

NIH Public Meeting on Norvir/Ritonavir March-in Request May 25, 2004

Agenda

Introductory Remarks by Dr. Mark Rohrbaugh

Written Comments Received:

- Senator Birch Bayh
- Robert Huff, Editor, GMHC Treatment Issues
- Norman J. Latker, former Patent Counsel, HEW
- John Erickson, President & CSO, Sequoia Pharmaceuticals
- Dan Ravicher, Executive Director, Public Patent Foundation
- C. Peter Magrath et al., National Association of State Universities and Land Grant Colleges, Association of American Universities, and American Council on Education
- Carl E. Gulbrandsen, Managing Director, Wisconsin Alumni Research Foundation
- Katharina Phillips, Council on Governmental Relations
- Patricia Harsche Weeks, Immediate Past President, Association of University Technology Managers
- Joseph P. Allen, President, National Technology Transfer Center
- Heather L. Mason, Vice President, Pharmaceutical Specialty Operations, Abbott Labs
- Benjamin Young, OHHP, Organization of Healthcare Providers
- Lynda Dee, Co-Chair, AIDS Treatment Activists Coalition, Drug Development Committee
- Julie Britton Haden, West Virginia Coalition for People with HIV/AIDS
- Rhonda Connard and Amanda Lowther, Co-Coordiators, Covenant House AIDS Program
- Michael Weinstein, President, AIDS Healthcare Foundation
- Stephan E. Lawton, Vice President & General Counsel, BIO
- David D. Ho, Director & CEO, The Aaron Diamond AIDS Research Center
- David Gollaher, President & CEO, California Health Care Institute
- David Miller, President, iBio™
- David Halperin, Attorney Counselor
- James Love, President, Essential Inventions, Inc.
- Jerome Reichman, Bunyan S. Womble Professor of Law, Duke University School of Law



PUBLIC MEETING
National Institutes of Health - Building 50
May 25, 2004

- 9:00 **INTRODUCTION**
- 9:05 The Honorable Birch Bayh
- 9:20 Ted Poehler, Ph.D., Vice Provost for Research, Johns Hopkins University,
American Association of Universities
- 9:35 Daniel Ravicher, Executive Director, Public Patent Foundation
- 9:50 John Erickson, President & Chief Scientific Officer, Sequoia Pharmaceuticals
- 10:05 Robert Huff, Editor, *Treatment Issues*, Gay Men's Health Crisis, NYC
- 10:20 **BREAK**
- 10:30 Norman J. Latker, former Patent Counsel, Department of Health, Education and
Welfare
- 10:45 James Love, President, Essential Inventions, Inc.
- 11:00 Andrew Neighbour, Board Member and Chair, Intellectual Property Committee,
Council on Governmental Relations
- 11:15 Jerome Reichman, Bunyan S. Womble Professor of Law, Duke University School
of Law
- 11:30 Benjamin Young, M.D., Ph.D., Organization of Healthcare Providers
- 11:45 Jeff Leiden, M.D., Ph.D., President and Chief Operating Officer, Pharmaceutical
Products Group and Chief Scientific Officer, Abbott Laboratories
- 12:00 **ADJOURN**

INTRODUCTORY REMARKS

Welcome . . .

My name is Dr. Mark Rohrbaugh and I am the Director of the Office of Technology Transfer at the NIH.

Seated next to me is my Deputy Director, Dr. Bonny Harbinger.

Doris Campos-Infantino, the Deputy Ombudsperson for the National Institutes of Health, will be serving as the moderator for this public meeting.

This public meeting is being held pursuant to requests from various constituencies that the Government exercise its march-in rights under the Bayh Dole Act in connection with patents owned by Abbott Laboratories. The constituencies expressed concern over the price of ritonavir (sold under the tradename Norvir), which is covered by these patents and marketed by Abbott for the treatment of patients with HIV/AIDS.

The purpose of this public meeting is to give us an opportunity to listen to comments from representatives of constituencies and to hear various points of view. These comments and viewpoints then will be considered by the NIH in making the decision of whether we have received information that might warrant the exercise of march-in rights. The NIH will make that initial determination and, if necessary, will initiate any formal march-in proceeding as required under the regulations. We will make every effort to come to a decision as quickly as possible.

I will now turn this meeting over to Ms Campos-Infantino.

**STATEMENT OF SENATOR BIRCH BAYH TO THE
NATIONAL INSTITUTES OF HEALTH**

MAY 25, 2004

I appreciate NIH's invitation to comment on the intent of Congress when it enacted the Bayh-Dole law. I am accompanied by Joe Allen, currently President of the National Technology Transfer Center, and formerly my primary staff member who worked on this legislation. The focus of my comments will be the contention that Bayh-Dole gives NIH the ability to control the price of a product developed under the law by exercising the march-in rights provided in Section 203 of its provisions.

Before proceeding, I should emphasize that I am not being compensated to appear here today. Also, I should note that I am not familiar with the specifics of the drug which is the basis of the petition before NIH, so I will not comment on the merits of this particular case. However, I do know the intent of this legislation which I was privileged to sponsor with my friend, Senator Bob Dole.

As NIH proceeds with this examination of the petition, it should prove informative to the responsible officials here at NIH and the petitioners as well, to be reminded of the history behind the introduction and passage of Bayh-Dole. Particular attention should be given to the economic environment which existed prior to the introduction of Bayh-Dole.

By the late 70s, America had lost its technological advantage:

- We had lost our number one competitive position in steel and auto production. In a number of industries we weren't even No. 2.
- The number of patents issued each year had declined steadily since 1971.
- Investment in research and development over the previous 10 years was static.
- American productivity was growing at a much slower rate than that of our free world competitors.
- Small businesses, which had compiled a very impressive record in technological innovation, 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.

What had happened to American innovation, which had sparked generation after generation of international economic success?

Our investigation at the Patent and Trademark Office disclosed that the U.S. government owned 28,000 patents, only 4 percent of which had been developed as a product for use by the consumer.

Close examination disclosed that most patents procured as a result of government research grants, particularly those developed in university laboratories, resulted from basic research. The ideas patented were in the embryonic stages of development. Often millions of dollars were required to produce the sophisticated products necessary for marketability. Since the government refused to permit ownership of the patents, private industry and business refused to invest the resources necessary to bring the products to consumers. As Thomas Edison said: "Invention is 1% inspiration and 99% perspiration." With regard to publicly funded research, government typically funds the inspiration and industry the perspiration.

The well-intentioned voices, such as Senator Russell Long and Admiral Hyman Rickover, opposed Bayh-Dole on the basis "If the taxpayer funds the research, the taxpayer should own the ideas produced." However, the result of this policy was billions of taxpayer dollars spent on thousands of ideas and patents which were collecting dust at the PTO. The taxpayers were getting no benefit whatsoever.

Changes to Bayh-Dole should be made only after giving careful consideration to what has been accomplished by those who have utilized the provisions of the law. The London "Technology Economist Quarterly" called Bayh-Dole "Possibly the most inspired piece of legislation to be enacted in America over the past half century." (I have attached the full text of the article for your information.)

The Economist estimated that Bayh-Dole created 2,000 new companies, 260,000 new jobs, and now contributes \$40 billion annually to the U.S. economy. This assessment was made almost six years ago and more progress has been made since then.

One is entitled to second guess us and say that we should have allowed the government to have a say in the prices of products arising from federal R&D. However, if changes are believed warranted, we have a process for doing so. That is to amend the law. You simply cannot invent new interpretations a quarter of a century later. This is what is being proposed.

When Congress was debating our approach fear was expressed that some companies might want to license university technologies to suppress them because they could threaten existing products. Largely to address this fear, we included the march-in provisions that are the subject of today's meeting.

The clear intent of these provisions is to insure that every effort is made to bring a product to market. If there is evidence that this is not being done, the funding agency can "march-in" and require that other companies be licensed. If the developer cannot satisfy health and safety requirements of the American taxpayer, agencies may march-in.

It was first brought to my attention that attempts were underway to rewrite history when I saw an article in the **Washington Post** on March 27, 2002, entitled *Paying Twice for the Same Drugs*. The crux of the article was that:

Bayh-Dole ... states that practically any new drug invented wholly or in part with federal funds will be made available to the public at a reasonable price. If it is not, then the government can insist that the drug be licensed to more reasonable manufacturers, and if refused, license it to third parties that will make the drug available at a reasonable cost.¹

This view mistakes how our law works. Bob Dole and I responded in a letter to the editor of the **Washington Post** on April 11, 2002 setting the record straight.²

You can imagine my surprise when I see the same arguments were being formally presented in a petition to NIH in an attempt to control drug prices. The quotations in the petition flagrantly misrepresent the legislative history supporting Bayh-Dole. The petition shows complete lack of understanding of how the legislative process works. The current petition says: "The clear language of the Bayh-Dole act requires reasonable pricing of government supported inventions."³ It later adds: "The legislative history evidences an intent to require that government supported inventions be priced reasonably."⁴

All but one of the citations in the petition used to conclude that march-in rights were intended to control prices actually refer to hearings on bills other than Bayh-Dole. While perhaps interesting, these are not pertinent legislative history. I could find only one citation from the real legislative history. Here is the petition language:

This consensus was recorded in the Senate's Committee Report on the bill, which explained that march-in rights were intended to insure that no 'windfall profits,' or other "adverse effects result from retention of patent rights by these contractors."⁵

The petition footnote on this section adds "statement of Senator Bayh that the march-in provisions were meant to control the ability of 'the large, wealthy, corporation to take advantage of Government research and thus profit at taxpayers' expense."¹⁶

Rather than being a statement of fact, my quotation is actually taken from a question I asked the Comptroller General on another topic altogether.

¹ Peter Arno and Michael Davis, "Paying Twice for the Same Drugs," Washington Post 27 Mar. 2002: A21.

² Birch Bayh and Robert Dole, "Our Law Helps Patients Get New Drugs Sooner," Washington Post 11 Apr. 2002: A28.

³ Petition to use Authority Under Bayh-Dole Act to Promote Access to Ritonavir. Supported by National Institute of Allergy and Infectious Diseases Contract No. AI27220 (Essential Inventions, Inc., 2004) 9.

⁴ Ibid., 10

⁵ Petition to use Authority Under Bayh-Dole Act to Promote Access to Ritonavir. Supported by National Institute of Allergy and Infectious Diseases Contract No. AI27220 (Washington: Essential Inventions, Inc., 2004) 10.

⁶ Ibid.

The petition language taken from the Committee report mixes up references to two different sections of the law so that the original meaning is unrecognizable.

Let's see what happens when the petition quotes are placed in their proper context. I highlighted the following language referred to in the petition as it actually appears in the legislative history.

With regard to the petition's footnote, during his testimony I asked Elmer Staats, then the Comptroller General of the United States, a question regarding concerns expressed about the Bayh-Dole bill. Here it is:

Mr. Bayh: "The other criticism comes from those that feel that this bill is a front to allow *the large, wealthy corporation to take advantage of Government research dollars and thus to profit at the taxpayers' expense*. We thought we had drafted this bill in such a way that this was not possible. Would you care to comment on this scenario as a valid criticism?"

Mr. Staats: "Of course, this is the key question. There is no doubt about that. In my opinion, the bill does have adequate safeguards..."

The petition also mixes up Senate Judiciary Committee report language describing two unrelated parts of Bayh-Dole. Here's how the report actually reads with the petition extract highlighted:

The agencies will have the power to exercise march-in rights to insure that no **adverse effects result from the retention of patent rights by these contractors.**⁷

That was the language on section 203, the march-in rights provision. The report continues:

The existence of section 204 of the bill, the Government pay back provision, will guarantee that the inventions which are successful in the marketplace reimburse the Federal agencies for the help which led to their discovery. Although there is no evidence of "*windfallprofits*" having been made from any inventions that arose from federally-sponsored programs, the existence of the pay back provision reassures the public that their support in developing new products and technologies is taken into consideration when these patentable discoveries are successfully commercialized."⁸

⁷ United States. Congress. Senate. Committee on the Judiciary, University and Small Business Patent Procedures Act: Report of the Committee on the Judiciary. United States Senate, on S.414 (Washington: U.S. Government Printing Office, 1979) 30.

⁸ Ibid.

Thus, it is only by inappropriately combining language describing an entirely different section of the law that the words "**windfall profits**" can be made to refer to march-in rights. They clearly do not. Such a representation is highly misleading.

When read in context, the real meaning could not be clearer. Rather than controlling product prices, the language actually provided that the Government should be able to recoup a percentage of its investment when an invention from its extramural funding hits a home run in the market.

In fact, this payback provision of Section 204 was later dropped from the bill altogether because the agencies said that the administrative costs of tracking university royalties would far outweigh any monetary benefits from the one-in-a-million breakthrough invention.

NIH itself has found that price controls are not contemplated by Bayh-Dole. Under pressure in 1989, NIH placed a provision in its intramural collaborations with industry that resulting inventions must demonstrate "a reasonable relationship between the pricing of a licensed product, the public investment in that product, and the health and safety needs of the public."⁹

When industry collaborations began evaporating, and NIH explored the reasons and found:

Both NIH and its industry counterparts came to the realization that this policy had the effect of posing a barrier to expanded research relationships and, therefore, was contrary to the Bayh-Dole Act.¹⁰

If NIH found that price controls on its intramural research are "contrary to the Bayh-Dole Act," how can the same provisions be applied to extramural research?

If Congress does decide to amend Bayh-Dole someone must clearly define what is a "reasonable price." Congress must keep in mind that the vast majority of technologies developed under the law are commercialized by small companies that "bet the farm" on one or two patents. Copycat companies are always waiting until an entrepreneur has shown the path ahead. They can always make things cheaper since they have no significant development costs to recover.

What will happen to the start-up companies arising from Bayh-Dole that are driving our economy forward with this sword hanging over their heads? What evidence is there that large drug companies will not simply walk away from collaborations with our public sector? That is what happened to NIH.

⁹ National Institute of Health, NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interests are Protected (Washington: U.S. Government Printing Office, 2001) 9.

¹⁰ Ibid., 8.

NIH wisely realized that the greater good is to allow American taxpayers to have access to important new products and processes, along with the new jobs and taxes they create than to try and regulate prices.

Bob Dole and I made the same choice in 1980. I still believe that we were correct.

I empathize with the countless individuals in the U.S. and around the world who are suffering from AIDS. If it can be shown that the health and safety of our citizens is threatened by practices of a government contractor, then Bayh-Dole permits march-in rights, not to set prices, but to ensure competition and to meet the needs of our citizens. However, such a procedure must be supported by hard evidence that the need exists. Speculative claims and misrepresentation of the legislative history supporting Bayh-Dole will not suffice.

Let me urge the wisdom of approaching such a decision with great caution. The success of Bayh-Dole goes far beyond the efforts of Bob Dole and Birch Bayh. This legislation combined the ingenuity and innovation from our university laboratories with the entrepreneurial skills of America's small businesses. Most importantly, this combination created the incentive necessary for private investment to invest in bringing new ideas to the marketplace. The delicate balance of ingenuity, entrepreneurship, and incentive upon which the success of Bayh-Dole has depended must not be disrupted.

A few of the products which have been produced in the last six years are:

- Taxol, the most important cancer drug in 15 years, according to the National Cancer Institution.
- DNA sequencer, the basis of the entire Human Genome Project.
- StormVision™, which airport traffic and safety managers use to predict the motion of storms.
- Prostate-specific antigen test, now a routine component of cancer screening.
- V-Chip, which allows families to control access to television programming.

It would be the ultimate folly to march in and alleviate the problem addressed by the petition, availability of a drug to treat AIDS today, and in so doing dampen the ingenuity, entrepreneurial skills and incentive necessary to develop a permanent cure for AIDS, or for that matter the cure for other diseases that plague all too many American mothers, fathers, children and seniors today.

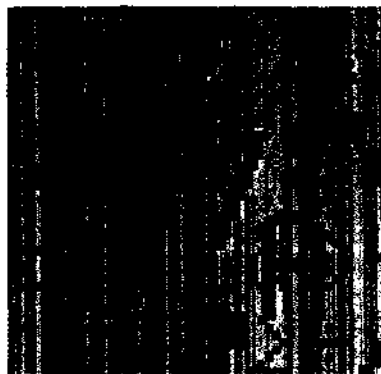
As you search for a solution to the problem before us today, be aware of unintended consequences tomorrow. Insuring the health of our citizens requires the wisdom and determination for a long journey. The procedures of Bayh-Dole have saved countless lives and pain and suffering. It provides an incentive for further progress in the future.

Thank you

Works Cited

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- . University and Small Business Patent Procedures Act: Report of the Committee on the Judiciary, United States Senate, on S.414. Washington: U.S. Government Printing Office, 1979.

Innovation's golden goose



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The reforms that unleashed American innovation in the 1980s, and were emulated widely around the world, are under attack at home

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. 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 augmentation 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 measure helped to reverse America's precipitous slide into industrial irrelevance.

Before Bayh-Dole, the fruits of research supported by government agencies had belonged strictly to the federal government. Nobody could exploit such research without tedious negotiations with the federal agency concerned. Worse, companies found it nigh impossible to acquire exclusive rights to a government-owned patent. And without that, few firms were willing to invest millions more of their own money to turn a raw research idea into a marketable product.

The result was that inventions and discoveries made in American universities, teaching hospitals, national laboratories and non-profit institutions sat in warehouses gathering dust. Of the 28,000 patents that the American government owned in 1980, fewer than 5% had been licensed to industry. Although taxpayers were footing the bill for 60% of all academic research, they were getting hardly anything in return.

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 car-

ried 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 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 such attack in America.

No free lunch

There has always been a fringe that felt it was immoral for the government to privatise the crown jewels of academic research. Why, they ask, should taxpayers be charged for goods based on inventions they have already paid for?

That is easily answered. Invention, as TQ has stressed before, is in many ways the easy bit. A dollar's worth of academic invention or discovery requires upwards of \$10,000 of private capital to bring to market. Far from getting a free lunch, companies that license ideas from universities wind up paying over 99% of the innovation's final cost.

Then there is the American Bar Association, which has lobbied hard to get the government's "march-in" rights repealed. The government has kept (though rarely used) the right to withdraw a licence if a company fails to commercialise an invention within a reasonable period. This was to prevent companies from licensing academic know-how merely to block rival firms from doing so. The lawyers argue that the government could use its walk-in rights to bully pharmaceutical firms into lowering the price of certain drugs.

Whatever the merits of their case, suffice it to say that the sole purpose of the Bayh-Dole legislation was to provide incentives for academic researchers to exploit their ideas. The culture of competitiveness created in the process explains why America is, once again, pre-eminent in technology. A goose that lays such golden eggs needs nurturing, protecting and even cloning, not plucking for the pot. Readers who agree or disagree can share their own views at www.economist.com/forums/tq. •

Public Meeting at the National Institutes of Health (NIH)

May 25, 2004

The Public Health Impact of Abbott Laboratories'
Unreasonable Terms for Norvir

Robert Huff
Editor, GMHC Treatment Issues
Gay Men's Health Crisis
New York

Good Morning.

My name is Bob Huff. I am the editor of GMHC Treatment Issues, a monthly newsletter about HIV treatment research published by Gay Men's Health Crisis in New York, the world's first and largest AIDS service organization.

We've seen a revolution in AIDS treatments over the past ten years, but the therapies we have are not perfect. I'm here today because I am keenly interested to see that the innovation of more effective and less toxic HIV drugs continues.

In the first part of December 2003, the HIV/AIDS treatment community was shocked to hear that Abbott Laboratories was raising the price of its HIV drug, Norvir, five-fold. The price per 100mg pill would increase from \$2.14 to \$10.71 apiece.

As you've heard, although Norvir was developed and approved by the FDA as an anti-viral drug -- an inhibitor of the HIV protease enzyme -- due to excessive toxicity, it is no longer used as such. Instead it is now used for an off-label indication in much lower doses to take advantage of one of its side effects, namely the inhibition of a metabolic pathway in the liver that effectively improves the concentration of other drugs in the blood. In current clinical practice, most other HIV protease inhibitors are "boosted" by Norvir, which increases their effectiveness. In other words, Norvir enables other drugs to work better.

Here is a before-and-after price chart that shows the six approved HIV drugs that can be boosted by Norvir, and how the price increase has affected their overall cost. Note that the price of Norvir in its approved dosage as an antiviral is far out of proportion to the others. Also note that the price of the drug Kaletra, which is also made by Abbott and contains a small boosting dose of Norvir in each pill, did not change and is now the lowest price boosted protease inhibitor on the market. It is clear that the practical and intended effect of the Norvir price increase was to position Kaletra in advantage to its competitors.

Here is another chart that shows a timeline for the development of some HIV drugs that require Norvir boosting. It includes two protease inhibitors that were approved last year (Reyataz and Lexiva) and several currently in development. It seems clear to me that the Norvir price increase was calculated to come just after these two new drugs received approval. But I'm more concerned about the drugs that are still on the path to approval -- and about potentially useful drugs that may now never enter clinical development -- because they would be at the mercy of Abbott's monopoly on Norvir.

I would like to argue that Abbott's failure to make Norvir available on reasonable terms will adversely affect the development of new drugs that depend on metabolic boosting and will limit the amount of research that will be conducted on existing drugs that require boosting. I believe that the public health is threatened by the restricted availability of Norvir caused by Abbott's unconscionable price increase.

Abbott's abuse of their patent on Norvir will limit patient access to drugs, limit research, limit options for doctors and limit the innovation of new-generation drugs of this type. This is why you are being asked to protect the public against Abbott's unreasonable use of the Norvir patents.

Before a pharmaceutical manufacturer decides to invest hundreds of millions of dollars into bringing a promising compound along the path to FDA approval, the company projects the market for the drug over the entire expected life of the product. While this isn't easy, given the rapid

pace of change in HIV therapy, it is necessary to forecast whether the drug will be competitive and will repay the considerable investment of clinical development. For the makers of Norvir-boosted drugs in the pipeline, Abbott's price increase has thrown these forecasts into chaos.

In seeking to mitigate the impact of the 400% increase in the price of Norvir, Abbott has announced it will make the drug available at the old price for research purposes to companies that are developing a drug that requires Norvir-boosting. However this offer expires once the new Norvir-dependent drug receives FDA approval and goes on the market.

Yet research on these drugs can not and must not end with approval. Post-market research, so-called Phase IV studies, are important to "fill in the blanks" about how a drug behaves in real-world settings and to provide controlled data that helps physicians make the most appropriate use of all the drugs in their armamentarium.

Much of this Phase IV research is mandated by the FDA and some is initiated by the company for marketing purposes. For the recently approved protease inhibitors, the 400% increase in the price of Norvir means that the cost of post-marketing research has now increased dramatically. One pharmaceutical executive estimated that the cost of post-approval research could go up by \$20 to \$30 million. And this is for drugs that have already been approved, with FDA-mandated post-market research already planned and budgeted.

The impact on drugs still in the pipeline is far more insidious.

A drug company's Phase IV research commitments are decided in negotiations with the FDA. The FDA says it will grant accelerated approval based upon available safety and efficacy data, but only if the company will show a plan for continuing research on the drug after entering the market. These research plans are negotiated based on what the FDA would like to see and what the drug company can afford. The simple fact is that after the 400% rise in the price of Norvir, companies will not be able to afford as much post-market research. And the high price of Norvir will effectively tie the hands of the FDA in what they can ask of companies. This is going to hurt patient care.

There are four Norvir-dependent drugs in the pipeline that this will affect. Abbott's monopoly on Norvir means that there will be less post-marketing research and, consequently, less important real-world medical information produced on how to use these drugs, for example, in women, in people of color, in prisons, in combination with other drugs, in people with hepatitis infections or in people with liver or kidney disease. Much of this research will become too expensive. How much important, useful and desperately needed medical information will never see the light of day because of Abbott's abuse of its patent monopoly on Norvir?

Then there are the government research networks, such as the AIDS Clinical Trials Group (ACTG) at the National Institutes of Health. An investigator might want to use a Norvir-boosted drug in studies of treatment strategies for people with few remaining options, or in women, or in special, under-studied populations. But if they can't afford the Norvir, then they will have to abandon those studies or turn to Kaletra. Even if Abbott would agree to provide Norvir for free ~~(and so far they have refused)~~, these government researchers will have to ask: How useful will the resulting data be down the road if we study drugs that, while promising, will, in practice, be unaffordable and go unused? So, once again, Abbott's Norvir monopoly will hold back research, limit medical knowledge and hurt patient care.

But my main concern is with what Abbott's monopoly on Norvir means for the future. One pharmaceutical executive I spoke to, in evaluating the impact of Abbott's action, posed this as a rhetorical question: "Who would risk developing a Norvir-boosted protease inhibitor after this price increase?" What he meant was that, not only will the high price of Norvir place any new Norvir-dependent drug into an uncompetitive price stratum, but Abbott's unpredictable behavior has made depending on them or their products an unsupportable risk. It's difficult enough to project market conditions for new HIV drugs that don't need Norvir; it's very unlikely that a corporate market analysis will ever again justify investment in drugs of this type. In the words of another pharmaceutical executive, after the

drugs currently in the pipeline empty out, "We've seen the end of the line for boosted protease inhibitors."

And that is a shame, because we desperately need new protease inhibitors to treat drug-resistant HIV. The so-called HIV salvage population is the fastest growing market segment in HIV therapy. Drugs with incremental benefits have continued to trickle onto the market over the past few years, but in practice, this has resulted in many patients simply adding the latest therapy onto a failing regimen, which starts the cycle of resistance all over again. Unless a person switches to multiple drugs that his virus is susceptible to, the development of resistance seems inevitable.

For drugs in the protease inhibitor class -- which are very durable HIV therapies -- Norvir has assumed a crucial, enabling role by assuring that sufficient blood levels of the active antiviral drugs are achieved. Looking ahead, we can foresee the continued need for new protease inhibitors that will have novel resistance profiles, that will have less toxicity, and that are more durable. Some of the drugs in the pipeline have some of these qualities, but none has all of them. Most observers expect the protease inhibitors in the pipeline to continue towards approval because their sponsors have already made substantial financial commitments to their development. But how many important, useful, and desperately needed drugs will now never see the light of day -- because of Abbott's monopoly on Norvir? Abbott's unreasonable terms for Norvir will inhibit innovation, restrict research, limit medical options and hurt people with HIV.

Finally, the pricing issue aside, Abbott has not been a responsible custodian of this drug. Although Norvir's usefulness is as a metabolic booster and not as a protease inhibitor as they had hoped, the company has not made the drug available in dosages that would optimize the use of Norvir for this purpose. With only a 100mg pill of Norvir available, many patients who would only require 50mg or less for boosting are being subjected to unnecessary toxicity. (Kurowski)

Furthermore, Abbott has not sought FDA approval for Norvir as a metabolic boosting agent and continues to represent the drug in medically inaccurate terms, while encouraging continued off-label use.

Also, Abbott has, I have been told by several pharmaceutical executives, been unwilling to offer reasonable terms for licensing Norvir for co-formulation with other companies' drugs, even though a co-formulated pill is widely considered to help simplify drug regimens and improve patient adherence and therapeutic outcomes. The FDA, in a recent guidance document on fixed dose combinations (FDC) said:

"Kaletra (lopinavir/ritonavir), an approved FDC, is an antiretroviral combined with a metabolic booster; a low dose of ritonavir... Other HIV protease inhibitors are often administered with low doses of ritonavir and may be suitable for co-packaging or co-formulation. *FDA encourages sponsors to develop FDCs for this type of drug combination to help in simplifying regimens.*" (FDA)

Yet Abbott, in order to protect its own, more toxic Kaletra product, continues to resist this.

To sum up, Abbott has behaved unconscionably, and perhaps illegally, in increasing the price of Norvir, and in doing so they have abused the privilege of their patents.

- o They have attempted to manipulate the market and restrict patient access to competing drugs that have less toxicity.
- o They have increased the financial burden their competitors face in performing important post-market research.
- o They have tied the hands of the FDA in how much post-market research can be required of drugs approaching approval.
- o They have stifled innovation and have killed the market chances for any new drug candidate that would require Norvir.
- o They have not been responsive to the medical need for safer and more rational doses of Norvir.
- o They have refused reasonable offers to license Norvir for co-formulation into patient-friendly combinations with other drugs.

With at least ten HIV drugs (and I haven't discussed potential drugs for hepatitis C and other illnesses) dependent on Norvir to achieve optimal efficacy and minimal toxicity, I believe Norvir should be considered a public amenity and be contracted to more responsible custodians.

I'd like to note that I think the case of Norvir is an exceptional one, and that I fully support industry development programs that build on government funded research. It seems clear that the intent of the Bayh-Dole Act was to stimulate innovation, and in this it has been very successful. But it also seems clear that a mechanism was provided to address abuse, and that, in Norvir, we are confronted with that rare case.

Under Abbott's monopoly control of Norvir, drug access (both to Norvir and to dependent drugs), patient care, innovation, research, and medical options are being restricted. The public interest would best be served by making this vital resource more broadly available under much more reasonable terms.

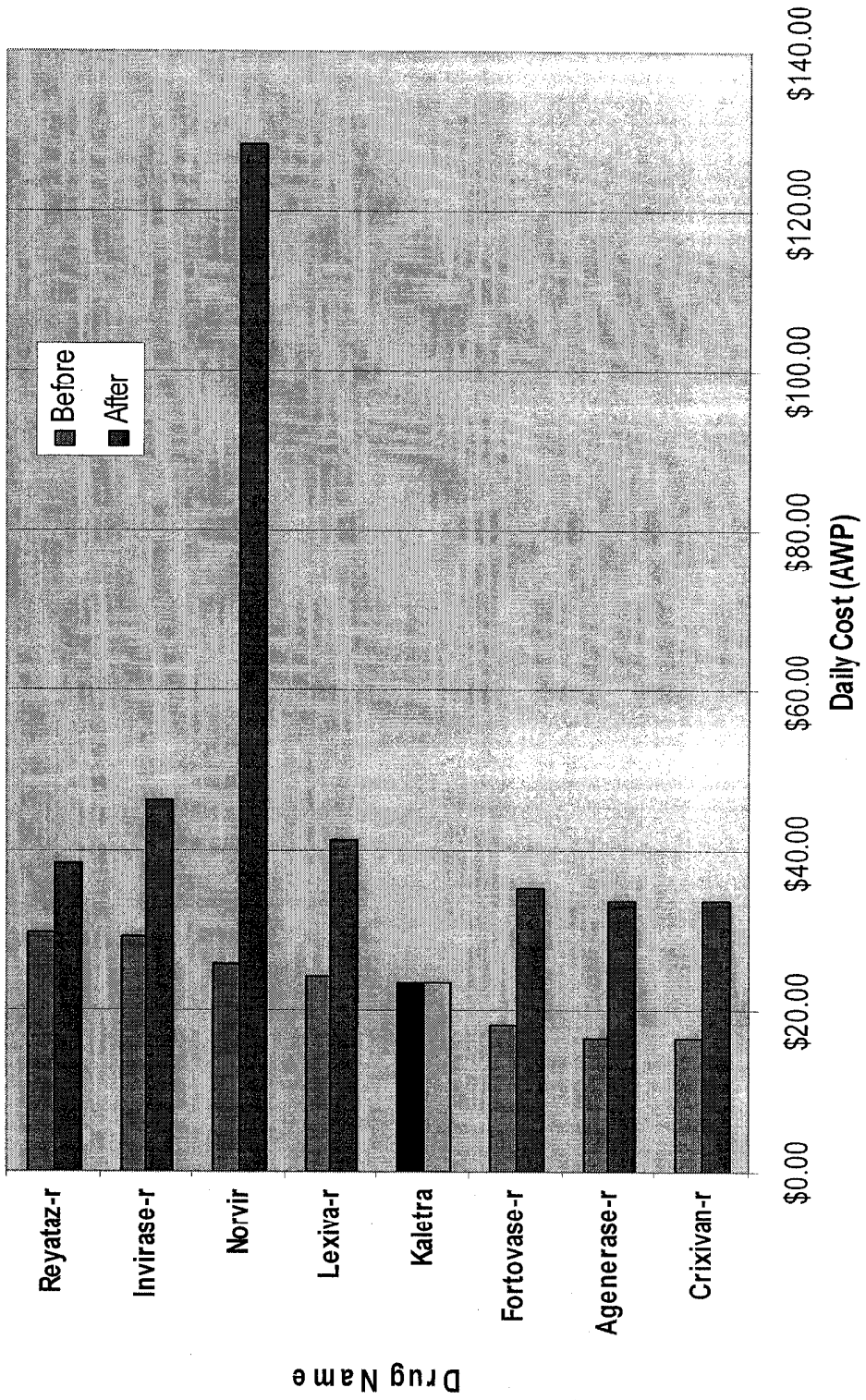
Thank you.

References:

Kurowski ML. Influence of 50 mg, 100 mg and 200 mg ritonavir on the pharmacokinetics of amprenavir after multiple doses in healthy volunteers for once daily and twice daily regimens. 1st IAS Conference on HIV Pathogenesis and Treatment. 8-11 July 2001. Buenos Aires. Abstract 351.

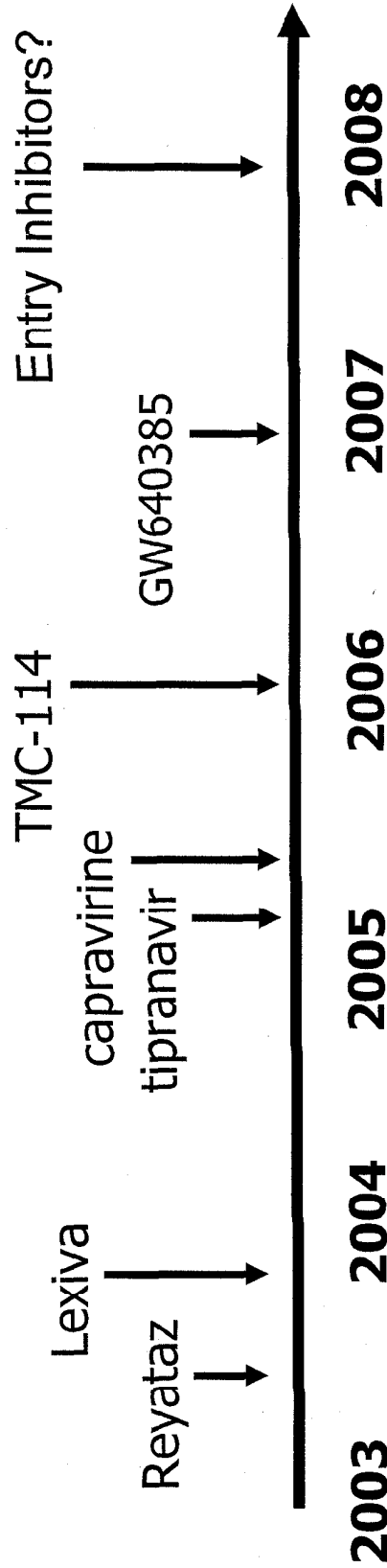
U.S. Food and Drug Administration (FDA). Guidance for Industry: Fixed Dose Combination and Co-Packaged Drug Products for Treatment of HIV. DRAFT GUIDANCE, May 2004.

Boosted HIV Drug Prices Before and After Norvir Price Increase



HIV Drug Pipeline

Drugs dependent on Norvir boosting



400% Norvir
price
increase

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 202c which sets out all the contractors obligations.

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 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 under sec.202c.

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. Healthcare reform is long overdue. It will be a long, bruising political battle, but the country must, and will, address it.

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 undeniably 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.

It is also legally impossible. 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.

ON THE ROLE OF THE US GOVERNMENT IN THE DEVELOPMENT OF NORVIR^R

My name is John Erickson. I am the President and Chief Scientific Officer of Sequoia Pharmaceuticals Inc., a small for-profit drug discovery company located in Maryland, focused on the development of new therapeutic approaches to combating drug resistant infections with an emphasis on HIV/AIDS. I am also the Founder of the Institute for Global Therapeutics, a non-profit, 501(c)(3) organization founded by my wife and I to develop safe, effective and affordable new therapeutic approaches to combating drug resistant infections, with an emphasis on HIV/AIDS, for resource-poor settings. I have been involved in HIV/AIDS drug discovery and development for most of my career, first as a researcher and project leader, later as a government laboratory director, and, most recently, as an entrepreneur-scientist, investor and fund-raiser of for-profit and non-profit drug discovery activities. Most of my drug discovery work has focused on the development of new HIV protease inhibitors such as Norvir^R.

I was a scientist at Abbott from 1985-1991, during which time I initiated a new research program to discover HIV protease inhibitors. Because we received federal funding for this program, and because this program ultimately led to the development of Norvir, I have been asked to describe the role that US government funding played in the development of Norvir. I am not here to give a learned opinion of the petition, nor on the legal aspects of the petition. I am here out of a sense of civic duty and in the spirit of Abraham Lincoln who said "If you give the people the truth, the [Re]public will be safe". But I cannot help but take the opportunity of this forum to also comment on the larger issue of drug pricing, a powerful market force that has daily and long-term effects on drug discovery activities whether they are in profit or non-profit settings.

Now for some historical facts.

In 1988, Abbott received a grant under a federally chartered program known as the National Cooperative Drug Discovery Group for AIDS (which I will refer to as the

NCDDG program or grant). The NCDDG programs for AIDS were administered by the National Institute of Allergy and Infectious Diseases in the Department of Health and Human Services. The purpose of the NCDDG program was to promote synergy among government, industry and academic laboratories to translate basic research findings on HIV into novel antiretroviral therapies. The NCDDG-AIDS program was a response to the national health crisis that HIV/AIDS represented in the 1980's. At that time, and in sharp contrast to today, targeted antiviral research programs were largely non-existent in the pharmaceutical industry. Thus, the NCDDG program also was a tacit recognition by the government that getting the pharmaceutical industry engaged in this effort would be essential for the rapid development of new and effective antiviral drugs.

The award of the NCDDG-AIDS grant gave the HIV project a much-needed funding boost. In my opinion, it catalyzed the development of the antiviral program. I have often been asked "if not for the NCDDG grant, would Norvir exist today?" A fair question, that no one can answer with certainty. What is certainly true is that the federal grant facilitated the research that led directly to the development of Norvir. Let me explain.

As the Principal Investigator, I was responsible for the conduct of research performed under the grant. I used the funding to recruit a team of scientists to develop a new type of antiviral drug that we hoped would inhibit the spread of HIV infection by blocking a viral-encoded enzyme, called HIV protease. This was an entirely new area of research that required a critical mass of scientists from different disciplines. Without the prestige and dollars that came with the NCDDG award, it is unlikely that the HIV protease inhibitor project would have received internal funding at the time. Interest in HIV as a therapeutic area by pharmaceutical companies was the exception rather than the rule in the late 80's. The NCDDG grant gave us an opportunity to take a risk that management was not yet prepared to take on its own. The helping hand of government risk-sharing was accepted again by Abbott a few years later when it was time to take a drug candidate known as A77003 into the costly clinical development phase of research.

A77003, an early precursor of Norvir, was a highly potent inhibitor of HIV, but could not be administered in oral form. Since we had no idea whether a protease inhibitor would be effective in an HIV-infected patient, we thought it made sense to do a proof-of-concept study to test the drug's efficacy using a parenteral route of administration. However, Abbott was not ready to undertake the clinical development of A77003 because it was concerned that an intravenous compound would not generate sufficient revenue to justify the investment. When the government saw the potential benefit of our new medicine, it agreed to fully fund and to conduct the necessary pre-clinical and clinical development phases up to and through Phase II trials. Abbott agreed to manufacture and provide the necessary drug quantities for the studies. And so, in 1991, a drug development collaboration was born between Abbott, the National Cancer Institute and the National Institute for Allergies and Infectious Diseases. A77003 never made it beyond early Phase I studies; but the commitment of the government to assist Abbott in dollars and in-kind in the development of its protease inhibitor program was never in doubt.

In 1991, I was recruited to the NCI to establish a structure-based drug design research program focused on cancer and AIDS. I continued working with some of my former research team members from Abbott to understand the critical features of how symmetry-based inhibitors interacted with the target enzyme; we published several papers together during the period 1991-1994 or so. I also began a study to evaluate the resistance profile of Norvir when, around 1995, our collaboration was terminated by Abbott, due to a growing concern that the government might try to exert price controls on Norvir. The company [Abbott] worried that if the AIDS community came to perceive that the government had played a major role in the development of Norvir, that it might try to pressure the government to influence the price of Norvir downwards. This demonstrates the powerful influence that even the perception of drug price tampering by the government can have on fragile public-private partnerships.

I want to turn now to the subject of how Norvir is actually used in the fight against HIV/AIDS today. Norvir is not a typical HIV drug. In addition to its antiviral activity, Norvir has the unexpected property of inhibiting its own metabolism, which makes it stay

in circulation longer. Since it inhibits the same metabolic enzymes that are responsible for breaking down and eliminating many other drugs, including competitors' protease inhibitors, co-administration of Norvir with these drugs can lead to higher than normal blood levels and prolonged circulation half-lives. This effect is termed "pharmacokinetic boosting". Because of the boosting effect, low dose Norvir is commonly co-prescribed in all antiviral cocktails that contain a protease inhibitor. It is commonly accepted practice to prescribe Norvir as an "off label" booster with all six FDA-approved protease inhibitors. You might think from what I have said that Norvir would be the ideal protease inhibitor to take all by itself, since it effectively boosts itself. However, due to poor tolerability and adverse side effects Norvir is rarely prescribed in antiviral dosages [1200 mg/day]. Instead, it is taken in 50 or 100 mg 'baby' doses along with one of the other protease inhibitors. Abbott has replaced Norvir by a new first-line protease inhibitor, Kaletra^R, which is actually a co-formulation of low dose Norvir combined with a high dose of lopinavir, a Norvir analogue that has a superior safety profile.

So, it's important to understand that the price increase of Norvir that is at the center of today's hearing does not really affect the price of Kaletra, even though it contains Norvir. What it does affect, though, is the price of every competing protease inhibitor because they must all be taken with Norvir, which is sold separately at a price comparable to that of the active antiviral agent. The net result of the price increase is that Kaletra has gone from being one of the more expensive protease inhibitor options, before the price hike, to the least expensive protease inhibitor after the price hike. It is also one of the most effective protease inhibitors on the market today, and is responsible for helping to turn AIDS from a death sentence to a chronic, treatable disease. There are still many problems to be solved in HIV therapy, including the growing problem of drug resistant HIV infections.

I would like to turn the focus of my remaining remarks on the issue of drug prices. It is difficult to find the right balance between the interests of a private company, where success is measured primarily by revenues and share value, and the public interests of the nation, where success is measured by our personal health and well-being. This is a public policy discussion that needs to take place on national, state and local levels. My hope is

that this hearing, catalyzed by the consumer advocacy group Essential Inventions, and convened by the DHHS, will become an important component of an ongoing dialogue on how we, as a nation, deal with the health of our own people.

An important viewpoint was expressed at a meeting I attended in Malaysia earlier this year, in which Mary Robinson, former President of Ireland, stated so eloquently the case for health being a basic human right. If we as a society come to embrace the notion of health as a human right, in the same way as we view the education and welfare of our children as a basic right, then, and only then, will we begin to develop the frame of mind needed to justify directing our public funds to support the costly and high-risk, but essential, R&D required to bring new drugs to the marketplace.

To put it in other terms, if the public wants lower drug prices, the public should be willing to front the risk money for drug development. I don't think we Americans believe in free-riding, but we also don't like being taken for a ride by the rest of the industrialized world whose governments provide price protection. As long as drugs and health care services are considered to be commodities, then drug prices, like energy prices, will be driven by market forces, and may run counter to the public good.

In conclusion, I hope that this historic hearing over whether the government should exercise its statutory 'march-in' rights over Norvir will become part of a record of a thoughtful dialogue between the public and private sectors on how best to share the enormous R&D risks involved in bringing important new drugs to the nation, and eventually to the world's public health marketplaces.

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April 29, 2004

Dr. Mark Rohrbaugh
Director of the Office of Technology Transfer
Office of Intramural Research
National Institutes of Health
6011 Executive Blvd., Suite 325
Rockville, MD 20852

Re: Analysis of Patents Relevant to the Ritonavir Petition

Dear Dr. Rohrbaugh:

As Executive Director of the Public Patent Foundation ("PUBPAT"), a not-for-profit legal services organization working to protect the public from the harms caused by wrongly issued patents and unsound patent policy, I write to provide patent related information and analysis pertinent to Essential Inventions' Petition to Promote Access to Ritonavir ("Ritonavir Petition").

By way of introduction, I am a registered patent attorney with extensive experience litigating, licensing, prosecuting, and otherwise counseling clients with respect to patents. Prior to founding PUBPAT, I practiced patent law with Skadden, Arps, Slate, Meagher & Flom, LLP, Brobeck, Phleger & Harrison, LLP, and Patterson, Belknap, Webb & Tyler, LLP, all in New York, and served the Honorable Randall R. Rader, Circuit Judge for the U.S. Court of Appeals for the Federal Circuit in Washington, D.C. A substantial segment of my experience has focused on pharmaceutical patent issues, including the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act") and the role of the Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations publication ("Orange Book"). In addition to litigating several generic pharmaceutical patent infringement cases, otherwise called ANDA cases, I have also comprehensively evaluated the patent portfolios of pharmaceutical companies and issued opinions regarding the scope and validity of specific pharmaceutical patents.

PUBPAT has undertaken a review of the patents pertaining to Abbott Laboratories' ritonavir drug products. In total, there are 5 patents listed by Abbott in the Orange Book for its approved ritonavir capsule product. Of those 5, the Ritonavir Petition would, if granted, provide access to 4, leaving only one patent, U.S. Patent No. 6,232,333 ("333 patent"), as a potential barrier to making an effective generic ritonavir capsule product. Table 1 below sets forth the Orange Book patent listing for Abbott's ritonavir capsule product and also indicates which of those patents are subject to the Ritonavir Petition.

<u>Patent No.</u>	<u>Listed for Abbott's Ritonavir Capsule</u>	<u>Subject to the Ritonavir Petition</u>
5,541,206	Yes	Yes
5,635,523	Yes	Yes
5,648,497	Yes	Yes
5,846,987	Yes	Yes
6,232,333	Yes	No

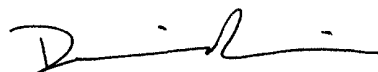
Table 1: Orange Book Listed Patents for Abbott's Ritonavir Capsule

The '333 patent, unlike each of the other 4 patents listed for Abbott's ritonavir capsule, does not claim the active ingredient, ritonavir, itself. Rather, it merely claims a pharmaceutical composition containing ritonavir. Upon initial review, we have serious doubts about the validity of the '333 patent and its applicability to an effective generic ritonavir product. One issue regarding the '333 patent's validity is that its Abstract and Specification purport to teach an invention providing "improved bioavailability." Yet, no such limitation is present in any of the '333 patent's claims. Such a missing limitation means that the scope of the claims is much broader than what the patent otherwise purports to cover. This breadth of the claims increases the likelihood that they are invalid.

Regardless, the existence of the '333 patent in no way detracts from the importance or utility of the Ritonavir Petition. Access to the technology claimed in the 4 other patents that pertain to ritonavir is absolutely necessary to making an effective ritonavir capsule product available to the American public on fair terms. Further, a potential producer of a generic ritonavir product is much more likely to challenge the '333 patent if it stands alone as the sole patent at issue than if the other 4 patents must also be dealt with. This is especially true since the '333 patent has such glaring validity issues and may be much more easily designed around than the other 4 patents since it does not cover the active ingredient ritonavir itself.

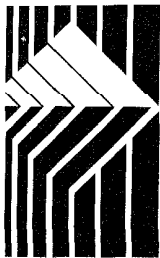
In conclusion, there is absolutely no patent related reason to quell support of the Ritonavir Petition. If PUBPAT can be of any further assistance with respect to this matter, please do not hesitate to contact me.

Sincerely,



Dan Ravicher

cc: James Love
Essential Inventions, Inc.



April 22, 2004

Dr. Mark Rohrbaugh
Director of the Office of Technology Transfer
Office of Intramural Research
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, MD 20852

Dear Dr. Rohrbaugh:

On behalf of the National Association of State Universities and Land-Grant Colleges (“NASULGC”), the Association of American Universities (AAU), and the American Council on Education (“ACE”), we are writing to share our views about the two petitions filed with the National Institutes of Health (NIH) to exercise Bayh-Dole march-in rights to require Abbott Laboratories to lower the price of several drugs developed from NIH extramural research.

The petitions are rooted in the proposition that march-in rights can be exercised to maintain the accessibility and affordability of an essential medical invention. Neither the plain meaning nor the public policies that undergird the Bayh-Dole Act permit a march-in based on affordability. March-in is not a surrogate for government price controls on products that result wholly or in part from federal funding. March-in is reserved only for the purpose of prompt commercialization of federally funded inventions and to avoid the possibility of the stifling of new product development.

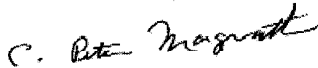
The subject of delivering affordable health care to the American public is a serious one, worthy of policy debate; it is ongoing in Congress in the context of Medicare reform and drug reimportation. Debate about the quality and accessibility of health care is especially worthwhile when life-saving drugs involving potentially fatal diseases, such as HIV-AIDS, are involved. But, the Bayh-Dole Act is not the proper forum for this debate. The Act does not confer regulatory authority on the NIH to impose price controls either globally or on a case-by-case basis. Nor should the Patent Act, in which the Bayh-Dole Act resides, be used as a compulsory mechanism for reasonable drug pricing.

If the NIH were to interpret its authority so as to exercise march-in rights, we are deeply concerned that the Bayh-Dole Act, one of this country’s most successful statutes, could be subjected to a litany of unintended consequences. The ability of universities to make their federally funded technologies available for public benefit would be undermined, and the incentive for the private sector to invest in federally funded discoveries would be removed. In the final analysis, the synergy between federal funding, university research and the private sector for product development could be lost.

Dr. Rohrbaugh
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April 22, 2004

In short, the Bayh-Dole Act has become a driving force for successful research activities from which the U.S. economy and the American public have benefited. Any administrative action taken by the NIH must recognize the success of the Act and its limitations as a price-control mechanism.

Cordially,



C. Peter Magrath
President, NASULGC



Nils Hasselmo
President, AAU



David Ward
President, ACE

CPM/rh



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April 15, 2004

Dr. Mark Rohrbaugh
Dir. of the Office of Technology Transfer
Office of Intramural Research
National Institutes of Health
6011 Executive Blvd. Suite 325
Rockville, MD 20852

Dear Dr. Rohrbaugh:

WARF will celebrate its 79th anniversary this year. We were one of the first university affiliated technology offices in the United States. Howard Bremer of WARF was instrumental in the development of the Bayh-Dole Act. Given this history we write to oppose the recent petitions filed by Mr. James Love and Mr. Sean Flynn of Essential Inventions, Inc. requesting the National Institutes of Health invoke the march-in provisions of the Bayh-Dole Act to invalidate exclusive drug patents held by Abbott Laboratories and Pfizer Inc.

The Bayh-Dole Act is a patent law and not a price control law. There is nothing in Bayh-Dole that gives the government authority to march-in to control prices. March-in rights are intended to insure development of important products that improve the human condition and add to the U.S. economy. The Act has achieved tremendous success. When Bayh-Dole was enacted in 1980, less than 30 universities had technology transfer programs. Today, there are over 300 university technology transfer programs that are using local ideas, contacts and initiatives to insure the development and use of federally supported research.

The granting of this petition would be a severe blow for all of the university technology transfer offices. The patent received by universities would be encumbered. The consequence of that would be to make it difficult if not impossible to license technologies to the private sector. The twenty-five years of Bayh-Dole success of partnerships between federal government, university research and private sector development could be lost. How ironic it would be if as countries all over the world are attempting to implement their version of Bayh-Dole, our government would make a decision that could destroy the program that these countries are attempting to implement.

The Bayh-Dole Act is an important catalyst for university private sector collaborators. All sectors of our economy have benefited. Please do NOT take any actions that could put these benefits in jeopardy.

Sincerely,



Carl E. Gulbrandsen
Managing Director



COUNCIL ON GOVERNMENTAL RELATIONS

1200 New York Avenue, N.W., Suite 320, Washington, D.C. 20005
(202) 289-6655/(202) 289-6698 (FAX)

April 5, 2004

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

Dear Dr. Rohrbaugh:

The Council on Governmental Relations (COGR) is an association of 150 of the leading research universities in the United States and several affiliated hospitals and research centers. COGR focuses on understanding federal policies and complying with federal regulations pertaining to sponsored research at universities. Among the most important policies and regulations of interest to our members are those pertaining to the transfer of federally funded research results at universities to the private sector under the Bayh-Dole Act of 1980 (P.L. 96-517; 35 USC 200-212).

The Bayh-Dole Act plays a critical role in enabling university innovations that have been crucial to U.S. economic growth and competitiveness. Bayh-Dole established the major mechanism for successfully transferring federally funded research results from the laboratory to products and services, which benefit all Americans. Bayh-Dole's success is derived from its consistency with America's commitment to free market principles and incentives.

Many studies have demonstrated the phenomenal success of the Bayh-Dole Act. For example, according to an article in the December 12, 2002, *The Economist*, "The Bayh-Dole Act of 1980 is perhaps the most inspired piece of legislation to be enacted in America over the past half-century....this unlocked all the inventions and discoveries that have been made in laboratories throughout the United States with the help of taxpayers' money...."

We understand that NIH has been asked to answer recently submitted petitions for exercise of march-in rights that, according to the authors of the legislation, Senators Birch Bayh and Robert Dole, are based on a fallacious premise. March-in rights accrue to the government only for the purpose of ensuring prompt commercialization of federally funded inventions and to avoid the possibility of companies stifling the development of new products. The legislation does not empower the government in any way to influence or to dictate licensing or commercialization terms for technologies. NIH itself has confirmed this interpretation (NIH Plan to Ensure Taxpayers' Interests are Protected, July 2001).

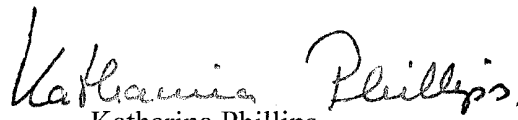
Dr. Rohrbaugh
April 5, 2004
Page Two

NIH may feel challenged to review its longstanding interpretation of the conditions under which the government may exercise march-in rights. Given the critical role played by the Bayh-Dole Act in the continuing success of university technology transfer, COGR believes that any proposed change to such a longstanding interpretation should be subjected to close scrutiny. If this were to become necessary, all stakeholders in the continuing success of technology transfer from universities should participate fully in the consideration of the scope of government march-in rights to ensure that the public-private partnership in innovation is maintained.

COGR is concerned that a substantial reinterpretation of the Bayh-Dole's march-in provisions could undermine the ability of universities to make their federally funded technologies available for public use. Any such 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 and obligations between the three partners - government, universities and industry - which has been the basis for the success of this legislation. History has proven how important incentives are for encouraging technology transfer from the universities. It would be ironic, indeed, if a change in the current understanding of march-in rights were to impair the dissemination of, and public benefit from, university research results.

For these reasons, COGR urges the NIH to make a strong statement in support of the proper exercise of march-in rights as stated by Senators Bayh and Dole, which was recently reconfirmed in their letter dated April 11, 2002 in the Washington Post. NIH surely is aware of the importance of the Bayh-Dole Act to public-private partnerships in innovation. We see no reason to tamper with this proven platform for promoting government investment in discovery and its application for public use and benefit.

Sincerely,


Katharina Phillips



ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS®

60 Revere Drive, Suite 500, Northbrook, IL 60062 USA

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

Dear Dr. Rohrbaugh:

We are writing on behalf of the Association of University Technology Managers (AUTM®), to comment on the petition to use the authority under the Bayh-Dole act to promote access to: (a) Ritonavir, supported by National Institute of Allergy and Infectious Diseases Contract no. AI27220; and (b) Latanoprost, supported by U.S. Public Health Service Research Grant Numbers EY 00333 and EY 00402 from the National Eye Institute, filed by Essential Inventions, Inc. with Secretary Thompson on January 29, 2004. AUTM® is a nonprofit association with membership of more than 3,200 technology managers and business executives who manage intellectual property at over 300 universities, research institutions, teaching hospitals and a similar number of companies and government organizations.

While the subject of delivering affordable health care is certainly a serious issue for the United States, we believe it must be addressed through other means. There are no expressed authorities in the Act or implementing regulations that would support the petitioner's position for Governmental actions such as those requested. As noted in 35 U.S.C. 200, the general description of the authorities reserved to the government are limited, "...to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against non-use or unreasonable use of the invention..." (underlining added).

The general reservation of rights in the Government is specifically implemented in the march-in provision of 35 U.S.C. §203, which should not be read to be any broader than intended in the general reservation of 35 U.S.C. §200, which would be necessary to grant the requested march-in request. Indeed, such actions as proposed by the petitioner were never contemplated by the Congress and are not reflected in a proper understanding of the legislative history of the law. On the contrary, it is clear that such authorities would actually frustrate the stated policy and objectives of the Act to create incentives for commercial development by assuring, when necessary, an exclusive patent position (see 35 U.S.C. 200).

We believe that an NIH interpretation of the Bayh-Dole Act as advocated by Essential Inventions would disable the Act. The primary basis for the Act lies in the belief of individual action as opposed to government action and the power of the market. Most inventions resulting from government research are conceptual

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in nature and require significant investment by the private sector to bring them into practical application. This is particularly true of life science inventions requiring licensure by the Food and Drug Administration. Commercial concerns are unlikely to invest substantial financial resources in the commercial development of any invention, funded in part by the government, knowing that the government could challenge their competitive position after the product was introduced onto the market. As was the experience in the years before the passage of the Bayh-Dole Act, when government policy was to grant only non-exclusive licenses, no drugs for which the government held title were developed and made available to the public.

Currently, exclusive licenses of federally funded inventions are believed to be dependable. This dependability can be maintained only if all those involved in the process retain full confidence that the march-in remedy will be exercised only in those extraordinary circumstances clearly anticipated by the Act. In 1997, Harold Varmus, then Director of the NIH, recognized this potential when he rejected the march-in petition of CellPro after it lost a patent infringement suit brought by Johns-Hopkins University, Becton Dickinson and Baxter. In issuing his determination, he stated:

"The patent system, with its resultant predictability for investment and commercial development, is the means chosen by Congress for ensuring the dissemination and development for new and useful technologies. It has proven an effective means for the development of healthcare technologies."

On May 13, 2003, after a detailed study of technology transfer mechanisms, the President's Council of Advisors on Science and Technology concluded:

"Existing technology transfer legislation works and should not be altered."

Interpreting agency authority to exercise march-in rights as advocated by the petitioner would be a major alteration to the existing technology transfer legislation. Granting a march-in in this instance would, we believe, serve only a narrow interest and be contrary to the broader public interest the Act is intended to serve. While we do not wish to diminish the seriousness of the issue of delivering affordable health care we believe it must be addressed through other means and urge the NIH to reject Essential Inventions's petition.

Sincerely,

A handwritten signature in cursive script that reads "Patricia Harsche Weeks". The signature is written in black ink and is positioned above the typed name.

Patricia Harsche Weeks
Immediate Past President
AUTM



Robert C. Byrd
National Technology Transfer Center
at Wheeling Jesuit University

March 31, 2004

Dr. Mark Rohrbaugh
Director of the Office of Technology Transfer
Office of Intramural Research
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, MD 20852

Dear Dr. Rohrbaugh:

I recently became aware of a petition addressed to you by Mr. James Love, President of Essential Inventions, Inc. requesting that the National Institutes of Health exercise the march-in rights provision of the Bayh-Dole Act to lower the price of several drugs developed from NIH extramural research.

While the subject of delivering affordable health care is certainly a serious issue, 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.

The interpretation of the intent of Congress in passing this landmark legislation reflected in Mr. Love's petition is, therefore, entirely fanciful.

While serving former Senator Birch Bayh on the Senate Judiciary Committee, I staffed the hearings and wrote the report of the Senate Judiciary Committee on the bill. I also served for many years as the Director of Technology Commercialization at the U.S. Department of Commerce. There I oversaw the implementation of the regulations for Bayh-Dole and chaired the Interagency Committee on Technology Transfer which developed guidelines for utilizing the Federal Technology Transfer Act, under whose authorities NIH develops many of its intramural partnerships with U.S. industry.

Regrettably, Mr. Love and several others making the same case mix up the legislative history of the Bayh-Dole Act with hearings on rival legislation that was not enacted. The **only** legislative history with any bearing on the law are the hearings of the U.S. Senate Judiciary Committee in the 96th Congress on S. 414, the University and Small Business Patent Procedures Act (commonly called Bayh-Dole), the report of the Senate Judiciary Committee on the same, and the Senate debates on S. 414.

Fortunately, we do have an unambiguous opinion from Senators Birch Bayh and Robert Dole themselves on the topic at hand. The *Washington Post* ran an article by Professors Peter Arno and Michael Davis on March 27, 2002, **Paying Twice for the Same Drugs**, making the same arguments as Mr. Love. They wrote:

Bayh-Dole is a provision of U.S. patent law that states that practically any new drug invented wholly or in part with federal funds will be made available to the public at a reasonable price. If it is not, then the government can insist that the drug be licensed to more reasonable manufacturers, and, if refused, license it to third parties that will make the drug available at a reasonable cost.

A joint letter by Senators Bayh and Dole on April 11, 2002, to *The Washington Post* effectively refutes this argument. Here is the complete text of what the authors of the law said was their intent with regard to fair pricing of resulting products:

As co-authors of the Bayh-Dole Act of 1980, we must comment on the March 27 op-ed article by Peter Arno and Michael Davis about this law.

Government alone has never developed the new advances in medicines and technology that become commercial products. For that, our country relies on the private sector. The purpose of our act was to spur the interaction between public and private research so that patients would receive the benefits of innovative science sooner.

For every \$1 spent in government research on a project, at least \$10 of industry development will be needed to bring a product to market. Moreover, the rare government-funded inventions that become products are typically five to seven years away from being commercial products when private industry gets involved. This is because almost all universities and government labs are conducting early-stage research.

Bayh-Dole did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. This omission was intentional; the primary purpose of the act was to entice the private sector to seek public-private research collaboration rather than focusing on its own proprietary research.

The article also mischaracterized the rights retained by government under Bayh-Dole. The ability of the government to revoke a license granted under the act is not contingent on the pricing of a resulting product or tied to the profitability of a

company that has commercialized a product that results in part from government-funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product. (Emphasis added).

The law we passed is about encouraging a partnership that spurs advances to help Americans. We are proud to say it's working.

Birch Bayh/Bob Dole

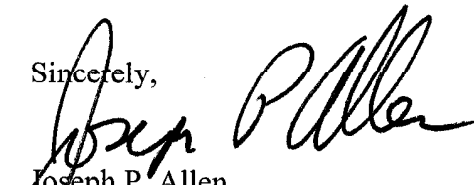
In their typically succinct manner, the authors of the law effectively rebut the argument now before you.

The Bayh-Dole Act has become a linchpin of our economy. While not perfect, the U.S. record of commercializing new products and services funded by the Government is the envy of the world. **The Economist Technology Quarterly** said: "Possibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole act of 1980." Any legislative or administrative actions undertaken to alter this Act must be done very carefully.

We have already witnessed well intended Congressional attempts to impose fair pricing clauses on NIH intramural research partnerships. These efforts failed. Technology transfer cannot be a vehicle for trying to control prices. Rather than allowing Government to dictate drug prices, companies simply walked away from partnering with NIH. Wisely recognizing its mistake, Congress rescinded the fair pricing requirement. NIH's subsequent success in building effective partnerships with industry is well documented, and is a great benefit to the public.

President Johnson asked in 1968 how many NIH owned inventions had been commercialized. The answer was none. At that time there were no incentives for industry to undertake the risk and expense inherent in developing such early stage inventions. We should reflect that because of the Bayh-Dole Act, many life saving drugs and therapies are now available for those in need. By altering this delicately balanced law, we may well discover that publicly funded inventions go back to gathering dust on the shelves. Before Bayh-Dole such discoveries were not available at any price.

Sincerely,



Joseph P. Allen
President
National Technology Transfer Center

ABBOTT

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CORRESPONDENCE
CONTROL CENTER

Heather L. Macdon
Vice President, Pharmaceutical
Specialty Operations

Abbott Laboratories
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200 Abbott Park Road
Abbott Park, Illinois 60054-8183

Telephone (847) 938-2285
Fax (847) 938-4277
E-Mail: Heather.Macdon@abbott.com

March 26, 2004

John G. Aubrey, Jr., Ph.D.
Chairman Emeritus
Academy of Medical Art & Sciences
Business Solutions for Medicine
10455 N. Central, Suite 109-131
Dallas, Texas 75231

Dear Dr. Aubrey,

We are responding to your recent correspondence to Miles White on behalf of Business Solutions for Medicine regarding the recent re-pricing of Norvir® (ritonavir). Abbott appreciates your taking the time to contact us and we value your input.

Regrettably, your letter contains considerable misinformation about the re-pricing action and we would like to take the opportunity to provide you with the facts.

Your letter inaccurately states that Norvir's "increase largely gets passed directly to the patient."

In fact, there is little if any, direct impact to the patient. Abbott has taken extraordinary measures to ensure that patients who need Norvir will have access to it. AIDS Drug Assistance Programs (ADAPs) and Medicaid, which provide HIV drugs to uninsured and underinsured patients, are not impacted by the re-pricing.

- Unlike other companies in this area, Abbott has permanently frozen Norvir soft gel capsules at its previous price of \$1.71 per 100 mg dose for ADAPs, and is the only company to take such a step with one of its drugs. ADAPs provide medication for 20 percent of U.S. AIDS patients.
- Abbott is also the first in the industry to eliminate income requirements for its Patient Assistance Program to ensure that all HIV patients without prescription drug coverage or public assistance can receive Norvir free, regardless of financial status.

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- Further, Abbott offers Norvir free to patients who exceed their annual drug coverage maximum, or who are on ADAP waiting lists.

You write that "many times, the patient is responsible for a single co-pay for an HIV drug prescription" and that Norvir's price increase "is potentially serving to empty the wallet of seriously, critically and/or terminally ill HIV/AIDS patients relying upon Norvir as part of their HIV drug cocktail."

Co-payments and premiums for HIV patients with private insurance receiving Norvir remain unchanged, to our knowledge.

- Antiretrovirals comprise 1.5 percent of the nation's private payer pharmacy budget, and at its new price, Norvir accounts for less than .1 percent of this budget.
- Abbott has committed to making a 30-count bottle available to patients as soon as possible, in addition to the 120-count bottle available today. This should address patients with co-insurance who have experienced an increase in their initial out-of-pocket expenses at pharmacies (representing less than 5 percent of privately insured patients). These patients typically have *out-of-pocket caps* at \$1,500 to \$2,500, well below the cost of HIV medicines. We are also addressing this issue on a case-by-case basis through our Patient Assistance Program.

It is important to note that Abbott is not aware of *any* patient who has gone without Norvir as a result of the re-pricing. Any patient you are aware of, who does not have access to Norvir should contact Abbott directly at 1-800-222-6885. We will take immediate steps to work toward resolving the situation.

You write that the Norvir re-pricing "raises questions in [your] mind if indeed Abbott has infringed upon regulations set forth in anti-trust legislation." In the same vein, you further note you have "discovered the Attorneys General of New York and Illinois have launched criminal investigations into this pricing practice at Abbott."

In fact, Abbott is in full compliance with both federal and state competition laws. Abbott is cooperating with Attorneys General who have questions about the re-pricing of Norvir.

Keep in mind that at its most commonly used dose (100 mg), Norvir remains most often the lowest-cost component of HIV treatment regimens. Its boosting properties are truly unique as it makes other components of the HIV regimen more effective. Perhaps given your concerns about the cost of therapy, you should also look at these high-cost components of HIV regimens and the respective cost of their daily dose.

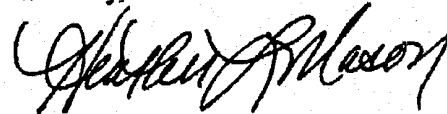
Additionally, in order to properly analyze this issue, one would hope that you would look at the full spectrum of HIV drugs and their respective clinical value to patients compared to Norvir, and how their pricing reflects this value. We believe the focus of criticism should properly be on companies who introduce new drugs at premium prices with limited patient benefit. Some of these drugs represent only moderate improvements or reformulations of older medications.

At \$8.57 per day, the cost of its most commonly used dose, Norvir has an appropriate clinical value/cost ratio in our opinion. By comparison, other new protease inhibitor drugs, such as Lexiva® (GlaxoSmithKline) and Reyataz® (BMS), both of which Norvir makes more effective – are priced at \$19 to \$33.50 per dose.

Abbott is proud of its 20-year history of pioneering contributions in HIV therapy. We will continue on this path of excellence as we pursue the next generation of protease inhibitor therapies.

We hope that you will use these facts to help correct any other misinformation.

Sincerely,



Heather L. Mason
Vice President, Pharmaceutical Specialty Operations
Abbott Laboratories

cc: The Honorable Tommy G. Thompson
Secretary, Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

The Honorable Ted Stevens
Chairman, Committee on Appropriations
United States Senate
522 Hart Senate Office Building
Washington, DC 20510

The Honorable C.W. Bill Young
Chairman, Committee on Appropriations
United States House of Representatives
The Capitol, Room H-218
Washington, DC 20515

The Honorable Christopher H. Smith
Chairman, Committee on Veterans' Affairs
United States House of Representatives
335 Cannon House Office Building
Washington, DC 20515

The Honorable William H. Donaldson
Chairman
United States Securities and Exchange Commission
450 Fifth Street, N.W.
Washington, DC 20549

The Honorable Geoffrey S. Connor, Esq.
Secretary of State
State of Texas
P.O. Box 12877
Austin, TX 78701

The Honorable Greg Abbott, Esq.
Attorney General
State of Texas
300 West 15th Street
Austin, TX 78701

The Honorable Eduardo J. Sanchez, M.D., M.P.H.
Commissioner
Texas Department of Health
1100 West 49th Street
Austin, TX 78756

The Honorable Jim Hine
Commissioner
Texas Department of Human Services
701 West 51st Street
Austin, TX 78751

OHHP

Organization of Healthcare Providers

March 10, 2004

The Honorable Tommy Thompson
Secretary, Department of Health and Human Services
200 Independence Ave., S.W.
Washington D.C. 20201

Dr. Mark Rohrbaugh
Director of the Office of Technology Transfer
Office of Intramural Research
National Institutes of Health
6011 Executive Blvd, Suite 325
Rockville, MD 20852

Dear Secretary Thompson and Dr. Rohrbaugh:

The undersigned clinicians write in strong support of the March-In petition filed last month by the nonprofit Essential Inventions, Inc., for an open license for the supply of ritonavir, sold by Abbott Laboratories as Norvir®. An open license would allow full and open competition for the supply of ritonavir, which we believe is a fitting remedy to abusive pricing practices of Abbott Laboratories.

There is widespread dissatisfaction among HIV health care providers nationwide with Abbott Laboratories regarding the decision to increase the price of ritonavir by more than 400%. This increase, if allowed to stand, will have devastating consequences for the future of HIV care in the United States.

Ritonavir is the only effective boosting compound available to increase the effectiveness of existing treatments for HIV/AIDS. Without ritonavir, other compounds are dramatically less effective. Ritonavir is an essential component of almost every protease inhibitor-based antiretroviral treatment for HIV/AIDS.

Abbott's price increase effectively makes its Kaletra product, which includes ritonavir and was not subject to the price increase, the cheapest boosted protease inhibitor on the market. This will have adverse consequences for the care of patients as doctors and patients will feel pressure to use Kaletra, even when it is not the best treatment for a patient.

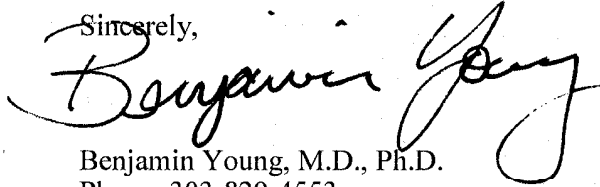
There is no legitimate justification for Abbott's 400% increase in the price of ritonavir, announced just two weeks before Christmas. Abbott is taking advantage of a monopolistic situation, where its product is the only effective protease inhibitor boosting agent.

We are shocked and dismayed that Abbott has raised the price of ritonavir in the U.S., where taxpayer dollars funded its discovery, but not in Europe and other wealthy countries. This fact hardens our opinion that Abbott's price increase lacks any legitimate justification. At least when U.S. taxpayers fund the discovery of a medicine, they should not be subject to

arbitrary and discriminatory prices out of proportion with the prices for the same drug in other comparable markets.

We encourage you to act to remedy this dire situation. Abbott is not making this important government invention available to the public on reasonable terms. Your action is needed to protect the health and safety of people with HIV/AIDS from the effects of Abbott's abusive price increase.

Sincerely,



Benjamin Young, M.D., Ph.D.

Phone: 303-829-4553

E-mail: DenverIDC@aol.com

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3. Carl Stein, M.D.
4. Joseph Jemsek, M.D.
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7. Richard J Feldman, MD
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9. Robert Killian, M.D./M.P.H.
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11. Kenneth Gould M.D.
12. Ricardo Alvarez, M.D.
13. Barbara Lee Perlmutter, M.D.
14. Wayne Bockmon, M.D.
15. Mario J Fonseca, M.D.
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17. Debrah Archer, F.N.P.
18. William Jay Robbins, M.D.
19. Leslie A. Baken, M.D.
20. Toby Dyner, M.D.
21. Townson Tsai, M.D.
22. Chandra Kantor, A.R.NP.
23. Pablo Tebas, M.D.
24. Charles Steinberg, M.D.
25. Victor Lewis, M.D.
26. James Shearer, PA-C
27. J. Manuel Patino, M.D.
28. Paola Greiger, M.D,
29. Virginia Cafaro, M.D.
30. Martin Kramer, PA-C



Drug Development Committee

February 26, 2004

Mark L. Rohrbaugh, Ph.D., J.D.
Director, Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard
Suite 325
Rockville, MD 20852

RE: ESSENTIAL INVENTIONS, INC. PETITION TO USE BAYH-DOLE AUTHORITY TO PROMOTE ACCESS TO RITONAVIR, SUPPORTED BY NIAID CONTRACT NIAID CONTRACT NO.: AI27220

Dear Dr. Rohrbaugh:

The AIDS Treatment Activist Coalition (ATAC) is a national coalition of AIDS activists, many living with HIV/AIDS, working together to end the AIDS epidemic. ATAC's Drug Development Committee (DDC) works with government, academia and Industry to provide a community perspective to the development of new HIV drugs and the utilization of HIV therapies. We are writing to support the petition by Essential Inventions, Inc., requesting that you exercise the "march-in" provisions of the Bayh-Dole Act with respect to Norvir, a government funded invention by Abbott Laboratories.

Abbott shocked the AIDS affected community and endangered many lives by increasing the price of Norvir by 400% in December 2003. A full treatment of Norvir will now cost over \$46,000, making it by far the most expensive protease inhibitor on the market.

The most common use of Norvir is as a "booster" for other protease inhibitors. For six of the seven non-Abbott protease inhibitors on the market, boosting with Norvir is necessary to achieve maximum medical benefits. Thus, Abbott's price increase has anticompetitively raised the price of its competitors' products.

Abbott did not raise the price of its own Norvir-boosted protease inhibitor, Kaletra. The disparity in the price of Kaletra versus other Norvir boosted protease combinations will negatively impact the health and safety of people with HIV/AIDS in a number of ways. Some insurers may limit people's access to protease inhibitor combinations other than Kaletra and may ban reimbursement for Norvir in its full dose. Many could be left with substandard treatment options, leading to increased risk for illness and even loss of life.

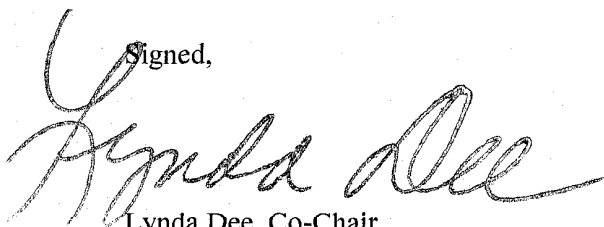
AIDS Drug Assistance Programs, which are already capping enrollment and rationing access to medications because of a lack of needed resources, will see their ranks swell as people are forced out of private sector insurance options and will feel financial strain by commitments to pay private insurance medicine co-payments for many patients. Pharmaceutical assistance programs operated by cities under Title I of the Ryan White Act and non-profit treatment clinics around the country are being saddled with the full price increase to the detriment of their ability to serve their patients.

The price increase will also have a negative impact on the development of new protease inhibitors that require a boosting dose of Norvir. For example, tipranavir, a new protease inhibitor by Boehringer-Ingelheim, needs to be boosted with 400 milligrams of Norvir. At the new Norvir price, the booster component alone for tipranavir will cost over \$16,000 a year, destroying the drug's potential to compete with other protease inhibitors for a share of the market for first-line treatments. Therapies that require Norvir boosting may now be abandoned due to the astronomical price of Norvir. This threatens "salvage" patients, the very people who need new anti-HIV drugs the most because they have become resistant or intolerant to all other marketed anti-viral options.

We endorse Essential Inventions' proposed terms for a Bayh-Dole license. First, the license should be open to all qualified applicants so that competitive forces can work to lower prices to consumers to the lowest possible amount, consistent with providing due reward to the patent holder. Second, under the circumstances, we believe that Essential Inventions' proposed royalty term to Abbott of 5% of net generic sales is generous. Third, we endorse the concept of a research and development contribution based on sales of generic Norvir to ensure that use of Bayh-Dole rights does not detract from needed efforts to fund research and development for new HIV/AIDS treatments. We agree with Essential Inventions' petition that there may be multiple ways to structure the fund, and to ensure that the fund is transparent and directed toward research and development of new AIDS drugs.

We urge that you act with great haste to alleviate the negative impacts to health and welfare that people with AIDS are facing because of Abbott's unreasonable and abusive pricing of a government funded invention.

Signed,



Lynda Dee, Co-Chair
AIDS Treatment Activists Coalition
Drug Development Committee
111 N. Charles Street, Suite 500
Baltimore, MD 21201

Gay Men's Health Crisis (GMHC), NYC
Treatment Action Group (TAG), NYC
HealthGap
Center for AIDS, Houston
Test Positive Aware Network, Chicago
The Access Project, NYC
AIDS Treatment Data Network, NYC
The Harm Reduction Coalition, NYC
Being Alive, Long Beach
Program for Wellness Restoration, Houston
AIDS Action Baltimore
Community HIV/AIDS Mobilization Project (CHAMP), NYC
Essential Innovations, Inc.
AIDS Treatment Activists Coalition (ATAC) Save AIDS Drug Assistance Program (ADAP) Committee
Ohio AIDS Coalition

Hyacinth AIDS Coalition, New Brunswick, NJ
Positive for Positives, Cheyenne, Wyoming
Title II Community AIDS National Network (TIICAN)
New Mexico Poz Coalition
Planet Poz, Albuquerque , NM
Wyoming: Positives For Positives
Foundation for Integrative AIDS Research (FIAR), Brooklyn, NY
Being Alive, Los Angeles
Housing Works, Albany Advocacy Center
NYC AIDS Housing Network
Michigan Positive Action Coalition (MI-Poz)
New Mexico AIDS InfoNet
The Peoples Caucus, San Antonio, TX
San Francisco AIDS Foundation
ACT UP/NY
ACT UP East Bay, Oakland, CA
HIV Advocacy Council of Oregon and Southwest Washington
International Foundation for Alternative Research in AIDS (IFARA)
AIDS Action Project Northwest (AAPNW), Portland, OR
Organization of HIV Healthcare Providers
Benjamin Young, M.D., Ph.D., Chair, Denver I.D. Consultants
Edwin, DeJesus, M.D., Vice Chair, Denver I.D. Consultants
Howard A. Grossman, M.D., Secretary, Denver I.D. Consultants
Bill Owen, M.D., Treasurer, Denver I.D. Consultants
Eric Goldman, Esquire

CC: Mark L. Rohrbaugh, Ph.D., J.D.,
Director, Office of Technology Transfer
National Institutes of Health

ATACSignOnMR



WEST VIRGINIA
Coalition FOR People
WITH HIV/AIDS
EST. 1993

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CORRESPONDENCE CONTROL CENTER

The Honorable Tommy Thompson
Secretary
Department Of Health and Human Services
200 Independence Ave, S.W.
Washington, D.C, 20201

Dear Mr. Secretary,

We write to support the request by Essential Inventions, Inc. that you exercise the provisions of the Bayh-Dole Act with respect to Norvir, a government funded invention by Abbott Laboratories.

Abbott shocked the AIDS affected community and endangered many lives by increasing the price of Norvir by 400% in December 2003. A full treatment of Norvir will now cost over \$46,000, making it by far the most expensive protease inhibitor on the market.

The most common use of Norvir is a booster for other protease inhibitors. For six of the seven non-Abbott protease inhibitors on the market, boosting with Norvir is necessary to achieve maximum medical benefits. Thus, Abbott's price increase has anticompetitively raised the price of its competitor's products.

Abbott did not raise the price of its own Norvir-boosted protease inhibitor, Kaletra. The disparity in the price of Kaletra versus other Norvir boosted protease combinations will negatively impact the health and safety of people with HIV/AIDS in a number of ways. Some insurers may limit people's access to protease inhibitor combinations other than Kaletra and may ban reimbursement for Norvir in its full dose. Many could be left with substandard treatment options, leading to increased risk for illness and even loss of life.

AIDS Drug Assistance Programs, which are already capping enrollment and rationing access to medication because of a lack of needed resources, will see their ranks swell as people are forced out of private sector insurance options and will feel financial strain by commitments to pay private insurance medicine co-payments for many patients. Pharmaceutical assistance programs operated by cities under Title I of the Ryan White Care Act and non-profit treatment clinics around the country are being saddled with the full price increase to the detriment of their ability to serve their patients.

The price increase will also have a negative impact on the development of new protease inhibitors that require a boosting dose of Norvir. For example, tipranivir, a new protease inhibitor by Boehringer-Ingelheim, needs to be boosted with 400 milligrams of Norvir. At the new Norvir price, the booster component alone for tipranivir will cost over \$16,000 a year, destroying the drug's potential to compete with other protease inhibitors

OUR MISSION

The West Virginia Coalition for People with HIV/AIDS' mission is to assist people of all ages who are infected with and affected by HIV/AIDS to live an independent and integrated life in the community.

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PHONE: 304 344.1479 • FAX: 304.344.1479
jazzolari@wvcovenanthouse.org

CARITAS HOUSE, INC.
P.O. BOX 345
MORGANTOWN, WV 26507
304 598 5111

COMMUNITY NETWORKS
P.O. BOX 5064
MARTINSBURG, WV 25402
304 263 8059

COVENANT HOUSE, INC.
600 SHREWSBURY STREET
CHARLESTON, WV 25301-1211
304 344 0530

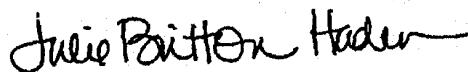
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(05 incoming)

for a share of the market for first-line treatments. Therapies that require Norvir boosting may now have to be abandoned due to the astronomical price of Norvir. This threatens salvage patients, the very people who need new anti-HIV drugs the most because they have become resistant or intolerant to all other marketed anti-viral options.

We endorse Essential Inventions' proposed terms for a Bayh-Dole license. First, the license should be open to all qualified applicants so that competitive forces can work to lower prices to consumers to the lowest possible amount, consistent with providing due reward to the patent holder. Second, under the circumstances, we believe that Essential Inventions' proposed royalty term to Abbott of 5% of net generic sales is generous. Third, we endorse the concept of a research and development contribution based on sales of generic Norvir to ensure that use of Bayh-Dole rights does not detract from needed efforts to fund research and development for new HIV/AIDS treatments. We agree with Essential Inventions petition that there may be multiple ways to structure the fund, and to ensure that the fund is transparent and directed toward research and development of new AIDS drugs.

We urge that you act with great haste to alleviate the negative impacts to health and welfare that people with AIDS are facing because of Abbot's unreasonable and abusive pricing of a government funded invention.

Sincerely,



Julie Britton Haden
West Virginia Coalition for People with HIV/AIDS



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Feb 10, 2004 14:04:47 WVS# D6
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600 Shrewsbury Street
Charleston, West Virginia 25301-1211
wvcovenanthouse.org

February 2, 2004

The Honorable Tommy Thompson
Secretary
Department Of Health and Human Services
200 Independence Ave, S.W.
Washington, D.C. 20201

Dear Mr. Secretary:

We write to support the request by Essential Inventions, Inc. that you exercise the provisions of the Bayh-Dole Act with respect to Norvir, a government funded invention by Abbott Laboratories.

Abbott shocked the AIDS affected community and endangered many lives by increasing the price of Norvir by 400% in December 2003. A full treatment of Norvir will now cost over \$46,000, making it by far the most expensive protease inhibitor on the market.

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The price increase will also have a negative impact on the development of new protease



Working for
Justice for All

Emergency Assistance Program
phone (304)344-8433
fax (304)344-9258

Covenant House
phone (304)344-8053
fax (304)344-4331

Residential & Resource Program
phone (304)344-0530
fax (304)344-9259
1-877-470-0752

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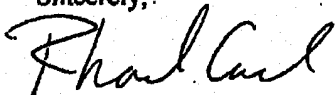
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inhibitors that require a boosting dose of Norvir. For example, tipranivir, a new protease inhibitor by Boehringer-Ingelheim, needs to be boosted with 400 milligrams of Norvir. At the new Norvir price, the booster component alone for tipranavir will cost over \$16,000 a year, destroying the drug's potential to compete with other protease inhibitors for a share of the market for first-line treatments. Therapies that require Norvir boosting may now have to be abandoned due to the astronomical price of Norvir. This threatens salvage patients, the very people who need new anti-HIV drugs the most because they have become resistant or intolerant to all other marketed anti-viral options.

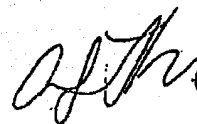
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We urge that you act with great haste to alleviate the negative impacts to health and welfare that people with AIDS are facing because of Abbot's unreasonable and abusive pricing of a government funded invention.

Sincerely,



Rhonda Connard



Amanda Lowther

Co-Coordinator
Covenant House AIDS Program



Working for
Justice for All

AIDS
HEALTHCARE
FOUNDATION

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Feb 08, 2004 07:39:19 WS# 08
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www.aidshealth.org

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Charles Farthing, MD
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AHF Pharmacies
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AHF Prevention & Testing
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323.436.5012

Positive Healthcare/Florida
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AHF Research
323.913.1033

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323.860.5262

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Long Beach	Westside
N. Hollywood	

January 28, 2004

The Honorable Tommy Thompson
Secretary
Department of Health and Human Services
200 Independence Ave., S.W.
Washington D.C. 20201

Re: Release of ritonavir patents under Bayh-Dole due to
anticompetitive practices for NIH developed pharmaceutical

Dear Secretary Thompson:

I am writing to express my concern regarding the recent 500% price increase for the AIDS drug Norvir, (ritonavir) a protease inhibitor produced by Abbott Laboratories. As the largest AIDS organization in the United States, caring for over 12,000 patients in California, Florida, and New York, AIDS Healthcare Foundation is writing on behalf and in support of Essential Medicines, Inc., to request that you exercise the US government right (pursuant to the Bayh-Dole Act) to issue licenses to third parties for generic manufacture of ritonavir.

As you know, Norvir is an antiretroviral medication that is used in combination with other medications to suppress the HIV virus. Norvir is rarely used as the sole protease inhibitor in combination antiretroviral therapy because the required dosage, 600 mg, is generally poorly tolerated. However, it is frequently prescribed in smaller doses (100 mg or 200 mg) to boost the effectiveness of other protease inhibitors, including Fortovase (a Roche drug), Crixivan (a Merck drug), Agenerase (a GlaxoSmithKline drug), and Invirase (also a Roche drug, similar to Fortovase). According to the Seattle Times, about 80% of antiretroviral regimens contain Norvir. In addition, Invirase is clinically not recommended to be prescribed *without* a small dose of Norvir, because the Norvir assists with the absorption of Invirase. Ritonovir is an ingredient, along with another protease inhibitor, lopinavir, in Abbott's drug, Kaletra.

With the December price increase, the cost of a typical one day supply (100mg) has grown from \$1.17/day to \$8.50/day. This makes a ritonavir-containing regimen much more expensive, *unless* Abbott's Kaletra is used. Abbott has not increased the price of Kaletra. While Abbott has claimed that the price Norvir increase is necessary to fund an upcoming reformulation, it is our contention that the increase is a ploy to force patients off their current regimens and on to Kaletra. This

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AIDS
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FOUNDATION

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Stephen Bowen, MD
Cynthia Dant
Jonathan Kaplan, Esq.
Judith Briggs Marsh
Kathy Mendez, Esq.
Ron Meyers
Lawrence Peters
Marjorie Richy
Senator Art Torres (Ret)
Michael Weinstein

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6255 W. Sunset Blvd., 21st Floor
Los Angeles, CA 90028 USA
Tel 323.860.5200
Fax 323.962.8513
www.aidshealth.org

AHF Healthcare Centers
888 AIDS.CARE

Charles Feilthung, MD
Chief of Medicine

Alice
South Africa
Uganda

California
Antelope Valley
El Monte
Hollywood
Los Angeles - Downtown
Los Angeles - West Adams
Los Angeles - Westside
Oakland
Redondo Beach
San Fernando Valley
San Francisco
Upland
Whittier

Florida
Jacksonville

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323.766.2326

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Positive Healthcare/Florida
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AHF Research
323.913.1033

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323.860.5262

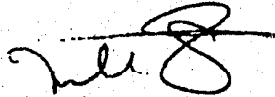
Anwater Village	Pasadena
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Beverly	S. Pasadena
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E. Los Angeles	Venice
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Hollywood	W. Hollywood
Long Beach	Westside
N. Hollywood	

aggressive and anticompetitive move will dramatically increase the price of non-Abbott protease inhibitor regimes that are used with ritonavir as a booster. The price increases for ritonavir and the aggressive pricing for other ARV drugs such as T-20, are placing enormous pressure on third party payers and patients.

Norvir has been available for retail since 1996, making it one of the older available protease inhibitors. Over 20,000 people in the U.S. depend on Norvir, in various combinations recommended by their physicians, for their continued health and well-being. This drastic increase in price is completely unjustified.

Because of Abbott's anticompetitive action and because that substantial NIH funding was used in the development of ritonavir, we urge you to issue a third party patent to Essential Medicines, inc.

Sincerely,



Michael Weinstein
President



BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

May 24, 2004

Mark Rohrbaugh, Ph.D., J.D.
Director of the Office of Technology Transfer
Office of Intramural Research
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852

Dear Dr. Rohrbaugh:

On behalf of the Biotechnology Industry Organization (BIO), I am writing to express our views regarding two petitions filed by Essential Inventions, Inc., on January 29, 2004 that request that Bayh-Dole march-in authorities authorize third parties to use patents necessary for the manufacture and sale of two drug products, ritonavir and latanoprost. The petitions assert that both products were developed with assistance from NIH funding mechanisms. Both petitions take the position that the prices for the drug products in the U.S. are unreasonable, and that this factor authorizes exercise of march-in authorities. For both legal and policy reasons, BIO strongly disagrees with the petitioners' view that march-in powers should be used to impose price controls.

BIO is a trade association representing more than 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations in the United States. Our members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products and as such rely heavily on strong, predictable patent protection around the world. The vast majority of our members have no products on the market: they have patents as their sole assets. Small biotechnology companies use these patent assets to generate the hundreds of millions of dollars necessary to develop and commercialize a biotechnology product. While federal funding of preliminary research is critical to new product discovery, it is private sector funding that enables the development of a biotechnology product. Private sector investors are more likely to invest in product development when they can expect a return on their investment. Thus, any action by the government that undermines the ability of patent holders to exercise their patent rights is of concern to BIO.

1225 EYE STREET, N.W., SUITE 400
WASHINGTON, D.C. 20005-5958

202-962-9200
FAX 202-962-9201
<http://www.bio.org>

Success of Bayh-Dole

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.”¹ According to the Association of American Universities, domestic universities obtained an average of fewer than 250 patents per year prior to Bayh-Dole.² Fewer than 5 percent of the 28, 000 patents being held by federal agencies had been licensed compared with 25 percent to 30 percent of the small number of federal patents for which the government had allowed companies to retain title to the invention. By fiscal 2002, survey results showed that two decades of Bayh-Dole had increased the number of university patents issued annually to over 3600 and over 4600 new licenses and options were reported by 219 institutions.³

The Bayh-Dole Act has been instrumental in bringing together the public sector and private sector to move innovative federally funded biotechnology from the bench to the bedside. It has done so by encouraging the licensing of federally funded inventions to private enterprise. Since Bayh-Dole’s enactment, technology partnerships have led to the founding of more than 1,100 companies based on NIH and university research. More than 370 biotechnology products have been commercialized since the Act’s passage. NIH has concluded that “[c]urrent practices in technology transfer have yielded a dramatic return to the taxpayer through the development of products that, without the successful public-private relationship, might not be available.”⁴ 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 2002.⁵ This revenue helps to fund new research and training programs at these institutions.⁶

Legal Analysis

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.”⁷ Neither the plain meaning of the Act, its legislative history nor the

¹ 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>.

² 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>.

³ Association of University Technology Managers, *AUTM Licensing Survey: FY 2002, Survey Summary at 12*, available at <http://www.autm.net/surveys/02/2002public.pdf>.

⁴ A Plan to Ensure Taxpayers’ Interests Are Protected, *supra* Part F.

⁵ AUTM Licensing Survey: FY 2002, Survey Summary, *supra* at 18.

⁶ A Plan to Ensure Taxpayers’ Interests Are Protected, *supra* Part C.2.a.

⁷ 35 U.S.C. § 203(a)(1), (2).

public policies underlying it contemplate use of the march-in authority because of the price of a commercially available product. Yet the march-in petitions suggest that “open licenses” should 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.”⁸ Accordingly, the Senate bill authorized NIH to take action through the exercise of march-in rights only in the rare case “when the invention is not being used and it appears that there is a public need to use the invention.”⁹ By contrast, the committee report makes no mention the use of march-in rights as a tool for insuring “reasonable” prices.

The Act’s co-authors, former Senators Birch Bayh and Bob Dole, have stated that the 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.”¹⁰

The petitions urge an inappropriate use of march-in powers to impose price controls on products developed with the aid of federal funds. The Bayh-Dole Act’s overriding benefit to the public is to make it possible for early-stage research to be leveraged into initial funding for the creation of private companies that will commercialize new products. Simply put, it was never the intention of Congress that the march-in powers of Bayh-Dole Act be used as a method of price setting. To the contrary, Bayh-Dole’s march-in authority allows the federal government to compel licensing of a federally funded invention only if the government believes that (1) the patent owner has not commercialized the invention in a reasonable time, (2) a public health need is not being met by the recipient of the federal grant, or (3) a public noncommercial use requires licensing. These measures were included to ensure that the overall goal of the Act—to spur the interaction between public and private research to benefit the public—would be met. Not one word of the march-in provision, or Bayh-Dole’s legislative history, suggests that the price charged for a product serves as a basis for exercising march-in rights.

Previous NIH Positions Reject Use of Price Controls

NIH has already concluded that Bayh-Dole does not contemplate the imposition of price controls. In 1995, NIH reversed an attempt to impose a “reasonable pricing” requirement on parties to its Cooperative Research and Development Agreements (“CRADAs”).

⁸ S. Rep. No. 96-480, at 3 (1979).

⁹ Id. At 18.

¹⁰ Birch Bayh & Bob Dole, Letter to the Editor, Our Law Helps Patients Get New Drugs Sooner, Wash. Post, April 11, 2002 at A28.

Looking back on this experiment, NIH acknowledged that the policy “had the effect of posing a barrier to expanded research and development and, therefore, was contrary to the Bayh-Dole Act.”¹¹ When NIH removed the reasonable price barrier, the number of CRADAs promptly increased.¹²

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.¹³ 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.”¹⁴

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.”¹⁵

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

¹¹ A Plan to Ensure Taxpayers’ Interests Are Protected, *supra* Part C.6.

¹² *Id.* Part C.6 & App. 4.

¹³ 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 (May 30, 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).

¹⁴ 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 Center, 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 and obligations between the three partners – government, universities and industry - which has been the basis for the success of this legislation”).

¹⁵ Determination in the Case of Petition of CellPro, Inc., <http://www.nih.gov/news/pr/aug97/nihb-01.htm>

therapeutic drugs.”¹⁶ 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.”¹⁷ The same report matter-of-factly observed that “neither NIH nor universities have a role in drug pricing.”¹⁸

Conclusion

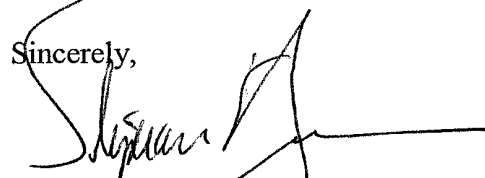
In the biotechnology industry, the vast majority of funding necessary to develop new products comes from the private sector. But private sector investors will not invest in the development of research that they do not believe will yield a return on their investment. As such, the exercise of march-in powers to set price controls would defeat the overarching goal of the Act—which is to facilitate commercialization of government funded research.

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. 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.

For the reasons outlined in this letter, BIO urges the NIH to (1) adopt a policy that makes it clear that a company’s pricing decision does not serve to trigger march-in authorities under Bayh-Dole; and (2) deny both petitions submitted by Essential Therapeutics.

Thank you for the opportunity to provide comments on this important matter. Please call me at (202) 962-9215 or Lila Feisee, BIO’s Director for Intellectual Property, at (202) 962-9502 to discuss any questions you may have.

Sincerely,



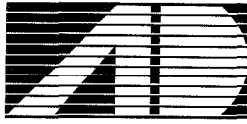
Stephan E. Lawton
Vice President & General Counsel

SL:fz

¹⁶ A Plan to Ensure Taxpayers’ Interests Are Protected, *supra* Part A.

¹⁷ *Id.* Part F.

¹⁸ *Id.* Part D.1.



THE AARON DIAMOND AIDS RESEARCH CENTER

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Dr. Elias A. Zerhouni
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

May 24, 2004

Dr. Mark Rohrbaugh
Director of the Office of Technology Transfer
Office of Intramural Research
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, MD 20852

Dear Drs. Zerhouni and Rohrbaugh:

I am writing out of concern related to the issues raised in connection with the petition regarding Abbott Laboratories and the exercise of march-in rights under the Bayh Dole Act. As an independent researcher at the Aaron Diamond AIDS Research Center in New York, I began collaborating with Abbott Laboratories in 1991 and was one of the investigators working on the testing of protease inhibitors for safety and efficacy throughout all the phases of clinical development. While I do not wish to express any legal opinion with respect to provisions of Bayh Dole, I do think it important for those faced with rendering a decision on this petition to recall both the circumstances and the climate related to the discovery of protease inhibitors in general, and Norvir in particular.

First, it is valuable to put the development of protease inhibitors in their historical context by recalling the early days of the HIV epidemic. Quite simply, large numbers of people were dying painful deaths at an alarming rate after an AIDS diagnosis. Treatment options were limited to a few medications that simply were not potent enough to make an impact on the mortality rates at the time, and the demand for new treatments was intense. For researchers and for the pharmaceutical industry, the task of finding these new treatments represented an enormous investment and a significant gamble. For example, during my work on Abbott's protease inhibitors, it was determined that one such compound showed promise, but later was found not to work well enough when tested in patients. Another looked more promising, but again when tested in patients; it fell short in its efficacy. While the literature reflected great excitement about the promise of protease inhibitors in 1994 and 1995, in 1993 nothing about their efficacy was certain.

When protease inhibitors were being investigated, there was no way to know if they would work – and even if they did work - we weren't yet sure how they could be used. It involved a great deal of trial and error to reach the point where experimental discoveries such as protease inhibitors actually became useful drugs. In today's environment, it is easy to forget what those days were like. The grim treatment options of the early days contrast with today's array of effective therapies because of the advances made in therapeutics over the last 15 years.

I think it particularly important at this point to draw some emphasis as well to the role that the National Institutes of Health played at the time when it awarded grants to assist in protease inhibitor research efforts. Abbott was a recipient of such a grant. However, when it came to the actual clinical testing of protease inhibitors, the development of Norvir was accomplished through the investment of the company and through the institutional resources of investigators such as myself. The amount of money used in discovery is but a fraction of the sum spent to fully develop a drug for market. The discovery may have been subsidized, but the testing and development were not.

After Abbott tested various molecules, Norvir emerged as its most effective compound. Once Norvir was introduced into infected subjects during clinical trials, we saw a reduction in viral load that was unprecedented and it then seemed logical to combine this with 3TC and AZT. The eventual result is the very different AIDS epidemic that still challenges us today, though in a vastly different way. Mortality dropped significantly. Lives were extended. Quality of life was vastly improved. Eventually, Norvir's role as a boosting agent to other anti-viral therapies became known, extending the benefit of its role beyond what was conceived during its initial use.

The development of Norvir is a prime example of the benefits of a public-private partnership. The investment in discovery on the part of the National Institutes of Health - and Abbott itself - was followed up by the much more significant investment by private industry to test and develop the discovery and bring it to market.

As a witness of this development, I felt compelled to write and share this perspective with you. If you have any follow-up questions, please do not hesitate to contact me.

Sincerely,

A handwritten signature in black ink, appearing to read "David D. Ho". The signature is written in a cursive, slightly slanted style.

David D. Ho, M.D.

May 19, 2004

Elias A. Zerhouni, M.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Zerhouni:

On behalf of the California Healthcare Institute (CHI), whose more than 220 members include our state's premier life science companies and academic research institutions, I would like to express concern regarding the recent action to impose the march-in provision of the Bayh-Dole Act (Bayh-Dole) against Abbott Laboratories.

Healthcare access and affordability is a serious national issue, and was the focus of the recently enacted Medicare Prescription Drug and Modernization Act of 2003 (MMA). This landmark legislation will improve prescription drug coverage for our nation's seniors and most needy. Bayh-Dole, however, is not the proper vehicle for addressing concerns about drug access and costs.

Bayh-Dole was intended to stimulate the transfer of medical technology between academic institutions and commercial companies. In passing this law, Congress recognized that federal funding of basic science was, by itself, insufficient to bring new medicines to the bedside. The complex and expensive process of transforming discoveries into products required a legal framework in which the intellectual property derived from federally-funded research could be licensed by a university to a company in exchange for royalties or other appropriate considerations. To ensure that important innovations would not languish, march-in provisions were built into the law to allow government to broaden the scope of patents in order to move inventions into the market place if a commercial company lacked the resources necessary to do so. Neither Bayh-Dole nor its march-in provision pertains to the issue of affordability in the marketplace. Certainly Bayh-Dole was not intended to act as a price control mechanism.

Allowing march-in rights based on price would go against the very aim of Bayh-Dole. Indeed, the product in question, Norvir, is already available on the market and has been used effectively by patients. The government cannot encourage industry to bring products to market by extending patents only to take them away once the product is commercialized. The result would be a return to the status quo prior to enactment of Bayh-Dole when taxpayer dollars were invested in research that had minimal chance of reaching the market. By weakening intellectual property rights, the exercise of march-in rights in this case would have devastating effects on the future of medical innovation in the United States

I strongly urge NIH to consider not only the original intent of the Bayh-Dole march-in provisions but the original aim of the Bayh-Dole Act itself – to stimulate the commercialization of discovery, not stifle it – and reject exercise of march-in rights in this case.

Sincerely,



David Gollaher, Ph.D.
President & CEO

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210232



David E. Miller
President

May 21, 2004

Elias A. Zerhouni, M.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Zerhouni:

The Illinois Biotechnology Industry Organization, better known as iBIO™, represents scores of biotechnology companies in this state that work to develop and bring new life-saving and –enhancing drugs and medical products to market.

I am writing out of concern regarding the recent petitions requesting imposition of the march-in provisions of the Bayh-Dole Act against Abbott Laboratories' license for the invention it has productized as the drug Norvir. Such an action would subvert both the language and underlying legislative intent of Bayh-Dole.

The purpose of the Bayh-Dole Act was to stimulate the transfer of technology between university researchers and private sector firms with the resources to develop these inventions and bring them to market so as to benefit the public. The idea was that licensing of federally- funded inventions would provide an incentive for private industry to develop products through the grant of commercialization rights.

Absent these incentives, Congress reasoned, there was little chance of many such potentially useful inventions ever reaching the market. There exists widespread agreement that the incentives provided by the Act have been hugely successful in making new products, including many new drugs, available to the public.

Congress was concerned that in some instances licensed inventions might languish in the hands of the licensees. It therefore built march-in provisions into the law to allow the government to step in if a private company lacked the resources necessary or otherwise failed to bring a product to market or to address public health needs after obtaining its license. The march-in provisions would, in those limited instances, allow the government to grant additional licenses for the same product.

There is nothing in the Act that provides for substitution of a funding agency's judgment on appropriate pricing of the product or allowance for the agency's imposition of price controls through exercise of march-in rights. The only relevant questions under Bayh-Dole are: Is the firm actively making the invention publicly available, and is it benefiting public health needs?

In my research on this matter I have found no claims by any party that Abbott has failed to take, in the Act's language "within a reasonable time, effective steps to achieve practical application of the subject invention" in its "field of use", or that Norvir has failed to effectively address public health needs. Norvir is widely available and has been used effectively by the target HIV patient population. Norvir has strengthened the ability of other drugs, provided by both Abbott and Abbott's competitors in this highly competitive category, to suppress the effects of HIV infection. In some instances, Abbott has made the drug available to people worldwide at no charge and reduced charge.

The petitions for imposition of march-in processes were brought by parties complaining about the price of the product, not its market availability or effectiveness in addressing health needs; what they are saying, in effect, is that Bayh-Dole requires licensees to distribute their products so that every person in every circumstance can access them.


Granting the petitions based on this reasoning would effectively re-write the provisions of Bayh-Dole. Doing so would also subvert the Act's legislative intent.

Widely quoted studies from Tufts University and the Boston Consulting Group indicate that pharmaceutical companies require hundreds of millions of dollars and an average of 10 years to bring a new drug to market. (Abbott reports that it spent more than \$300 million dollars to develop Norvir.) More recently, the Bain research group has calculated that, taking into account the many failures for each successful drug candidate, the true cost of each successful drug is over one billion dollars.

Imposing ad-hoc pricing judgments as a pretext for invocation of march-in rights, after a licensee has made substantial investments in testing and product development, would obliterate the very incentives Congress sought to create by enacting Bayh-Dole. The result would be a return to the previous status quo, when taxpayer dollars were invested in research that sat on the shelves.

I therefore urge you to reject these petitions and, in so doing, uphold the language of the Act and its underlying intent to spur development of inventions that benefit the public. Please do not hesitate to contact me if you have any questions regarding this matter.

Sincerely,


David Miller
President

The Bayh-Dole Act and March-In Rights

David Halperin¹

May 2001

I. Summary

The Bayh-Dole Act, 18 U.S.C. section 200 et seq., enacted in 1980, was aimed at turning federally-funded research and development into useful patented inventions, in order to benefit American research institutions, industries and consumers. From the beginning, a stated objective of the Act was to protect the American public against “unreasonable use” of government-funded inventions. 18 U.S.C. section 200. The march-in rights provision was included as a means to vindicate that interest. It gives the federal agency under whose funding agreement an invention was made the right to grant a license to a responsible new applicant if, among other things, the current manufacturer has failed to make the product “available to the public on reasonable terms,” 18 U.S.C. sections 201(f), 203(1)(a), or if “action is necessary to alleviate health or safety needs which are not reasonably satisfied” by the current manufacturer. 18 U.S.C. section 203(1)(b).²

The research and development needed to create numerous drugs now on the market was funded primarily by the American people through their tax dollars. The key patents to many of these drugs were filed by universities, and then licensed to private companies. In many cases, these private corporations have provided only a small fraction of the overall R&D investment in the products, but charge high monopoly prices. These prices do not reflect the cost of production of the drugs, which are routinely only a fraction of the sale price. In some cases, generic competitors in other countries sell the drugs at prices less than 5 percent of the U.S. price.

The exact outlay by industry licensees for licensing, research, development, production, and other expenses is typically unknown, because the licensees generally refuse to disclose such data. However, in the course of a governmental review of a product under Bayh-Dole, it should be possible to make the data public, so a complete, rational and fair assessment can be made.

Even without such disclosures, the high prices of many products currently on the market is *prima facie* unwarranted in terms of the purposes of Bayh-Dole and of federal patent law. If these laws are meant to encourage and reward investment and innovation, then the windfall profits obtained by industry licensees turn that purpose on its head:

¹ Attorney and Counselor, Washington, DC. Special Assistant for National Security Affairs and speechwriter to President Clinton (1998-2000); fellow, Harvard Law School Berkman Center for Internet & Society (1997); solo legal practitioner (1994-97); co-founder, Progressive Networks (now RealNetworks) (1993-94); counsel, Senate Intelligence Committee (1991-93); law clerk, U.S. District Judge Gerhard Gesell (1989-91). Yale Law School JD 1989, Yale College BA 1984. The author prepared this paper at the request of the Consumer Project on Technology, Washington, DC.

² Regulations governing the procedures for the exercise of march-in rights are at 37 CFR section 401.6.

Companies which contributed comparatively little to the R&D for particular drugs receive a monopolist's price *as if they undertook all of the R&D themselves*.

The losers under this arrangement are the American people, who have been forced to pay twice for the drugs: first, through taxpayer funding for R&D; and today, through higher Medicare and other government program expenditures, higher insurance premiums, and, higher patient out-of-pocket expenses and other costs associated with the exorbitant prices.

No federal agency has ever asserted its march-in rights with respect to a Bayh-Dole-conferred patent. Indeed, only once has a federal agency ever been petitioned to do so. (See below.) Now the Government should apply a brake to runaway prices for critical medicines created with taxpayer money.

The Secretary of Health and Human Services should take action to help restore appropriate balance to federal policy under Bayh-Dole; to help ensure that overall U.S. policy with respect to research and patents is rational and effective; and to uphold the interests of American taxpayers, insurers, and government.

II. Argument: The Case for Exercising March-in Rights

The 1980 Bayh-Dole Act embodied a new approach to intellectual property rights in the fruits of federally-sponsored research. Under the previous approach, much of this research remained government property or was placed in the public domain. But there was a perception that federal inventions were often underutilized. There was concern that a failure to remedy this problem would weaken the ability of U.S. firms to compete with foreign companies. There also were substantial differences among the procedures and standards used by federal agencies with respect to a funding recipient's right to obtain title to an invention created with federal monies. The process by which a contractor sought to obtain such rights was often burdensome and delayed the transformation of research into useful products.³

The new approach posited that encouraging patenting of the results of federal research, and licensing to private firms, would prompt greater use of federally-sponsored inventions, spur U.S. industries, and create American jobs. The Bayh-Dole Act gave incentive to non-profit entities and small businesses to patent the products of government-funded research by authorizing them to retain patent ownership for themselves, to license those patents, and to retain royalties from them.⁴ Subsequently, a

³ See S.Rep. 96-480 at 15-25; Barbara M. McGarey and Annette C. Levey, *Patents, Products, and Public Health: An Analysis of the CellPro March-In Petition*, 14 Berkeley Tech.L.J. 1095, 1097-98 (1999); Peter S. Arno & Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Derived in Whole or in Part from Federally Funded Research*, 75 Tulane L. Rev. 631, 640, 656 (2000); Mary Eberle, *March-In Rights Under the Bayh-Dole Act: Public Access to Federally Funded Research*, 3 Marq.Intell.Prop.L.Rev. 155 (1999).

⁴ Federal regulations implementing the Bayh-Dole Act are at 37 CFR section 401.1 et seq.

1983 Executive Memorandum and 1987 Executive Order extended the benefits of Bayh-Dole to all government contractors, including larger businesses.⁵

The objectives of the Bayh-Dole Act, as set out by Congress are as follows:

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.

35 U.S.C. section 200.

The Bayh-Dole Act sought to create a uniform, streamlined process across all federal agencies for patent license transfers. Under the Act, federal contractors generally have the right to elect ownership rights to any invention created with federal funds.

As one scholar has put it, the Bayh-Dole approach is, in fundamental ways, “counterintuitive ... [I]t seems to require the public to pay twice for the same invention -- once through taxes to support the research that yielded the invention, and then again through higher monopoly prices and restricted supply when the invention reaches the market.”⁶

To address such concerns, Congress built into the Act a number of obligations aimed at ensuring that the public’s investment would be used in the public interest. Under the Act, contractors must disclose each subject invention to the funding agency

⁵ Memorandum to the Heads of Executive Departments and Agencies: Government Patent Policy, Public Papers of the Presidents 248 (Feb. 18, 1983); Executive Order 12591, 52 Fed.Reg. 13414 (1987).

⁶ Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 Va.L.Rev. 1663, 1666 (1996). Professor Eisenberg further states:

Second, by calling for exclusive rights in inventions that have already been made through public funding (and thus, presumably, without the need for a profit incentive), it contravenes the conventional wisdom that patent rights on existing inventions result in a net social loss ex post, a loss that we endure only to preserve ex ante incentives to make future patentable inventions. Third, by promoting the private appropriation of federally-sponsored research discoveries as a matter of routine, it calls into question the public goods rationale for public funding of research. And fourth, by providing incentives to patent and restrict access to discoveries made in institutions that have traditionally been the principal performers of basic research, it threatens to impoverish the public domain of research science that has long been an important resource for researchers in both the public and private sectors.

Id., at 1666-67.

within a reasonable time after discovery. They must elect within two years of disclosure whether or not to retain title. They must agree to file patent applications prior to any statutory bar date. If a contractor fails to meet any of these obligations, it risks forfeiting title to the Government.⁷ Moreover, under the Act the Government reserves for itself a nonexclusive, paid-up license to practice or have practiced on its behalf any subject invention, in the United States or in other countries.

In addition, the Bayh-Dole statute includes the march-in provision that is the focus of this paper. Section 203 provides, in relevant part:

With respect to any subject invention in which a small business firm or nonprofit organization⁸ has acquired title under this chapter, the Federal agency under whose funding agreement the subject invention was made shall have the right, in accordance with such procedures as are provided in regulations promulgated hereunder to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, to grant such a license itself, if the Federal agency determines that such

(a) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use; [or]

⁷ A recent study by the U.S. General Accounting Office shows that contractors and universities in fact engage in regular violations of Bayh-Dole requirements, particularly widespread failure to report the patents that they obtain through government-funded research. U.S. Gen. Accounting Office, GAO/RCED-99-242, Technology Transfer: Reporting Requirements For Federally-Sponsored Inventions Need Revision 6, 10-12 (1999); see Arno & Davis at 676-679, 686-687.

⁸ After the 1983 Executive Memorandum extended Bayh-Dole benefits to all federal contractors, including large corporations, Congress by statute expressly extended the march-in rights provision, along with other aspects of the Bayh-Dole law, to such entities:

Nothing in this chapter [35 U.S.C. sections 200 et seq.] is intended to limit the authority of agencies to agree to the disposition of rights in inventions made in the performance of work under funding agreements with persons other than nonprofit organizations or small business firms in accordance with the Statement of Government Patent Policy issued on February 18, 1983, agency regulations, or other applicable regulations or to otherwise limit the authority of agencies to allow such persons to retain ownership of inventions except that all funding agreements, including those with other than small business firms and nonprofit organizations, shall include the requirements established in [section] 202(c)(4) and section 203 [the march-in rights provision] of this title. Any disposition of rights in inventions made in accordance with the Statement or implementing regulations, including any disposition occurring before enactment of this section, are hereby authorized.

(b) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees

The phrase “practical application,” used in subsection 203(a), is defined elsewhere in the Act to mean:

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.

18 U.S.C. section 201(f).

The march-in rights provision of the law was contained, essentially verbatim, in the original version of the bill as it was introduced by Senators Bayh and Dole on February 9, 1979.⁹ However, the concept of government march-in rights, and the “reasonable terms” standard for exercising them, were much older. In 1963, President Kennedy issued a Presidential Memorandum on patent policy that allowed for exclusive licensing of government patents in some circumstances but required that such licensing be “on reasonable terms.”¹⁰ A 1968 government-commissioned report supported the use of march-in rights when a contractor failed to offer the invention “on reasonable terms.”¹¹ President Nixon’s Patent Policy Statement of 1971 tied the exercise of march-in rights to whether a licensed invention “is being worked and ... its benefits are reasonably accessible to the public.”¹²

Another provision in the original Bayh-Dole bill, section 204, provided for automatic recoupment of part or all the government investment in R&D after the subject invention had earned a particular level of profits.¹³ Although at least one of the bill’s sponsors, Senator Thurmond, considered this provision “[p]erhaps the most significant feature of the bill,”¹⁴ and it was included in the Senate-passed version of the bill¹⁵, it was eventually dropped.

The legislative history of the Bayh-Dole Act and similar bills introduced in the same period shows that the march-in rights provision was repeatedly cited by bill

⁹ S.414, 96th Cong., 1st Sess.

¹⁰ Subcommittee on Domestic and International Scientific Planning and Analysis of the House Committee on Science and Technology, 94th Cong., Background Materials on Government Patent Policies: The Ownership Of Inventions Resulting From Federally Funded Research and Development (Committee Print 1976) at 6.

¹¹ Id., at 196.

¹² Id., at 10, 14-16.

¹³ Id.

¹⁴ The University And Small Business Patent Procedures Act, Hearings Before the Senate Committee on Judiciary, 96th Cong., 1st Sess., 1979, at 34 (statement of Sen. Thurmond).

¹⁵ See S.Rep. 96-480, at 34.

advocates as a meaningful and appropriate guarantee that the public interest would be protected.¹⁶

For example, there is this testimony from Dr. Betsy Ancker-Johnson, vice president of General Motors and former Assistant Secretary of Commerce:

DR. ANCKER-JOHNSON. Mr. Chairman ... you have written into this legislation march-in rights which, should something go wrong, gives the Government an absolute method to correct it. It seems to me that you have made the possibility for abuse virtually nonexistent by including this section in the bill.

Senator BAYH. How do you perceive those march-in rights would accomplish what you suggest?

DR. ANCKER-JOHNSON. Should there be any abuse, Mr. Chairman, whatsoever, these criteria would be applied by the Federal Government and so make it possible for the Government to ... obtain the rights to that patent and distribute them to whoever it deemed best for the exploitation of that technology for the welfare of the people. So you have this excellent guarantee written into the bill, and it seems to me you have fully provided for any remote possibility of abuse.

It is notable that the witness spoke not of patent non-use -- the danger that the government contractor would simply leave the technology on the shelf -- but patent *abuse*.

As Professors Arno and Davis, who exhaustively reviewed the legislative history, conclude, “there was never any doubt” that the “reasonable terms” standard for march-in rights “meant the control of profits, prices and competitive conditions.”¹⁷ As they note¹⁸, there are many references in the legislative record to the value of march-in rights for maintaining competitive market conditions. James E. Denny, Assistant General Counsel

¹⁶ See The University And Small Business Patent Procedures Act, Hearings Before the Senate Committee on Judiciary, 96th Cong., 1st Sess., 1979, at 44 (statement of Elmer B. Staats, Comptroller General of the United States), 70 (statement of Dr. Hector F. DeLuca, chairman, biochemistry department, University of Wisconsin Madison), 187 (statement of Howard Bremer, president, Society of University Patent Administrators); Patent Policy, Hearings Before the Subcommittee on Science, Technology, and Space of the Senate Committee on Commerce, Science and Transportation, 96th Cong., 1st Sess. at 182 (statement of Gerald J. Mossinghoff, Deputy General Counsel, NASA); Patent Policy, Hearings Before the Subcommittee on Science, Technology, and Space of the Senate Committee on Commerce, Science and Transportation, 96th Cong., 1st Sess., at 366 (statement of Dale W. Church, Deputy Under Secretary of Defense for Acquisition Policy); Government Patent Policy, Hearings Before the Subcommittee on Science, Research and Technology of the House Committee on Science and Technology, 96th Cong., 1st Sess., 1979, at 54 (statement of John E. Maurer, director, Patent Department, Monsanto Corp.); Government Patent Policy, Hearings Before the Subcommittee on Science, Research and Technology of the House Committee on Science and Technology, 96th Cong., 1st Sess., 1979, at 182 (statement of Dr. Ralph L. Davis, Purdue Research Foundation); 1977 Small Business Hearings at 189-95 (statement of John H. Shenefield, Asst. Attorney General, Antitrust Div., Dept. of Justice).

¹⁷ Arno & Davis, at 662.

¹⁸ *Id.*

for Patents, U.S. Energy Research and Development Agency, testified that march-in rights were appropriate “where the contractor is misusing the invention to the detriment of competitive market forces.”¹⁹ Ky P. Ewing, Assistant Attorney General for the Antitrust Division, testified, “[M]arch in’ provisions should help assure that the availability of exclusive rights ... does not disrupt competition in the marketplace.”²⁰

Harry F. Manbeck, General Patent Counsel for General Electric Company, emphasized the connection between unwarranted prices and the exercise of march-in rights: “[I]f [a contractor] fails to supply the market adequately at a fair price, then there is reason for requiring it to license both the background patents and the patents stemming from the contract work.”²¹

Other testimony expressly linked the invocation of march-in rights to the existence of “windfall profits” on a subject invention. Written responses to the Senate from U.S. Comptroller General Staats reported that the Department of Energy “said that march-in rights to protect the public’s interest were developed to take care of and address the patent policy issues of *contractor’s windfall profits*, suppression of technology, and *the detrimental effects to competition from granting contractors rights to inventions*.”²² Mr. Manbeck of General Electric testified as to march-in rights, “We think it is part of the answer to the so-called windfall situation.”²³

Questioning Comptroller General Staats, Senator Bayh noted that a criticism of the bill, “comes from those that feel that this bill is a front to allow the large, wealthy, corporation to take advantage of Government research and thus to profit at taxpayers’ expense. We thought we had drafted the bill in such a way that this was not possible.” Staats replied, “In my opinion, the bill does have adequate safeguards.”²⁴

Another witness, R. Tenney Johnson, who had served as chief or deputy legal counsel to five cabinet departments or agencies (and subsequently served in the Reagan Administration as general counsel at the Department of Energy), discussed the bill’s

¹⁹ Patent Policy: Hearings on S.1215 Before the Subcommittee on Science, Technology and Space of the Senate Committee on Commerce, Science and Transportation, 96th Cong. 150 (1979).

²⁰ Patent and Trademark Law Amendments of 1980: Hearings Before a Subcommittee of the House Committee on Government Operations at 102 (1980)

²¹ Government Patent Policy: Hearings Before the Subcommittee on Science, Research and Technology of the House Committee on Science and Technology, 96th Cong. at 48 (1979)

²² The University And Small Business Patent Procedures Act, Hearings Before the Committee on Judiciary, 96th Cong., 1st Sess., 1979, at 56 (responses of Mr. Staat). Mr. Staat’s further characterized DOE’s view as follows: “The Department believes that march-in rights, although available to the Government for more than 10 years, have not been utilized because such problems are illusory and not actual. If and when negative effects result from allowing a contractor to retain title to an invention of commercial importance, march-in rights are there to address them. Otherwise, DOE believes they will never be used.” Id. We submit that the situation posited by this discussion -- negative effects result from allowing a contractor to retain title to an invention of commercial importance -- has now become reality and compels Government action.

²³ Patent Policy, Hearings Before the Subcommittee on Science, Technology, and Space of the Committee on Commerce, Science and Transportation, 96th Cong., 1st Sess. At 317 (statement of Mr. Manbeck).

²⁴ The University And Small Business Patent Procedures Act, Hearings Before the Senate Committee on Judiciary, 96th Cong., 1st Sess., 1979, at 44.

provision for the assertion of government rights in connection with need for the Government to take action to protect public health or safety²⁵:

Whenever you discuss patent policy, you very quickly come up with the question of what do you do with a cure for cancer? Are you going to let one company have that? Obviously, a priceless invention. As I say, you are likely not to have a single patent on that, but you need to have some protection against that possibility.

I think that such a possibility might arise in a contract where the work was expressly at the point of discovering whether there was an answer to cancer. The Government might need to acquire title, because that would be an exceptional circumstance.

Admiral Hyman Rickover, the father of the nuclear Navy and an opponent of the Bayh-Dole approach (“These inventions are paid for by the public and therefore should be available for any citizen to use or not as he sees fit”²⁶), had a different view. He prophetically argued that the march-in rights provision would not be enforced²⁷:

The Government has had march-in rights since 1963, but to my knowledge has never used them. To be in a position to exercise these rights a Government agency would have to stay involved in the plans and actions of its patent holders and check up on them.

If a Government agency ever decided to exercise its march-in rights and the patent holder contested the action, no doubt the dispute could be litigated for years. For this reason, I believe this safeguard is largely cosmetic. It would result in much additional paperwork but would probably be used no more than in the past.

In fact the legislative history of the Bayh-Dole Act reveals at least one instance where a government agency, the Department of Defense, had exercised march-in rights.²⁸ But Admiral Rickover’s cynicism on this point now appears, unfortunately, well-grounded. The bill’s sponsors and supporters were not cynical about the march-in rights provision, and their expectations deserve to be vindicated now.

The record also reveals that the march-in rights provision was retained despite the fact that a number of industry representatives argued aggressively against that provision,

²⁵ Patent Policy, Hearings Before the Subcommittee on Science, Technology, and Space of the Committee on Commerce, Science and Transportation, 96th Cong., 1st Sess. At 44 (statement of Mr. Johnson).

²⁶ The University And Small Business Patent Procedures Act, Hearings Before the Senate Committee on Judiciary, 96th Cong., 1st Sess., 1979, at 157 (statement of Adm. Rickover).

²⁷ The University And Small Business Patent Procedures Act, Hearings Before the Senate Committee on Judiciary, 96th Cong., 1st Sess., 1979, at 159-60 (statement of Adm. Rickover).

²⁸ Patent Policy, Hearings Before the Subcommittee on Science, Technology, and Space of the Committee on Commerce, Science and Transportation, 96th Cong., 1st Sess., at 366 (statement of Dale W. Church, Deputy Under Secretary of Defense for Acquisition Policy). (“Only once can I recall there was a case where we exercised march-in rights. It was a case involving two patents held by MIT. There was a complainant who felt as though the patents were not being utilized. As to one of the patents, it was found that MIT was using it and was allowed to retain exclusive title. In the case of the other, we found that MIT was not effectively using it, and they did provide for the complainant to use the patent.”)

as well as the provision allowing the government to revoke a contractor's license.²⁹ The fact that Congress, in the face of industry complaints, nevertheless retained the march-in rights provision demonstrates that these provision were not included casually, that they were not simply boilerplate.

In the course of the hearings on the legislation, the Electronic Industry Association urged Congress to redefine the phrase "practical application" -- a trigger for the exercise of march-in rights -- to reduce the obligations of the contractor and thus the risk that the government would actually assert march-in rights: "The definition of 'practical application' appears too stringent. We would suggest a rewrite to indicate that 'application' means ... 'that the invention is being worked *or* that its benefits are available to the public either on reasonable terms or through reasonable licensing'"³⁰ Congress declined to adopt this change, and maintained the standard that a "practical application" is achieved -- and march-in rights conditions are avoided only if the invention is being practiced *and* it is available to the public on reasonable terms.³¹

There is nothing to suggest that Congress kept the provision and yet expected it to lay dormant forever. Indeed, the language of the Senate report suggests an expectation that march-in rights would indeed be asserted from time to time: "'March-in' is intended as a remedy to be invoked by the Government and a private cause of action is not created in competitors or other outside parties, although it is expected that *in most cases complaints from third-parties will be the basis* for the initiation of agency action.'" S.Rep. No. 96-480, at 34 (1979) (emphasis added).

It also is worth noting that the Bayh-Dole bill, as enacted in 1980, limited benefits to non-profit institutions and small businesses. The bill's sponsors believed that to extend benefits to large corporations would doom the bill, because consumer and antitrust advocates worried that big companies, on balance, did not need the help and in fact could use Bayh-Dole benefits to weaken market competition and hurt the public welfare.³² The extension of Bayh-Dole to large corporations came not through a carefully-considered legislative process, but through executive action by the Reagan Administration. In 1984, Congress effectively ratified this action by the Administration, but at the same time it expressly provided that, if the Government was going to give Bayh-Dole benefits to large

²⁹ See, e.g., Government Patent Policy, Hearings Before the Subcommittee on Science, Research and Technology of the House Committee on Science and Technology, 96th Cong., 1st Sess., 1979, at 169-71 (statement of Patrick Iannotta, president, Ecolotrol, Inc.); Government Patent Policy: Hearings Before the Subcommittee on Domestic and International Scientific Planning and Analysis of the House Committee on Science and Technology, 94th Cong. At 173 (statement of Charles S. Haughey, Patent Counsel, Hughes Aircraft Co.); 1980 Joint Hearing at 523-24 (testimony of Robert B. Benson, Director, Patent Dept., Allis-Chambers Corp.). As James E. Denny, Assistant General Counsel for Patents, U.S. Energy Research and Development Agency, stated, "[I]ndustry does not like either the concept of a revocable license or the 'march-in' rights, and views them with great suspicion." 1976 Hearings at 435.

³⁰ Patent Policy: Hearings on S.1215 Before the Subcommittee on Science, Technology and Space of the Senate Committee on Commerce, Science and Transportation, 96th Cong. at 221 (1979) (statement of Peter F. McCloskey, President, Electronic Industry Assn.) (emphasis added).

³¹ See Arno & Davis, at 666.

³² See Eisenberg, 82 Va.L.Rev. at 1695-96; Bradley Graham, Patent Bill Seeks Shift To Bolster Innovation, Washington Post, Apr. 8, 1979, at .

businesses, then the Government would retain the rights it had with respect to other Bayh-Dole inventions: (1) a nonexclusive, paid-up license to practice on behalf of the United States the subject invention; and (2) march-in rights.³³ The views expressed in 1980 -- regarding the potential for large corporations to abuse Bayh-Dole rights -- should be taken into account: In the case of large corporations, the Government has a particularly strong obligation to consider whether Bayh-Dole patent monopolies are serving the public interest.

American pharmaceutical companies have profited greatly from the Government benefits provided under Bayh-Dole and the subsequent extension of Bayh-Dole to large corporations. And these benefits to drug companies have come on top of other substantial federal aid through the tax code.³⁴ A company's own R&D expenditures can be deducted annually from taxable income. Internal Revenue Code section 174. The pharmaceutical industry, in particular, has benefited enormously from specific tax code provisions, including the foreign tax credit, the orphan drug tax credit, the general business tax credit, and a tax code provision that offers substantial benefits for manufacturing products in Puerto Rico. A 1999 analysis concluded that pharmaceutical makers have one of the lowest effective tax rates and one of the highest after-tax profit rates of any industry.³⁵

The American public has received little direct financial return on its investment in health care research and development. Indeed, in the years 1985 through 1994, NIH received slightly less than \$76 million in royalties, \$40 million of which came from a single license for the HIV antibody test kit. From 1993 through 1999, royalties reached a total of nearly \$200 million, reaching \$45 million in 1999. But that figure still represents less than one percent of NIH's funding for 1999.³⁶

³³ The provision, codified at 35 U.S.C. section 210(c), states:

Nothing in this chapter is intended to limit the authority of agencies to agree to the disposition of rights in inventions made in the performance of work under funding agreements with persons other than nonprofit organizations or small business firms in accordance with the Statement of Government Patent Policy issued on February 18, 1983, agency regulations, or other applicable regulations or to otherwise limit the authority of agencies to allow such persons to retain ownership of inventions except that all funding agreements, including those with other than small business firms and nonprofit organizations, shall include the requirements established in paragraph 202(c)(4) and section 203 of this title. Any disposition of rights in inventions made in accordance with the Statement or implementing regulations, including any disposition occurring before enactment of this section, are hereby authorized.

³⁴ See U.S. Office of Tech. Assessment, *Pharmaceutical R&D: Costs, Risks and Rewards* 183-99 (1983); Arno and Davis, 75 *Tulane L.Rev.* at 638-39.

³⁵ Memorandum from Gary Guenther, Analyst in Business Taxation and Finance, to Joint Economic Committee 1-7 (Dec. 13, 1999), cited in Arno and Davis, 75 *Tulane L.Rev.* at 639.

³⁶ Arno & Davis at 639-40, citing Nat'l Insts. Of Health, *NIH Technology Transfer Activities FY 1993-FY1999*, available at <http://ott.od.nih.gov/newpages/webstats99.pdf>; Nat'l Insts. Of Health, *Federal Obligations For Health R&D, By Source or Performer: Fiscal Years 1985-1999*, available at <http://silk.nih.gov/public/cbz2zoz@www.awards.sourfund.htm>.

Of course, the public has also benefited from Bayh-Dole in other ways -- to the extent the law has helped create jobs, spur research, and bring to market useful products.³⁷ But in at least some cases the price for these benefits has been too high.

Two scholars who recently conducted a careful review of the overall record under the Bayh-Dole regime conclude³⁸:

[P]erhaps more important than the absence of any [direct return on taxpayer investment] is the inevitability of even greater public or consumer expenditures demanded by the monopolies obtained by industry over publicly financed inventions, and the resulting supracompetitive profits and prices. The public has already paid for the costs of research. The government's failure to police these economic abuses is the untold scandal of federally financed inventions and of the failure of the Bayh-Dole Act, which was meant to provide that policing.

In many instances, the taxpayers have not received their due benefits from the Bayh-Dole bargain. That is because industry licensees have ignored their obligations under the statute to sell the fruits of taxpayer research on reasonable terms and consistent with public health and safety needs. As a result, the only way for the taxpayers' interests to be vindicated, the only way to bring publicly-funded medicine to citizens at a fair price, is for the Secretary to take action and exercise march-in rights.

Only once before has the Government received a petition for Bayh-Dole march-in rights: a petition filed with the Secretary of Health and Human Services in 1997 by CellPro, Inc. seeking a license for certain patents for stem cell separation technology created by Johns Hopkins University with support from the National Institutes of Health ("NIH").³⁹ CellPro was already manufacturing an FDA-approved device based on the

³⁷ One recent scholarly account summarizes the following progress in the years since Congress enacted Bayh-Dole: Although the federal government still provides the bulk of funding for university research, industry funding for such research has grown by a factor of five since passage of the Act. Licenses granted by universities have increased by a factor of ten. Royalties paid to universities increased nearly four-fold from 1981 to 1992 and more than doubled between 1991 and 1995. However, as this account notes, it is not clear how much of this expansion is the result of Bayh-Dole and how much expansion would have occurred in any case, because of a general increase in intellectual property patenting and licensing and advances in biotechnology and other fields. Tamsen Valoir, *Government Funded Inventions: The Bayh-Dole Act and the Hopkins v. CellPro March-in Rights Controversy*, 8 Tex.Intell.Prop.L.J. 211, 234-36 (2000). As this account notes, though the Bayh-Dole era has brought substantial increases in patents, licensing and royalties in fields that have benefited from the law, "this growth parallels that seen in other industries that are generally independent of government funding." Id. at 239.

³⁸ Arno & Davis at 640.

³⁹ As Barbara McGarey, Deputy Director, Office of Technology Transfer, National Institutes of Health has noted, the legislative history of Bayh-Dole shows that Congress anticipated that the petition of a private party would be the likely trigger for the Government to consider asserting march-in rights. McGarey and Levey, 14 Berkeley Tech.L.J. at 1099, citing S.Rep. No. 96-480, at 34 ("'March-in' is intended as a remedy to be invoked by the Government and a private cause of action is not created in competitors or other outside parties, although it is expected that in most cases complaints from third-parties will be the basis for the initiation of agency action.") McGary and Levey report in their article that, though they are aware of no

technology.⁴⁰ Hopkins' licensee, Baxter, had obtained approval to market and was marketing its device in Europe, had filed for U.S. FDA Pre-Market Approval with respect to its device, and its device was in use in clinical trials in the United States. Determination In The Case of Petition of CellPro, Inc., National Institutes of Health, Office of the Director, August 1, 1997, at 5. Dr. Harold Varmus, director of NIH, concluded that the exercise of march-in rights was "not warranted at this time." *Id.*, at 1. But NIH retained jurisdiction over the matter "until such time as a comparable alternative product becomes available for sale in the United States." *Id.*

The facts and equities in the CellPro case were very different than they are with respect to some drugs today. That case was about alleged failure to exploit a patent, while today there are products that are widely available to the public but not, it appears, on reasonable terms and not in accordance with public health and safety needs. In CellPro, NIH concluded that Baxter had met the requirements of Bayh-Dole, because it was "vigorously pursuing" FDA approval of its product. *Id.*, at 5. Moreover, in separate civil proceedings, a court had held CellPro liable for willfully infringing Hopkins' patents, after negotiations between Baxter and CellPro for a licensing agreement had failed. *Id.*, at 1, 5. Finally, Hopkins and Baxter changed the equities in the CellPro case by agreeing, notwithstanding their victory in the civil patent case, to refrain from enforcing their patent rights in order to allow the continuing sale of the CellPro device until the comparable Baxter product was approved for sale by the FDA. *Id.*, at 6-7. In those circumstances, it would have been difficult for NIH to justify the need for march-in rights.

The Bayh-Dole Act calls for the assertion of federal march-in rights where such action "is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in [the applicable] field of use." In terms of specific request for the exercise of march-in rights, this is the standard to which decision-makers must look.

"Practical application" means "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." (emphasis added). 18 U.S.C. section 201(f).

The requirement that a Bayh-Dole contractor make inventions available "on reasonable terms," must be read to include the obligation to sell at a reasonable price. In comparable legal contexts, the phrase "reasonable terms" has been considered to include price. See, e.g., *Byars v. Bluff City News Co.*, 609 F.2d 843, 864 n. 58 (5th Cir. 1979) (in applying a reasonable terms requirement in a particular antitrust context, citing "[t]he difficulty of setting reasonable terms, especially price"); *American Liberty Oil Co. v.*

other formal petitions for march-in rights, "There have been various inquiries to federal agencies from third parties regarding possible march-in, but all have been resolved informally." 14 Berkeley Tech.L.J. at n.79.

⁴⁰ See McGarey and Levey, 14 Berkeley Tech.L.J. passim; Mary Eberle, *March-In Rights Under the Bayh-Dole Act: Public Access to Federally Funded Research*, 3 Marq.Intell.Prop.L.Rev. 155 (1999); Tamsen Valoir, *Government Funded Inventions: The Bayh-Dole Act and the Hopkins v. CellPro March-in Rights Controversy*, 8 Tex.Intell.Prop.L.J. 211 (2000).

Federal Power Commission, 301 F.2d 15, 18 (5th Cir. 1962) (holding that, under statute authorizing the FPC to establish reasonable terms and conditions, the “price ... must be reasonable”).

A reasonable price for a product is one that covers costs, accounts for risk, and allows a reasonable profit. See, e.g., *Williston Basin Interstate Pipeline Co. v. FERC*, 165 F.3d 54, 57 (D.C.Cir. 1999). In evaluating whether the price of a medicine, one critical to keeping people alive, is reasonable, one should consider also whether the price imposes substantial hardships on patients who need it and the health care system working to support those patients.

In the context of a medical product, risk factors would include: the risk that research and development might not produce a safe and effective product; the risk that the FDA might fail to approve a product for such reason; and the possibility that a competitor might produce a comparable product that is better, cheaper or both.

A reasonable profit would be one that accounted for risk and ensured that the assignee of the patent would indeed have sufficient incentive to make the product. In the Bayh-Dole context, a reasonable profit would be less than a “windfall” profit, a level of profit comparable to that enjoyed by a monopolist who had done all the research and development itself.

Given the strong concern expressed throughout the legislative history of Bayh-Dole that taxpayers’ interests be vindicated, when it comes to a critical, life-saving medicine, evaluation of the reasonableness of the price must also take into account the ability of purchasers to afford the good. In the Bayh-Dole context, it is reasonable to assert that a reasonable price for critical good financed by the public is not a price that creates hardship for the overall public or for individual members of the public.

These factors must be assessed on a case-by-case basis.

The government might be reluctant to engage in the practice of scrutinizing the prices of goods offered by government contractors. But such practice is a regular responsibility of government -- agencies as well as courts -- in many spheres. And it is a practice that is manageable in this context. Moreover, as discussed above, it is a practice that is part of the applicable law, under the march-in rights and “reasonable terms” provisions of the Bayh-Dole Act.

Government evaluates and sets prices or rates in a number of contexts. Price-setting is standard procedure for utilities and other regulated industries that are granted monopoly or substantial market power by government. Section 2-305(1) of the Uniform Commercial Code provides that if a contract price is not settled, “the price is a reasonable price at the time for delivery....” The UCC, in force in 49 states, gives courts the authority to determine reasonable prices where the parties have failed to set prices, and courts have regularly done just that. See, e.g., *Koch Hydrocarbon Co. v. MDU Res. Group Inc.*, 988 F.2d 1529, 1534-35 (8th Cir. 1993) (evaluating, pursuant to UCC section

2-305, what constitutes a reasonable price for natural gas); *N. Cent. Airlines, Inc. v. Cont'l Oil Co.*, 574 F.2d 582, 592-93 (D.C. Cir. 1978) (evaluating under UCC section 2-305 what constitutes a reasonable price for aviation fuel). The Patent Act directs courts, upon a finding of infringement, to award at least “a reasonably royalty” to the patent owner.

After public outcry over the pricing of AZT, the first Bush Administration adopted the policy of requiring firms to sign "reasonable pricing" clauses in return for entering into Cooperative Research and Development Agreements (CRADAs) with the federal government, or exclusive licenses to federal government owned research on pharmaceuticals.⁴¹ This policy went further than the Bayh-Dole Act in some respects. First, it created reasonable pricing requirements even in cases where there were no patents to license. Second, the policy introduced a specific obligation to demonstrate that prices were reasonable in light of the government support for the development of the product.⁴²

One of the first drugs to be commercialized with this reasonable pricing clause was the cancer drug Taxol, which was subject to a US government CRADA with BMS. The US government did not own patents on Taxol, but gave BMS the exclusive rights to data from US government funded clinical trials, which BMS used to establish safety and efficacy of Taxol with the US FDA. This effectively gave BMS a five year monopoly on Taxol sales in the US. The NIH was criticized by consumer groups for its management of the Taxol reasonable pricing obligation, and specifically for allowing BMS to charge prices that were roughly twenty times the prices the U.S. government had previously paid for generic supplies of Taxol.⁴³

In 1995 the NIH decided that it would abandon the reasonable pricing clause, rather than enforce it. There were several efforts in the U.S. Congress to restore the reasonable pricing clause, but those efforts failed.

⁴¹ An account of the experience and debate over this policy is found in the *Reports of the NIH Panels on Cooperative Research and Development Agreements: Perspectives, Outlook, and Policy Development*, July 21, 1994 and September 8, 1994, National Institutes of Health.

⁴² The Public Health Service (PHS) adopted, as Section 16 of Appendix A of the model PHS CRADA Agreement, a statement that “NIH/ADAMHA have a concern that there be a reasonable relationship between the pricing of a licensed product, the public investment in that product, and the health and safety needs of the public. Accordingly, exclusive commercialization licenses granted for NIH/ADAMHA intellectual property rights may require that this relationship be supported by reasonable evidence.”

⁴³ U.S. Congress, Committee on Small Business, Subcommittee on Regulation, Business Opportunities, and Energy, *Exclusive Agreements Between Federal Agencies and Bristol-Myers Squibb Co. for Drug Development: Is the Public Interest Protected?* Hearings, July 29, 1991, Serial No. 102-35; HHS-OIG, *Technology Transfer and the Public Interest: Cooperative Research and Development Agreements at NIH*, OEI-01-92-01100, Washington, DC, November 1993; James Love, "Pricing of Drugs Developed with Public Funds, Comments Presented to the Second NIH CRADA Forum, September 8, 1994; James P. Love, "Health Registration Data Exclusivity, Biomedical Research, and Restrictions on the Introduction of Generic Drugs," statement to Subcommittee on Labor, Health and Human Services and Education and Related Agencies Committee on Appropriations U.S. Senate, October 21, 1997.

In 2000, the House of Representatives considered an amendment by Rep. Sanders prohibiting the use of NIH funding to grant exclusive or partially exclusive patent licenses under Bayh-Dole except in accordance with the Bayh-Dole Act provision, 35 U.S.C. section 209, requiring that a federally owned invention and its benefits be made available to the public “on reasonable terms.”⁴⁴ It was, in essence, an amendment that called on NIH simply to enforce existing law.⁴⁵ The House debate on the amendment returned repeatedly to the Bayh-Dole requirement that medicines made with federal research dollars be sold on “reasonable terms.”⁴⁶ Rep. Sanders told his colleagues:

Our amendment requires that the NIH abide by current law and ensure that a company that receives federally owned research or a federally owned drug provide that product to the American public on reasonable terms. This is not a new issue ...

While a reasonable pricing clause is not the only device that will protect the investment that American taxpayers have made in numerous profitable drugs, this amendment makes clear that Congress will not stand by while NIH turns over valuable research without some evaluation that the price charged to consumers will be reasonable as is required by current law.

This amendment requiring NIH to enforce “reasonable terms” requirements with respect to pharmaceutical makers passed the House last year by a vote of 313-109.

Opponents to the exercise of march-in rights can be expected to argue just what some industry representatives asserted in opposing the inclusion of the march-in rights provision in the original Bayh-Dole legislation: That the assertion of Bayh-Dole rights would, henceforth, discourage businesses from licensing, developing, and creating products based on, federally funded research. One is tempted to respond that industry representatives who want to make this claim, after march-in rights have been asserted by a federal agency, should be required to put their money where their mouth is, and refrain from entering into agreements where any federal research money is involved. Such enterprises would quickly realize the folly in rejecting still-profitable contracts and allowing willing competitors to scoop them up.

If the Government acted to apply a brake to runaway profits now, companies might see the wisdom in cutting prices for particular products to reflect better such factors as the ratio between the federal contribution to research and development and the company’s own contribution; costs; risk; and the public interest. But there would still be the potential to make healthy, attractive profits. And thus there would still be incentive to participate with the federal Government in funding research, and to patent and license products in which the Government played a role.

⁴⁴ See 146 Cong.Rec. H4291-93; 35 U.S.C. sections 209(c)(1)(A) (license granted “only if ... the interests of the Federal Government and the public will best be served by the proposed license, in view of the applicant’s intentions, plans and ability to bring the invention to practical application or otherwise promote the invention’s utilization by the public”) and 201(f) (defining “practical application” to include the “reasonable terms” requirement).

⁴⁵ Arno & Davis, at 666-67.

⁴⁶ 146 Cong.Rec. at H4291-93.

Indeed, in asserting march-in rights in appropriate cases, the Government could actually spur private industry to increase its contribution to research and development on efforts in which the federal Government also has provided or is providing support. The reason why is plain: If the Government makes clear that the relative contributions of Government and the contractor are a factor in determining, for purposes of Bayh-Dole, whether the contractor is making the product available on “reasonable terms,” then the more the contractor contributes to research, the weaker the potential argument for anyone claiming that the contractor’s price is unreasonable.

At least some industry representatives shared this view at the time Congress considered the Bayh-Dole legislation. H.F. Manbeck, general patent counsel at General Electric, said during hearings on the bill, “I am in agreement ... that march-in rights will not hurt the affected contractor and not act as a disincentive to the innovation process. Absolutely.”⁴⁷

And one recent scholarly analysis agreed that “companies will not refuse to invest in federally funded research if a funding agency exercises march-in rights.”⁴⁸ Why? Because the Bayh-Dole license transfers remain a good bargain for industry:

For federally funded technology a balance must be struck between permitting licensees to commercialize their technology and disrupting this development by compelling patent owners to license their technology to third parties. Granted, this forced licensing will arguably generate some uncertainty in the licensing of federally funded research. However, companies will not turn their backs on this cost-effective resource of federally-subsidized university technology.

And, also, because the grant of march-in rights “when necessary” is critical to maintaining public support for this bargain.⁴⁹ In other words, if the Government declines to thoroughly review the evidence and act in the face of evidence of drugs sold at high monopoly prices, it would weaken the public’s confidence in the fairness and efficiency of the Bayh-Dole Act regime and the overall regime governing the creation and sale of critical medicines. The public may conclude that there no circumstances under which a Bayh-Dole beneficiary company will be scrutinized for charging unwarranted prices. In that light, the public, and then perhaps the public’s representatives in Congress, may decide that Bayh-Dole bargain, as so redefined, is not such a good deal for the taxpayers after all. That could create momentum for repealing laws that give the fruits of public research to private industry. In the long run, industry would be better served by the Government taking action now on behalf of fair prices for consumers and a fair return for taxpayers.

⁴⁷ Government Patent Policy, Hearings Before the Subcommittee on Science, Research and Technology of the House Committee on Science and Technology, 96th Cong., 1st Sess., 1979, at 157 (statement of H.F. Manbeck)

⁴⁸ Eberle, March-In Rights, 3 Marq.Intell.Prop.L.Rev. at 178.

⁴⁹ Eberle, March-In Rights, 3 Marq.Intell.Prop.L.Rev. at 173-74.

Just as evaluating prices for reasonableness is an appropriate government function in certain circumstances, the granting of a license to a responsible party, where a Bayh-Dole contractor has not met its responsibilities, is comparable to government action in related contexts. Courts have ordered compulsory licenses, at reasonable royalty rates, as a remedy for antitrust violations. See *United States v. Glaxo Group Ltd.*, 410 U.S. 52, 64 (1973) (“Mandatory selling on specified terms and compulsory patent licensing at reasonable charges are recognized antitrust remedies). United States law provides for the grant of compulsory licenses under certain conditions in a range of situations: with respect to copyrights, for secondary transmissions by cable television systems⁵⁰, for making and distributing phonorecords of certain musical works⁵¹, and for performance of sound recordings via digital audio transmissions⁵²; with respect to patents, for certain air pollution prevention inventions⁵³ and for inventions related to nuclear energy.⁵⁴

III. Conclusion

The 1980 Bayh-Dole bill struck a bargain between Government, research institutions, industry, taxpayers and consumers, aimed at spurring research and bringing new inventions to the market for the benefit of all. The bargain was amended by the Reagan Administration in 1983 to extend the benefits of Bayh-Dole licensing to large corporations. Now it is time for the bargain to be enforced. It is time to correct an imbalance that has led to unjust enrichment and unwarranted hardship.

Two NIH officials recently concluded that the “greatest value” of the march-in rights provision of Bayh-Dole likely is its “in terrorem effect,” its use “as the proverbial Sword of Damocles, suspended over the federally-funded invention licensing process....”⁵⁵ But this deterrent value has been diminished over time.

If the Government maintains its record of never exercising march-in rights, then government contractors will understand that there are few if any foreseeable circumstances in which such march-in rights ever will be granted. They will understand that they can obtain on the cheap tremendous benefits from taxpayer-funded research and then, without risk of sanction, turn around and charge the same taxpayers highly-inflated monopoly prices, even for medicines critical to combating fatal diseases. They will understand that devoting great resources to research is only the second-best strategy for reaping big profits; the better one being to let federally-funded research labs carry the research load and expense and then to charge a patent-holder’s monopoly price anyway.

⁵⁰ 17 U.S.C. section 111.

⁵¹ 17 U.S.C. section 115.

⁵² 17 U.S.C. section 114(f); see *Recording Indus. Ass'n of Am. v. Librarian of Congress*, 176 F.3d 528 (D.C.Cir. 1999).

⁵³ 42 U.S.C. section 7608.

⁵⁴ 42 U.S.C. section 2183.

⁵⁵ McGary and Levey, 14 Berkeley Tech.L.J. at 1116.

Continued government inaction will confirm once and for all the worst fears of Bayh-Dole's harshest critics back in 1980: that, as Senator Long then put it, the bill was a massive "giveaway," a law "deleterious to the public interest," a regime under which Americans are "forced to subsidize a private monopoly twice: first for the research and development and then through monopoly prices."⁵⁶

By contrast, if the Government finally acts to exercise march-in rights in appropriate circumstances, it could produce a critical change with respect to medicines and medical technologies created with federal funding. Patent holders and licensees might begin adjusting their prices to better reflect their actual contributions to research. This could produce substantial cost savings for insurers, governments, and patients, and allow more resources to go to other health care costs -- and, in the case of the global AIDS crisis, also to those overseas suffering from this disease. If industry concluded it could no longer enjoy an almost totally free ride on federal research dollars, and that larger profits depended on making a greater contribution to research and development, that should encourage industry to devote greater, not fewer, resources to R&D. And there will remain strong profits and thus tremendous incentive for industry to continue marketing patented products made mostly with federal research and development money.

⁵⁶ Hearings Before the Subcommittee on Monopoly & Anticompetitive Activities of the Senate Select Committee on Small Business, 95th Cong. At 233 (1977) (statement of Sen. Long); Patent Policy: Joint Hearing Before the Senate Committee on Commerce, Science and Transportation and the Senate Committee on the Judiciary, 96th Cong. 463-65 (statement of Sen. Long).

Statement of James Love
President, Essential Inventions, Inc.
NIH Meeting on Norvir/Ritonavir March-In Request
May 25, 2004

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Introduction

Essential Inventions has asked the Department of Health and Human Services (DHHS) to exercise its march-in rights in six patents held by Abbott Laboratories that are used in the manufacture and sale of ritonavir, a drug used to treat AIDS. Essential Inventions also has a separate petition asking DHHS to exercise march-in rights in the Columbia University patent on Xalatan, a drug used for the treatment of glaucoma. These petitions ask the government to protect the public, under the particular provisions set out in the Bayh-Dole Act.

Policy Basis for Norvir March-In Request

In December 2003, Abbott Laboratories increased the price of ritonavir by 400 percent. The price increase was not uniform. Some US public sector programs will not face the 400 percent price increase. No foreign consumers will face the 400 percent price increase. Abbott did not increase the price of Kaletra, an Abbott fixed dose combination product that combines ritonavir and lopinavir. As a consequence of the discriminatory price increase, US employers/insurers/consumers who buy ritonavir with private sector insurance will pay five to ten times more than employers/insurers/consumers in other high-income countries. US insurers will place pressure on patients to switch to the Kaletra fixed dose combination. Non-Abbott drug developers will be effectively excluded as a first line treatment on most formularies, reducing potential markets and undermining incentives for R&D.

The 400 percent price increase for a treatment for a deadly disease comes eight years after Ritonavir was introduced into the US market, having already generated billions of dollars in revenue to Abbott (for Norvir, the standalone product, and Kaletra, the co-formulated fixed dose combination). Patients living with AIDS, and employers and insurers that pay for AIDS treatments, are all concerned that the very aggressive price hike by Abbott will encourage other companies to sharply increase prices for AIDS drugs.

Table 1
Retail Price of Norvir in Six Countries
(Monthly: sixty 100 milligram tabs)

Australia	\$ 52.04
Belgium	\$ 58.91
Canada	\$ 58.97
Germany	\$ 111.91
Italy	\$ 132.00
USA (CVS, Washington, DC)	\$ 642.90

Table 2
Retail Price of Norvir Boost, Before and After Price Increase
Annual average wholesale cost

Boehringer-Ingelheim/Tipranavir 400 milligrams/day	Before	\$ 3,129	
	After	\$16,644	
	Difference		\$12,515
Merck/Crixivan 200 milligrams/day	Before	\$1,564	
	After	\$7,822	
	Difference		\$6,258
Abbott/Kaletra 200 milligrams/day	Difference		\$0

The fundamental questions posted by the Norvir march-in request are the following:

Is it appropriate for Abbott to increase the price of ritonavir, a government funded invention, by 400 percent in one day, after the company has already earned billions on the drug? Is it appropriate for Abbott to price ritonavir, a government-funded invention, 5 to 10 times higher in the United States than in other high-income countries? It is appropriate for Abbott to price ritonavir, a government-funded invention, 5 times higher when the drug is used in combination with non-Abbott owned protease inhibitors, than the price when ritonavir is used in connection with Abbott’s own protease inhibitor lopinavir.

If DHHS determines that the answer to any of these three questions is no, it should grant the march-in request.

Legal Basis for March-In

In the terms of the Act, the first ground for the march-in is that the “action is necessary because the contractor or assignee has not taken, or is not expected to take within a

reasonable time, effective steps to achieve practical application of the subject invention.”¹ The Act defines “practical application” as the utilizing of the invention in such a way “that its benefits are to the extent permitted by law or government regulations available to the public on reasonable terms.”²

Abbott is not making the product available to the public on “reasonable terms.” It is not reasonable to raise the price of an essential life saving drug by 400 percent. It is not reasonable to price an essential life saving drug 5 to 10 times more in the United States than in Europe, Canada or other high-income countries. It is not reasonable to charge 5 times more just because ritonavir is used with a competitor’s protease inhibitor.

These acts are not reasonable. They are outrageous pricing abuses.

The second ground is that the “action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees.”³ There is evidence in the record that the price increases for ritonavir is creating hardships on persons living with AIDS. There is also evidence that the recent price increase is having a harmful impact on the pipeline for new AIDS drugs, by reducing the expected market share for Abbott’s competitors. Indeed, if Abbott charges different prices for ritonavir depending upon which drugs it is used with, and discriminates against its competitors, it is unlikely that there will be significant new investment in AIDS drugs that require ritonavir as a boosting agent. This is the most serious threat to the health and safety needs of persons living with AIDS.

The NIH has received letters in opposition to this petition that assert that the Bayh-Dole march-in provisions were not intended to address abuses of patent rights that concern the pricing of drugs.⁴ It is difficult to imagine how the term making “available to the public on reasonable terms” would exclude prices. Professor Jerome Reichman of Duke University Law School has looked at this issue for us, and will present in a separate statement his views on how the term “available to the public on reasonable terms” should be interpreted.

Any fair reading of the legislative history of the Bayh-Dole Act and also the pre-Bayh-Dole Act debates over the patenting of federally funded inventions reveal longstanding concerns over the potential for abuses stemming from monopoly pricing of inventions.⁵

¹ 35 U.S.C. § 203(a)(1).

² 35 U.S.C. § 201(f).

³ 35 U.S.C. § 203(a)(2).

⁴ Joseph P. Allen, President National Technology Transfer Center, letter to Mark Rohrbaugh, March 31, 2004. Norman J. Latker, letter to Mark Rohrbaugh, April 14, 2004.

⁵ American Association for the Advancement of Science (AAAS), *The Protection by Patents of Scientific Discoveries: Report of the Committee on Patents, Copyrights, and Trademarks*. New York: Science Press, 1934; Robert Weissman, “Public Finance, Private Gain: The Emerging University-Business-Government Alliance and the New U.S. Technological Order,” Undergraduate thesis, Harvard University, 1989; Peter S. Arno & Michael H. Davis, “Why Don’t We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Derived in Whole or in Part from Federally Funded Research,” 75 *Tulane L. Rev.* 631, 640, 656 (2000); David C. Mowery, Richard Nelson,

As described in some detail in the attached memo prepared by David Halperin, the legislative approval of the Bayh-Dole was clearly tied to the existence of the march-in provision as a general safeguard to protect the public from abusive pricing of federally funded inventions, including medicines.⁶

We do not claim the NIH is required to exercise federal march-in rights on every federally funded patent, or even for many federally funded patents. Nor is the NIH obligated to exercise its royalty free rights in the patents. The federal government has broad discretion to act, but also broad discretion to not act. The NIH has never used a march-in petition to grant licenses to patents on drugs. But even the possibility of a march-in proceeding may have influenced licensing practices in the past, not only for drugs, but for the licensing of patents on stem cell lines or other research tools.

Whatever the NIH does in this proceeding will influence the terms under which future products are made available to the public. If the NIH decides, for example, that government funded inventions should not be priced higher in the United States than in other high income countries, it will be a straightforward rule that patent owners can both understand and easily follow. Likewise, the NIH could adopt policy guidance on other practices that should be avoided, such as the Abbott effort to charge far more for a drug if used with a competitor's product, or decisions to sharply increase prices on highly profitable products.

On the other hand, if the NIH denies the petition, the opposite signal will be sent to patent owners. The facts in the Abbott case are so extreme that a "sky is the limit" or "anything goes" precedent will have been sent. This will likely lead to even more aggressive pricing on federally funded inventions, and perhaps even for medicines in general.

Government Role in Development of Ritonavir.

Ritonavir was initially developed on a US government grant to Abbott. The NIH not only provided Abbott with approximately \$3.5 million to finance Abbott's discovery and development of ritonavir, but the NIH also undertook its own research on ritonavir, employing Dr. John Erickson, a former Abbott researcher who played an instrumental role in obtaining the initial NIH grant to Abbott. Abbott acknowledges US government rights in six of the key patents for ritonavir.

Abbott claims that the US contribution to the development of ritonavir was small compared to Abbott's. Abbott deliberately under-estimates the economic value of NIH contributions in the early stages of development, and ignores the continued US government investment in research on ritonavir.

To fairly evaluate that the economic value of the \$3.5 million grant to Abbott, one must recognize the risky nature of the public investment. The odds of success for investments

Bhaven N. Sampat and Arvids A. Ziedonis, *Ivory Tower and Industrial Innovation: University-Industry Technology Transfer Before and After the Bayh-Dole Act*, Stanford Business Books, 2004.

⁶ David Halperin, "the Bayh-Dole Act and March-In Rights," 2001.

in pre-clinical research are low. Most NIH funded grants to develop AIDS drugs are unsuccessful. Only a few such grants lead to a commercial product. The pharmaceutical industry itself frequently emphasizes that risk must be considered when calculating investment costs. Often we are told that every compound has only a 1 in 5,000 chance of commercial success. This is more a polemic than an actual estimate, but consider for a moment if this were the true risk. The risk-adjusted value of the US government investment would then be \$3.5 million multiplied by 5,000, or \$17.5 billion. And this does not even include the adjustments for inflation and the cost of capital that industry economists typically include in cost estimates. There is no good estimate of the actual risks in the initial investment stage, but in any reasonable analysis it would be significant. Joseph DiMasi and his colleagues have estimated the cost of pre-clinical research, adjusted for risk and capital costs, to be approximately \$335 million.⁷ This is a good starting point for thinking about the value of the initial NIH investment in ritonavir.

Abbott claims to have spent hundreds of millions on the development of ritonavir, but this is a “trust us” number. We have almost no details from Abbott. The initial FDA approval of ritonavir was based upon clinical trials that involved 1,583 patients. This is less than 30 percent of the number of patients the DiMasi study says are average for new drug approvals. The trials were also relatively short, and the FDA approval time for Norvir was extremely short -- only 70 days.⁸ When trials and FDA approval times are shorter, company costs are generally lower -- certainly in terms of the cost of capital. These objective data are evidence that Abbott’s costs for clinical development were below average.

Subsequent to FDA approval, the NIH continued to pour money into ritonavir R&D. The NIH has sponsored a large number of post market clinical trials involving ritonavir, and has given out dozens of grants.

Abbott’s role has also been important. Ritonavir has been a successful collaboration between the NIH and Abbott. It has also been a highly profitable collaboration for Abbott, as reflected both in its sales of Norvir and the sales of ritonavir as a component of Kaletra. Ritonavir has generated billions of dollars for Abbott. And the US government has received zero royalties from ritonavir.

Patent Landscape for Ritonavir

Ritonavir is sold in different formulations and presentations. For each presentation, Abbott has registered differed patents in the *FDA Orange Book*. If the NIH grants licenses to Abbott’s six ritonavir patents to Essential Inventions, we will consider our options for providing generic versions of ritonavir. We have asked several patent lawyers and experts to review the patent landscape for ritonavir to determine if it is possible to produce and market a generic version of ritonavir if we are successful in obtaining the

⁷ Joseph A. DiMasi, Ronald W. Hansen, Henry G. Grabowski, "The price of innovation: new estimates of drug development costs," *Journal of Health Economics* 22 (2003) 151–185.

⁸ The request for FDA marketing approval was December 21, 1995. The FDA approval for ritonavir was March 1, 1996.

march-in licenses. We believe this is feasible. Our priority is for the 100 milligram tablet. The following is an excerpt from an analysis by the Daniel Ravicher of the Public Patent Foundation on the capsule formation of ritonavir:⁹

PUBPAT has undertaken a review of the patents pertaining to Abbott Laboratories' ritonavir drug products. In total, there are 5 patents listed by Abbott in the Orange Book for its approved ritonavir capsule product. Of those 5, the Ritonavir Petition would, if granted, provide access to 4, leaving only one patent, U.S. Patent No. 6,232,333 ("333 patent"), as a potential barrier to making an effective generic ritonavir capsule product. Table 1 below sets forth the Orange Book patent listing for Abbott's ritonavir capsule product and also indicates which of those patents are subject to the Ritonavir Petition.

Patent No.	Listed for Abbott's Ritonavir Capsule	Subject to the Ritonavir Petition
5,541,206	YES	YES
5,635,523	YES	YES
5,648,497	YES	YES
5,846,987	YES	YES
6,232,333	YES	NO
Table 1: Orange Book Listed Patents for Abbott's Ritonavir Capsule		

The '333 patent, unlike each of the other 4 patents listed for Abbott's ritonavir capsule, does not claim the active ingredient, ritonavir, itself. Rather, it merely claims a pharmaceutical composition containing ritonavir. Upon initial review, we have serious doubts about the validity of the '333 patent and its applicability to an effective generic ritonavir product. One issue regarding the '333 patent's validity is that its Abstract and Specification purport to teach an invention providing "improved bioavailability." Yet, no such limitation is present in any of the '333 patent's claims. Such a missing limitation means that the scope of the claims is much broader than what the patent otherwise purports to cover. This breadth of the claims increases the likelihood that they are invalid.

Regardless, the existence of the '333 patent in no way detracts from the importance or utility of the Ritonavir Petition. Access to the technology claimed in the 4 other patents that pertain to ritonavir is absolutely necessary to making an effective ritonavir capsule product available to the American public on fair terms. Further, a potential producer of a generic ritonavir product is much more likely to challenge the '333 patent if it

⁹ April 29, 2004. Daniel Ravicher letter to Mark Rohrbaugh, "Analysis of Patents Relevant to the Ritonavir Petition."

stands alone as the sole patent at issue than if the other 4 patents must also be dealt with. This is especially true since the '333 patent has such glaring validity issues and may be much more easily designed around than the other 4 patents since it does not cover the active ingredient ritonavir itself.

Proposed Remedy Includes Novel R&D Mandate

The march-in remedy proposed by Essential Inventions includes a novel proposal for the creation of an R&D Fund for AIDS treatments, funded by generic suppliers of ritonavir. Essential Inventions has proposed a mandatory R&D contribution of \$.004 per milligram (typically \$292 per year per patient), but the NIH could choose any figure. This R&D mandate would be in addition to the payment of reasonable royalties to Abbott. The structure of the R&D Fund management would be left to the NIH, but it could include either public or private sector management of the R&D fund, and different approaches to managing the intellectual property rights of the Fund. The proposal is modeled after an R&D mandate that the NIH imposed on Bristol-Myers in the early 1980's in connection with the Bristol-Myers marketing of cisplatin, a US government funded cancer drug. It is important to Essential Inventions that the exercise of the march-in right does not undermine investments in R&D, and the mandate that generic producers contribute to the R&D Fund is a mechanism to ensure that R&D levels are increased to socially desirable levels.

Concluding Comments

In the 24 years since the Bayh-Dole Act has passed, it has attracted a broad base of support among policy makers and researchers. The Act is also subject to criticism over a wide range of issues, including the tensions between sharing information and claiming property rights in research, and concerns over unjust pricing of some government-funded technologies. It is important that the bargain struck in the Bayh-Dole Act be considered fair to taxpayers.

The Norvir march-in case will be an important precedent, no matter what the outcome. For those who defend the policy of giving patent rights to grant recipients and contractors, and allowing patent owners much flexibility in using exclusive rights, there is an important issue. Is it sustainable in the long run to treat the taxpayers as if their only interest in the patents is to ensure that products are commercialized, regardless of the terms? The failure to use the march-in clause, ever, for any set of facts, will create the impression that the Act has been captured by those who profit from the commercialization of the taxpayer funded research. In the long run, this may undermine support for the broader policy of giving grant recipients title of US government funded research.

TESTIMONY BEFORE NIH PUBLIC HEARING ON
MARCH-IN RIGHTS UNDER THE BAYH-DOLE ACT

Washington, D.C., May 25, 2004

Statement of Jerome H. Reichman
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Statement of Jerome H. Reichman

I am Jerome H. Reichman, the Bunyan S. Womble Professor of Law at Duke University School of Law, in Durham, North Carolina. I have recently written a three-part, book length study, entitled *Nonvoluntary Licensing of Patented Inventions: The Law and Practice of Canada and the United States*, for the United Nations Conference on Trade and Development (UNCTAD), in Geneva, Switzerland.¹ Because of my expertise on compulsory licensing in domestic and foreign law, I have been asked to comment on the meaning of certain provisions in the Bayh-Dole Act that require patented products resulting from federally funded research to be made “available to the public on reasonable terms.”²

In general, the compulsory licenses that States may impose on foreigners’ patented inventions under current international law—that is, under the Paris Convention for the Protection of Industrial Property of 1883 and the WTO Agreement on Trade-Related Aspects of Intellectual Property of 1994 (TRIPS Agreement)³—fall into five categories. These are:

1. Antitrust violations
2. Abuses of the patentee’s exclusive rights
3. Compulsory licenses to promote some overriding public interest
4. Government use of patents
5. Dependent patents, i.e., licenses that allow an improver to use a dominant patent so as to avoid blocking technological progress.⁴

Most developed countries have enacted statutes enabling government authorities to authorize third-party private uses of patented inventions when breaking the inventor’s legal monopoly is deemed necessary to correct an abuse of the patentee’s exclusive rights or to promote some overriding public interest.⁵ The line between “abuse” and “public

¹ J. H. REICHMAN WITH CATHERINE HASENZ AHL, NON-VOLUNTARY LICENSING OF PATENTED INVENTIONS, PART I—HISTORICAL PERSPECTIVE, LEGAL FRAMEWORK UNDER TRIPS AND AN OVERVIEW OF THE PRACTICE IN CANADA AND THE UNITED STATES (UNCTAD/ICTSD, September 2002) [hereinafter HISTORICAL PERSPECTIVE]; PART II—THE CANADIAN EXPERIENCE (UNCTAD/ICTSD, October 2002) [hereinafter THE CANADIAN EXPERIENCE]; PART III—THE LAW AND PRACTICE OF THE UNITED STATES (UNCTAD/ICTSD, forthcoming 2004) [hereinafter LAW AND PRACTICE OF THE UNITED STATES].

² 18 USC §§200, 201(f), 203(1)(a).

³ [cites]

⁴ See TRIPS Agreement, *supra* note 3, art. 31; REICHMAN WITH HASENZ AHL, HISTORICAL PERSPECTIVE, *supra* note 1.

⁵ See REICHMAN WITH HASENZ AHL, LAW AND PRACTICE OF THE UNITED STATES, *supra* note 1 [cites at fn 497]

interest” is seldom sharply delineated, and in many instances statutory definitions of abuse invoke the public interest as an additional criterion for intervention. Typical grounds for triggering these compulsory licenses are the “need to ensure adequacy of supply” and “to regulate the availability of products deemed vital to security, *public health*, or environmental protection.”⁶

The United States Congress has consistently declined to enact any general compulsory licensing provision of the kind adopted by other countries. In this country, compulsory licenses are available for antitrust violations and for government use of patents, while courts may decline to enforce patents in infringement actions under common-law doctrines of misuse. Beyond these limited circumstances, the availability of a nonvoluntary license for abuse or on public interest grounds in the United States depends primarily on specialized enabling statutes or on specialized clauses incorporated into specific statutes.⁷

The Bayh-Dole Act’s requirement that patented products be made available “to the public on reasonable terms” is one of the clearest examples of such a specialized enabling clause. It may be compared with a Canadian statute that authorized compulsory licenses for acts of abuse, which occur, *inter alia*, “if the demand for the patented article in Canada is not being met to an adequate extent and on reasonable terms.”⁸

The legislative history of the Bayh-Dole Act confirms that qualified experts viewed the relevant provisions as authorizing a compulsory license either for abuse or on public interest grounds.⁹ For example, Harry F. Manbeck, then General Patent Counsel for General Electric [and later a Commissioner of Patents] stated that “[I]f [a contractor] fails to supply the market adequately at a fair price, then there is reason for requiring it to license both the background patents and the patents stemming from the contract work.”¹⁰ U.S. Comptroller General Staats expressed DOE’s views that “march-in rights *to protect the public’s interest* were developed to take care of and address ... [a] contractor’s *windfall profits* ... and detrimental effects to competition...”¹¹

The reason for express legislative concerns about abuse and the public interest in the Bayh-Dole context are clear from the record. Under normal conditions, the patentee assumes the full risk of his or her research and development expenditures, and in U.S. law, there are relatively few constraints on the licensing practices by means of which the patentee tries to recoup that investment and turn a profit. Under Bayh-Dole, however, the government will have funded a significant part of the patentee’s R&D costs and thus attenuated the risk. While there was a consensus that releasing the research product to

⁶ [cites at fn 498].

⁷ *Id.* [cite 503]

⁸ See REICHMAN WITH HASENZ AHL, THE CANADIAN EXPERIENCE, *supra* note 1, at 20-22 (discussing §65(2) of Canada’s Patent Act of 1985).

⁹ See generally Halperin, at ____.

¹⁰ [cite Halperin, n. 21] (emphasis supplied).

¹¹ [cite *id.*, n. 22]

private industry would augment applications and benefit economic growth generally, the march-in provisions were added to ensure that patentees' did not abuse their position by making the products available to the public on unreasonable terms that could lead to "windfall profits, [the] suppression of technology, and ... detrimental effects to competition."¹²

A State's ability to impose compulsory licenses to regulate abuses of a foreign patentee's exclusive rights under domestic law has been regulated by article 5A of the Paris Convention for more than 75 years, and these provisions were incorporated into the TRIPS Agreement of 1994. The large body of state practice in implementing these norms over time was succinctly and authoritatively summarized by Bodenhausen in 1967, as follows:

[W]hen national legislation is aiming at preventing *the abuses which might result from the exercise of the exclusive rights conferred by the patents*, the rules given in paragraphs (3) and (4) [of article 5A, Paris Convention] are mandatory for the member states...

[E]xamples of such abuses may exist in cases where the owner of the patent, although working the patent in the country concerned, refuses to grant licenses on reasonable terms and thereby hampers industrial development, or does not supply the national market with sufficient quantities of the patented product, or *demand excessive prices, for such products*. The member states are free to define these, and other abuses.¹³

This international practice is consonant with the legislative history of the march-in right under Bayh-Dole, as appears, for example, from Harry Manbeck's reference to a contractor's failure "to supply the market adequately at a fair price," quoted above. In his and other's views, march-in rights were thus "part of the answer to the so-called windfall situation."¹⁴

Apart from the legislative history, which is consistent with international practice, it cannot logically be doubted that the language in the Bayh-Dole Act requiring patented products to be made available to the public on reasonable terms encompasses the patentee's pricing strategy. All unreasonable terms and conditions that rise to the level of actionable abuses have as their object the power, directly or indirectly, to increase the licensor's prices beyond the level that competition would otherwise ensure and thus to enhance profits. When patentees impose "field of use" or other licensing restrictions, when they engage in illegal tying, or as in the case at hand, they adopt a marketing

¹² Staat, Halperin n. 23; see generally Halperin; Arno & Davis.

¹³ G. H. C. BODENHAUSEN, GUIDE TO THE APPLICATION OF THE PARIS CONVENTION FOR THE PROTECTION OF INDUSTRIAL PROPERTY AS REVISED AT STOCKHOLM IN 1967 70-71 (1968) (emphasis supplied).

¹⁴ Cite at Halperin nn. 21, 23.

strategy consistent with the practice known as “monopoly leveraging,”¹⁵ they are not conducting scientific or economic experiments for the sake of increasing academic knowledge. They pay their lawyers to devise contractual conditions that will enable them to raise prices and make more money.

In this connection, one should recall that individual members of the public do not typically negotiate with their pharmacies when they purchase medicine. They buy the product and pay the price that market conditions permit the pharmacist to charge. These conditions, in turn, result from the contracts stipulated between patent holders as licensors and their various licensees. When the Bayh-Dole Act affirms that the resulting products must be made available to the public on reasonable terms, it can only mean that the underlying licensing agreements should not undersupply the market, unduly distort competition, or otherwise leverage the procurement of active ingredients in ways that boost the price to unreasonable “windfall” levels that many users cannot afford.

While the Bayh-Dole march-in provisions thus clearly contemplate practices that produce excessive prices—what Manbeck and others called “windfall profits”—and would make no sense if they did not, I hasten to add that the Act in no way implies a regime of price controls, like that adopted in Canada and many EU countries. Indeed, loose assertions about “price controls” merely create confusion and divert attention away from the real issues bearing on the patentee’s specific marketing strategies.

Statutes that seek to prevent abuses or otherwise to protect the public interest, like the march-in provisions of the Bayh-Dole Act, normally leave patentees free to adopt the marketing strategies they deem suitable. They do not require regulatory approval of prices, as would be the case under, say, Canada’s regulatory agency, the Patented Medicines Prices Review Board (PMPRB).¹⁶ By the same token, the marketing strategies that the patentee actually adopts, and their impact on the availability of the relevant products to the consumers on reasonable terms, is always open to public scrutiny and challenge on objective grounds of abuse. In the Bayh-Dole context, this would necessarily require attention to the taxpayers’ interests as well as those of the patentee, including the ability of purchasers to afford critical, life-saving medicines and not be charged prices that “create ... hardship for the overall public or for individual members of the public.”¹⁷

In the case at hand, there is objective evidence that Abbott has imposed a 400% price increase in order to steer consumers away from competing products that would otherwise be made available to the public at much lower prices. There is further evidence that this strategy imposes hardship on patients that would particularly benefit from the lower priced products. At least one leading expert in the field believes that Abbott’s strategy may turn out to violate prescriptions against one form of abuse known as monopoly

¹⁵ Interview with Professor Arti Rai, Duke University School of Law.

¹⁶ See REICHMAN WITH HASENZ AHL, *THE CANADIAN EXPERIENCE*, *supra* note 1, at 43-44.

¹⁷ Halperin, at 13.

leveraging.¹⁸

These are questions of fact and law that require investigation and due deliberation.¹⁹ Although the practices under review appear questionable to me, it is not my task to anticipate the conclusions that the NIH may reach. I am here to testify that, under the march-in provisions of the Bayh-Dole Act as they were adopted, the NIH does have a solemn obligation to undertake this enquiry in good faith, with a view to determining whether the products of federally funded research are in fact being made available to the public under reasonable terms and conditions.

¹⁸ Image Technical Services, Inc. V. Eastman Kodak Co., 125 F.3d 1195 (9th Cir. 1997).

¹⁹ See, e.g., Arti K. Rai and Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 294 (2003).