research labs. The most vocal critics are the supporters of the anti-commons theory and although evidence of the existence of the anti-common effect seems to be merely anecdotal, testing of the theory can never be completely conclusive as it is impossible to structure a world without patents against which to test the current scientific research framework, nor have the detractors provided an alternative which provides scientists, universities, venture capitalists, and manufacturers with the

same impetus to innovate and translate those innovations into useful products for societal consumption.

Perhaps, the proposed Nine Points to Consider, if followed by universities, are a satisfactory compromise to the debate. These considerations were put forth in an aspirational, rather than proscriptive, sense to encourage others in the profession to set a higher standard by stretching the boundaries of conventional licensing practices and sharing with the greater technology transfer community the insights that they gain in doing so. Universities share certain core values that can and should be maintained to the fullest extent possible in all technology transfer agreements. Although there may be general agreement on the commonality of goals in nurturing future research and using the innovations of university research to provide the broadest possible benefit to the public, there is a multiplicity of approaches for achieving the desired result. The aim was to encourage academic technology transfer professionals to analyze each licensing opportunity individually, but with certain principles in mind. When crafting agreements with industry, a balance must be struck between business needs of commercialization partners and the shared values of academic institutions.

As often is the case, such guidance as to implementation of practices that will advance the mission of university technology transfer lags behind the collective awareness of both the needs that exist and the role in fostering an environment in which such needs can be met effectively. Given the recent criticism from some sectors that question the motives and methods underlying university technology commercialization activities, however, it is especially important that the principles used to support patent commercialization decision-making be recognized as serving the best interest of the public not just of individual institutions. Beyond the simple economics of any agreement, it is our hope that our colleagues will give serious

consideration to these additional points before finalizing the terms and conditions of any technology transfer agreement. In the end, fostering thoughtful approaches and encouraging creative solutions to complex problems that may arise will enable universities to license technologies in the public interest and for society's benefit.

Why the Revisionist Attacks on the Bayh-Dole Act Are Wrong—and Dangerous to Our Future

Summary

It's no secret that the U.S. economy faces serious challenges. However, the U.S. has tremendous advantages for succeeding in the technology markets creating wealth in the 21st Century, if we chose to utilize them.

That choice lies with the policy makers and depends upon their recognizing the inherent strengths of the U.S. innovation system. This paper focuses on a key component of that innovation chain: the combination of our unparalleled research universities and the entrepreneurial spirit which drives the private sector functioning under the auspices of the Bayh-Dole Act of 1980. That partnership turned the results of publicly funded science into products, jobs and companies benefiting U.S. taxpayers both economically and through an improved quality of life

While this linkage is generally believed to have been very successful, a persistent school of critics have charged that this is not the case. These advocates have become more vocal in recent years, urging policy makers to make changes in the Bayh-Dole Act correcting what they view as its shortcomings. And many appear to be accepting their arguments at face value. However, it is important to note that these critics lack the perspective of the pre- Bayh-Dole era and its associated difficulties associated with turning government funded research into tangible commercial and social benefits for the taxpaying public. Reversing this trend, the Bayh-Dole Act enabled billions of private sector dollars to be invested in developing federally-funded inventions, creating millions of jobs for Americans, significant wealth for the U.S., higher standard of living while helping to reestablish the U.S. as a competitive leader in a growing global economy

Because the recommended changes to Bayh-Dole would have profound-- and potentially very harmful-- impacts on the ability of the U.S. to respond to renewed international economic competition in the 21st Century, any such changes must be carefully considered.

Therefore, it is our purpose to examine the charges against Bayh-Dole against the facts and to set the record straight. Thus examined, the common revisionist arguments against Bayh-Dole are shown to be unfounded, based on anecdotes or incorrect interpretations of data where the logical conclusions should have pointed in the opposite direction .

Reams of objective data exist supports the conclusion that the Bayh-Dole Act greatly improved the commercialization of federally-funded research, that the system is

working very well, and that the public sector-private sector partnerships which were generated under the Act are essential both to our well being and the competitive position of the U.S..

That these conclusions are correct is amply apparent from the fact that our most serious economic rivals have or are now adopting their own versions of Bayh-Dole to better compete with the U.S. in the global market economy. Such imitation is the most sincere form of economic flattery. It would be ironic, indeed, if U.S. policy makers chose this critical moment to weaken the established U.S. innovation system. That system, which is the envy of the world, is needed more than ever at this critical time to maintain a prosperous U.S. economy in an increasingly high technology world. The choice is ours to make.

BACKGROUND

The U.S., Europe and Asia are gearing up for a new round of competition to create wealth from high technology industries driving the international economy. In many ways, this is a replay of the 1970's and 80's when it appeared that Japan and Germany were riding the wave of the future—and many predicted that America's best days were behind it.

At that time, the U.S. had lost its lead in traditional fields like automotives, electronics, steel, etc. Many experts confidently predicted that Japan and Germany would soon eclipse the U.S. in the few remaining markets where we led.

However, these predictions did not come true. Instead, the U.S. enjoyed a tremendous burst of entrepreneurial activity that restored our competitive advantage, laying the groundwork for decades of economic growth. This turnaround came through adopting many new policies that were hotly debated at the time. One was the passage of the Bayh-Dole Act of 1980. Here's how the Economist Technology Quarterly summarized its impact:

> *Remember the technological malaise that befell America in the late 1970's? Japan was busy snuffing out Pittsburgh's steel mills, driving Detroit off the road, and beginning the assault on Silicon Valley. Only a decade later, things were very different. Japanese industry was in retreat. An exhausted Soviet Empire threw in the towel. Europe sat up and started investing heavily in America. Why the sudden reversal of fortunes? Across America, there had been a flowering of Innovation unlike anything seen before.*
>
> *Possibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole Act of 1980. Together with amendments in 1984 and augmentations in 1986, this unlocked all the inventions and discoveries*

that had been made in laboratories throughout the United States with the help of taxpayers' money.

More than anything, this single policy helped to reverse America's precipitous slide into industrial irrelevance.

Further on the article summarized the law:

The Bayh Dole Act did two big things at a stroke. It transferred ownership of an invention or discovery from the government agency that had helped to pay for it to the academic institution that had carried out the actual research. And it ensured that the researchers involved got a piece of the action.

Overnight, universities across America became hotbeds of innovation, as entrepreneurial professors took their inventions (and graduate students) off campus to set up companies of their own. Since 1980, American universities have witnessed a tenfold increase in the patents they generate, spun off more than 2,200 firms to exploit research done in their labs, created 260,000 jobs in the process, and now contribute $40 billion annually to the U.S. economy. America's trading partners have been quick to follow suit. Odd then, that the Bayh-Dole act (sic) should now be under such attack in America.

The Economist Technology Quarterly, Dec. 14, 2002

Before examining the specific charges used to attack the law, it is helpful to examine why Congress enacted the Bayh-Dole Act, and what it does.

Prior to 1980, inventions made with federal funding were rarely developed into commercial products . Because most government funded inventions resulted from the conduct of basic research they are very early stage in their development. Therefore, it requires considerable time and investment by the private sector to turn them into useful products. These investments of time and money are not insubstantial. It is frequently estimated that product development requires 10 development dollars for every dollar spent in research. Developing new drugs can cost between $800 million to $1.3 billion over more than a decade. Even with such expenditures, commercial success is far from a sure thing. Many more products fail in the marketplace than succeed. Without an ability to protect such investments, commercial development is not possible.

Federal policies at the time mandated that any invention made with federal funding—whether made by employees, contractors or grantees—would be assigned to the government. They were then generally made available to all applicants through non-exclusive licenses. Thus, a company foolish enough to develop a federally funded

invention could not protect its commercialization expenses since competitors could gain equal access to the technology from the federal government.

It became clear that such practices rarely turned publicly government funded research into commercially available goods. A series of presidential policy memoranda, dating back to the Kennedy Administration, did allow contractors or grantees to petition funding agencies to acquire ownership of government-funded inventions on a case by case basis. Decisions on such petitions could take 18 months or more and subsequent decisions were generally negative. When agencies did grant a petition, they usually also attached many restrictions on the use of the invention..

Not surprisingly, that general policy discouraged innovative small businesses from accepting federal research contracts because the inability to control resulting inventions undercut their capacity to compete in commercial markets. Additionally, federal agencies and their employees could not receive royalties if their discoveries were commercialized.

President Lincoln, himself a patent owner, envisioned the patent system as "adding the fuel of interest to the fires of genius." With regard to federally funded research, it was evident that those fires were extinguished. This was no small loss because the federal government was funding the majority of basic research – precisely where breakthrough inventions were most likely to occur- and approximately 50% of all the R&D in the country at the time.

That this general policy was not effective in promoting technology transfer was recognized in by the National Institutes of Health (NIH). It was apparent that few, if any, NIH funded discoveries were ever commercialized. Consequently, in the 1970's NIH adopted an administrative policy allowing universities with the proven capability to manage inventions to own inventions they made with NIH support. Termed the "Institutional Patent Agreement" (IPA), this was the precursor to a revolution in federal patent policies. The program proved so successful that is was later adopted by the National Science Foundation.

However, reversals of the IPA program under the Carter Administration prompted universities to approach Senators Birch Bayh (D-IN) and Robert Dole (R-KS) requesting that the IPA program be made statutory and applicable to all federal agencies, and that it be extended to small business contractors.

After examining the dismal record at commercializing federally funded inventions and the pending loss of competitive markets to Japan and Germany, Congress adopted the NIH/NSF approach in 1980 in what would become the Bayh-Dole Act.

One important piece of data examined by the Senate Judiciary Committee as it considered the bill was that the government was successfully licensing less than 5% of

the 28,000 inventions it had amassed. Universities and small companies presented compelling evidence that potentially important discoveries would never be developed as long as the government took them away from their creators, thus destroying the incentives the patent system was intended to foster. . Senators Bayh and Dole stated that such inefficiencies denied U.S. taxpayers the full benefits of their investment in publicly funded research.

Congress agreed with the Senators' conclusion and overwhelmingly passed the University and Small Business Patent Procedures Act-- commonly known at the Bayh-Dole Act. The Bayh-Dole Act encourages the development of inventions made by non-profit organizations and small business companies through the use of Federal funds by:

- Allowing ownership of such inventions by those entities;
- Providing universities the discretion to license their inventions and discoveries under terms that encourage prompt commercialization through university-industry partnerships;
- Stipulating that a percentage of royalties generated through successful commercialization efforts be shared with inventors. Royalties can also be used to pay for administrative costs associated with technology transfer, with the balance remaining designated to fund additional research, or for educational purposes;
- Providing that preferences be given to licensing small businesses and a requirement for substantial U.S. manufacturing where an exclusive license is granted for the United States;
- Allowing the government to practice the invention royalty free for governmental and treaty purposes; and
- Allowing the government to "march in" to require additional licensing if legitimate efforts are not being made by a licensee to develop the invention or the licensee cannot produce sufficient quantities to meet a pressing national need (an action that has not been necessary in practice).

Congress subsequent to the passage of the Bayh-Dole Act created the Court of Appeals for the Federal Circuit, which destroyed many of the myths that afflicted the U.S. patent system, thereby restoring faith in the reliability of U.S. patents. Congress also enacted the Small Business Innovation Research Act (SBIR) to bring more cutting edge companies into government research. SBIR built upon the assurances of the Bayh-Dole Act that small companies owned inventions they made under federal funding.

The Bayh-Dole act brought into play important factors and resources which other nations simply could not match:

1. The U.S. government funds far more R&D than our competitors, much in basic research where breakthrough technologies are likely to occur.

2. This research is largely conducted at universities and other non-profit institutions that remain world leaders in their fields.
3. The Bayh-Dole Act translated this investment in science into practical applications which met important health, safety, environmental, food production, and other important needs.
4. The U.S. is the leader in forming small, high technology companies which take the lead in driving new markets . Many of these companies are spun out of universities because of Bayh-Dole.
5. A key asset of these small companies in attracting venture funding and competing in technology markets against larger companies are the patents they own or licensed which protect their commercial position and the business risks they have assumed. Thus, the U.S. patent system greatly helped create this revival.

Even though the impact of the Bayh-Dole Act seemed evident as the U.S. enjoyed a reversal of fortune as described earlier in the Economist Technology Quarterly, a small group of academics grounded in the social sciences began questioning it. Their arguments can be summarized as follows:

- Bayh-Dole really wasn't that important. Universities were commercializing inventions anyway;
- Key data Congress used to pass the Bayh-Dole Act-- the small number of 28,000 government owned patents that were licensed-- was misleading;
- Bayh-Dole is not a model that should be adopted by developing countries.

The next section reviews each charge in greater detail.

The Bayh-Dole Act and Revisionist Attacks

The Bayh Dole Act of 1980 is now almost 30 years old. There are not many pieces of legislation that have maintained their viability and significance in a changing environment for as long However, it is being subjected to revisionist interpretations of its effects, benefits, and the fundamental needs which caused its inception, passage and implementation.

Representative of these viewpoints is a paper by David C. Mowrey et al entitled "The Growth of Patent and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980." Res. Pal 30, 99-119 (2001) and later papers by critics such as Arti Rai and Robert Cook-Deegan (eg. So et al "Is Bayh-Dole Good for Developing Countries? Lessons from the Experience," PLOS Biology, October 2008 Vol. 6 Issue 10), and the writings of Rebecca Eisenberg. The fundamental Mowrey et al premise is that the Bayh-Dole Act was not as influential in promoting the transfer of technology as has been credited; that the university technology transfer effort would have occurred

anyway. Both papers also cite assertions by Rebecca Eisenberg that experts at the time misunderstood why so few of the 28,000 government managed patents were being utilized before Bayh-Dole. This failure to commercialize these inventions was a key piece of evidence presented at the hearings on the bill. Supporters said that it showed that the old patent policies (whereby government took inventions away from their creators) was ineffective in achieving subsequent commercialization.

Mowrey et al further postulate that: "The theory behind Bayh-Dole was that companies needed exclusive patent rights to develop and commercialize the results of university research."

Actually the driving force and theory behind Bayh-Dole was that the public was not reaping the full potential benefit from the taxpayer's support of basic research, with expenditures amounting to billions of dollars each year. Passage of the Bayh-Dole Act represented the ultimate step in a long term effort toward reshaping government patent policy, and was Congress' response to the paramount question:

> "In whose hands—the federal government or the inventing organizations-- is the ownership and management of federally funded inventions best placed so important discoveries are promptly developed to benefit the U.S. taxpayer?"

It is not denied that about the same time the Bayh-Dole Act was passed, there was a confluence of forces which had an effect upon universities' technology transfer efforts. However, we find the proposition advanced in Mowrey et al to be a flawed conclusion The Congressional intent for enacting the law is made abundantly clear in the provisions Senators Bayh and Dole wrote in the legislation as the Policy and Objectives of the Act in 1980 (25 U.SC. 200):

> *It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise, to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.*

That the effect of the Act was so profound, beneficial and far reaching is because of several primary factors:

1. It established a uniform patent policy for all agencies of the federal government.

2. It changed the presumption of title to inventions made in whole or in part with federal monies from the government to universities, non-profit institutions and small business.

3. It established a certainty of title in such inventions which encouraged the private sector to engage in relationships with university and non-profit research organizations leading to the development and commercial use of many inventions for the public benefit.

4. The protection offered by the chosen vehicle for technology transfer--the U.S. patent system-- provides needed incentives for the private sector to undertake the considerable risk and expense necessary to take early stage university discoveries from the laboratory to the marketplace. Strong patent protection is also vital to small businesses, who have obtained the vast majority of licenses from universities, so they can engage the venture capital community for needed funding—and for protection against dominant companies in their markets.

Mowrey et al focus on the increased patenting and licensing efforts by the university sector in the 1970's, prior to the Bayh-Dole Act, as proof of their premise that the Act was not a determinative factor in the increase in university technology transfer, as they allege that it was already occuring. Rather than minimizing why Bayh-Dole was necessary, the period before its enactment clearly established that ownership and management by universities of their inventions was clearly a superior policy than what had preceded it. There had been an utter failure to commercialize university inventions when the National Institutes of Health had retained all rights to inventions made in whole or in part with federal money and adopted a non-exclusive licensing stance.

Indeed, NIH found that not a single drug had ever been developed when the government had retained patent ownership—clearly not a record that was benefiting the U.S. public. Therefore, a revolutionary approach was announced. NIH established an administrative policy titled the Institutional Patent Agreement (IPA).

The IPA program allowed universities with established technology transfer offices to own and manage inventions made with NIH funding. The program began at NIH in 1968 and was so successful that the National Science Foundation adopted it in 1973. The program continued its success, but during the Carter Administration efforts were made to end it because of personal philosophical reasons by the new Secretary of Health, Education and Welfare (the agency is now Health and Human Services). That philosophy, much like those of many of the current critics of the Bayh-Dole Act, called for a return to case by case determination by NIH of whether inventions made by NIH-

funded universities should be retained by NIH or the ownership transferred to the inventing universities for management.

It was this movement to end the most successful patent policy in any federal agency which led universities to approach Senators Bayh and Dole, arguing that effective patent policies must have a legislative mandate so they could not be changed at the whim of a political appointee.

The potential to arbitrarily make changes in patent policies at the agency level and the adherence to a non-exclusive licensing mandate established a lack of predictability unnerving to potential industrial partners. They would not expend the sizeable amounts of private sector time and money needed to turn a patented university based early stage technologies into a marketable products if the government could change the rules at a whim .

Shortly after introducing their bill, Bayh and Dole held a press conference using examples of potentially important medical discoveries that were being strangled in red tape because of NIH's weakening of the IPA program. As a result a rapid succession of co-sponsoring Senators from across the political spectrum began signing onto the proposed Bayh-Dole bill.

The critics either misunderstand or misinterpret the connection between the IPA program and the Bayh-Dole Act. It would seem that misunderstanding and/or misinterpretation finds it basis in the recitation in "Changes in University Patent Quality After the Bayh-Dole Act: A Re-Examination by Bhaven N. Sampat, David C. Mowrey and Arvids A. Ziedonis that:

> *The Bayh-Dole Act was passed in the throes of the "competitiveness crisis" of the 1970s and 1980s,* ***in response to the belief that IPAs and other arrangements for university patenting of publicly funded research results impeded technology transfer and commercialization of these results, thereby weakening U.S. competitiveness.*** *(emphasis added) (p.3)*

Although the authors recognize the existence of the IPA program, pointing out that by 1978, 72 institutions were participating in that program, they make no connection between the advent of the IPAs and increasing university sector patenting and licensing in the time period when most of the predominant research universities were operating under such agreements.

In fact, both the University of California and Stanford University, which occupy much of the "empirical" evidence in Mowrey et al, operated under IPAs prior to the passage of Bayh-Dole.

The impact of Bayh-Dole on individual universities like MIT that had already been active in technology transfer is also illustrative. It could be argued that Bayh-Dole did not really impact the legal structure of patent ownership at MIT, because MIT had an existing agreement with the government that generally gave it ownership of its inventions. However, Bayh-Dole did have a major impact because it pushed MIT as well as other universities to recognize that utilizing inventions for the benefit of society could often be best accomplished though commercialization – which required the help of the private sector.

For example, a novel idea for a new pharmaceutical product did not benefit patients unless it was available commercially. Likewise, newly discovered material would not make planes lighter and stronger unless it could be made commercially.

Within one year of MIT's rethinking its licensing activities as a result of Bayh-Dole, the number of licenses increased nearly 1000%. During the next twenty years, the MIT Technology Licensing Office formed nearly 800 new companies. A recent study of MIT spin-off companies shows that these companies alone would be the 17th largest economy of the world. See *http://web.mit.edu/newsoffice/2009/kauffman-study-0217.html?tr=y&auid=4551551*

While MIT clearly was spinning out companies before Bayh-Dole passed, the rate of new company formation based upon MIT inventions and discoveries went up exponentially after its enactment.

Another point the critics raise for the increase of university patenting, making it appear to undercut the influence of Bayh-Dole, was the large subsequent infusion of federal money, primarily through NIH, in the support of life science research. However, the IPA program and later the Bayh-Dole Act were critical incentives for recipient universities to file patent applications to protect important discoveries emanating from research supported by these funds. This would not have happened if NIH had retained its policy to take title to inventions made in whole or in part with NIH funds.

Clearly, it was the incentive of patent ownership and, therefore, certainty of title upon which the private sector could rely in a licensing arrangement that spurred the increase of university patenting under the IPA program. This increased patenting activity accelerated even more after Bayh-Dole was enacted because it applied uniformly to all federal funding agencies and all universities could then engage in technology transfer activities.

Thus, there is little doubt that the negotiation, establishment and existence of the IPAs were of predominant importance in the rapid growth of the university technology transfer function. Moreover, those agreements and the provisions in them were the template for the Bayh-Dole Act. Fundamentally, Bayh-Dole is a codification of terms and provisions of the IPAs. Indeed, when Senators Bayh and Dole first introduced the bill

that matured into the Bayh-Dole Act in 1978, they used as examples for the need of a legislative mandate, several inventions the development and commercialization of which were threatened by the Carter Administration's undermining of the IPA program.

The Mowery et al paper, "Changes in University Patent Quality After the Bayh-Dole Act" contains another misunderstanding about the history of the Bayh-Dole Act. That assertion is highlighted below in the context it appears:

> *The Bayh-Dole Act was passed in the throes of the "competitiveness crisis" of the 1970's and 1980's in response to the belief that IPA's and other arrangements for university patenting of publicly funded research results impeded technology transfer and commercialization of these results, thereby weakening U.S.* competitiveness. *In particular, the framers of Bayh-Dole argued that if universities could not be granted clear title to patents and allowed to license them exclusively, firms would lack that incentive to develop and commercialize university inventions.* ***This argument was based on the "evidence" that government owned patents had lower utilization rates than those held by contractors, evidence that Eisenberg (1996) has shown to be faulty.*** (emphasis added)
>
> *Numbers, Quality, and Entry: How Has the Bayh-Dole Act Affected U.S. Patenting and Licensing, by Bhaven N. Sampat, David C. Mowery and Arvids A. Ziedonis, P. 3*

There is ample and adequate empirical evidence to support the proposition that the Bayh-Dole Act, drawing on the preceding IPA program, was a decisive factor in the promotion and growth of the technology transfer profession in the university, non-profit and small business sectors of the economy. Simple statistical evidence, such as the rapid growth of membership in the Association of University Technology Managers (AUTM) as well as the number of technology transfer offices established within the university community – from about 30 in 1972 to approximately 300 in 2007-08 – bear that out.

Moreover, data presented in the annual AUTM Licensing Survey showing increasing year-to-year activities in invention disclosures, patenting and licensing are also evidence of the positive effects of the Bayh-Dole Act. The ultimate measure of the wisdom in passage of the Bayh-Dole Act and its success in transferring technology for the public benefit – the Act's primary objective – can be found in a compilation by AUTM entitled "The Better World Report" listing, with appropriate descriptions, some of the many university technology-based inventions that have been developed for the market place and which have contributed to the lives, health, safety and welfare of the public– a virtual panoply of inventions in many and diverse scientific disciplines.

Consider the following:

- *University technologies helped create 5,724 new companies in the U.S. since the enactment of the Bayh-Dole Act in 1980.* In FY 2006 alone, 553 new companies were spun off based upon campus discoveries and inventions. Astoundingly, that is more than two new companies formed each working day of the year. Formation of new, technology based companies drive state economic development.
- *University research created 4,350 new products from FY1998–2006, with 697 introduced in FY 2006 alone.* This means that 1.32 new products were introduced every day for that period. Such success is unique to the U.S.
- *Federally funded research at universities and federal laboratories resulted in 130 new drugs, vaccines, or in vivo diagnostic devices being developed for public use.* Many of these discoveries were treatments for infectious diseases and new cancer therapies. The majority of licenses initially went to small companies licensed under the provisions of the Bayh-Dole Act.
- *There were almost 5,000 existing active university licenses in FY 2006-- each representing a university-industry partnership.* The majority of such licenses were with small businesses and start up companies. Although the bulk of licensing arrangements were non-exclusive in nature, the majority of exclusive licenses issued were to small businesses and start-up companies, which require strong patent protection to succeed in highly competitive markets with larger, well established and well-financed competitors.
- *Important health related and life-saving discoveries commercialized under Bayh-Dole include:*

Synthetic penicillin	Human growth hormones
Treatments for Crohn's disease	Avian Flu vaccine
Cisplatin and carboplatin cancer therapeutics	Taxol
Hepatitis B vaccine	Citracal calcium supplement

The Mowery et al premise that the "evidence" disproving the commonly held theory that government-owned inventions had lower utilization rates than those held by contractors (read universities) is based on an article by Rebecca Eisenberg titled "Public Research and Private Developments: Patents and Technology Transfer in Government-Sponsored Research", Vol. 82:1663 Virginia Law Review.

This same argument is repeated by critics such as Arti Rai and Robert Cook-Deegan in their article "*Is Bayh-Dole Good for Developing Countries? Lessons from the US Experience.*" The paper, intended to warn other countries of the "dangers" in adopting a Bayh-Dole type law includes the following:

> Nevertheless, many advocates of adopting similar initiatives in other countries overstate the impact of BD in the US... They also cite data (originally used by US proponents of the Act) on the low licensing rates for the 28,000 patents owned by the US government before BD to imply that the pre-BD legal regime was not conductive to commercialization. But as Eisenberg has argued, that figure is misleading because the sample largely comprised patents (funded by the Department of Defense) to which firms had already declined the option of acquiring exclusive title. Moreover, these figures are of questionable relevance to debates about public sector research institutions, because most of the patents in question were based on government-funded research conducted by firms, not universities or government labs. (PloS Biology, October 2008, Volume 6, Issue 10, e262, page 2078.

As will be shown, this assertion is wrong on both counts.

In her paper, Ms. Eisenberg maintains that "the primary argument against government ownership was a statistical one", based on the "testimony of numerous witnesses" that "only a small percentage of its estimated 28,000 - 30,000 patents had been successfully licensed and exploited commercially". She further submits that "...the statistical evidence presented was inadequate to document this claim" because it "reflected a huge selection bias; as it consisted largely of inventions made by contractors whose research was sponsored by DOD... that could have retained title to the patents if they had wanted to do so."

On the basis of her analysis, Ms. Eisenberg concludes that, "It is hardly surprising that few firms were interested in taking licenses from the Government to patents that had already been rejected by contractors that could have been owned by them outright if they had found them at all commercially interesting."

Ms. Eisenberg alleged that 17,632 of the 28,021 inventions in the government patent portfolio were made by Department of Defense (DOD) contractors, waived to the government because they lacked commercial importance.

However, review of the actual data indicates that, in fact, Ms. Eisenberg's conclusion is simply wrong.

The evidence that fewer than 5% of government owned inventions were being successfully licensed came from the 1976 Federal Council for Science and Technology (FCST) combined report.[12]

[1] See footnote 57 of 1 above.
[2] Norman J. Latker - served as DHEW representative when Patent Counsel, DHEW.

In her paper, Ms. Eisenberg fails to note that the 1976 report clearly establishes that the 17,632 DOD patents includes:

(1) 6,026 U.S. patents granted during the 1970-1976 reporting period to ***DOD employees*** obligated to assign their rights to DOD; and
(2) 2,594 U.S. patents based on reported inventions during the 1970-76 reporting period from contractors.

In addition, some portion of the 2,594 inventions were taken from ***universities and other non-profits*** that, because of the DOD title policy then in place prior to the passage of the Bayh-Dole Act, had no choice but to assign their inventions to the government .

Combining the two categories above totals 8,620 patents accrued to the DOD patent portfolio during the 1970-76 reporting period or about one half of the 17,632 DOD patents identified in the report.

The remaining 9,012 patents (17,632 - 8,620) are unexpired patents granted and assigned to DOD prior to 1970 that remained open for licensing within the 1970-76 reporting period. Since there is no data in the '76 report indicating the source of the patents granted before 1970, it is not unreasonable to assume that the ratio of these patents is approximately equal to that of the 1970-76 reporting period. That is they were 70% government employee generated, and 30% contractor generated (including universities and non-profit organizations).

Accordingly, of the 9,012 patents granted before 1970, 6,310 would be government employee generated patents, and 2,702 would be contractor generated patents. Thus, the total DOD employee generated patents is 12, 336 (6026+6310) and the total DOD contractor generated patents is 5,296 (2594+2702)

Since DOD employee generated patents came from cutting edge federal laboratories like the Naval Medical Center at Bethesda, Maryland, or the Walter Reed Hospitals in Washington D.C. , they most certainly do not fit Ms. Eisenberg's characterization as "rejected" inventions without commercial interest. Nor do they fall within her definition of "contractor" inventions.

The remaining 5,296 patents generated by actual DOD contractors most certainly do not support Ms. Eisenberg's allegation that the patents available for licensing "reflected a huge selection bias; (consisting) largely of inventions made by contractors whose research was sponsored by DOD."

The DOD contractor-generated portion of the government patent portfolio amounts to no more than 19% (5296/28021) rather than the 63% (17632/28021) erroneously alleged by Ms. Eisenberg.

There is also no empirical or documentary evidence advanced that even the 19% of the government patent portfolio identified as above are based on inventions "rejected by contractors" as not "at all commercially interesting", as alleged by Ms. Eisenberg.

Moreover, title to an unidentified number of the 5,296 patents that were generated by *university and other non-profit contractors* was simply taken by DOD, whether they had commercial potential or not.

It's not even possible to support Ms. Eisenberg's contention that there was little commercial value in the unknown subset of patents from for-profit contractors. Most large company contractors of the time kept their government and commercial research operations segregated because of fears that federal agencies would try to assert ownership to important discoveries. In addition, some percentage of this category of inventions was generated by *small business contractors*, who like universities, had no choice but to assign any inventions made to DOD. Thus, Ms. Eisenberg's assertion is not even proven in the limited subset of industry contractors.

In summary, the revisionist theory that the supporters of the Bayh-Dole Act misinterpreted the lack of commercialization of 28,000 government owned inventions does not hold up. . The actual data speaks for itself and strongly belies that theory.

The revisionists are also turning their sights abroad. An article by several critics "Is Bayh Dole Good for Developing Countries? Lessons from the U.S. experience" (cited above) warns of the dangers of following the U.S. model in a series of recitations of virtually every objection the critics have come up with over the past 30 years. Building their case, the critics say:

> Finally, and most importantly, the narrow focus on licensing of patented inventions ignores the fact that most of the economic contributions of public sector research institutions have historically occurred without patents through dissemination of knowledge, discoveries, and technologies by means of journal publications, presentations at conferences and training of students. (pg. 2078)

Such arguments present a false dichotomy. Bayh-Dole has not harmed the dissemination of knowledge in the U.S., nor has it prevented journal publications, presentations for the training of students, etc. Indeed, it complements the historic mission of university research by making its contribution to social good much more tangible through the creation of new products directly benefitting the taxpaying public.

More fundamentally, how developing countries in a competitive global economy can hope to prosper by putting their university research freely into the public domain (as the authors advise) is not addressed. As shown, this was certainly not the case in the U.S.

Unless innovative companies have the incentive of strong intellectual property laws they cannot undertake the considerable risk and expense of product development. Thus, public sector research lies fallow, despite the claims of the critics . If their theory actually worked in the hard, cold light of day, surely the late, unlamented Soviet Union would have led the world in innovation. Rather than following the same course that failed in the U.S. before Bayh-Dole, developing countries would be well advised to heed other advisors.

South American economist Hernando De Soto's groundbreaking book, **The Mystery of Capital,** forcefully demonstrates that the fundamental weakness of perennially under-developed countries is the inability of their citizens to establish clear ownership of their property, both physical and intellectual. Without the incentive of ownership, wealth creation is not possible.

At its founding the United States of America was also a "developing country." One of the primary reasons causing the American Revolution was an imperial system which doomed its colonies to remain only the providers of raw materials devoid of manufacturing capabilities. It was to reverse this unjust and subservient role and develop a society based on internal innovation that the Founding Fathers placed the intellectual property protection provision in Article I, Section 8 of the Constitution. Their faith in creating such incentive through a strong and viable patent system were well place.

As President Abraham Lincoln aptly stated, without a patent system "any man might instantly use what another had invented; so that the inventor had no special advantage from his own invention. The patent system changed this; secured to the inventor, for a limited time, the exclusive use of his invention and thereby added the fuel of interest to the fire of genius, in the discovery and production of new and useful things." Strangely, the modern critics think the way to innovation is by turning Lincoln's dictum on its head. They could not be more wrong.

As inventor Frederick Cottrell said while founding Research Corporation: *".....a number of meritorious patents given to the public absolutely free have never come upon the market chiefly because what is everybody's business is nobody's business".*

It was precisely because inventors could secure protections for their discoveries that in the 20th century in the U.S. a huge era of innovation resulted. It can be hardly disputed that because of that protection the benefits to humanity have been unprecedented. While the critics bemoan the ability of the patent system to grant such ownership of intellectual property with the only alternatives being open source technology or trade secrets, neither of which provides motivation and incentives for innovation it is truly the protection that the patent system creates that makes the commercial development of ground breaking discoveries possible.

Developing countries would do well to consider these hard won lessons when urged by external "experts" to freely give their research away. Interestingly, South Africa recently enacted a Bayh-Dole law to help integrate its research universities fully into their economy. That a country has changed so dramatically under leaders like Nelson Mandella can look past the speculative fears of the critics, and lay the ground work for a confident future should give hope to us all.

The referenced article (supra) also alleges that Bayh Dole harms the advancement of science. Interestingly, unlike their anecdotes, actual data shows that the law has substantially contributed to the U.S. economy, and that U.S. science is actually better because of university-industry research collaborations. Additionally, university researchers are successfully balancing patenting and publishing, and not shifting their focus away from fundamental research.

In 2005, according to the President's Council of Advisors on Science and Technology (PCAST), fully 29% of articles authored worldwide by scientists and engineers were from the U.S. "Publication and citation of scientific results in peer-reviewed journals is one common metric for evaluating research outputs.....The United States remains the world leader in citations of S&E (science and engineering) research articles. The number of U.S. articles with co-authors by sector is a metric that can be used as an indicator of public-private research partnerships. Between 1995 and 2005, co-authorship with academic institutions increased by 10.3 percent, the largest percentage point increase of all cross-sector co-authorships."

University-Private Sector Research Partnerships in the Innovation Ecosystem, President's Council of Advisors on Science and Technology, November 2008, p. 22.

This co-mingling of the best and brightest minds in the public and private sector was fostered by the Bayh Dole Act. Before passage, industry segregated its most creative researchers from university collaborations because the federal government could take away resulting inventions when federal support of university research was also present.

The health of U.S. scientific publications is also reflected in the findings of the National Science Board's Science and Engineering Indicators reports. Traditionally, about three fourth's of all U.S. scientific and engineering scientific publications come from academia. In its 2008 report, it found:

> Although the U.S. share of world article output and article citations has declined, the influence of U.S. research articles has increased, as indicated by the percentage of U.S. articles that are among the most highly cited world-wide. In 1995, authors from U.S. institutions had 73% more articles in the top 1% of cited articles in all S&E fields than would be expected based on U.S. total article output; in 2005, the percentage had grown to 83%.

That the share of U.S. world - wide output has fallen is not because U.S. scientists and engineers are publishing less, but because of the huge explosion of international publications particularly from Asia. However, while the percentage of U.S. publications has decreased, their scientific impact has increased.

Scientific papers by U.S. researchers are the most cited across every field of science (p. 5-49). The number of citations by other authors is the standard criteria for determining the significance of a scientific publication in its field. The report explains:

"In other words, a country whose research has high influence would have higher shares of its articles in higher citation percentiles. This is the case in every field for U.S. articles." "....only U.S. publications display the ideal relationship of consistently higher proportions of articles in the higher percentiles of article citations across the period." "However, when citation rates are normalized by the share of articles during the citation period to produce an index of highly cited articles, the influence of U.S. articles is shown to increase..... In other words, the United States had 83% more articles than expected in the 99th percentile of cited articles in 2005, while the European Union had 16% fewer than expected and the Asia-10 had 59% fewer than expected." (p 5-49 to 5-50)

The U.S. ranked number 1 in every one of the broad science and engineering fields surveyed in the study for 2005. It also held this ranking in 1995. (5-41)

Another classic argument espoused by the critics is that Bayh Dole lures academic researchers away from basic research toward applied research in order to attract industry sponsors. Of course, it is precisely because university researchers are doing fundamental research that industry cannot do or chooses not to do that makes academic alliances so attractive. Nevertheless, the National Science Foundation looked at the allegation in its **2004 Science and Engineering Indicators** report. Here's what it found:

> Emphasis on exploiting the intellectual property that results from the conduct of academic research is growing....Among the criticisms raised about this development is that it can distort the nature of academic research by focusing it away from basic research and toward the pursuit of more utilitarian, problem-oriented questions. Did such a shift toward applied research, design and development occur during the 1990's, a period when academic patenting and licensing activities grew considerably?....
>
> Two indicators can be examined to determine whether any large-scale changes occurred. One indicator is the share of all academic R&D expenditures directed to basic research. Appendix table 5-1 shows that basic research share increased slightly between 1990 and a996 and that there was hardly any change in this measure between 1998 and 2002. The second indicator is the response to a question S&E doctorate holders

in academia were asked about their primary or secondary work activities, including four R&D functions: basic research, applied research, design and development.
The available data, although limited, provide little evidence to date that pressures on academic institutions and faculty to change research agendas led to a shift toward more applied work.

The **2006 Science and Engineering Indicators** in a section entitled "Has Academic R&D Shifted Toward Applied Work?", said again evidence "does not show any decline in the basic research share since the last 1980's" and concludes: "the available data, although limited, provide little evidence to date of a shift toward more applied work."

Once again, by examining the data, the charges fall flat.

To reinforce what the Bayh Dole Act has contributed to the U.S. economy and the world wide benefit of mankind one need only to look at some of the inventions listed below which arose from basic research in academia and which have reached the marketplace. Among inventions and discoveries arising in academia that have reached the marketplace and have contributed to the health, safety, convenience and welfare of the public are the following.

List inventions

Conclusion

The Bayh-Dole Act has clearly exceeded the expectations of its authors and is as viable and needed in today's economic crisis as it was in 1980 . Its contributions to the benefit of the United States and its citizens was recognized by a resolution of the U. S. House of Representatives on December 6, 2006 as follows:

The Bayh-Dole Act (Public Law 96-517) has made substantial contributions to the advancement of scientific and technological knowledge, fostered dramatic improvements in public health and safety, strengthened the higher education system in the United States, served as a catalyst for the development of new domestic industries that have created tens of thousands of new jobs for American citizens, strengthened States and local communities across the country, and benefited the economic and trade policies of the United States.

Why was the Bayh-Dole Act a determinative factor in the evolution of university technology transfer and technology transfer in general? There are a number of reasons that the critics conveniently overlook:

1. It produced order out of chaos because it established a uniform government patent policy.

Prior to the Bayh-Dole Act, when federal monies were utilized in whole or in part in the making of an invention there were some 20 agency policies depending on where the research was funded. There were frequently more than one policy in an agency. Because universities receive federal funds from a wide number of sources, this made it extremely difficult, if not impossible, to sort out the applicable policies and restrictions on patenting and licensing by the university. The most restrictive of the policies generally controlled, but all funding agency policies applicable had to be considered as did the bureaucratic climate and restrictions within a given agency. Consequently, -- with the exception of the IPA program--, it was seldom that a federally supported university invention found its way into the marketplace.

2. It was the first statutory authority for government agencies to obtain, hold and license patents generated within government laboratories.

3. It was the template for the subsequently passed Federal Technology Transfer Act which promoted technology transfer from federal laboratories and recognized the contributions of federally employed inventors. Indeed, the first version of this legislation by Senator Dole was written as an amendment to Bayh-Dole.

4. It called for the sharing of royalties collected by the contractor with inventors, thus recognizing their imaginative scientific contributions and supplying them with the incentive to consider the practical applications of the results of their research. It also promoted the contractors use of the expertise of inventors in the technology transfer function.

5. It promoted collaboration among scientists having diverse funding from different federal sources to explore and embrace interdisciplinary approaches to solving scientific challenges.

6. It promoted the science-innovation interface through the establishment of a new university-industry relationship because of the certainty of title to inventions retained by the university sector under the provisions of the Act – an element, if not THE element, critical to private sector development of inventions for the marketplace.

7. It promoted private sector as well as government investment in university research.

8. It promoted innovation and the attendant creation of jobs through, in part, its mandate to give preference to U.S. industry and small business in technology transfer practices.

9. It protected confidential information in the possession of the contractor and its licenses from undue and untimely disclosure - a prime consideration to the private sector in a globally competitive economy.

10. It preserves certain rights in the government to protect the public against non-use or unreasonable use of inventions supported in whole or in part with federal (taxpayers) money.

11. It provides the university and non-profit sectors the possibility for generating income to support research and educational activities through the technology transfer function.

To now suggest that the Bayh-Dole Act was not a critical factor in the development of university technology transfer, and that this evolution would have occurred anyway is simply not a supportable premise.

Prior to the passage of the Bayh-Dole Act and the predecessor Institutional Patent Agreements, the environment in which technology transfer existed was, at best, inhospitable, and at worst, hostile. That environment slowly progressed through creation of the IPA program and later the enactment of the Bayh-Dole Act to one that encouraged the technology transfer function.

The result has been of tremendous benefit to the U.S. taxpayer in terms of the availability of important new products—particularly in biomedicine—and improved national competitiveness. Indeed, the U.S. is widely recognized as the most efficient nation on the world in the integration of its research universities into the national economy. The proof is in the number of competing nations seeking to adopt the Bayh-Dole model abroad. This movement is occurring despite the efforts of many domestic critics.

Unfortunately, in recent years and with increasing regularity, the Bayh-Dole Act of 1980 has come under relentless scrutiny and attack through the efforts of revisionist historians and their rhetorical pronouncements, with little basis in empirical data. These activities seem to be an apparent effort to resurrect the "policies" that failed so clearly prior to the advent of the Bayh-Dole Act and, even, the Institutional Patent Agreements.

It seems an anomaly that a piece of legislation which arose out of conflict almost 30 years ago and which, from all indications, has proven its worth, is now again being decried on many of the same bases as were advanced in arguments against its initial passage.

Outspoken claims, which find little basis in empirical evidence, under the guise of guardianship of the public interest or welfare provide a rich field for the cultivation of political power and special interests.

One must recognize that such initiatives are extremely dangerous in an evolved and evolving technologically-focused and increasingly fragile global economy. Intellectual property and its ownership have become the preferred currency for economic growth, where invention and innovation are the hallmarks of not only technological leadership but of survival.

The authors do acknowledge that improvement can always be made in the technology transfer system.
While it is always possible to find licensing decisions that could be open to criticism or universities who are more difficult to deal with than others, it is important to note the difference between poor implementation of Bayh-Dole as opposed to blaming Bayh-Dole for suboptimal practices.

The bottom line is that the Bayh-Dole Act over its 30 years of implementation continues to provide a superb framework for government funded research to benefit Americans through job and wealth creation. This is a lesson it would be well to remember, and perhaps one that the critics could take to heart.

As Nietzsche said: "Convictions are more dangerous foes of the truth than lies."

Presentation of Norman J. Latker
at Conference on Technology Transfer -
University Opportunities and Responsibilities
Case Western Reserve University - October 15, 1974

Anything identified as opinion, of course, in no way represents Administration or Department of Health, Education, and Welfare policy.

On the eve of this country's bicentennial anniversary, I think it appropriate to revisit the Constitution and its framers to refresh our memories on the birth of the intellectual property clause.

As we all know, the Constitution was drafted in the context of a struggle with a government which had abused its obligations to defend the rights of its citizens. Thus, it was no accident that the salient portion of the Constitution drafted for the purpose of protecting your liberties made the Government the servant and protector and not the master of your individual rights.

Thus, the fifth amendment of the Bill of Rights provides that:

> "No person shall . . . deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use without just compensation."

It appears that the absence of any one of the three words, "life" -- "liberty" -- or "property" could have the effect of negating the other two. This seems especially true if you were not guaranteed the right of "property" under the conditions specified, since private "property"

is a necessity if you are to have control of your "life" and "liberty". I might add inferentially that it is contended by some that the free enterprise system is dependent on/or sprang from these words, since without the protection of private property from arbitrary intrusion, that system could not exist. Certainly the words distinguish our society from the various forms of the world's collectivist societies.

Now, we all know that the word "property", even at the time of the framing of the Constitution, included "intellectual property". But notwithstanding the generic protection of property in the fifth amendment, the framers chose to be even more explicit about this specific category of property, and provided this language in Article I, Section 8:

> "The Congress shall have power to . . . promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writing and discoveries."

Why -- this special handling of this category of property?

There was no recorded debate in the Convention on September 5, 1787, when Article I, Section 8, was presented, and it was approved unanimously. That the products of the mind should prospectively receive legal protection, even from a centralized Government to be formed, was a principle upon which no one disagreed, probably due to some positive prior experience and examination. Within the eighteenth-century context of natural laws or rights, intellectual property had received affirmative expression not only in English and Commonwealth laws, but in the Declaration of

Independence, which provided that "All men are endowed by their Creator with certain unalienable rights", and "that to secure these rights, governments are instituted among men . . .".

Madison, the chief architect of the Constitution, did not end his interest in intellectual property with the Constitutional Convention. He made the following illuminating statements in support of the prospective Federal authority to award patents and copyrights:

In the Federalist on January 23, 1788:

> "The utility of this power will scarcely be questioned. The copyright of authors has been solemnly adjudged, in Great Britain, to be a right of common law. The right to useful inventions seems with equal reason to belong to the inventors. The public good fully coincides in both cases with the claims of individuals. The States cannot separately make effectual provision for either of the cases, and most of them have anticipated the decision of this point by laws passed at the instance of Congress."

In a letter to Thomas Jefferson on October 17, 1788, he made a more important insight:

> "With regard to monopolies, they are justly classed among the greatest nuisances in Government, but is it clear that as encouragements to literary works and ingenious discoveries they are not too valuable to

> be wholly renounced? [These two sentences appear to be an attempt by Madison to distinguish between past monopolies of commodities granted as personal favors and the suggested monopoly for novel intellectual property.] Would it not suffice to reserve in all cases a right to the public to abolish the privilege at a price to be specified in the grant of it? [This appears to be the first reference to Government "march-in" rights!] Monopolies are sacrifices of the many to the few. Where the power is in the few, it is natural for them to sacrifice the many to their own partialities and corruptions. Where the power, as with us, is in the many, not in the few, the danger cannot be very great that the few will be thus favored. It is much more to be dreaded that the few will be unnecessarily sacrificed to the many." (Parenthetical sentences and emphasis added.)

In this statement, and especially the last sentence, the answer to the need for specific protection of intellectual property, notwithstanding its generic inclusion in the fifth amendment, seems apparent. First, the use of the term "monopolies" suggests that Madison knew that the nature of an individual piece of intellectual property is such that it could be useful to all people and at the same time be susceptible of ownership by one person, while on the other hand, diversity of ownership of all other categories of property precluded the possibility

of monopoly. The strong possible argument against an indefinite monopolization of valuable intellectual property and its end product under only the fifth amendment and his recognition that "The States cannot . . . make effectual provision", suggests that Madison knew that the rights of the creative few would be in danger without clarification in the Constitution. Thus, a compromise was struck under which intellectual property was to be owned for only a limited term in exchange for the creator's right to exclude. It was under these circumstances that intellectual property -- that property which makes possible the use of all other property -- obtained special consideration in the Constitution.

There is little that I've presented that appears to be subject to question. Even those who have difficulty with the intellectual property clause do not advocate its repeal. Their argument has not been directed against the Government's responsibility for protection of private property and the special reward promised by the intellectual property clause, but erosion of the concept through convincing of an immediate need to limit the reward in the "public interest" or because of public involvement in the difficult delivery process which intellectual property must move through before reaching the public in useable form. These arguments, used in inappropriate situations, are probably what Madison considered "to be dreaded".

As we discussed on previous occasions, since the inception of the patent system, this country has moved from a rural to a highly industrialized nation. In the process, resources and creators flowed into highly sophisticated industrial research organizations. Such creators were

required to assign their creative rights to the organization without any added compensation over and above their salaries. As I noted on that occasion in greater elaboration, this arrangement was tolerated by society and confirmed in the courts as to private organizations and their employees.

When the 17 billion dollars of Federal funds began flowing into research some twenty-five-or-so years ago, through the funding of the Federal Government's contract and grant system, the simplistic policy that "What the Government (or public) pays for (or even partially pays for), it should own" was applied in practice to the total inventive result of some Government funded research programs. This was really an extension of the already developed and accepted concept applied to private industry, discussed above, that an employer (here, the Federal Goverment) can take assignment from an employee (in this case, the Government's grantees or contractors).

As I indicated previously, I thought utilizing this concept in all Government contracting situations to be poor policy,as it did not maximize delivery of inventive results to the public, or protect the equities of all the parties involved, in my experience or that of others. This was explicitly pointed out to DHEW by the GAO in its 1968 Report to the Congress on "Problem Areas Affecting Usefulness of Results of Government-Sponsored Research in Medicinal Chemistry", which provided;

> "On the basis of our observations, we proposed that the Department direct its efforts toward timely determination of rights to potentially patentable

> inventions in order to reduce uncertainties as to the status of invention rights. We proposed also that the Department clarify the intended use of Institutional Patent Agreements, of which only limited use has been made, but which appeared be a useful device for assigning ownership rights while protecting the public interest."

After my review of the Constitution, I believe that the legal basis for this finds some support.

Now, the primary argument of advocates of a Government-title policy without reservation maintain that those Government research programs utilizing a Government-license policy result in an "unjustified windfall" in the contractor. Notwithstanding the fact that no Government research program really utilizes a Government-license policy without reservation, consistency would lead one to the belief that a Government-title policy without reservation results in an "unjustified windfall" in the Government. If there really were such a "windfall" in the Government, the policy would be constitutionally suspect, since there is a suggestion that "private property" is being "taken for public use without just compensation", since the chain of title, as provided by Article I, Section 8, must start with the inventor, and proceeds to the Government only through contractual assignment.

In truth, "just compensation" for future inventions generated under Government contracts cannot possibly be determined at the time of contracting, no matter what patent clauses are used, and any equitable

policy in which the Government wished to retain exclusive rights would have to be based on compensating the owner of the exclusive rights at a time when its commercial value could be assessed. Compensation would ordinarily be in excess of the contract price, unless the invention were the specific object of the contract, which ordinarily is not the case. In fact in the area of grant research it is by definition never the case. (I would point out that anyone supporting a Government-title policy without reservation at the time of contracting would need to establish that all future inventions were the specific object of their contracts; otherwise, the Government would be the recipient of a "windfall".)

Now, I consider it nonproductive to belabor the arguments supporting the two extremes of possible Government patent policy. I have chosen to fault the one extreme not for the purpose of supporting the other, but merely because it is the former that has become the more vocal. Unfortunately, when one extreme surfaces and the other remains silent, the Government policies that sit in the middle become pressured to give ground to the vocal extreme. Since as you all know, DHEW patent policy already sits in a middle ground, we cannot responsibly move without abandoning the protection of some of the equities of the parties involved. But, unfortunately, this type of resistance provides to the extremist the argument that we, in turn, are extremist in our position.

Now, of all the variant policies one finds under the President's Statement of Patent Policy, which in itself provides the framework within

which reasonable men can find a middle ground, I believe DHEW's to be the most acceptable. It emerged from the crucible of debate with the clear recognition of the Government's obligation to protect the equities of all the parties, including the general public.

DHEW has two methods of making disposition of invention rights. Its standard policy is to defer determination until the invention is identified. We never take title at the time of contract, thus obviating any possible claim of unjust enrichment. In the majority of cases in which the inventing organization seeks to retain the exclusive rights to an identified invention they have made, we grant the request, subject to the kind of conditions Madison discussed. Thus, there is a requirement that if the organization chooses to license its rights, it first determines whether nonexclusive licensing will result in obtaining further development funds. If exclusive licensing appears necessary on the basis of market conditions, then we limit such licensing to five years from first commercial sale or eight years from the license, whichever occurs first. You all know that there are other "march-in" conditions that needn't be detailed here. If the organization itself chooses to develop the invention, the limitation on its exclusive position parallels that which it could give to a licensee. The grant of a request is nearly always based on the fact that further risk capital is necessary to develop and bring the invention to the marketplace and the Department does not intend to provide these funds, ordinarily because such funds have not been appropriated. This is equivalent to a decision that the invention was not the specific object of the contract,

and we do not wish to pay "just compensation" over and above the contract in order to maintain full rights in the invention. The decision to retain rights in an identified invention in the instances where this has been done was based on a finding that there was an intention to contribute the additional funding necessary to bring the invention to the marketplace. This is tantamount to a decision that the invention was the specific object of the contract and, therefore, the contract price plus the additional investment is "just compensation" for the taking.

Further, in our Institutional Patent Agreement program, under which grantees with patent management capabilities are afforded a first option to any invention made under their grant, an objective decision was made by the Department that because of the basic nature of the research supported, any invention that evolved could not be the specific object of the grant and would always require further development which we would not support. Thus, in this situation, we basically decided that "just compensation" over and above the grant would always be required in order to maintain full rights in the Government, and that we did not wish to make such payment. I would add that the decision to permit the first option in the institution is conditioned, on the same limiting conditions utilized under our deferred determination policy.

Now, in practice, what has happened since the 1968 GAO Report? The statistics we have collected can be considered to be only approximate in that they were accumulated very rapidly through our files and with conversations with the parties in interest. The statistics are

on the low side, as not all the interested parties could provide information to us within the time frame necessary, and most that gave us statistics were conservative when they felt figures could not be readily verified.

First, in regard to the GAO comments on Department performance, I would note, that since January 1,1969, the Department has entered into 41 new Institutional Patent Agreements, bringing the total number to 56. Second, in regard to determinations under our deferred determination policy, average processing time is running between 15 and 20 weeks from time of receipt of a petition to final determination. This compares to a situation in 1968 when petitions basically were not processed.

Now, in regard to rights dispositions, our files indicate that 167 patent applications were filed since 1968 by institutions who chose to exercise their first option to invention rights under their Institutional Patent Agreement. Under the 167 patent applications filed, the universities have negotiated 29 nonexclusive licenses and 43 exclusive licenses. In addition, seven options to license have been negotiated. Seventeen joint-funding arrangements with commercial organizations, involving only the possibility of rights to future inventions, have been made. I consider this an important statistic since it indicates a willingness to make arrangements prior to the time that inventions have been made on the basis that the institution has the flexibility of providing to the concern some invention rights if an invention should evolve from the jointly funded effort. The institution gains this ability to negoti-

ate by virtue of its Institutional Patent Agreement. We are advised that on the basis of all the agreements noted, approximately 24 million dollars of risk capital was committed to the development or making of inventions evolving with DHEW support.

Under our deferred determination policy, it was determined that since July 1, 1968, 178 petitions has been reviewed. Of these 178, 162 petitions were granted. Under the 162 petitions granted, the institutions involved and responding have to date granted 15 nonexclusive licenses and 35 exclusive licenses. These licenses have generated a commitment of risk capital of approximately 53 million dollars. One of the petitions granted involved a burn ointment discovered at a university, which was patented for the university by Research Corporation, licensed to a pharmaceutical company, clinically tested under the direction of the company, and cleared by the Food and Drug Administration on the company's initiative. The drug is now commercially available.

To my knowledge, this is the only drug outside the Cancer Chemotherapy Program which was initially discovered with Department support and has reached the marketplace through the investment of risk capital from the drug industry. We are aware of at least five other drugs outside Cancer Chemotherapy at various states of development which were discovered with Department support and are now being developed with private support under licenses made possible under our deferred determination policy. (I cannot at this time advise whether the licenses granted under inventions retained under IPA's involve any drug development situations, but it is presumed they do.) These numbers compare to zero situations at the time of the GAO Report.

The approximately 75 million dollars committed to development of Department initiated inventions, although on the face appearing to be insignificant in comparison to the one-and-a-half billion dollars yearly devoted to research and development at DHEW, is in fact substantial when compared to the 100 million dollars devoted to directed research with profit-making organizations in 1973 and to lesser amounts in preceding years. The comparison to the 100 million dollars is deemed more realistic, since the 75 million dollars committed is substantially all for development purposes (directed research).

Much more significant than the figures involved is the information being provided by members of our audience which indicates that in the last two years industrial organizations have been actively pursuing university research, which I believe to be clearly the result of the audience's active solicitation of collaborative arrangements, which, in turn, was partly motivated by the flexibility provided by our patent policy. Thus, while the GAO Report indicated that in many instances investigators formerly could not reach the point of conclusive failure with their innovations, that pathway appears to be open, along with the hope of successful utilization.

In light of the above, I believe Mr. Madison would be pleased that DHEW had not "wholly renounced" monopolies as "encouragements to literary works and ingenious discoveries".

In times of stress, other countries have abandoned, to their ultimate regret, commitments to individual rights for what was claimed to be the immediate "public interest". The concept of individual rights and the intent to protect them stems from the natural law understanding that rational individual thought leads to survival of all, while collectivism leads to ultimate abuse of such rights.

We are asked now by some to "wholly renounce" the intellectual property clause on the basis of that portion of Government research funds commingled with those of the private sector in order to complete the arduous task of bringing an idea from the lab to a finished product in the marketplace. There are too few who understand that to do so could ultimately mean the liquidation of the private ownership of all intellectual property other than that kept secret, or the fractionalization of all collaborative effort involving Government funding. As the man said, "The price of liberty [and property] is eternal vigilance".

NJLatker:dyw:cam - 10/18/74

Latker, Carole (NIH/NIGMS) [E]

From: Carole Latker [latkerc@bellatlantic.net]
Sent: Thursday, December 30, 2010 11:38 AM
To: Latker, Carole (NIH/NIGMS) [E]
Subject: FW: Follow up to the meeting
Attachments: Statement of Senator Birch Bayh on the 30th Anniversary of Bayh-Dole.docx; Enacting Bayh-Dole.docx

Importance: High

-----Original Message-----
From: Joe Allen [mailto:jallen@allen-assoc.com]
Sent: Friday, December 03, 2010 9:43 PM
To: Carol latker; Carole Latker
Subject: Follow up to the meeting
Importance: High

Great to see you and to meet Benjamin. Hope you enjoyed the meeting.

I checked with AUTM and they didn't get a sign in sheet of those who attended the event. Jodi Talley with AUTM said that she was going to send you some shots of Benjamin accepting Norm's award. You might also check with the editor of IPWatchDog. His wife also took some great pictures. You can email him at: gquinn@ipwatchdog.com.

Please let Norm know that we missed him and are hoping that he bounces back soon. Attached is Senator Bayh's statement from the meeting and an article I wrote for IPWatchDog on how we got Bayh-Dole passed that mentions Norm prominently. Thought he might enjoy reading them.

Thanks for taking the time to attend the celebration. I'm glad that your grandson got a chance to see how much people that worked with Norm
respect him and appreciate what he's done for the US (and the world).
Norm helped me in countless ways over the years. If there is ever anything that I can do to help, please let me know.

Hope you and your family have a joyous holiday season!

Statement of Senator Birch Bayh

On the 30th Anniversary of the Bayh-Dole Act

I'm delighted to be here today to say "Happy Birthday" to the Bayh-Dole Act on its 30th anniversary. It's great to look around the room and see so many friends who worked so hard to make this day possible along with those who appreciate what the law means to our country, and indeed, the world.

Bayh-Dole teaches several lessons worth recalling:

- A handful of motivated citizens really can change the course of a nation;
- An idea whose time has come can bridge the partisan divide; and
- Each generation must cherish and protect the entrepreneurial spirit that built America for it is our greatest national asset, but can also be lost if neglected or discouraged.

The story of Bayh-Dole began one day in 1978 when I received a call from Ralph Davis who ran the technology transfer office at Purdue University. When Ralph told me that potentially important discoveries made on campus were being prevented from fully benefiting the taxpayers supporting the research, he had my full attention. When he said that Purdue's experience was shared by universities and small companies across the nation, I told him to let me know what needed to be done. He did, and set the wheels in motion for what was to become the University and Small Business Patent Procedures Act of 1980, commonly known as Bayh-Dole.

So we might say that Bayh-Dole is another gift of the Boilermakers to a grateful nation!

Thus, Bayh-Dole was created because of a glaring problem-- billions of hard earned tax dollars invested annually in government R&D were being squandered by ineffective government patent policies. If this research cannot be taken out of the labs and turned into products, the public is being short changed. Even so, it was a long, tough road to travel, and we only succeeded by the smallest of margins. Turning around long standing government policies, no matter how ineffective, is never easy.

Bayh-Dole reflects the American spirit. It shows that innovation thrives when we honor the intellectual property system the Founding Fathers handed down to us. Bayh-Dole allows the entrepreneurial spirit in the public and private sectors to join together turning early stage research into products benefiting our own citizens-- and indeed, those around the world.

It is appropriate that government funds the long range research which simply cannot be performed by industry. But commercial development must be done by the private sector. This is a very arduous, expensive endeavor. It is best accomplished when those making the inventions are trusted to know best how their discoveries should be managed.

Some then and now scoffed at such a concept as hopelessly naive. They find the siren call of centralized government management irresistible. Perhaps this is because they fancy themselves as the central managers. But bitter experience proves that a "Washington knows best attitude" when it comes to innovation leads to disaster. Unfortunately, our critics never seem to learn this lesson.

So the burden is on us to constantly educate policy makers how valuable Bayh-Dole is to the continued health and wealth of the United States. We must show that the Bayh-Dole system is delicately balanced. That the law remains unchanged over 30 years is a testimony to its careful craftsmanship. Anyone urging that it be amended must face a daunting burden of proof supported by facts, not emotion, before they are taken seriously.

And in this debate, you must not underestimate the impact you can make. Many always moan that citizens really can't change government. Yet Bayh-Dole shows that this is simply not true. That doesn't mean that the process is easy or quick-- but what in life that's worthwhile ever is? A handful of determined men and women made the law a reality and have preserved it for 30 years. Later today we will honor several key people who worked so hard behind the scenes to pass and protect Bayh-Dole. Now we need new hands to help carry the banner that they have borne for so long.

I also want to say a word about my friend and colleague Senator Bob Dole who unfortunately could not be with us today. Bob is a true representative of "The Greatest Generation" that literally saved the world, and then came home to build the most prosperous nation in history.

In 1942, Bob joined the army and was assigned to the Italian front. Today we don't hear much about the vicious fighting in Italy. It was not glamorous. The campaign consisted of pushing the German's off a seemingly endless series of fortified mountains at great personal cost. The farther we advanced, the tougher it became. As a 22 year old Second Lieutenant, Bob was doing what Second Lieutenant's do-- leading from the front. Just weeks before the surrender, Bob Dole was hit by fire from a German machine gun. He was hurt so badly that another GI gave him the largest dose of morphine possible, then wrote "M" on Bob's forehead in his own blood, because if following squads gave Lt. Dole another shot he would die. Bob lay on the battlefield for nine hours before being evacuated. He remained hospitalized for more than three years. Upon recovery he studied law and dedicated his life to public service.

It was an honor to serve with Senator Dole for so many years. He and I were on different sides of the aisle, and fought hard for our beliefs. Yet, we developed a deep respect for each other. We shared a common goal: that ground breaking inventions would no longer waste away on the shelves of government, and teamed up to make our vision a reality. It was only because our political partnership effectively bridged the partisan divide that Bayh-Dole was passed. We were able to show our colleagues that our bill reflected fundamental concepts upon which both the right and left could agree. And even then, we barely made it across the finish line before time ran out.

The basis of Bayh-Dole is believing that American innovation flourishes best when the incentives and protections of the patent system are allowed to operate as intended. In this belief, we shared good company. Abraham Lincoln said there were three great events that advanced humanity:

- The discovery of America
- The invention of the printing press, and
- **the development of the patent system**

If you look at the top of the Department of Commerce facing the White House you can read Lincoln's words: *The patent system adds the fuel of interest to the fires of genius.* And he knew what he was talking about. Abe Lincoln is the only president who owned a patented invention.

Unfortunately, before Bayh-Dole his wise counsel went unheeded in federal R&D policies. And America paid a great price.

As Bob and I looked at what was being generated from the billions of dollars spent annually on government supported research we found a very meager return. There were more than 20 federal patent policies then in place across the various agencies, but all were based on the premise that inventions made with government support should be taken away from the inventing organization and licensed non-exclusively by the bureaucracy. We asked the Comptroller General how this system was working. He reported that there were 28,000 inventions caught in this web with less than 5% ever licensed for development.

We also found that not a single new drug has been commercialized when the government owned the patent.

The reason was readily apparent. When government takes inventions away from the creators, it extinguishes the fuel of interest the patent system was intended to create. As inventor Frederick Cottrell said:" *A number of meritorious patents given to the public absolutely free have never come upon the market chiefly* ***because*** **what is everyone's business is nobody's business."**

These policies effectively disconnected university and federal laboratory research from the U.S. economy. They caused our most innovative small companies to shun government research because accepting federal dollars meant giving up any hope of developing innovative products they might invent.

We also saw the United States' traditional lead in technology fading away across the board. Some said we should be resigned to being a service based economy since the U.S. simply could not create competitive products any longer. Beltway pundits confidently predicted that centralized economic planning like that of "Japan, Inc." was the new model we should adopt. Such ideas always find receptive ears in Washington.

But Bayh-Dole offered a different way out of the swamp.

We chose to listen to Lincoln, not those then in fashion. Bayh-Dole introduced patent incentives to federal research. Our bill was based on the premise that government should do what it does best-- fund basic and long range research that industry simply cannot afford to do, and then rely on those making inventions to manage them in the public interest by providing a few simple rules.

We recognized that industry is accepting tremendous risk developing early stage university and federal laboratory inventions, and must be protected by strong patent licensing agreements. We believed that the best approach was relying on those actually making the discoveries to know best how these deals should be structured. We said the universities must share royalties with their inventors so all would benefit from successful partnerships.

And we did not create any new bureaucracy.

At the time, many considered our approach lacking in sophistication and nuance. Some still do. However, the results speak for themselves. The **Economist Technology Quarterly** said it best:

Possibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole Act of 1980... More than anything, this single policy helped reverse America's precipitous slide into industrial irrelevance.

And such claims are not mere jargon; the facts bear them out. Here's just a sample of what Bayh-Dole has done:

- Created more than 6,500 new companies with about 600 created last year in the midst of a serious economic recession, *or an average of about two new companies every working day of the year;*
- Created more than 5,000 new products;
- Spawned more than 130 new drugs, vaccines or devices protecting public health around the world;
- Helped create entire new industries like biotechnology;
- Contributed at least $187 **billion** to the US Gross National Product while creating a minimum of 279,000 new jobs in just a nine year period, and
- A new report by the National Academy of Sciences found that the critics were wrong when they claimed that Bayh-Dole would undermine traditional academic norms.

Perhaps it's only appropriate to add here how ironic it is that some now look down their noses at university technology transfer officials given the contribution they have made to the nation.

Perhaps the best evidence of our success is that other nations are rapidly adopting Bayh-Dole laws of their own to better compete with us. They rightly view Bayh-Dole as a proven best practice. Their seriousness of purpose was demonstrated to me when I spent my birthday in Beijing a few years ago being quizzed by Chinese leaders why our system worked so well. It seems sometimes that the law is better appreciated abroad than here at home.

Let me conclude with a few words of warning. We never seem to run short of ivory tower theorists who fault Bayh-Dole and urge us to adopt their latest pipe dreams instead. What they lack in practical experience and solid data they make up in emotion and rhetoric. As General Grant observed about the arm chair experts constantly sniping at him while he was slowly but surely bringing the Civil War to a successful end:

"The most confident critics are generally those who know the least about the matter criticized."

Our critics are now urging that government be empowered to impose licensing restrictions on universities to meet fancied dangers. They claim that some fields of technology should even be exempted from Bayh-Dole because patenting should be discouraged. They criticize the university technology transfer model as hopelessly out of date. They would take us back to the failed policies of the past. We have been down this road before and know where it leads-- and it's not a good place. So it is up to us to constantly remind policy makers of our prior hard learned lessons, or they may be repeated.

However, a serious problem was identified by the National Academy report. The oversight authority Bob and I established in the bill is not functioning as Congress intended. Unfortunately, the report wrongly faults the law for this lapse. Bayh-Dole clearly established a high level policy oversight function with enough teeth to insure **uniform** implementation by all agencies. The system successfully operated for the first 15 years of Bayh-Dole. It was led by those familiar and supportive of the law. An effective policy office developed and implemented the regulations for Bayh-Dole, prevented agencies from misusing the exceptional circumstance provision to take research out from under the law, halted attempts to override Bayh-Dole in international agreements, helped craft Executive Order 12591 making Bayh-Dole the centerpiece of innovation policy, and worked with Congress to expand the principals of Bayh-Dole to the federal laboratory system. That sounds pretty effective to me.

The real cause of the current problem came as the expert staff left, succeeding policy officials appeared disinterested in Bayh-Dole, and oversight gradually fell off the radar screen. If not corrected, such neglect will create serious problems because the law cannot run on auto pilot much longer. Otherwise the essential principal of Bayh-Dole -- *creating a uniform patent policy across all agencies*-- falls by the wayside. This simply must not be allowed to happen. Which reminds me of a story.

Late in his life Benjamin Franklin was asked by a young person what the Founding Fathers were leaving to posterity. Franklin replied: "*A republic, if you can keep it.*" So let me close with this paraphrase on behalf of all of us who worked to enact the law all those years ago:

We've given you Bayh-Dole. It's now up to you to keep it.

Thank you