THE SUCCESS OF THE BAYH-DOLE ACT'S TECHNOLOGY TRANSFER POLICIES

Executive Summary

On May 25, 2004, the National Institutes of Health ("NIH") will hold a public meeting addressing its march-in authorities to grant an open patent license under the Bayh-Dole Act with respect to a product allegedly sold at an unreasonably high price. This paper provides information on the benefits of the Bayh-Dole Act and the problems that would be created if the Act were used as a price-control mechanism.

The Bayh-Dole Act is the cornerstone of sustained progress in the U.S. biotechnology industry, facilitating a remarkably productive partnership between government, academia and industry. Catalyzed by Bayh-Dole, the number of patents issued annually to universities has increased from about 250 to over 3600 in just over 20 years. During that same time, Bayh-Dole has also encouraged commercialization of these inventions through exclusive licenses, thus contributing to a significant increase in Americans' life-expectancy.

According to the co-authors of the Act, former Senators Birch Bayh and Bob Dole, their law "did not intend that government set prices on the resulting products." Indeed, these respected legislators explained in a 2002 letter to the editor of the Washington Post that the Bayh-Dole Act intentionally omits any "reference to a reasonable price that should be dictated by the government." March-in powers like those addressed in the upcoming NIH meeting were instead designed for the unusual situation in which exclusive licensees entirely fail to commercialize an invention brought about through government funding.

NIH has similarly acknowledged that a comparable — and now defunct — reasonable pricing policy "had the effect of posing a barrier to expanded research and development and, therefore, was contrary to the Bayh-Dole Act." Furthermore, NIH in 1997 denied the only other march-in petition ever presented to it, reasoning that the uncertainty created by an exercise of march-in rights could "have far-reaching repercussions on many companies' and investors' future willingness to invest in federally funded medical technologies." If a march-in petition were granted, NIH said, "[t]he ability of universities to make their federally funded technologies available to the public would be undermined, and the incentive for private sector to invest in federally funded discoveries would be removed."

Today, NIH's use of march-in authorities could still introduce a level of uncertainty that would lead private enterprise to withdraw from the Bayh-Dole equation and destroy the successful Bayh-Dole system. Because the Bayh-Dole Act was never intended as a price-control mechanism, any interpretation allowing price-based march in would destroy the essential fabric of the Act.

Discussion

The National Institutes of Health ("NIH") recently announced that it would hold a public meeting on May 25, 2004 to solicit comments on the use of government march-in authorities under the Bayh-Dole Act (the "Act"), 35 U.S.C. § 203, for Norvir (ritonavir), a drug manufactured by Abbott Laboratories using inventive technologies developed with NIH funds. The Bayh-Dole Act has been called "[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century."[1] Accordingly, NIH's consideration of its march-in authority over the price of a commercially available product should begin with a complete understanding of the unqualified success of the Act's technology transfer policies.[2]

For over two decades, the Bayh-Dole Act has been the cornerstone of sustained progress in the U.S. biotechnology industry, facilitating a remarkably productive partnership between government, academia and industry. As NIH itself has recognized, "[f]ederally funded biomedical research, aided by the economic incentives of Bayh-Dole, has created the scientific capital of knowledge that fuels medical and biotechnology development. American taxpayers, whose lives have been improved and extended, have been the beneficiaries of the remarkable medical advances that have come from this enterprise."[3] According to the Association of American Universities, domestic universities obtained an average of fewer than 250 patents per year prior to Bayh-Dole.[4] By fiscal 2002, survey results showed that two decades of Bayh-Dole had increased the number of university patents issued annually to over 3600.[5]

Thanks to Bayh-Dole, these new patents are reaching the public by way of private-industry commercialization. The Congressional Joint Economic Committee has estimated that advances in health care like these have contributed to an increase in U.S. life expectancy since 1970 valued at $2.4 trillion.[6] NIH logically has concluded that "[c]urrent practices in technology transfer have yielded a dramatic return to the taxpayer through the discovery of new technologies that extend life and improve the quality of life and through the development of products that, without the successful public-private relationship, might not be available."[7] Moreover, Bayh-Dole's technology transfer policies have benefited American universities, which according to one survey received $1.337 billion in gross income from patent licenses in fiscal 2002.[8] This revenue helps to fund new research and training programs at these institutions.[9]

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[1] *Innovation's Golden Goose*, The Economist Technology Quarterly, Dec. 12 2002.
[2] *Cf.* Letter from Rep. Sherrod Brown (D-OH) to Elias Zerhouni, Director, NIH (March 27, 2004) (requesting a public hearing on Norvir).
[3] Department of Health and Human Services, National Institutes of Health, A Plan to Ensure Taxpayers' Interests Are Protected Part F(July 2001), *available at* http://www.nih.gov/news/070101wyden.htm.
[4] Association of American Universities, *University Technology Transfer of Government-Funded Research Has Wide Public Benefits* (June 2, 1998), *at* http://www.aau.edu/research/TechTrans6.3.98.html.
[5] Association of University Technology Managers, *AUTM Licensing Survey: FY 2002, Survey Summary* at 12, *available at* http://www.autm.net/surveys/02/2002spublic.pdf.
[6] U.S. Congress, Joint Economic Committee, *The Benefits of Medical Research and the Role of NIH* at 17 (May 2000), *available at* http://rxpolicy.com/studies/nih-randd-jec.pdf.
[7] A Plan to Ensure Taxpayers' Interests Are Protected, *supra* Part F.
[8] *AUTM Licensing Survey: FY 2002, Survey Summary*, *supra* at 18.
[9] A Plan to Ensure Taxpayers' Interests Are Protected, *supra* Part C.2.a.

The Bayh-Dole Act permits the government to "march in" and force a patent holder to grant third-party licenses if the patent holder is not taking "effective steps to achieve practical application of the subject invention" or if "action is necessary to alleviate health or safety needs."[10] Neither the plain meaning of the Act, its legislative history, nor the public policies underlying it contemplate a march in based on the price of a commercially available product. Yet the recently filed march-in petitions[11] suggest that "open licenses" ought to be granted if prices of commercially available products are higher in the United States than in other countries. Such an interpretation of the Act is without precedent or legal basis.

The Report of the Senate Judiciary Committee explained that the Bayh-Dole Act "is designed to promote the utilization and commercialization of inventions made with government support."[12] Accordingly, the Senate followed a recommendation that the bill include march-in rights that would allow government to take action in the rare case "when the invention is not being used and it appears that there is a public need to use the invention."[13] By contrast, the report makes no mention of march-ins as a tool for determining "reasonable" prices.

The pertinent portions of the Act's legislative history also comport with the position of the Act's co-authors, former Senators Birch Bayh and Bob Dole, who have stated that their law "did not intend that government set prices on the resulting products." Indeed, the Act's authors pointed out that "[t]he law makes no reference to a reasonable price that should be dictated by the government." Furthermore, "[t]his omission was intentional; the primary purpose of the act was to entice the private sector to seek public-private research collaboration rather than focusing on its own proprietary research."[14]

The author of the Judiciary Committee's Report, Joseph P. Allen, recently reaffirmed this interpretation of the Act. In a letter to the Director of NIH's Office of Technology Transfer, Allen flatly stated that "the provisions of the Bayh-Dole Act do not provide for governmental actions such as those requested by Essential Inventions. Indeed, such actions were never contemplated by the Congress and are not reflected in the legislative history of the law." In Allen's words, the interpretation of the Bayh-Dole Act advocated in Essential Inventions' petitions is "entirely fanciful."[15]

Another of Bayh-Dole's drafters, Norman J. Latker, has categorically asserted that the Act "is not an instrument to control drug prices." Latker — who was also the architect of the Act's implementing regulations and a former patent counsel to the US Department of Health, Education and Welfare — explained that he finds "disturbing" the petitioner's "attempt to transform a

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[10] 35 U.S.C. § 203(a)(1), (2).

[11] See March-In Petitions from Essential Inventions, Inc. to Secretary Tommy Thompson, U.S. Department of Health and Human Services (January 29, 2004)

[12] S. Rep. No. 96-480, at 3 (1979).

[13] *Id.* at 18.

[14] Birch Bayh & Bob Dole, Letter to the Editor, *Our Law Helps Patients Get New Drugs Sooner*, Wash. Post, April 11, 2002 at A28.

[15] Letter from Joseph P. Allen, President, National Technology Transfer Center, to Mark Rohrbaugh, Director of the Office of Technology Transfer, NIH 1 (March 31, 2004).

fundamental piece of intellectual property law into an administrative mechanism to control drug prices, with no regard for the consequences."[16]

Implicitly acknowledging the absence of authority to affect drug pricing under Bayh-Dole, a few members of Congress have attempted on several occasions to pass legislation that would require the recipients of federal research funds to enter "reasonable price agreements" with the Department of Health and Human Services. Each of these efforts failed to garner support sufficient for passage. Thus, the Bayh-Dole Act — which as discussed above does not sanction the determination or enforcement of "reasonable" prices — continues to govern federal technology transfer policy.

NIH has already concluded that Bayh-Dole does not contemplate the imposition of price controls. In 1995, NIH reversed a failed attempt to impose a "reasonable pricing" requirement on parties to its Cooperative Research and Development Agreements ("CRADAs"). Looking back on this experiment, NIH acknowledged that its reasonable pricing policy "had the effect of posing a barrier to expanded research and development and, therefore, was contrary to the Bayh-Dole Act."[17] When NIH removed the reasonable price barrier, the number of CRADAs promptly increased.[18]

NIH has likewise previously presented its views on the important policy considerations raised by any grant of march-in rights. In rejecting the march-in petition of CellPro, Inc. in 1997, NIH recognized that the uncertainty created by an exercise of march-in rights could "have far-reaching repercussions on many companies' and investors' future willingness to invest in federally funded medical technologies." Numerous universities and university groups, similarly cognizant of the dangerous uncertainty created by a march-in, opposed the CellPro petition.[19] Many of these groups have already begun voicing their disapproval of the recent march-in petitions, warning that "[t]he ability of universities to make their federally funded technologies available to the public would be undermined, and the incentive for private sector to invest in federally funded discoveries would be removed."[20]

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[16] Letter from Norman J. Latker to Mark Rohrbaugh, Director of the Office of Technology Transfer, NIH 1 (April 13, 2004).

[17] A Plan to Ensure Taxpayers' Interests Are Protected, *supra* Part C.6.

[18] *Id.* Part C.6 & App. 4.

[19] See Letter from Gerhard Casper, President, Stanford University, to Harold Varmus, Director, NIH (June 10, 1997); Letter from David J. Ramsay, President, University of Maryland at Baltimore, to Harold Varmus, Director, NIH (July 10, 1997); Letter from Richard K. Koehn, Vice President for Research, The University of Utah, to Donna E. Shalala, Secretary, Department of Health and Human Services (July 11, 1997); Letter from E. Gordon Gee, President, The Ohio State University, to Harold Varmus, Director, NIH (July 21, 1997); Letter from Cornelius J. Pings, President, Association of American Universities, to Harold Varmus, Director, NIH (June 5, 1997); Letter from Jordan J. Cohen, President, Association of American Medical Colleges, to Harold Varmus, Director, NIH (May 30, 1997); Letter from Milton Goldbert, President, Council on Governmental Relations, to Harold Varmus, Director, NIH (June 26, 1997).

[20] Letter from National Association of State Universities and Land-Grant Colleges, Association of American Universities and American Council on Education to Mark Rohrbaugh, Director of the Office of Technology Transfer, NIH 2 (April 22, 2004); *see also* Letter from Joseph P. Allen, President, National Technology Transfer Center, *supra*; Letter from Katharina Phillips, President, Council on Governmental Relations, to Mark Rohrbaugh, Director of the Office of Technology Transfer, NIH (April 5, 2004) (stating that any "change in march-in authority or in expanding their exercise by government agencies could result in the loss of the very delicate balance of rights

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In denying CellPro's petition, NIH was particularly "mindful of the broader public health implications of a march-in proceeding, including the potential loss of new health care products yet to be developed from federally funded research." Its written decision emphasized that "[t]he patent system, with its resultant predictability for investment and commercial development, is the means chosen by Congress for ensuring the development and dissemination of new and useful technologies. It has proven to be an effective means for the development of health care technologies."[21]

In October 2000, Congress instructed NIH to "prepare a plan to ensure that taxpayers' interests are protected" in light of "the mounting concern over the cost to patients of therapeutic drugs."[22] NIH's response to this Congressional directive emphasized the incredible success of the system created by the Bayh-Dole Act and concluded that "contravening the provisions of Bayh-Dole may have a deleterious effect on biotechnology development."[23] The same report matter-of-factly observed that "neither NIH nor universities have a role in drug pricing."[24]

As the public debate continues on the use of march-in authorities, NIH must be careful not to alter the Bayh-Dole landscape in such a way as to introduce a level of uncertainty that would lead private enterprise to withdraw from the Bayh-Dole equation. That withdrawal would destroy the successful Bayh-Dole system. Because the Bayh-Dole Act was never intended as a price-control mechanism, any interpretation allowing price-based march in would destroy the essential fabric of the Act.

(... cont'd)

and obligations between the three partners - government, universities and industry - which has been the basis for the success of this legislation").

[21] Determination in the Case of Petition of CellPro, Inc., http://www.nih.gov/news/pr/aug97/nihb-01.htm

[22] A Plan to Ensure Taxpayers' Interests Are Protected, *supra* Part A.

[23] *Id.* Part F.

[24] *Id.* Part D.1.

From: James Love <james.love@cptech.org>
To: Norman Latker <NJL@browdyneimark.com>
Date: 6/2/04 6:10PM
Subject: Re: [techno-l] My May 25 Statement at NIH meeting on the EssentialInventions Petition

Norman. It is our contention that the term, "contractor" is defined in 35 USC 201(c):

"(c) The term "contractor" means any person, small business firm, or nonprofit organization that is a party to a funding agreement." O.K

And, the term "practial application" is defined in 35 USC 201(f).

"(f) The term "practical application" means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms." O.K.

We claim that the term "available to the public on reasonable terms" includes, but is not limited to, price. In Senator Bayh's 1997 Cellpro March-In petition, he focused on the royalties, which is another term, and he also said the NIH should regulate royalties because they have an impact on the cost of medical care. *

You say, "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," further that "it cannot mean "reasonable prices," because contractors, in the view of the drafters, would not normally be setting prices."

*1 "in the view of the drafters" is a good one.... on what authority do you claim to know this? Contractors can set prices. Ask the Department of Defense, the Department on Energy, or the NIH. They can set royalties. They can do a lot of things.

What the Act does is provide that the government can issue a compulsory license, if the patent owner does not make "practical application" of the patent, as defined in 201(f), which includes the obligation that the benefits of the invention be "available to the public on reasonable terms."

The terms by the contractor could be different things, such as in the Cellpro case, the royalties. But as professor Reichman pointed out, the terms under which an invention is developed -- price, royalties, market resale restrictions, etc," normally have an effect on the prices consumer pay. The government may also consider other issues, such as it may have in the negotations over the WARF stem cell patents.

* Contractors can affect prices directly, by charging prices themselves, or indirectly, by licensing inventions to parties that charge unreasonble prices.

connect

It seems pretty stupid to me that "available to the public on reasonable terms" would never allow the NIH to consider the one of the most relevant terms to the public -- the price.

You may wish and hope that the NIH never looks at prices. Abbott may wish the same. And NIH clearly can ignore prices if it wants to. But the Statute, the regulations, and the contracts written into all of these grants and contracts, give the goverment broad powers to march-in if the government does not believe the prices (or other terms) are reasonable.

The patent owner can develop an invention itself, it can license it to one or more third parties, under a variety of different economic terms, exclusive or none-exclusive, and it can supervise or ignore the prices charged by the licensee. It can do just about anything. But the government retains rights to march-in, if the "benefits" of the invention are not "available to the public on reasonable terms." (a) and (c) are just different grounds for exercising march-in rights under 203.

Why don't you give us the Latker defintion of "available to the public on reasonable terms." You seem to have trouble with the "available to the public" part of "reasonable terms," but the statutes includes both. You might re-read the Halperin memo and ask why Congress declined to replace and with or, as was requested by some.

"the invention is being utilized *and* that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms."

Maybe if the *and* was replaced by *or* you would have had a stronger case.

Tell us also why the House and the Senate versions of the bill included the much more agressive recoupment provisions that were only dropped in conference.

Jamie

Norman Latker wrote:

> As I indicated earlier Essential Inventions contention that "reasonable terms" must mean "reasonable prices" is no longer credible based on the correct reading of the Act set out in my May 25 statement below. If Jamie does not agree he is free to make his case on this board. I do not believe he will do so because he has committed himself to his misrepresentation of the Act all over capitol hill. As I suggested earlier, the most effective way to undue the damage he has done is request that the appropriate official at your institution make know to your state's representatives on capitol hill the importance of the Act to your state's economy and the damage that will be done if they buy into Jamie's misrepresentation of the Act. You and the public are the Act"s direct beneficiaries. While we in Washington are doing the best we can, It is you that must step forward to defend the Act. If you can convince yourselves that this is someone else's responsibility, be assured that Jam
ie is still on capitol hill misrepresenting the Act.
>
> 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.
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From: Carole and Norman Latker <Latkerc@bellatlantic.net>
To: <njl@browdyneimark.com>
Date: 5/24/04 9:50PM
Subject: [Fwd: Re: [techno-l] David Halperin memo on March-In]

-------- Original Message ---------
Subject: Re: [techno-l] David Halperin memo on March-In
Date: Mon, 24 May 2004 02:48:08 -0400
From: Carole and Norman Latker <Latkerc@bellatlantic.net>
To: Carole and Norman Latker <Latkerc@bellatlantic.net>
References: <4F8ED7FD1C9AA54BAC61A29E284F69CB13BACB@orpheus.njrc.org>
<40B12228.5030402@cptech.org> <40B14647.3090504@bellatlantic.net>

Jamie
You say that your position is not an attack on Bayh-Dole. O.K. Then please answer this question for the board. Why would a drug company invest what they estimate to be up to $ 900 million to bring a drug lead generated with NIH funding to the marketplace if the government could second guess their pricing decision after the fact? Frankly, if I was a drug company that had already made such an invest and was then told that the government could challenge my pricing determination I would think that my goverment had treated me unfairly. If you chose to respond, I don't think suggesting that only a lackey of the drug industry or a hard hearted s.o.b could ask such a question will suffice.

Carole and Norman Latker wrote:

> Jamie
> For now I will give you the benefit of doubt that you believe your
> petition is a one shot deal and not an attack on Bayh-Dole.
> But your quote in The Chicago Tribute to the effect that a decision
> either way will set a precedent raises the doubt. It implies that you
> have a bag of other drugs that you will go after if you succeed. I
> can still let that pass. But what I will not let pass is a
> continuation of your reliance on the Tulane article. This article is
> the most mean spirted political polemic I have ever seen. It is a
> flat out attack on Bayh-Dole specifically and on the patent system
> generally. It exposes the "conspiracies" involved in the Act's
> implementation and uses as its primary authorities the people opposed
> to its passage in the first place especially Adm. Rickover. Adm.
> Rickover's experience with government patent policy was limited to
> inventions made in performance of the government program to build
> atomic submarines totally at government expense. He couldn't of cared
> less about the serious problems we had in the life sciences.
> Notwithstanding all of that, the article's interpretation of
> "reasonable terms" is just plain wrong. You are clearly a personable
> and intelligent young man. I wish you luck in achieving your goal but
> not at the expense of Bayh-Dole.
>

> James Love wrote:
>
>> Brockbank, Brad wrote:
>>
>>> In pursuit of your (debatable) interpretation of a single one of
>>> those goals, your advocacy threatens to undermine the others -- at
>>> the expense, I would submit, of the broader public interest in the
>>> other objectives of the Act. This, I believe, and not some
>>> allegiance to the pharmaceutical industry, is what explains most of
>>> the opposition of the academic technology transfer community to your
>>> petition.
>>
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>>
>> Brad, I don't think this is fair. We have not made a general
>> objection to the policy of giving away title to inventions, or even
>> allowing grant recipients to choose exclusive rights. I agree that
>> exclusive rights are sometimes a necessary incentive for atracting
>> investment in develoopment of projects. I am not attacking the
>> Bayh-Dole Act in the petition. I am tring to get the government to
>> enforce one of the provisions in the Bayh-Dole Act. The provision I
>> want enforced is the one that asks that inventions be available to
>> the public on reasonable terms. We are not asking that the NIH
>> engage in price regulation for every government funded invention. We
>> are asking that the NIH authorize march-in against Abbott for
>> extraordinary patent abuses, and we recommend more generally that US
>> taxpayer funded inventions not be more expensive in the USA than in
>> Europe or Canada. I don't think this is the same as a wholesale
>> attack on the act.
>>
>>
>>> Defense of the true, or at least the primary, intents of Bayh-Dole
>>> is not the same thing as defense of Abbott.
>>
>>
>>
>> Defense of the Bayh-Dole Act is one thing. Claiming that Abbott
>> has done nothing to justify a march-in is a defense of what Abbott
>> has done, or an assertion about the statute that does not seem very
>> candid to me.
>>
>>> Politically, I've never understood why some so-called guardians of
>>> "the public interest" insist so often on guarding what becomes an
>>> ever-narrowing view of the public interest by antagonizing (via
>>> personal attacks, assumption of purely economic motives,
>>> mischaracterization, and smear by association) those who might
>>> otherwise be supportive of their ultimate goals, but do not support
>>> their chosen means to those ends.
>>
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>> I never understood that either. And if someone claims that I am
>> seeking to undermine the Bayh-Dole Act purposes, it seems odd to me,
>> because I am just asking that the government apply the Bayh-Dole Act.

>>
>> What Abbott has done is extraordinary. If the technology transfer
>> community sees me rather than Abbott as the problem, then this says
>> something about priorities. Certainly protecting taxpayer and
>> consumer interests is not everyone's high priority.
>>
>> If the NIH agrees with our critics, they will reject our petition,
>> and let patent owners (and the public) know that the sky is the
>> limit. Is that really in the *long run* interest of the defenders of
>> the Bayh-Dole Act? Maybe some recognition of the legitimate
>> interests of the taxpayer/consumer interests are more appropriate for
>> those who want the taxpayers to keep providing the funding for these
>> grants.
>>
>> Jamie
>>
>
>

From: Carole and Norman Latker <Latkerc@bellatlantic.net>
To: <njl@browdyneimark.com>
Date: 5/21/04 5:06AM
Subject: Re: [techno-l] Essential Inventions Petitions and Sanders' Amendmentsto DHHS Appropriations Bill

Jamie
First, your last paragraph requires me to note that I have AIDS in my family. My concern for AIDS victims is every bit equal to yours. However, it does not extend to undoing the Bayh-Dole Act which, as we hoped, acted to improve and extend the lives of millions of Americans. I am defending Bayh-Dole not Abbott. I believe everyone who cares about the well-being of Americans in the future should also be doing the same.With regard to acting, I don't think you should be pretending that your petition is a one shot deal. The authors of the Tulane article (the basis for your petition) explicitly state that they can make a case that every drug on the market is touched by government research dollars. They maintain that this makes them subject to the march-in provisions of the Act as they define them. That would make the Act useless in the future as an incentive to invest the millions necessary to bring an unproven drug lead through FDA .
Now to your argument that the Act gives NIH the authority to march-in if they find the sales price unreasonable. The Tulane article supports this by arguing that the "reasonable terms" language that can be read into sec.203a of the Act must be interpreted to include a reasonable price. However, on page _ the authors agree that "reasonable terms" includes other conditions. The "other conditions"can be easily identified from the Act and its authentic legislative history. They clearly do not include "price" within the context of sec.203a.The introductory language of 203 indicates that it applies generally to "contractors,assignees and licensees".However, Sec.203a applies only to "contractors and assignees" while the other sections under 203 apply to all three entities identified in the introduction. By design 203a does not apply to "licensees" who are in the end the people that set the sales price. Clearly, the contractors and assignees (which can only be a patent management org. under the Act) who must license are not required under the Act to set sale prices for their licensees who are not covered by 203a. If they tried do so on their own inititive everyne on this board call tell you what the result will.be. So much for the Tulane article argument that "reasonable terms must include prices.
But what does "reasonable terms" mean in the context of 203a? A license is a contract within which the word "terms" makes sense. "Terms" makes no sense in the context of a sale to the public because a sale is not a contract and carries no "terms". One of the clear meanings supported by the authentic legislative history of the Act is that "reasonable terms" translates into "reasonable royalties".

James Love wrote:

> Norman, the Bayh-Dole act does have march-in rights, and 201(f) refers
> to making inventions available to the public on reasonable terms.
> This means something.

>
> That said, while the Bayh-Dole gives the government rights in the
> patent, it does not eliminate other protections the firms have for
> their investments in trials. In the US, Europe, Australia and
> elsewhere, companies get separate rights in data from clinical trials.
> In the US this is 5 years of exclusive rights to use the data for FDA
> regulation. In Europe it is about 10 years. Abbott has some patents
> with Bayh-Dole rights in them, and they are very important. Abbott
> has also had rights in data, which are expired.
>
> If the tech transfer community wants to defend abbott, which increased
> its price by 400 percent in one day, and which charges US consumers 10
> times the prices it charges in many high income countries, and 5 times
> more in the US market when ritonavir is used with non-abbott products,
> then fine. But don't act as if it is a stretch to say this is not
> making the product available to the public on reasonable terms. It is
> just evidence that you resent the public has any say in how these
> taxpayer funded inventions are commercialized.
>
> Jamie Love
>
> Norman Latker wrote:
>
>> Below is a site to an undated news release from Cong. Sanders office
>> regarding his unsuccessful efforts to amend the DHHS appropriation
>> bill to require that all drugs developed with taxpayer dollars be
>> marketed at a "reasonable price"
>> He supports this on the mistaken fact that, "Almost all of the
>> health care research and development dollars in the United States,
>> both public and private, is spent on the development of prescription
>> drugs" and that the dominant public portion of this funding demands a
>> public equity in establishing a "reasonable price" for sale of drugs
>> touched by the public R&D portion.
>> This is incorrect on its face as any investigation (no matter how
>> modest) will establish that virtually all the public funding involved
>> is directed to thousands of basic research grants to explore the the
>> frontiers of the life sciences. Most likely none of these grants
>> involve creating the clinical data nessary in the development of a
>> drug for FDA licensure. At most, a minor portion of this funding will
>> result in identification of a composition of matter which evidences a
>> medicinal utility which could be pursued through the FDA with private
>> capital. Even the private R&D funding identified is not used for
>> producing the clinical data nessary to bring potential drugs
>> discovered during such R&D to the marketplace. In short, there is no
>> basis to presume that any of the research funding identified has
>> anything to do with paying for the clinical data necessary for FDA
>> licensure.
>> Of course, it quite clear that it is the private sector that funds
>> substantfally all the clinical data necessary whether the potential
>> drug involved is derived from public or private research. It is also
>> clear that if public research is the source, the private funding for
>> clinical data far exceeds by many multiples the funding for the
>> grants that produced the potential drug. Cong. Sanders unsuccessful
>> efforts have now morphed into a Tulane law article which falsely

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statistics

The Honorable Edward M. Kennedy
United States Senate
317 Senate Russell Office Building
Washington, DC 20510

Dear Senator Kennedy:

We are writing to seek your assistance on a matter that significantly impacts the Massachusetts economy. As you well know, the key component to the health and welfare of the American people is a strong, vibrant economy. As you also recall, during the 1970s and 1980s, the ability of the United States to compete in the world economy was seriously in doubt. An important ingredient in our subsequent success was passage under your leadership as Chairman of the Senate Judiciary Committee of legislation in 1980. This law, commonly termed the Bayh-Dole Act, provided that universities and small companies could take ownership of Government-funded intellectual property and license that intellectual property to US industry. Under our leadership at MIT, we built a technology licensing program that sought to accomplish the goals of Bayh-Dole. Since the law was passed, MIT alone has generated approximately 300 new companies with combined employment in Massachusetts estimated to be well in excess of 20,000 new jobs. The national impact of Bayh-Dole has been staggering, and several entire industries including biotechnology and the Internet were created largely through this effective mechanism for technology transfer. Unfortunately, Bayh-Dole is now under attack.

In the late '70s, virtually no inventions made with government supported R&D were being commercialized. This meant that tens of billions of taxpayer dollars were making no impact on our ability to deliver new products to the world community. This economic disconnect obviously harmed our ability to create new companies and jobs.

Quite simply, the Bayh-Dole Act, which you co-sponsored and vigorously supported, allows universities and small companies to own inventions they make with federal support. The government has the right to use the inventions for their own purposes, resulting products should be made in the United States, royalties back to the universities are invested in more research and to reward our scientists, and penalties can be imposed if companies are not moving resulting inventions aggressively to the market.

MIT strongly supported the bill. Several Massachusetts small businesses testified that their inability to develop inventions they made under federal contracts made it impossible for small high technology companies to work with the government. After the bill passed, the Small Business Innovation Research Act (SBIR) incorporated the principles of Bayh-Dole as a vital part of that law as well. As you know, the subsequent growth of small companies from our universities and the SBIR program are important parts of the economic blueprint of our state. This phenomenon is not limited to Massachusetts.

Recently the *Economist Technology Quarterly* summarized quite well what the Bayh-Dole Act has meant to the United States:

> "Remember the technological malaise that befell America in the late 1970s? Japan was busy snuffing out Pittsburgh's steel mills, driving Detroit off the road, and beginning its assault on Silicon Valley. Only a decade later things were very different ... 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 .... More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance ...
>
> Overnight, universities across America became hotbeds of innovation ... Since 1980, American universities have witnessed a tenfold increase in the patents they generate, spun off more than 2,000 firms to exploit research done in their labs, created 260,000 jobs in the process, and now contribute $40 billion annually to the American economy. Having seen the results, America's trading partners have been quick to follow suit. Odd then, that the Bayh-Dole act should now be under attack in America."

Unfortunately in the past year, there have been several interests who have strongly proposed that Universities should not retain the rights granted to it under Bayh-Dole. Some of these initiatives include companies that have testified before Congress suggesting that they should own all of a university's intellectual property developed with federal funds. NIH, DARPA, and the Advanced Technology Program (ATP) are among a few of the federal agencies or programs that have issued several basic research programs that restrict a university's ownership of the intellectual property it develops, thereby having serious national implications on educating the next generation of the world's best students and conducting cutting-edge research that would benefit the US in the same way it has for the past 24 years since the passage of the Bayh-Dole Act.

While these initiatives to limit the benefits of Bayh-Dole have caused MIT great concern, what is of utmost importance is the actions of some interests that recently petitioned the NIH and have testified at recent NIH hearings to use the Government's "march-in" rights in Bayh-Dole as an effort to control drug and product prices. These interests have misrepresented the intent of the Bayh-Dole Act to say that the Government retains the right to re-take control (through "march-in rights") over intellectual property if the Government does not like the prices charged by the company that has licensed the intellectual property. This argument was stimulated by an effort to lower the price of an AIDS drug that is commercially available. While MIT and the country are concerned about the ever-rising drug and product prices and the public policy issue of drugs being made available to all that need them, artificial use of Bayh-Dole's "march-in rights" that were intended to be used when an intellectual property funded in whole or in part by the Federal Government was not commercialized at all, would destroy the value of Bayh-Dole and in the future severely limit the commercialization of any intellectual property funded by the Government. Companies that have licensed or would like to license intellectual property for development of products that would benefit all in the United States and worldwide will not be willing to take the huge risk of having their license rights and markets destroyed by the use of the Bayh-Dole "march-in rights" when a third party who has not participated in the research or taken the development and financial risks to develop the much-needed product determines on its own that the price of a drug is too high. Use of the Government's Bayh-Dole "march-in rights" to control product prices would have a major chilling effect on venture capital investments in Government-funded technology, because profit margins could be at the whim of Washington bureaucrats.

Senator Birch Bayh spoke at the National Institutes of Health on May 25 and said that such attempts would be a death knell to the commercialization successes of many of our small companies and to research universities like MIT (his testimony is enclosed). We agree with Senator Bayh's analysis.

We would appreciate the opportunity to discuss with you the importance of the legislation. It appears that the Senate Judiciary Committee might have forgotten the leadership it once provided under your guidance that helped turn our economy around. It might be time for the Committee to reassert its role before others undo your work.

Sincerely,

Paul E. Gray
President Emeritus

John T. Preston
Founder and Former Director

Professor of Electrical Engineering of the Technology Licensing Office

Enclosure

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via fax 202-224-2417

The Honorable Edward M. Kennedy
United States Senate
317 Senate Russell Office Building
Washington, DC 20510

Dear Senator Kennedy:

Two stalwarts of MIT whom you know well, Paul Gray, President Emeritus, and John Preston, former Director of the Institute's Technology Licensing Office, have written the enclosed letter to you to express their concerns about the future of the Bayh-Dole Act of 1980. I commend their highly informed views to you. Your leadership role in securing passage of that profoundly important Act is one of your most significant contributions to research and technology transfer. The university community remains deeply grateful to you for your leadership in this regard.

As Congress considers such important technology transfer issues, I hope you will call upon my MIT colleagues for their expertise. They would be pleased to assist you and your staff in formulating responses to any proposals that threaten to revise the Act in ways that compromise its remarkable contributions to the nation.

Sincerely yours,

Charles M. Vest

CMV/lbm
Enclosures