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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.

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.

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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.

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

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

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

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

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

These conditions were translated into the legal language found in section 203 of the Act—what we now refer to as the "march-in" clauses, because they give the government the power to "march-in" and reassign intellectual property rights. These were conceived as extraordinary measures to be used only when there was overwhelming evidence to show that the public resources invested into an innovation were being wasted or abused.

Obviously, Abbott Laboratories has been enormously successful in bringing the benefits of Norvir to the public at large. The drug may be expensive—perhaps intolerably expensive, given the critical importance it

holds for people with AIDS. But by the criteria established by Bayh-Dole, Abbott has complied with the law.

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

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

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

None of this is supported by a correct reading of the Act and its legislative history.

In fact, if the drafters of Bayh-Dole had intended such an interpretation, we would have inserted specific criteria into the law to enable NIH—or any government funding agency —to assess what a reasonable price might be. No such criteria are found, because controlling patent rights on the basis of price was antithetical to what the drafters had in mind.

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

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

Let me provide some of those definitions now.

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

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

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

3) Assignees: These are defined by the Act as non-profit patent management organizations, which at the time brokered the license agreements between the contractor and the licensee. Their role has been marginalized in recent years as universities and research institutes have taken on the role themselves.

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

Section 203a does *not* apply to licensees.

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

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

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

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

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

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

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

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

Abbott Laboratories, as it happens, had no need to license its invention. It had title to the invention and the resources to bring it to the market without any assistance.

This exposes a minor ambiguity in Bayh-Dole. Obviously, "reasonable terms" in this particular case cannot mean "reasonable royalties." But neither can it mean "reasonable pricing", as a requirement of the contractor under its defined obligations.

In other words, we cannot spontaneously reinterpret 203a to mean that when a contractor brings a drug to market itself, it must price the drug "reasonably". "Reasonable terms" could not mean one thing for a licensee, and another for a contractor, unless the law contained specific language defining these meanings.

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

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

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

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

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

In the absence of government price controls, drug companies will seek to maximize their profits by balancing prices with the need for market penetration - and that is exactly what the drafters of Bayh-Dole expected. Pricing freedom is one reason often cited by the pharmaceutical industry for concentrating their research and development activities in the U.S. It is

why the U.S. remains the world leader in medical research, and why so many drugs are made available here first.

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

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

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

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

Mr. Love's petition must therefore be denied.

Thank you again for the opportunity to be here today.