Testimony of Robert Weissman
"The Role of Federally-Funded University Research in the Patent System"
Before the
Committee on the Judiciary
U.S. Senate
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Chairman Leahy and Members of the Senate Judiciary Committee, thank you for the opportunity to testify today on the important subject of federally funded research and development.

I am the director of Essential Action, a nonprofit advocacy organization that works on pharmaceutical access and other corporate accountability issues. I am also counsel to Essential Inventions, a separate nonprofit corporation that aims to promote the creation and distribution of essential inventions and other works that support public health and access to information. Information about the organizations is available at <www.essentialaction.org> and <www.essentialinventions.org>.

With colleagues, both organizations have urged federal agencies to exercise safeguards in the Bayh-Dole Act,[1] which governs the disposition of federally sponsored inventions, to address pharmaceutical pricing abuses and promote affordable access to medicines. Unfortunately, our efforts have failed.

The Bayh-Dole Act was signed into law in 1980, and effectively expanded through administrative and subsequent Congressional action over the next decade. The law aims to promote commercialization of government-funded inventions. It transfers title to government-funded inventions to universities and other contractors. Universities in turn are able to license the inventions to other parties, including on an exclusive basis.

Although federal agencies have actively embraced the Bayh-Dole mission of licensing federally funded inventions to private corporations, our experience shows that the government has abrogated its duty to ensure that pharmaceuticals incorporating federally funded inventions are reasonably priced.

The result is a public policy outrage, and a public health tragedy. U.S. taxpayers pay to fund R&D. The government turns the fruits of the research over to pharmaceutical and biotechnology companies, which then price gouge U.S. consumers and even the government itself. Thus the industry is able to execute a double swindle of the public. There is little doubt that U.S. consumers experience financial hardship as a consequence, and sometimes have been deprived of needed medicines. The Bayh-Dole licensing system has, in too many cases, distorted and concentrated markets, and facilitated abuses of market power, all with substantial deleterious consequences for pharmaceutical affordability and other public health objectives -- including promotion of the R&D enterprise. The public health consequences are most profound in the developing world, where high prices typically mean that patients go without life-saving and other essential

[1] 35 USC § 200 et. seq.

medicines. There is a U.S. taxpayer component in the global health arena as well, because U.S. aid monies are not uncommonly used to buy drugs invented with federal research support.

Bayh-Dole created the climate in which these abuses could occur, but they were not inevitable. Government agencies could have implemented Bayh-Dole on terms that would have prevented or at least greatly limited the abuses that have occurred. With few exceptions, they have declined to do so.

In my testimony today, I will describe our initiatives and the federal government's response. The first portion of my testimony briefly reviews the history of Bayh-Dole and associated statutes. The second section recounts our efforts to employ safeguards in Bayh-Dole. The third section presents and critiques the National Institutes' of Health (NIH's) stated rationale for refusing to apply price-restraining measures to pharmaceuticals incorporating NIH-funded inventions. Finally, I conclude with recommendations for policy changes and areas for the committee to examine as it begins its investigations into disposition of federally funded inventions. These recommendations draw both on our direct experience, and the overall experience in the Bayh-Dole era.

THE EVOLUTION OF THE BAYH-DOLE ACT

Since the early 1980s, the federal government under Bayh-Dole and related laws has routinely given away the fruits of the tens of billions of dollars of research it sponsors annually, granting private corporations exclusive rights to commercialize government-financed inventions while failing to include and/or enforce reasonable pricing requirements in the licenses.

It wasn't always so. The Bayh-Dole Act represented a significant shift from previous policy. Following the creation of a major federal role in research sponsorship in World War II, the Justice Department concluded in 1947 that "where patentable inventions are made in the course of performing a Government-financed contract for research and development, the public interest requires that all rights to such inventions be assigned to the Government and not left to the private ownership of the contactor." The Justice Department recommended also that "as a basic policy all Government-owned inventions should be made fully, freely and unconditionally available to the public without charge, by public dedication or by royalty-free, non-exclusive licensing."[2]

The Justice Department offered what remains a compelling case for non-exclusive licensing: "Public control will assure free and equal availability of the inventions to American industry and science; will eliminate any competitive advantage to the contractor chosen to perform the research work; will avoid undue concentration of economic power in the hands of a few large corporations; will tend to increase and

[2] "Investigation of Government Patent Practices and Policies: A Report of the Attorney General to the President," 1947, quoted in Background Materials on Government Patent Policy: The Ownership of Inventions Resulting in Federally Funded Research and Development. Volume II: Reports of Committees, Commissions and Major Studies, House Committee on Science and Technology, August 1976, p. 22.

diversify available research facilities within the United States to the advantage of the Government and of the national economy; and will thus strengthen our American system of free, competitive enterprise."

Even in 1947, the Justice Department position was not the uniform standpoint of the federal government. The Defense Department consistently maintained a policy of allowing contractors to gain title to government-sponsored inventions, so long as the Pentagon was able to maintain a royalty-free right to use the invention.

In the ensuing decades, government policy evolved unevenly between different agencies, with some gradual increase in exclusive rights transfers to private parties.

Beginning in the mid-1970s, big business, in collaboration with partners at major research universities, began lobbying for a major transformation in government patent policy. Based on highly questionable evidence, the business-university alliance argued that exclusive licensing was necessary to spur private sector innovation and development of government-funded inventions.

In 1980, Congress passed the Bayh-Dole Act, which authorized universities and small business contractors to take title to government-sponsored inventions. Universities were in turn permitted to exclusively license to private corporations, including big businesses. In 1983, President Reagan issued a Presidential Memorandum that instructed executive agencies to grant exclusive inventions to contractors of all sizes. In 1986, Congress passed the Federal Technology Transfer Act, which authorized federal laboratories to enter into exclusive contracts with corporations to develop and market inventions originating in the federal labs.

It is important to note that the Bayh-Dole Act was contentious at the time of passage. Other alternatives proposed at the time included a suggestion by Admiral Hyman Rickover that government inventions be licensed non-exclusively for a period of six months; and that if no party had indicated an interest in commercialization, that the patent then be open to competitive bidding for an exclusive license. A proposal by President Carter, which passed the House of Representatives prior to passage of the Bayh-Dole Act, would have limited the exclusive license granted by government to designated "fields of use." These ideas survive, at least in word, in law governing disposition of federally owned (as opposed to federally sponsored) inventions.

In the many hearings and years of debate that preceded Bayh-Dole, three intertwined concerns were preeminent. First was concern with the government getting repaid for its investment. Second was a concern that licensees would obtain windfall profits. The public had paid for the invention, cutting the investment costs of the company that would obtain control over the invention, but would the pricing fairly reflect the public subsidy? Would the monopoly patent rights enable the licensee to earn unfair superprofits? Third was the impact of the licensing arrangements on market competition and market structure. Patents provide monopolies for the covered invention, and patent protection is in perpetual tension with antitrust policies. Would the conferment of exclusive rights to

publicly funded inventions create or deepen market concentration? Would it enable licensees to engage in anti-competitive behavior?

Regarding windfall profits, "recoupment" was the preferred remedy, but was eliminated from the Bayh-Dole text before final passage. The only recoupment provision contained in the Bayh-Dole Act relates exclusively to contractor-managed federal laboratories.[3]

Other measures were included and did remain in the statute to address potential abuses.

These include:

• The allocation to the federal government of "a nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world," including a right for the federal government to license foreign rights to use the invention to other parties.[4] At the time of the Bayh-Dole debates, the federal government's paid-up license to use subject inventions was considered the most basic governmental right. Within the government, agencies such as the Defense Department that were favorably disposed to contractors retaining title insisted that governmental interests would be protected by maintaining the paid-up license.

• The right of the government to "march-in" and issue licenses to parties other than the contractor or a university licensee, including in circumstances when the federally sponsored invention is not achieving practical application, or to meet health needs, or when public use needs are not being met.[5] The statute defines "practical application" as being achieved when an invention "is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms."[6] In the debates leading up to Bayh-Dole's passage, march-in rights were advocated as a key tool to restrain pricing or patent abuse.[7]

• The right of the government not to grant title to a university or contractor "in exceptional circumstances when it is determined by the agency that restriction or

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[3] 35 USC § 202(c)(7)(E)(1).
[4] 35 USC § 202(c)(4),
[5] 35 USC § 203.
[6] 35 USC § 201(f).
[7] See Peter S. Arno and Mickey Davis, "Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed Upon Patents Deriving in Whole or in Part From Federally Funded Research," 75 Tul. L. Rev. 631 (2001). See also David Halperin, "Bayh-Dole Act and March-In Rights," March 2001, available at: <www.essentialinventions.org/legal/norvir/halperinmarchin2001.pdf>

Here was how General Electric's general patent counsel described the role of march-in rights: "[I]f [a contractor] fails to supply the market adequately at a fair price, then there is reason for requiring it to license both the background patents and the patents stemming from the contract work. (Harry F. Manbeck, Government Patent Policy: Hearings Before the Subcommittee on Science, Research and Technology of the House Committee on Science and Technology, 96th Congress, page 48 (1979).)

elimination of the right to retain title to any subject invention will better promote the policy and objectives of this chapter."[8]

Unfortunately, the concerns that Bayh-Dole would give rise to abusive behavior were prescient. Even more unfortunately, the government has largely failed to exercise the safeguards that Congress included in the statute, as our experience, and many others', shows.

ESSENTIAL INVENTIONS MARCH-IN REQUESTS

The Ritonavir March-In Case

In January 2004, Essential Inventions petitioned the National Institutes of Health to exercise its march-in rights for ritonavir, an HIV/AIDS drug marketed by Abbott under the brand-name Norvir. The petition and the NIH response are attached as Appendices A and B.[9]

The particular facts surrounding the Abbott's pricing of ritonavir made the march-in request particularly compelling. In December 2003, Abbott announced that it would raise the price of ritonavir, a drug that first came on the market in 1996, by 400 percent. Abbott was selective about the price increase, however. It did not apply to use of ritonavir in combination with another Abbott product, or outside of the United States. The company also said the price rise would not apply to public payers.

Abbott initially marketed ritonavir as a standalone protease inhibitor, to be used as part of a Highly Active Antiretroviral Therapy (HAART) drug "cocktail" for treating HIV/AIDS. The high doses of ritonavir for this purpose were accompanied by severe side effects, however. Over time, it turned out that ritonavir's best use was as a booster to other protease inhibitors -- a low dose of ritonavir can slow the ability of liver enzymes to break down a companion protease inhibitor, making it possible for a person on HAART to use lower doses of the companion protease inhibitor.

Abbott's 400 percent price increase raised the annual cost of using ritonavir as a standalone protease inhibitor from $9,387 to $46,935 per year.

More important was the price impact on use of ritonavir as a booster. The price jumped from $1,565 to $7,822. Abbott did not apply the price increase to all uses of ritonavir, however. The jump in the booster price applied only when ritonavir was used in conjunction with other companies' protease inhibitors. The price increase did not apply to use of ritonavir in conjunction with lopinavir, another protease inhibitor to which Abbott held patent rights. As a result, Abbott's ritonavir/lopinavir combination, sold as a two-in-one pill under the brand-name Kaletra, suddenly became much cheaper than other ritonavir-protease inhibitor combinations. Kaletra had been priced in the middle range of

[8] 35 USC § 202(a)(2).

[9] See also James Love, "Statement at the NIH Meeting on Norvir/ritonavir March-in Request," May 25, 2005, available at: <www.essentialinventions.org/legal/norvir/may25nihjamie.pdf>.

ritonavir-protease inhibitor combinations prior to the price increase. Afterwards, it was the cheapest, by a considerable margin. While Kaletra was priced at $8,559 a year and a single competitor was priced at $9,206, the rest ranged from more than $12,000 to more than $15,000 a year.

The anti-competitive effect of Abbott's price manipulation was clear. The price increase was a classic tying arrangement, with predictable consequences. The price differential between Kaletra and other ritonavir-protease inhibitor combinations meant that private insurers and patients in the private sector would tend to rely on Kaletra rather than alternatives.

More was at stake than simply money, though a lot of money was at stake. Not only did Abbott's pricing manipulation inevitably effect prescription decisions -- made for reasons other than the best interests of protecting patients' health -- it would affect the research agenda of other drug companies. The price rise for ritonavir changed the calculus for undertaking research into protease inhibitors that would rely on ritonavir -- any new product would be uncompetitive with Kaletra, so there was little incentive to invest in R&D.

"Looking ahead, we can foresee the continued need for new protease inhibitors that will have novel resistance profiles, that will have less toxicity, and that are more durable," explained Robert Huff, editor of Gay Men's Health Crisis Treatment News. "But how many important, useful, and desperately needed drugs will now never see the light of day -- because of Abbott's monopoly on Norvir? Abbott's unreasonable terms for Norvir will inhibit innovation, restrict research, limit medical options and hurt people with HIV."[10]

The United States government invested quite substantial resources into the development of ritonavir.[11] It funded Abbott's initial research on the drug, and thereby obtained Bayh-Dole rights in all but one of the patents Abbott claims on the project. NIH's investment in the preclinical phase at Abbott was approximately $3.5 million; if one applies the standard risk adjustments that the brand-name pharmaceutical industry typically employs when explaining the amount of investment in a product, this sum is huge. John Erickson, the principal investigator on the project at Abbott that invented ritonavir, says that early government funding played a key role in catalyzing support within the company to invest in the product's development.[12] After the Abbott team developed the precursor to

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[10] Robert Huff, "The Public Health Impact of Abbott Laboratories' Unreasonable Terms for Norvir," statement at a Public Meeting at the National Institutes of Health (NIH), May 25, 2004, available at <www.essentialinventions.org/drug/nih05252004/huff.doc>.

[11] To be clear, the level of government investment is irrelevant to whether Bayh-Dole rights attach. What matters is whether an invention was "conceived and reduced to practice" with the use of federal funds. If so, Bayh-Dole rights attach; if not, the government does not gain such rights, irrespective of how much it spends. Where such rights are in place, however, it is logical, in assessing the reasonableness of price for a federally funded invention, to examine the government and licensee's relative and absolute contributions to research and development of the invention.

[12] John Erickson, "On the Role of the U.S. Government in the Development of Norvir," statement at a Public Meeting at the National Institutes of Health (NIH), May 25, 2004, available at <www.essentialinventions.org/drug/nih05252004/erickson.doc>.

ritonavir, federal money paid for clinical studies. At a certain point, Abbott apparently rejected additional federal funding, for fear that the government would later want to impose restraints on what it could charge for the drug.

Abbott claims that it spent more than $300 million developing ritonavir, though it provides no details to support these claims. It is very likely that this figure includes the kind of risk adjustment the company does not make in describing NIH's contribution to the early development of the product. The available evidence suggests that Abbott's clinical trial expenses were low relative to the average. The clinical trials to obtain marketing approval were small, the trial proceeded faster than usual, and FDA approval was granted in just 70 days (during a period when the average review time was more than 16 months).

As noted above, the Bayh-Dole Act specifies that march-in rights may be exercised because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention."[13] The Act defines "practical application" as including "that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms."[14] A second ground exists if "action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees."[15]

We petitioned for the exercise of Bayh-Dole march-in rights on both of these grounds. We argued that Abbott has failed to make ritonavir available on reasonable terms. Following the arbitrary escalation of price, ritonavir as a standalone protease inhibitor is priced 3-to-5 times more than other protease inhibitors not invented on a government grant. This was not, and is not, reasonable. Ritonavir is priced five times higher when used with competitors' protease inhibitors than when used in Abbott's own co-formulated pill. This was not, and is not, reasonable. Ritonavir's price jump applied to the United States, but not other markets, leaving the government-funded product five or ten times more expensive in the United States than other high-income countries. This was not, and is not, reasonable.

We also argued that the health consequences of Abbott's actions -- the distortion of prescribing decisions, and the effect on the R&D protease inhibitor pipelines -- meant that Abbott is not satisfying health and safety needs, again reason enough under the statute for NIH to exercise march-in rights.

In our petition, we asked that NIH issue an "open license" for use of ritonavir, so that any qualified manufacturer could make and sell the drug on a worldwide basis. To ensure that such actions would not undermine efforts to support R&D, we recommended that each licensee under the march-in be required to pay a 5 percent royalty to Abbott, and contribute to a fund to research new treatments for HIV/AIDS.

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[13] 35 USC § 203(a)(1).
[14] 35 USC § 201(f).
[15] 35 USC § 203(a)(2).

Unfortunately, NIH rejected our petition.

"The record in this instance demonstrates that Abbott has met the standard for achieving practical application of the applicable patents by its manufacture, practice, and operation of ritonavir and the drug's availability and use by the public," the NIH found.

"Ritonavir has been on the market and available to patients with HIV/AIDS since 1996, when it was introduced and sold under the trade name Norvir as both a standalone protease inhibitor and a booster to increase the effectiveness of protease inhibitors marketed by other companies. Thus, the invention has reached practical application because it is being utilized and has been made widely available for use by patients with HIV/AIDS for at least eight years."

The logic of the NIH position was that Abbott met the Bayh-Dole standard of "practical application" by putting ritonavir on the market. This conclusion, however, ignored the statutory definition of "practical application," which specifies that the invention must be "available to the public on reasonable terms."

NIH dismissed our public health grounds for the petition as merely a restatement of the pricing controversy. "No evidence has been presented that march-in could alleviate any health or safety needs that are not reasonably satisfied by Abbott. Rather, the argument advanced is that the product should be available at a lower price, which is addressed below." This brief response failed to grapple not only with the way in which the price increase would impact prescription decisions -- a qualitatively different issue than whether patients or insurers are being charged too much -- but ignored altogether the unique impact of Abbott's actions on the R&D pipeline at other drug companies.

Finally, NIH said that the issue of drug pricing was one broader than the matter at hand. "The NIH agrees with the public testimony that suggested that the extraordinary remedy of march-in is not an appropriate means of controlling prices. The issue of drug pricing has global implications and, thus, is appropriately left for Congress to address legislatively." This was a bizarre conclusion. Our petition did not ask NIH to address drug pricing issues generally, but the specific case of Abbott's pricing of ritonavir, a government-funded invention. We did not ask the agency to manufacture authority for itself to wade into areas outside of its scope of expertise, but merely to exercise the safeguard implemented in the Bayh-Dole Act for the specific purpose of redressing pricing abuses and anti-competitive conduct.

It obviously was, and is, our position that NIH's decision was wrongheaded. We acknowledged at the time that NIH had discretion about whether it should act. But we believe its statutory interpretation was wrong on several grounds: the failure to consider reasonable pricing as part of the practical application standard; the refusal to consider derivative health consequences of anti-competitive conduct involving government-sponsored inventions; and the dismissal of price considerations as beyond the agency's authority under Bayh-Dole. We hope that NIH or the Secretary of HHS will revisit this

decision, either in the specific case of ritonavir, or in other abusive cases presented.

In light of NIH's excruciatingly cramped reading of its authority and obligations under Bayh-Dole, Congress should act to give more guidance on when march-in rights should be administered. There are many reasons that NIH has been reluctant to exercise its march-in authority, but one is its historic uncertainty about how to handle matters relating to drug pricing. As I suggest below, Congress should both express the sense that NIH and other agencies should more aggressively use existing Bayh-Dole march-in authority, but also provide greater clarity to NIH and other agencies on the circumstances in which march-in rights should be exercised.

The Latanoprost March-In Case

In January 2004, Essential Inventions petitioned the National Institutes of Health to exercise its march-in rights for latanoprost, a drug for the treatment of glaucoma. The petition and the NIH response are attached as Appendices C and D.

Latanoprost was developed by Columbia University professor Laszlo Z. Bito in 1982. Dr. Bito's research in the late 1970s and early 1980s was funded with over $4 million in grants from the National Eye Institute at the National Institutes of Health. Columbia University licensed the invention to Pharmacia, which was subsequently acquired by Pfizer. Pfizer sells latanoprost under the brand name Xalatan.

Pfizer's price for latanoprost is very high. At the time of our petition, the drugstore.com price was $50 (it is now $65). A bottle lasts 4-6 weeks, making the 2004 cost of a year's supply $450-$650. The manufacturing cost of latanoprost, according to news accounts, is less than 1 percent of the sales price.[16]

The price of Xalatan in high-income countries outside of the United States is much lower than in the United States. Our petition to NIH provided evidence that the prices were two-to-five times cheaper in other high-income countries.

Our petition argued that this pricing disparity was per se evidence that Pfizer's price was not reasonable, and should therefore trigger the exercise of march-in rights. We argued that "a reasonable price for U.S. consumers, who funded the early development of latanoprost, would be a lower price than in developed economies that did not invest in the development of the drug. Pricing policies for a U.S. government funded invention cannot be reasonable when they discriminate against U.S. consumers."

We proposed the adoption of a presumptive rule that "patent owners for the subject invention should not charge U.S. consumers more than is generally charged in countries that are defined by the World Bank as high income."

NIH rejected our petition, using much the same logic as in the ritonavir decision. NIH

[16] Jeff Gerth and Sheryl Gay Stolberg, "Drug Companies Profit from Research Supported by Taxpayers," New York Times, April 23, 2000.

again interpreted the requirement of achieving practical application of a subject invention as putting the product on the market. It ignored both the logic of the statute and its definition of practical application, which holds that a subject invention must be made available on "reasonable terms," meaning at a reasonable price:

> Pfizer has met the standard for achieving practical application of the applicable patents by its manufacture, practice and operation of latanoprost and the drug's availability and use by the public.
>
> Latanoprost has been on the market and available to glaucoma patients since 1996, when it was introduced and sold under the trade name Xalatan. Thus, the invention has reach practical application because it is being utilized and has been made widely available for use by glaucoma patients for at least eight years.

Regarding pricing issues, which the agency again treated as separate from the practical application requirement, NIH contended that "because the market dynamics for all products developed pursuant to licensing rights under the Bayh-Dole Act could be altered if prices on such products were directed in any way by NIH, the NIH believes that the extraordinary remedy of march-in is not an appropriate means of controlling prices. The issue of whether drugs should be sold in the United States for the same price as they are sold in Canada and Europe has global implications and, thus, is appropriately left for Congress to address legislatively."

REQUESTS THAT THE UNITED STATES UTILIZE ITS WORLDWIDE RIGHTS TO USE PATENTS FROM SPONSORED RESEARCH

Request that the United States Use License Rights for Pharmaceutical Procurement

In January 2007, Essential Inventions wrote to Robert Portman, then the head of the Office of Management and Budget, to suggest that the government utilize its paid-up, worldwide rights to use patents from sponsored research. This letter is attached as Appendix E.

To make the proposal specific, we requested that OMB grant Essential Inventions, and all qualified suppliers, the right to import or manufacture two AIDS drugs, d4T and ritonavir, for the purpose of supplying the federal government. The federal government directly or indirectly purchases these drugs through numerous programs, including the AIDS Drug Assistance Program (ADAP), the Department of Veterans Affairs, Medicare Part D and PEPFAR (the President's Emergency Plan for AIDS Relief).

We pointed out that d4T from Bristol-Myers Squibb is now priced at more than $3,600 per year on the Federal Supply Schedule, but generic d4T costs less than $50 per year in countries where generic competition is legal. Major savings are available for ritonavir as well. Generic ritonavir is available for as low as $190 a year, though the U.S. price would

probably be higher.[17]

OMB staff agreed to meet with us. They did not disagree that the U.S. government had the Bayh-Dole rights we identified. They did not disagree that exercising those rights would yield enormous savings for the federal government. However, they indicated that they would not respond to our letter in writing, and that if we wanted to pursue the matter further, we should contact other agencies.

In the Congressional debates leading up to passage of Bayh-Dole, the most ardent supporters of a policy to license federally funded inventions pointed to the importance of maintaining government rights to use those inventions. This was described as a key check on pricing abuse -- the safeguard that at least the government would not be asked to pay excessive prices for the inventions it had funded. The OMB refusal to act on our recommendation, or even respond in writing, suggests that what was viewed as the most minimal safeguard has now been abandoned, at least for pharmaceutical inventions.

Request that the United States License International Organizations to Use Its Rights in Federally Sponsored Inventions

Under Bayh-Dole, the federal government not only has a paid up license to use sponsored inventions on its own behalf, it has the ability to issue licenses to international organizations or foreign governments to use those inventions.

In 1999, James Love of the Consumer Project on Technology (now Knowledge Ecology International), Ralph Nader and I wrote to the National Institutes of Health, urging that NIH exercise its Bayh-Dole rights to issue licenses to the World Health Organization (WHO) for important HIV/AIDS and other medicines in which the federal government held rights. This letter and the NIH response are attached as Appendices F and G.

We pointed out that patent barriers interfered with many countries obtaining access to generic versions of those medicines; and that even where patent barriers were not an obstacle, limited economies of scale meant most countries could not on their own obtain the full, robust price benefits that generic competition can confer. "If the WHO uses efficient procurement programs, it can obtain production of these government funded inventions at a small fraction of current world prices," we wrote. "These lower prices would lead to expanded access to essential drugs and stretch public health budgets."

We urged that NIH enter into an agreement with WHO to enable this transfer, assess for which drugs it could transfer patent rights, and take steps to ensure that all new grants and contracts reference WHO's right to use patents in which the government gained Bayh-Dole rights.

The NIH declined our request. Then-NIH director Harold Varmus acknowledged that NIH had the authority to implement our proposal, but argued:

[17] Medecins Sans Frontieres/Doctors Without Borders, "Untangling the Web of Price Reductions," July 2007.

> This proposal, if implemented, would have powerful repercussions on the current framework for drug development arising from federally supported basic research. I am concerned that your proposal that the NIH employ its "Government use" license authorities to grant WHO standing authority to contract for the production of Government-supported inventions so as to make anti-AIDS drugs available for less cost than offered by pharmaceutical manufacturers would put the current system at risk without necessarily resulting in greater accessibility to these drugs. I am also troubled by the implications of the NIH intervening on behalf of sovereign foreign governments in a situation in which many of those governments have the authority to achieve the same result and in which U.S. intervention on this matter has not been requested.
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> Moreover, the AIDS crisis in developing countries is a public health problem involving much broader issues than access to anti-viral drugs. The question of the supply of drug products must be considered in the context of the equally important issues of medical infrastructure, public health programs, treatment monitoring and compliance, and emergence of drug-resistant HIV strains. Unilateral action by NIH with regard to NIH-supported patent rights would consequently be ill-advised and unlikely to succeed.
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> ... As a practical matter, it is reasonable to assume that companies will not undertake the development costs of these inventions if they believe the Government will readily allow third parties to practice the inventions.

In retrospect, some of these arguments look deeply misguided. The argument that efforts to lower the price of AIDS medicines without a comprehensive approach to addressing the problem in developing countries was disproved by history. The eventual lowering of prices helped spur donor aid and far-reaching programs that would not have been possible with high prices.

The idea that NIH would undermine developing countries' sovereign authority by helping lower the price of medicines when the countries did not act on their own ignores the complex reasons why many did not act, and also has been disproved by history. Many have taken steps on their own to lower prices for HIV/AIDS drugs, but others have not. But of those countries which have not exercised policy options to lower prices, none have complained when international developments -- including decisions by brand-name companies not to enforce patent claims -- have spurred generic competition and enabled them to benefit from lower prices. Most importantly, the NIH position ignores the reality of pharmaceutical manufacturing, in which economies of scale are vital. Individual countries may and should act on their own, but they cannot, on their own, benefit from robust generic competition. WHO or another global agency undertaking global procurement arrangements can achieve these benefits. The price reductions obtained by the Clinton Foundation for HIV/AIDS drugs are an example of this.

The broad argument Dr. Varmus made was that licensing Bayh-Dole rights to WHO would undermine pharmaceutical companies' willingness to develop government-sponsored inventions. But this argument was misplaced as well. Developing country markets represent a small share of the world market -- roughly 15 percent at present (and less when Dr. Varmus wrote his letter).[18] Pharmaceutical companies would not stop investing in R&D if their overall market was suddenly 15 percent smaller; indeed, the global pharmaceutical market in 1999 was roughly half the size that it is presently, and it was almost 15 percent smaller in 2004 than it was in 2006. Moreover, pharmaceutical company development costs are proportionately smaller for pharmaceuticals when the United States government contributed -- often quite substantially -- to the early stage research. And, to ensure a fair return for their investment, compensation can be paid to corporate licensees -- a reasonable royalty for sales in developing countries

A standard licensing arrangement with WHO or other agencies for access to federally funded inventions remains a good idea, and is discussed further below. But in the absence of a standard agreement, surely there must be cases where the right should be exercised. Can there be a more compelling case than antiretroviral drugs? These are life-saving medications to treat one of the worst pandemics the world has experienced since the Black Plague. Prices in developing countries have plummeted for first-line and older HIV/AIDS drugs thanks to generic competition, but patent barriers are keeping prices for second-generation and second-line medicines relatively high, threatening the ability of global AIDS treatment programs -- of which the United States is the largest funder -- to expand treatment and meet the UN target of universal access to antiretrovirals by 2010.

ASSESSING THE NIH RATIONALE FOR INACTION

In two important reports, NIH has reviewed its options for assuring that federal funded inventions are made available to the public on reasonable terms, and essentially concluded that it has no role. In "A Plan to Ensure Taxpayers' Interests are Protected,[19] NIH explained why it abandoned efforts to include "reasonable pricing" provisions in Cooperative Research and Development Agreements (CRADAs), licensing federally owned inventions to third parties. In "Affordability of Inventions and Products,"[20] a July 2004 report to Congress, the agency explained why it did not seek to assure fair pricing of federally sponsored inventions.

Although some of the arguments relate to NIH's institutional capacity, many of them echo the self-interested declarations of the brand-name pharmaceutical industry.

Below I review NIH's key contentions and offer responses.

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[18] IMS Health Reports Global Pharmaceutical Market Grew 7.0 Percent in 2006, to $643 Billion," (news release), available at: <www.imshealth.com/ims/portal/front/articleC/0,2777,6599_3665_80560241,00.html>. (Global sales totaled $643 billion in 2006. Sales in Latin America, Asia (excluding Japan) and Africa totaled $99.6 billion.)

[19] National Institutes of Health, "A Plan to Ensure Taxpayers' Interests are Protected," report to Congress, July 2001, available at <www.nih.gov/news/070101wyden.htm>.

[20] National Institutes of Health, "Affordability of Inventions and Products," report to Congress, July 2004, available at: <http://ott.od.nih.gov/NewPages/211856ottrept.pdf>.

NIH Position: The technologies developed in basic research laboratories are nascent, requiring extensive further development. Not all technologies arising from NIH-funded research lead to therapeutic drugs. The likelihood that a compound will reach the market is very low. There is a long lag time between when inventions are licensed and when they reach the market, making monitoring difficult.[21]

Response: It is true that most NIH-sponsored inventions do not lead to therapeutic drugs and those that do require more development.[22] But neither of these facts alters the reality that a company gaining exclusive license to an NIH-sponsored invention gains something of considerable value in the exchange. How valuable? The brand-name pharmaceutical industry famously likes to quote the Tufts Center for the Study of Drug Development estimate that the risk-adjusted cost of developing each new pharmaceutical product is $802 million. Risk is highest in the early phases of the development process, so relatively small dollar outlays in the preclinical phase for successful drugs constitute a very large chunk of the $802 million. The authors of the study alleging the $802 million figure place the cost of preclinical research for a successful drug at $336 million.[23] Government funding will generally not cover the entire preclinical costs of development, but it is often a large part, especially when one takes into account multiple grants beyond the one leading directly to creation of the invention.

It is true that there is a long time lag between licensing and a product getting to market, but it is not true that the delay poses particular monitoring difficulties. Where universities or federal labs or NIH are receiving royalties, they typically monitor whether milestones are met and how the sponsored invention performs if it makes it to market. Moreover, a reasonable pricing requirement, whether mandated by contractual terms or enforced by use of march-in rights, would not require much enforcing -- once the government demonstrated that it intended to enforce such obligations. Even relatively complex measures of determining fair pricing would be relatively simple to administer, once it was clear that the obligation was going to be enforced.

NIH Position: "NIH also found that the actual financial return to grantees and contractors was relatively low. Indeed, while universities and industry stressed that the current system under Bayh-Dole has been highly successful and a model now emulated by the world, they cautioned that the great majority of these patents do not generate significant revenues or even sufficient revenues to compensate the patenting expenses."[24]

Response: It is true that the great majority of patents generate little or no revenue, but

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[21] National Institutes of Health, "A Plan to Ensure Taxpayers' Interests are Protected," report to Congress, July 2001, available at <www.nih.gov/news/070101wyden.htm>.

[22] Note however that some NIH-sponsored inventions, known broadly as research tools, require little or no additional development. The particular issues surrounding research tools are briefly discussed further below.

[23] Joseph DiMasi et al., J. Health Economics 2003;22(2):151-185; see Costs and Returns for New Drug Development, Joseph A. DiMasi, FTC Roundtable on the Pharmaceutical Industry, October 10, 2006, slide 5, available at: <www.ftc.gov/be/workshops/pharmaceutical/DiMasi.pdf>.

[24] National Institutes of Health, "A Plan to Ensure Taxpayers' Interests are Protected," report to Congress, July 2001, available at <www.nih.gov/news/070101wyden.htm>.

this is no argument for why those inventions that do have market impact should not be priced fairly. In fact, that the universe of sponsored inventions with significant market impact is small suggests that monitoring should be relatively easy. It is also worth noting that the claim that most government-funded inventions were not being commercialized was the key, misleading rationale for adoption of Bayh-Dole; after a quarter century of experience, and even with the biotech revolution, it is clear that the vast majority of government-funded patents remain uncommercialized, simply because they do not have clear commercial value -- the exact circumstance as was the case before Bayh-Dole.

NIH Position: Efforts to obtain higher royalty rates would deter companies from undertaking development of federally owned or sponsored inventions, even if the royalty or recoupment provisions only applied to blockbuster drugs.[25]

Response: NIH contends that higher royalty rates or recoupment provisions applying only to blockbusters would deter companies from developing government-sponsored inventions, and, relatedly that it abandoned the reasonable pricing requirement for CRADAs because of this deterrent effect. As a matter of simple economics and raw business calculation, it is very hard to see how a corporation would make this decision. Developing government-funded inventions would remain highly profitable even with recoupment or, much more preferably, reasonable pricing conditions. It is conceivable that some companies would refuse to accept such obligations on principle, or out of concern that it might lead to other price-related regulation. But that cannot be a reason for the federal government to sacrifice taxpayer interest. The public interest cannot so be held hostage. There is also empirical evidence of brand-name companies willingness to pay large sums -- exceeding any recoupment requirements -- where they believe they may obtain blockbusters.[26]

NIH Position: "Even in those few cases in which an NIH-invented technology is an identifiable part of a final product, the invention would typically be one of numerous components that would go into building that product. ... Just as the provider of any one component of an automobile cannot dictate the cost of the final vehicle, the provider of a single technology in the development of a therapeutic drug cannot dictate the final cost of the drug."[27]

Response: It is true that there typically are multiple patents related to any pharmaceutical product, and that where there is a government owned or sponsored patent, there may be others in which the government does not hold rights. However, it is misleading to analogize this situation to a component in an automobile; there may be several or even many patents on a drug, but nowhere near as many as there are components to a car.

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[25] National Institutes of Health, "A Plan to Ensure Taxpayers' Interests are Protected," report to Congress, July 2001, available at <www.nih.gov/news/070101wyden.htm>.

[26] See for example, Gilead Sciences and Royalty Pharma Announce $525 Million Agreement with Emory University to Purchase Royalty Interest for Emtricitabine," Gilead, Emory University, Royalty Pharma news release, July 18, 2005, available at <www.news.emory.edu/Releases/emtri>.

[27] National Institutes of Health, "Affordability of Inventions and Products," report to Congress, July 2004, page 3, available at: <http://ott.od.nih.gov/NewPages/211856ottrept.pdf>.

Because of the government's involvement in early stage research, its patents will typically be the most, or among the most, important patents on a product. It will frequently be the case that the government patent covers a new molecule or composition -- the essence of a new drug -- and that a party with rights to that patent could work around (and frequently challenge as invalid) other claimed patents. The expert analysis we had conducted of the patent landscape in the ritonavir march-in case, for example, suggested this was the case for that drug.[28] That said, there are complexities that will emerge in some cases for products with more complicated patent landscapes, and how to address these challenges is an issue the committee should consider addressing in future hearings. An important operative principle may include reach-through mechanisms connected to Bayh-Dole rights, requiring a product that incorporates a government-sponsored invention to be fairly priced

NIH Position: Overall improvements in efficiency and time and reduction in risk to industry in bringing drugs to the marketplace should result in not only new and better drugs for the American public but also permit industry to price the drugs lower than they would otherwise."[29]

Response: It is absolutely correct that reducing risk to industry via federal funding should "permit industry to price the drugs lower than they would otherwise." This is the essence of the argument that there should be pricing restraints on government-funded inventions, or that excessive pricing should be a trigger for use of the march-in right. It is, however, demonstrably not the case that federal funding without any licensing or contractual measures, or use of policy tools such as march-in rights, will lead to lower drug prices.

NIH Position: "The cost of prescription drugs is a legitimate public concern that exists whether or not a drug was developed from a technology arising from federally funded research. NIH, however, has neither the mandate nor the authority to be the arbiter of drug Affordability."[30]

Response: It is not true that NIH does not have the mandate or authority to address drug pricing concerns. The Bayh-Dole Act gives granting federal agencies the authority to exercise march-in rights when an assignee is not achieving practical application of an invention, defined by statute as being made "available to the public on reasonable terms."

NIH Position: "Should a critical public health emergency arise, the NIH may require mandatory licensing or sublicensing if it determines that a technology is not being moved to practical application (35 U.S.C. § 203). Bayh-Dole, however, does not provide authority for the NIH to control the pricing of products resulting from inventions made by

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[28] Daniel Ravicher, statement at a Public Meeting at the National Institutes of Health (NIH), May 25, 2004, available at <www.essentialinventions.org/drug/nih05252004/ravicher.doc>.

[29] National Institutes of Health, "Affordability of Inventions and Products," report to Congress, July 2004, page 4, available at: <http://ott.od.nih.gov/NewPages/211856ottrept.pdf>.

[30] National Institutes of Health, "Affordability of Inventions and Products," report to Congress, July 2004, page 5, available at: <http://ott.od.nih.gov/NewPages/211856ottrept.pdf>.

funding recipients."[31]

Response: There is nothing in the Bayh-Dole Act mentioning public health emergencies. The statute provides four separate grounds for march-in rights, all much broader than public health emergencies. These include to achieve practical application -- defined, again, as making the invention "available to the public on reasonable terms;" meeting public health needs not satisfied by the contractor or licensee; and satisfying requirements for public use not met by the contractor or licensee.

NIH Position: "Many companies, therefore, have indigent patient programs to supply drugs to some patients on a discounted or no cost basis, thereby making them affordable to those patients."[32]

Response: It is unfortunate to see NIH citing industry indigent patient programs as an excuse for high drug prices. Those programs do not begin to cover all who need them; many who are able to afford medicines do so as an enormous financial hardship. Even those who can absorb high prices should not be price gouged. Many medicines are of course provided by private and public insurers, meaning that even when there are not direct access problems (as there often are with the insured, because of co-payment obligations), consumers, employers and the public are bearing the financial burden.

NIH Position: "Although establishing standards for the affordability of drugs and therapies is beyond the agency's mission or authority, the NIH contributes to affordability through research that leads to the development of a wider selection of drugs or new drugs, where no drugs were available. More alternatives can translate into more choices for the public, greater market competition, affordability and, ultimately, overall return to society by the improvement of the quality of life."[33]

Response: There is no empirical basis for the claim that placing more drugs on the market will yield greater market competition and affordability. Drug prices are rising steadily; brand-name pharmaceutical and biologics companies no longer attempt to justify their pricing strategies based on R&D costs, instead saying they will charge whatever the market can bear; and available evidence suggests that new drugs in the same therapeutic class as existing patent monopoly-protected medicines are priced at or above the cost of existing drugs.

NIH Position: The public gets an enormous return on the public investment in medical R&D, because new medicines improve the quality of life and lessen the cost of illness

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[31] National Institutes of Health, "Affordability of Inventions and Products," report to Congress, July 2004, page 5, available at: <http://ott.od.nih.gov/NewPages/211856ottrept.pdf>.

[32] National Institutes of Health, "Affordability of Inventions and Products," report to Congress, July 2004, page 5, available at: <http://ott.od.nih.gov/NewPages/211856ottrept.pdf>.

[33] National Institutes of Health, "Affordability of Inventions and Products," report to Congress, July 2004, page 6, available at: <http://ott.od.nih.gov/NewPages/211856ottrept.pdf>.

(e.g., through reduced hospital stays).[34]

Response: It is undoubtedly true that many of the drugs NIH has supported have not only had important lifesaving and quality of life effects, but have lessened the economic cost of illness. This is no argument, however, about why important medicines should be overpriced, or why the government should not demand reciprocity from corporations that profit directly from government-sponsored research. It is also an argument that proves too much. Taken to its logical conclusion, it suggests the government should directly subsidize the pharmaceutical industry with no limit. The argument can be used, and is used by the brand-name industry, to justify ever higher prices of medicines, with very little limit. People place a high value on staying alive, lessening illness and reducing pain and discomfort; that does not mean they should be charged whatever the market will bear.

RECOMMENDATIONS FOR REFORM AND FURTHER INVESTIGATION

There is obviously a rich set of issues for the Committee to explore as it continues its investigations into the role of federally funded research in the patent system. My recommendations do not seek to be comprehensive, and they draw primarily though not exclusively from experience with biomedical research. The first set of recommendations draws from Essential Invention and Essential Action's direct experience with Bayh-Dole. The subsequent recommendations stem from our examination of Bayh-Dole-related policies and practices.

1. Operationalizing March-In Authority

The NIH has adopted an interpretation of its march-in authority that is divorced from the plain language of the Bayh-Dole statute, the law's legislative history, and common sense. This must change.

Congressional statements and effective oversight might affect NIH's approach, but there is reason to be skeptical. Congress has periodically turned it attention to different aspects of Bayh-Dole related to royalty rates and reasonable pricing, but NIH has rebuffed demands that it pay attention to the affordability of the inventions it transfers to pharmaceutical and biotechnology companies. Thus, although existing statutory language should at least give the agency confidence in its authority to exercise march-in rights to address pricing abuses -- even if the authority is discretionary -- it is likely the case that legislative action will be necessary.

Reform proposals should consider both standards by which march-in rights should presumptively be exercised, and institutional roles in determining the exercise of march-

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[34] National Institutes of Health, "A Plan to Ensure Taxpayers' Interests are Protected," report to Congress, July 2001, available at <www.nih.gov/news/070101wyden.htm>; National Institutes of Health, "Affordability of Inventions and Products," report to Congress, July 2004, page 5, available at: <http://ott.od.nih.gov/NewPages/211856ottrept.pdf>.

in authority.

Ritonavir presents the easiest case for reform: a sudden, unprovoked escalation in price, with transparent anti-competitive intent and effect, and harmful public health consequences. Clear language explicitly stating that excessive pricing, abusive use of patents, and/or anti-competitive behavior are bases for the exercise of march-in rights should make clear that march-in rights should be exercised in case of behavior comparable to Abbott's price and market manipulation with ritonavir.

But the march-in authority should not be limited only to the most extreme cases. Absent a major reworking of Bayh-Dole, the march-in is the key method to ensure the public gets a return on the government investment in the form of restrained pricing. This central role does not mean march-in rights must frequently be exercised. Once background rules for pricing restraint are established, and shown to be enforceable through march-in rights, market norms will shift. Then march-ins will only need to occur occasionally if at all.

In the latanoprost case, we suggested that the standard for exercising march-in rights should be whether the medicine incorporating federal inventions is priced more than the average in other high-income countries. Setting medicine prices for U.S. consumers above the charge for consumers in other high-income countries -- in instances where the U.S. public paid for crucial research and development -- should presumptively be unreasonable. A virtue of the rich country price comparison test is that it is a simple calculation yielding a clear answer.

It would not be hard to develop other standards, however, which complement or substitute the rich country price comparison test. More elaborate formulas might inquire into the relative and absolute government and corporate investments in a medicine, based on disclosed costs from the pharmaceutical company developer. The standard could require that prices for products incorporating federally sponsored inventions be lower in price, relative to other medicines in the class or otherwise comparable. Government funded inventions should be cheaper proportionate to the private company's reduced investment costs. Drugs not incorporating this price discount would then be defined as presumptively not being made available to the public on reasonable terms.

Another possible model might be to cap returns on blockbuster drugs receiving significant government support. After a product receiving government support equivalent to 20 percent of development expenditures, say, generated revenues equal to 20 times disclosed investment costs, march-in rights could presumptively kick in. The standard could be calibrated to take into account various factors; my numbers here are illustrative only.

To ensure that the public interest in supporting R&D is advanced, march-in rules might require that licensees under march-in rights pay royalties to support R&D or perform specified R&D mandates. Royalties to the initial licensee may also be mandated.

Whatever standard is established, our experience in trying to use the march-in rights

makes clear that a new Congressional directive is needed, with clear and presumptive standards.

It would be wise also to consider lodging march-in authority with other agencies. NIH has repeatedly denied that it has the authority conferred on it by the Bayh-Dole Act; one reason undoubtedly is that it is uncomfortable with drug pricing issues. There is no obvious reason why the agency should feel more able to develop and maintain institutional expertise in licensing of patents than in ensuring the fruits of its investments are available and affordable to the public, but that appears to be the case. In light of the NIH's expressed discomfort with pricing issues, one solution might be to establish concurrent march-in authority with another agency, perhaps the Federal Trade Commission or Department of Justice.

Establishing clear and presumptive rules for march-in rights would also make it possible to create strong rights of appeal to courts in case of agency inaction. Citizen enforcement and rights to appeal adverse agency decisions against a clear standard would be a very powerful means of ensuring Congressional objectives of obtaining a fair return on public investment were met.

It would be useful to specify that march-in rights may be exercised immediately upon grant, and not be subjected to stay on appeal.[35]

2. Using Federal Rights In Government-Funded Inventions

From a normative perspective, it is utterly shameful that the U.S. government permits pharmaceutical and biotechnology companies to gain access to government-sponsored inventions, and then price gouge consumers -- the U.S. public. But it is preposterous that the government permits those corporations to price gouge the very government that helped pay to invent and develop the drugs they are selling.

The federal government has the power to remedy this inequity. Congress should pressure the executive branch to take advantage of the fully paid-up licenses it maintains for drugs in which it holds Bayh-Dole rights. These drugs are concentrated in the areas of AIDS and cancer treatment, two areas of especially high government expenditure, so the potential savings are quite considerable.

Logically, policy in this area should be centrally managed, through an agency such as Office of Management and Budget (OMB). If OMB declines to act, individual agencies could and should take action on their own.

However, if past experience is any guide, the individual agencies are not likely to act on their own, again suggesting the need for Congressional intervention. The issues are similar to those in the Bayh-Dole context: Congress should specify clear rules for when the government should exercise its paid-up license for the purpose of accessing generic

[35] See discussion in Arti K. Rai and Rebecca S. Eisenberg, "The Public Domain: Bayh-Dole Reform and the Progress of Biomedicine," 66 Law and Contemp. Prob. 289 (2003).

versions of medicines it purchases through various programs. Congress should also specify that paid-up licenses may be used for state programs administered with federal money. The rules that Congress establishes may parallel those for use of the march-in right, or they might perhaps more aggressively favor march-ins, on the grounds that the government as drug buyer should be able to benefit directly from its R&D investment leading to pharmaceutical inventions. Concerns about fair returns for the R&D contribution of licensees should be addressed through reasonable royalty payments.

3. Licensing U.S.-Sponsored Inventions for Use in the Developing World

The management of overseas rights in U.S. government-funded or owned intellectual property offers an enormous opportunity to advance global public health interests, at no cost to U.S. taxpayers.

As we explained in our 1999 letter, the United States already has the power to enter into agreements with international organizations to license them the rights to patents in which the government holds Bayh-Dole interests. As the recognition of the severity of global health problems grows, as the United States devotes increasing resources to addressing global health challenges -- including but not limited to HIV/AIDS -- and as discussions evolve at international organizations such as the World Health Organization over mechanisms to promote the objectives of both access to medicines and increasing innovation, it is time for the United States to manage its intellectual property assets purposefully.

If we leave aside the question of what legal rights the United States currently has, and dismiss the propagandistic claims about harms that will befall medical innovation if we promote access in developing countries, it is not hard to imagine better policies going forward. The United States should make its biomedical patent portfolio available for nonexclusive use in developing countries.

One attractive approach to this issue is embodied in the Public Research in the Public Interest Act of 2006, introduced by Senator Leahy as S.4040. The Public Research in the Public Interest Act would require university recipients of U.S. funds to license their inventions on a non-exclusive basis for use by low-income and lower-middle-income countries, and for research on neglected diseases. An attraction of the bill is its reach-through provisions, which require the developing country licensing provisions to apply to university licensees and sublicensees, to follow-on patents associated with the government-sponsored invention, and to testing data needed to obtain regulatory approval.

A similar outcome could be achieved if the U.S. government acted to use its existing rights to advance global public health objectives, by entering into agreements with international organizations to license technologies to them. There would be several benefits of licensing to a global public health patent pool, or international agency that effectively managed licenses to biomedical inventions for developing countries. The public patents could serve as "anchor tenants" for a patent pool, creating social and

market norms to facilitate private sector licensing to the pool. A global manager of patents and related rights could also undertake or organize efficient global registration and procurement arrangements.[36] A patent pool would also be well positioned to collect and distribute royalties, making it possible to compensate companies that contributed to development of drugs with Bayh-Dole rights. A royalty system could also be calibrated to developing countries' varying income levels, so that middle-income countries could obtain lower priced drugs, while also making fair-share contributions to R&D costs.

4. Improved and Transparent Reporting Mechanisms

More effective public understanding of the extent of NIH and other agencies' Bayh-Dole rights could be achieved with better reporting of inventions where Bayh-Dole rights apply.

There are several reporting-related issues.

Patents with Bayh-Dole rights are supposed to include a reference to the supporting grant and a statement that "The Government has certain rights in this invention." Searching the U.S. Patent and Trademark Office (PTO) reveals that nearly 30,000 patents granted since 1976 list "certain rights." Although it would be a very worthy investigation to review these patents, how they have been commercialized and what returns the public has received, this is beyond the capacity of most persons or monitoring organizations, and involves a universe beyond NIH grants.

It is possible to review the registration information for every new drug, by checking the drug's listing in the FDA's Orange Book, identifying relevant patents, and then checking those patents in PTO's database. This is time consuming, though doable. This method does not work for biologics, however, which are not listed in the Orange Book, and which are an increasingly important part of the pharmaceutical landscape.

NIH does collect detailed information on utilization of inventions developed with federal support, but this information is not made public,[37] due to confidentiality provisions in Bayh-Dole.[38] This confidentiality apparently extends even to listing drugs on the market for which the government maintains Bayh-Dole rights, even when much of the information is attainable from other public sources. The NIH publishes a list of FDA-

[36] For a detailed discussion of how patent pools could advance health interests, see Knowledge Ecology International, "The Use of Patent Pools to Expand Access to Needed Medical Technologies: KEI Comment to the World Health Organization (WHO) Intergovernmental Working Group (IGWG) on Public Health, Innovation and Intellectual Property Rights," September 30, 2007, available at <www.who.int/phi/public_hearings/second/contributions_section2/Section2_ManonRess-PatentPool.pdf>. For a working plan of a global public health patent pool, see Knowledge Ecology International, "The Essential Medical Inventions Licensing Agency: Working Plan," June 1, 2007, available at: <www.keionline.org/misc-docs/emila.pdf>.

[37] See Interagency Edison, available at: <https://s-edison.info.nih.gov/iEdison/index.jsp>.

[38] 35 USC Sec. 202 (c) (5).

approved drugs where the contractor has consented to release of the information,[39] but this is very limited. Perusing the illustrative examples in the summary reports from the Association of University Technology Managers makes clear how much is missing. The Committee should consider revisiting the confidentiality provisions in Bayh-Dole, as well as means to centralize, organize and make public information on existing Bayh-Dole rights.

A separate issue relates to whether Bayh-Dole rights are properly acknowledged.

In filing patent applications, contractors are supposed to note both the supporting grant and that "the Government has certain rights in this invention."[40] Failure to notify the government of its Bayh-Dole rights may lead to forfeiture of the university's title in the invention.[41]

But the Bayh-Dole rights apply only to "subject inventions," defined as "any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement."[42] Grants may be made to support work in an area, but if conception of the invention occurs with non-government funding, the government has no rights. This on-off approach in an area where funds may easily be co-mingled creates incentives and opportunities to circumvent the government's retention of rights.

Even where Bayh-Dole rights should attach, the university or contractor may not report them. Although the potential penalty for failing to report is forfeiture, various government monitoring agencies have found a high percentage of non-reporting.[43] This is an area worthy of further Committee investigation.

A final transparency issue relates to university publication of its license arrangements with corporations. Some universities have helpfully published standard form contracts, but this is only a modest first step. All university and federal agency licensing arrangements should be made publicly available, perhaps in connection with new government contracting databases now under construction. Permissible redactions for purported proprietary reasons should be kept to a minimum.

5. Establishing Government Rights in Sponsored Research Not Giving Rise to Patentable Inventions

The required Bayh-Dole nexus between government sponsorship and conception of the invention creates an opportunity to game the system, so that government funds are not used for the work leading directly to conception. We have received anecdotal reports that this is not uncommon.

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

[40] 35 USC § 201 (c)(6).

[41] 35 USC § 201 (c)(1).

[42] 35 USC §201(e).

[43] See Government Accountability Office, "Technology Transfer: Reporting Requirements for Federally Sponsored Inventions Need Revision," August 1999, GAO/RCED-99-242.

There is a much bigger consideration, however. NIH sponsorship monies that do not directly lead to conception of an invention confer no Bayh-Dole rights at all. This includes cases where federal funding supports a university's pre-clinical investigations with considerable funding, but not the funding leading directly to conception of an invention.

It also includes cases where the NIH supports clinical testing, a growing area of investment by the agency. There is growing interest in NIH supporting clinical testing of promising inventions that are not receiving private sector take-up. These instances involve the agency venturing further away from its mission in creating health-related informational public goods. This is not to say such a role for NIH is inappropriate; there is a very strong public rationale for NIH taking on this mission. But it is a context in which the agency is acting very much like a venture capitalist, albeit primarily only in areas that other venture capitalists do not wish to tread (except possibly in conjunction with government support). The case for a government demand of reciprocity for its investment is thus very strong -- but there is no such reciprocal requirement.

Consider the case of cetuximab, the generic name of the drug that led to Martha Stewart's securities-related conviction. Patent rights to the drug are held by ImClone. It is sold under the brand-name Erbitux. The drug is marketed by Bristol-Myers in the United States and Merck outside the United States. It is a targeted colon cancer treatment and now approved also for head and neck cancer. The U.S. price for the drug is on the order of $17,000 a month.

Although there is some uncertainty about the efficacy of the drug in extending survival time, it has positive properties in the way it treats tumors and new evidence suggests it may prove to be useful and important.

At $17,000 a month, it is already proving very profitable. Approved in 2004, Erbitux became a billion-a-year seller in 2006.[44] In North America, 2006 sales amounted to approximately $652.2 million, compared to approximately $413.1 million in 2005. Outside of North America, Merck's 2006 sales totaled approximately $428.2 million, compared to approximately $265.3 million in 2005.

It does not appear that United States has Bayh-Dole rights in cetuximab.[45] Although ImClone reports in its 10-K that "we have an exclusive license from the University of California to an issued United States patent for the murine form of ERBITUX, our EGFR antibody product"[46] the licensed U.S. patent number appears to be 4,943,533, which does not list any governmental interest.

Although the U.S. government may not have contributed the funds leading to the invention of the drug, it played a key role in getting it to market. The National Cancer

[44] ImClone Systems Incorporated 2006 10-K report to SEC, page 58.
[45] It is possible that Bayh-Dole rights do apply. Cetuximab is not listed in the FDA's Orange Book.
[46] ImClone Systems Incorporated 2006 10-K report to SEC, page 27.

Institute describes its role in the development of cetuximab as follows:

> 1980s: Erbitux (NSC 632307), known generically as cetuximab, is one of four NCDDG-developed agents approved by the FDA since the inception of the NCDDG. This agent, a chimera comprising human and mouse monoclonal antibodies against the epidermal growth factor receptor (EGFR), is based on Dr. John Mendelson's 1980s hypothesis that monoclonal antibodies against EGFR could block receptor activation, which in turn would interfere with the cell signaling that leads to increased cell proliferation, angiogenesis, invasion, and metastasis.
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> 1990s: In 1990, the NCDDG began work on Erbitux, and in 1999, ImClone Systems of New York commenced phase III trials in collaboration with Merck KGaA of Darmstadt, Germany. In 2001, Bristol-Meyers Squibb and ImClone agreed to co-develop this agent, and the first application for FDA approval was submitted in November of that year.
>
> 2001–present: ImClone submitted its original request for FDA approval in 2001, but the FDA determined that this application could not be reviewed because of missing information. However, in August 2003, ImClone submitted the results of a large, well-run trial, the results of the two earlier studies, and the missing information requested by the FDA, and Erbitux received approval for the treatment of metastatic colorectal cancer in 2004. Combinations of Erbitux and radiation or platinum-based chemotherapeutic agents are under exploration.[47]

Given the evident substantial governmental support for development of cetuximab, shouldn't the government have some power to restrain its abusive pricing?

The committee should consider how and what governmental rights may be established in cases where the government contributes significantly to a product reaching market, but not to the research leading to the patent. The core principle should be that there must be some reciprocity in the form of price restraints for government support for R&D that directly helps products get to market, especially when the government is making high-risk investments.

6. Assessing University Corporate Entanglements in the Bayh-Dole Context

Bayh-Dole has been a central component of the evolving university-industry relationship, but it is by no means the only element. Bayh-Dole paralleled and facilitated a range of university-industry organizational relationships, notably including university creation of, and investment in, start-up companies to commercialize university inventions, and large-scale corporate-sponsored research.

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[47] Developmental Therapeutics program, National Cancer Institute, "Success Story: Erbitux," available at <http://dtp.nci.nih.gov/timeline/noflash/success_stories/s17_Erbitux.htm>.

These organizational arrangements are fraught with danger. One concern relates to whether Bayh-Dole licenses are misallocated to firms not best positioned to advance the public interest. Such firms may not be best positioned to commercialize the inventions (a possible distortion with university-connected companies, where returns to the university may be much higher than a standard licensing arrangement) or which may use them for anti-competitive purposes (a particular concern with licenses to giant corporations with sponsorship deals) or which may not be best incentivized to make inventions available to the public on reasonable terms.

The massive size of recent corporate sponsorship arrangements intensifies the cause for concern. Consider the $500 million proposed deal between BP, University of California, Berkeley, the Lawrence Berkeley National Laboratory, and the University of Illinois at Urbana-Champaign. This deal contemplates "the largest proposed academia-industry research alliance in U.S. history,"[48] to be known as the Energy Biosciences Institute (EBI). The Institute, dedicated to "problems related to global energy production" and expected to research primarily biofuels, will encompass 24 laboratories spanning the three campuses, and will occupy state-of-the-art facilities in each, representing a significant public investment. The state of California, for example, has pledged $40 million to construct facilities specifically for the Institute's use.[49]

Now in the later stages of contract negotiations, the universities' proposal, released in March and accepted by BP, offers to lease BP private research facilities on the public UC Berkeley campus. These facilities would be off limits to UC Berkeley personnel. Within the closed facilities, BP would own all inventions developed, and researchers would have no obligation to publish research performed. Under terms of the deal, BP would retain the option to exclusively license and commercialize inventions developed in open facilities, even inventions developed entirely by university scientists, provided they are BP-funded.[50]

The agreement promises that "U.S. government rights will be reserved a) for inventions arising from U.S. federal funding at the UCB and UIUC campuses; and b) for all inventions owned by LBNL."[51]

Even stipulating good intentions by all parties involved, it is obvious that this deal will invite abuse. The inevitable co-mingling of funds will lead to uncertainty about where Bayh-Dole rights arise, and there will be every in-bred bias to manage the monies and reporting to lessen those rights. Where Bayh-Dole rights do attach, it is obvious that BP will have an inside track on exclusive licensing arrangements (as well as an ability to advocate for exclusive licensing where non-exclusive licensing may be possible). Thus will the oil goliath be positioned to leverage its investment and skim the benefits of

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[48] Discover Magazine, "Science's Worst Enemy: Corporate Funding," Jennifer Washburn, October 11, 2007, available at: http://discovermagazine.com/2007/oct/sciences-worst-enemy-private-funding.
[49] Energy Biosciences Institute proposal. Letter from Governor Arnold Schwarzenegger to The Right Honorable Lord Browne of Madingley, available at: http://www.ebiweb.org/proposal.htm.
[50] Energy Biosciences Institute proposal, pages 71-73, available at: http://www.ebiweb.org/proposal.htm.
[51] Energy Biosciences Institute proposal, page 72, available at: http://www.ebiweb.org/proposal.htm.

public research, and perhaps exert control over the direction of energy technology development.

These type of arrangements should be subject to careful scrutiny by the Committee as it conducts subsequent hearings into Bayh-Dole and management of federally funded inventions.

7. Fresh Thinking on Federally Sponsored Research, Patenting and Development

Central to Bayh-Dole's allocation of technology rights was the decision to forfeit the government's claim to title in inventions it sponsored, and to give exclusive rights to contractors. In the case of universities, the theory was that universities would best be able to speed their commercialization, including through exclusive licensing.

There was very little evidence to support this theory at the time Bayh-Dole was passed. Proponents relied primarily on a single study, which was inconclusive and who's findings they mischaracterized.[52] Although there is now a great deal of data related to university patenting and licensing, the actual evidence that Bayh-Dole is effective at achieving its objectives -- as opposed to alternative approaches -- remains inconclusive. As the Committee proceeds with its hearings on management and disposition of federally funded inventions, it will be useful to examine Bayh-Dole with an open mind, and to consider different patenting, licensing and development arrangements, to reform or augment current policy.

A. Alternative Pharmaceutical Development Models

Pharmaceutical development is actually the strongest case for the Bayh-Dole approach, because there is no question that, after an initial invention has been achieved, quite significant resources must still be deployed to develop and test medicines before they reach the approval stage. Even in this context, however, one could imagine alternative arrangements. The government could retain title, and do the licensing itself. In theory -- although not supported by NIH experience -- a government licensor might better seek to advance public interest aims, including not just commercialization, but commercialization on reasonable terms. Or, more profoundly, the government's role in clinical testing -- already expanding steadily -- could be expanded further, so that it takes inventions closer to the point of commercial application, at which point it could negotiate for shorter terms of exclusivity, or no exclusivity at all.[53]

B. Research Tools and the Anti-Commons

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[52] See Rebecca S. Eisenberg, "Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research," 82 Va. L. Rev. 1663 (1996); Robert Weissman, "Public Finance, Private Gain: The Emerging University-Business-Government Alliance and the New U.S. Technological Order," Undergraduate thesis, Harvard University, 1989.

[53] For one far-reaching approach, see the Free Market Drug Act, introduced as H.R. 5155, 108th Congress, 2d session.

Commerce Department regulations that require a first effort to license inventions non-exclusively properly reflect the recognition that there are multiple public benefits in competition as opposed to exclusive licensing. Non-exclusively licensed patents can remain more fundamentally a part of the information commons, promote market competition and advance antitrust objectives, and restrain pricing abuses. It is ironically the case, however, that nonexclusive licensing as practiced presently by universities may thwart these objectives.

The Association of University Technology Managers reports that roughly half of university licenses are provided on a non-exclusive basis. Many or most of these non-exclusive licenses involve research tools -- upstream inventions used in the research and development process. As Professors Arti Rai and Rebecca Eisenberg have noted, heavy patenting in this area, combined with demanding licensing terms (even where licensing is nonexclusive) has tended to create an anti-commons, where research institutions charge each other, and corporations, to use the intellectual equipment for research.[54] The situation is far worse where universities engage in exclusive licensing, but non-exclusive licensing with royalty payments has proven problematic as well. So long as this information is going to be patented, the patents should be licensed on a no-royalty basis, with no conditions attached. They should, effectively, be dedicated to the public. This will deprive universities of some income, but it will eliminate an innovation tax that provides no net income for research overall, and creates bureaucratic and time delays in the research process.

C. Nonexclusive Technology Development Models: Climate Change Technology Imperatives

The committee should look with care as well at technologies outside of the biomedical area. It is a certainty that federal investment in research to address climate change -- including in solar and alternative energy technologies and in energy efficiency technologies -- will soar in coming years. These markets are sure to boom in coming years, and the technology development process is likely to follow pathways that do not resemble drug development.[55] To address the frightening perils of climate change, we

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[54] Arti K. Rai and Rebecca S. Eisenberg, "The Public Domain: Bayh-Dole Reform and the Progress of Biomedicine," 66 Law and Contemp. Prob. 289 (2003).

[55] The post-World War II history of the tire industry illustrates how management of federally controlled patents can shape industry structure and promote competition. The need for alternative sources of rubber during the war led the government to undertake action to gain control of patents held by Standard Oil on rubber and to invest in synthetic rubber R&D. After the war, when the government disposed of its rubber patents and factories, it placed a number of limitations on disposal, including establishing competitive industry and selling facilities to some non-dominant firms (Charles Philipps, Competition in the Synthetic Rubber Industry, North Carolina Press, 1961.)

As has been the case with Bayh-Dole, this history and competitive culture shaped the industry's views on patent policy. In the period leading up to passage of Bayh-Dole, Firestone sent its chief patent counsel to testify before Congress and explain how nonexclusive licensing of synthetic rubber technology, developed under government sponsorship during World War II, prevented a monopolistic market.

"You will hear criticism of such a program [of nonexclusive licensing]," Stanley Clark

will need robust, competitive and efficient energy and energy services markets. There should be a presumption favoring open and collaborative development models that enable market players to obtain compensation through means other than enclosing the information commons and monopoly pricing. Management of patent policy and federally funded inventions will play an important role in determining how energy markets evolve and how efficient they are.

Chairman Leahy and members of the Senate Judiciary Committee, the public investment in biomedical and many other forms of R&D is a proud story for the U.S. government. The U.S. economy is far stronger than it would otherwise be, and U.S. consumers are far better off than they otherwise would be, as a result of the long tradition of government support for R&D. The information commons is richer and the public domain more robust. But in a world where so many ideas are reduced to patents, there must be a much more proactive management of U.S. patents and license rights to advance the multiple objectives of supporting innovation, bringing products to market, ensuring fair prices and access to new technologies, promoting market competition, and enhancing the public domain and information commons.

I would like to thank you and the Committee for inviting me to testify today, and I look forward to working with you in the future to ensure that the federally funded inventions and the patent system advance these multiple objectives.

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testified. "Some have told you and will tell you that unless the research contractors are given titles to the patents which are produced at government expense, the contractors will not accept government research and development contracts. Don't you believe it. They want those government funds and the rewards and advantages that come with such contracts and they won't turn them down. What they get can be, in many instances, very rewarding even without the patents and in any event there are no risks involved, the government assumes all of those."

"Among other benefits, he explained, "the research staff and the records of the contractor constitute a body of 'know-how' which inevitably remains the property of the contractors and may be a palpable asset." (Stanley Clark, Subcommittee on Monopolies and Anti-Competitive Activities, Senate Select Committee on Small Business, December 19-21, 1977, 95th Congress, 1st Session, page 222.)