Norman J. Latker

Statement Before NIH On
Essential Inventions Petition Regarding Norvir

May 25, 2004

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

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

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

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

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

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

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

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

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

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

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

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

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

This exposes a minor ambiguity in Bayh-Dole. Obviously, "reasonable terms" in this particular case cannot mean "reasonable royalties." But neither can it mean "reasonable pricing", as a requirement under sec.202c.

In other words, we cannot spontaneously reinterpret 203a to mean that when a contractor brings a drug to market itself, it must price the drug

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

While I feel I can provide some perspective on the Act, there is very little I can say with authority on the underlying issues that have prompted Mr. Love's petition.

Frankly, there are a number of things that I simply do not know.

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

Nor can I pretend to know what impact the price hike will have on those who need the drug to stay healthy, or on the healthcare finance system. I do not know if some people who need Norvir will now not have access to it. I don't know whether Abbott's promise to provide the drug for free to those who cannot afford it should be taken at face value.

It is worth noting that Senator John McCain has called on the Federal Trade Commission to investigate Abbott Laboratories for possible abuse of its monopoly power with respect to Norvir. Attorneys General in Illinois and New York are also looking into the matter. Again, I do not know precisely what criteria these organs of government might use to determine whether corrective action is warranted.

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

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

It is decidedly ill-suited for any other purpose.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Let me provide some of those definitions now.

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

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

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

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

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

Section 203a does *not* apply to licensees.

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

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

As the phrase "reasonable terms" found in 203a applies to *contractors*, and not to *licensees*, it cannot mean "reasonable prices," because contractors, in the view of the drafters, would not normally be setting prices. Further, they are not required to do so under 202c which sets out all the contractors obligations.

"reasonably". "Reasonable terms" could not mean one thing for a licensee, and another for a contractor, unless the law contained specific language defining these meanings.

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

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

It must be plainly understood that medical access problems in the United States stem *not* from the research and development regime, but from the way healthcare entitlements are ascribed and healthcare resources are distributed. ~~Healthcare reform is long overdue. It will be a long, bruising political battle, but the country must, and will, address it~~.

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

It is in fact the private sector that ponies up the resources to develop, test, obtain approval for, and market new drugs. It is an 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.

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

Mr. Love's petition must therefore be denied.

Thank you again for the opportunity to be here today.

From: Carole and Norman Latker <Latkerc@bellatlantic.net>
To: <njl@browdyneimark.com>
Date: 6/9/04 9:42AM
Subject: [Fwd: Re: [techno-l] My May 25 Statement at NIH meeting on theEssentialInventionsPetition]

fyi

-------- Original Message --------
Subject: Re: [techno-l] My May 25 Statement at NIH meeting on theEssential InventionsPetition
Date: Sat, 05 Jun 2004 18:43:50 -0400
From: Carole and Norman Latker <Latkerc@bellatlantic.net>
To: James Love <james.love@cptech.org>
References: <s0c06213.040@mail2.browdyneimark.com> <40C20A7A.5090500@cptech.org>

Jamie
The EIA quote you use from Arno/Davis is attributed in footnote 222 to Peter McCloskey in his 1979 statement on S.1215 (probably Stevenson-Wydler) before the Senate Committee on Commerce, Science and Transportation. As such it has nothing to do with the legislative history of Bayh-Dole or then established government patent policy. Similarly, 70 of the 82 footnotes Arno/Davis use to support their conclusions in their so-called legislative history of Bayh-Dole (pages 656-667) relate to statements made outside the 1979 Senate Judiciary hearings on Bayh-Dole. At least 22 of the 70 statements footnoted are attributed to well known opponents of contractor ownership under any conditions, i.e. Adm. Rickover, Sen. Long, Cong. Brooks, Ralph Nader,etc. None of these gentlemen testified against Bayh-Dole or bargained for your compulsory license provision as a condition for their acceptance of the Act. Why then are they included in the Arno/Davis "history"?
If you wish to continue to rely on statements outside the Act's legislative history, I believe Arno/Davis "history" should be revised to include at least a discussion of the DHEW administrative policy which was clearly identified in the hearings and elsewhere as the precursor of the Act. That had far more relevancy than anything touched on by Arno/Davis.Wouldn't that be fair? Last, Sen. Bayh went into some detail in his May 25 statement on how footnotes 200 and 201, which you used in your petition, was a misrepresentation of his public statements. For your benefit I will repeat for him that the policy of "recoupment" of a percentage of the sales on the behalf of the government has no logical connection to an endorsement of your compulsory license theory. If you believe otherwise spell it out in laymen's terms.
I don't think it is necessary to respond further as it is more of of what you think "reasonable terms" mean. I must say that's a more reasonable position than Arno/Davis's repeated insistency that it conclusively provides for your compulsory theory notwithstanding that that makes no sense in the context of the Act (don't forget Scalia)
You still have not come up with that "single word".

USG

James Love wrote:

> Norman Latkerwrote:
>
>> Of course, he will not be able to do that because there is not a
>> single word in all of established government patent policy, past or
>> present, which supports compulsory licensing based on an allegation
>> that the invention is being sold at an unreasonable price.
>

> Norman, you note the definition for the term "practical application"
> changed from the earlier Kennedy and Nixon patent policy statements,
> which defined the obligation to make "practical application" of an
> invention to include the requirement that:
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> "the invention is being worked and that its benefits are
> reasonably accessible to the public."
>
> To the newer definition:
>
> "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."
>
> As you note, the phrase "available to the public on reasonable terms"
> is a more clear mandate to look at the price than "reasonably
> accessable to the public," even though, I would claim that "reasonably
> accessible" means reasonably priced or affordable in most parts of the
> world. Moreover, it turns out that in hearing on government patent
> policy, industry efforts to narrow the definition now used in the
> Bayh-Dole Act, so that simple working would be good enough, (closer to
> your interpretation of the requirement), were not accepted. The
> industry wanted a definition that was "worked or that....," but the
> eventual definition was "utilized and that...."
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> In the course of the hearings on the legislation, the
> Electronic Industry Association urged Congress to redefine
> the phrase ôpractical application ö -- a trigger for the exercise
> of march-in rights -- to reduce the obligations of the
> contractor and thus the risk that the government would actually
> assert march-in rights: ôThe definition of æpractical application Æ
> appears too stringent. We would suggest a rewrite to indicate
> that application Æ means ... æthat the invention is being worked
> or that its benefits are available to the public either on
> reasonable terms or through reasonable licensing ö30
> Congress declined to adopt this change, and maintained the
> standard that a ôpractical application ö is achieved -- and
> march-in rights conditions are avoided only if the invention
> is being practiced and it is available to the public on
> reasonable terms. 31
>

> Do you claim the phrase "available to the public on reasonable terms"
> means "available to the public on ANY terms."?
>
> Jamie
>
> ----------
> Halperin notes:
> 30 Patent Policy: Hearings on S.1215 Before the Subcommittee on
> Science, Technology and Space of the Senate Committee on Commerce,
> Science and Transportation, 96th Cong. at 221 (1979) (statement of Peter
> F. McCloskey, President, Electronic Industry Assn.) (emphasis added).
> 31 See Arno & Davis, at 666.
>
>
> 1963 Kennedy Policy on Patents
> Memorandum and Statement of Government Patent Policy, 28 Federal
> Register 10,943-10946 (1963)
>
> (g) "To the point of practical application"--means to manufacture in
> the case of a composition or product, to practice in the case of a
> process, or to operate in the case of a machine and under such
> conditions as to establish that the invention is being worked and that
> its benefits are reasonably accessible to the public.
>
>
> 1971 Nixon Policy Statement on Patents
> Memorandum and Statement of Government Patent Policy, 36 Federal
> Register 16,886 (1971).
>
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> or to operate in the case of a machine and under such conditions as to
> establish the invention is being worked and that its benefits are
> reasonable accessible to the public.
>
> 1980 Bayh-Dole Act
> 35 USC 201(f)
>
> (f) The term "practical application" means to manufacture in the case
> of a composition or product, to practice in the case of a process or
> method, or to operate in the case of a machine or system; and, in each
> case, under such conditions as to establish that the invention is
> being utilized and that its benefits are to the extent permitted by
> law or Government regulations available to the public on reasonable
> terms.
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>> SECTION I (f)
>>
>> (f) Where the principal or exclusive [(except as against the
>> Government)] rights in an invention remain in the contractor, unless

>> the contractor, his licensee, or his assignee has taken effective
>> steps within three years after a patent issues on the invention to
>> bring the invention to the point of practical application or has made
>> the invention available for licensing royalty?free or on terms that
>> are reasonable in the circumstances, or can show cause why he should
>> retain the principal or exclusive rights for a further period of
>> time, the Government shall have the right to require the granting of
>> a nonexclusive or exclusive license to [an] a responsible
>> applicant(s) on [a nonexclusive royalty-free basis.] terms that are
>> reasonable under the circumstances.
>>
>> COMMENTS: The Federal Council for Science and Technology has
>> recommended that this section be amended to permit the Government to
>> require a contractor to grant licenses on terms that are reasonable
>> under the circumstances, rather than on a "nonexclusive royalty?free
>> basis." Although the granting of nonexclusive licenses may in some
>> cases be sufficient to encourage commercialization of an invention;
>> in other cases, some degree of exclusivity may be necessary.
>> Accordingly, the language as amended is sufficiently broad to permit
>> a requirement that the contractor grant an exclusive, as well as a
>> nonexclusive license. The language of this section has also been
>> amended to require the contractor to grant licenses only to
>> applicants who appear to be responsible, and who would appear to have
>> the ability to utilize the invention. In addition, the parenthetical
>> phrase "except as against the Government" has been deleted in view of
>> the amendments to Section 1(h).
>>
>> SECTION 1(g)
>>
>> (g) Where the principal or exclusive [(except as against the
>> Government)] rights to an invention are acquired by the contractor,
>> the Government shall have the right to require the granting of a
>> nonexclusive or exclusive license to [an] a responsible applicant(s)
>> [royalty?free or] on terms that are reasonable in the circumstances
>> (i) to the extent that the invention is required for public use by
>> governmental regulations, or (ii) as may be necessary to fulfill
>> health or safety needs, or (iii) for other public purposes stipulated
>> in the contract.
>>
>> COMMENTS: The Federal Council for Science and Technology has
>> recommended the deletion of the phrase "royalty?free" in view of the
>> fact that the application of this section is not predicated on the
>> fact that the contractor himself is not using the invention. In
>> extreme cases, however, the Federal Council believed that the phrase
>> "on terms that are reasonable in the circumstances" could be
>> interpreted* broadly enough to include a royalty?free license. This
>> section has also been amended to require licensing only to
>> "responsible" applicants. The addition of "safety" needs was made to
>> clarify the application of this provision to purposes of safety. The
>> parenthetical phrase "except as against the Government" has been
>> deleted in view of the amendments to Section 1(h).
>>
>> SECTION 1(h)
>>

>> (h) Whenever the principal or exclusive rights in an invention remain
>> in the contractor, the Government shall normally acquire, in addition
>> to the rights set forth in Section 1(e), 1(f), and 1(g),
>>
>> (1) at least a nonexclusive, nontransferable, paid up license to
>> make, use, and sell the invention throughout the world by or on
>> behalf of the Government of the United States (including any
>> Government agency) and States and domestic municipal governments,
>> unless the agency head determines that it would not be in the public
>> interest to acquire the license for the States and domestic municipal
>> governments; and
>>
>> (2) the right to sublicense any foreign government pursuant to any
>> existing or future treaty or agreement if the agency head determines
>> it would be in the national interest to acquire this right; and
>>
>> (3) the principal or exclusive rights to the invention in any country
>> In which the contractor does not elect to secure a patent.
>>
>> COMMENTS: The license rights of the Government and the contractor
>> originally set forth in Sections I(a), (b), (c), (e), (f), (g), and
>> (h) are now set forth in Sections 1(h) and (i). Section 1(h) covers
>> the situation where the principal or exclusive rights remain in the
>> contractor.
>>
>> Section 1(h) has been amended to include the minimum rights to be
>> retained by the Government in all cases where the contractor has been
>> given principal or, exclusive rights to an invention.
>>
>> Section 1(h)(1) defines the scope of the license that the Government
>> shall normally acquire both for its own use as well as for use by
>> States and municipal governments. A license for use by the States and
>> domestic municipal governments is normally acquired, unless the
>> agency head determines that it is not in the public interest to do
>> so. Section 1(h)(1) as amended spells out the meaning of the
>> definition of "governmental purposes," and therefore, that phrase no
>> longer appears in the Policy Statement.
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>> Techno-L archives are available on UVentures.com.
>> Techno-L is a free service provided by UTEK Corporation
>> (Amex: UTK) for technology transfer professionals.
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>> For additional commands, e-mail: techno-l-help@lists.uventures.com
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From: <jraubits@doc.gov>
To: "Norman Latker" <NJL@browdyneimark.com>
Date: 6/14/04 12:17PM
Subject: Re: article

Great

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John H. Raubitschek
Patent Counsel
U.S. Department of Commerce
Room 4835
14th and Constitution Avenue, N.W.
Washington, D.C. 20230
voice (202) 482-8010; fax (202) 482-0253

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Attorney-Client Communication
Attorney Work Product

"Norman Latker" <NJL@browdyneimark.com> 06/14/2004 11:58 AM

To <jraubits@doc.gov>
cc
Subject Re: article

John
Thanks very, very much for the B-D hearings. They are much better than I remembered. Staats's statement was unbieveably good. He hit on every important point in the evolution of B-D including slamming the '63 and '71 Pres. statements. I think we can greatly strenghten our case with an upfront synopsis of Staat's history which Arno/Davis cannot match. I would like to try my hand at it when I get the next draft. I am beginning to see how this undermines all the revisionest histories floating around. We are making good progress.

From: Carole and Norman Latker <Latkerc@bellatlantic.net>
To: <njl@browdyneimark.com>
Date: 6/9/04 9:42AM
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> (g) To the point of practical application--means to manufacture in the
> case of composition or product, to practice in the case of a process,
> or to operate in the case of a machine and under such conditions as to
> establish the invention is being worked and that its benefits are
> reasonable accessible to the public.
>
> 1980 Bayh-Dole Act
> 35 USC 201(f)
>
> (f) The term "practical application" means to manufacture in the case
> of a composition or product, to practice in the case of a process or
> method, or to operate in the case of a machine or system; and, in each
> case, under such conditions as to establish that the invention is
> being utilized and that its benefits are to the extent permitted by
> law or Government regulations available to the public on reasonable
> terms.
>
>
>
>>
>>
>> SECTION I (f)
>>
>> (f) Where the principal or exclusive [(except as against the
>> Government)] rights in an invention remain in the contractor, unless

>> the contractor, his licensee, or his assignee has taken effective
>> steps within three years after a patent issues on the invention to
>> bring the invention to the point of practical application or has made
>> the invention available for licensing royalty?free or on terms that
>> are reasonable in the circumstances, or can show cause why he should
>> retain the principal or exclusive rights for a further period of
>> time, the Government shall have the right to require the granting of
>> a nonexclusive or exclusive license to [an] a responsible
>> applicant(s) on [a nonexclusive royalty-free basis.] terms that are
>> reasonable under the circumstances.
>>
>> COMMENTS: The Federal Council for Science and Technology has
>> recommended that this section be amended to permit the Government to
>> require a contractor to grant licenses on terms that are reasonable
>> under the circumstances, rather than on a "nonexclusive royalty?free
>> basis." Although the granting of nonexclusive licenses may in some
>> cases be sufficient to encourage commercialization of an invention;
>> in other cases, some degree of exclusivity may be necessary.
>> Accordingly, the language as amended is sufficiently broad to permit
>> a requirement that the contractor grant an exclusive, as well as a
>> nonexclusive license. The language of this section has also been
>> amended to require the contractor to grant licenses only to
>> applicants who appear to be responsible, and who would appear to have
>> the ability to utilize the invention. In addition, the parenthetical
>> phrase "except as against the Government" has been deleted in view of
>> the amendments to Section 1(h).
>>
>> SECTION 1(g)
>>
>> (g) Where the principal or exclusive [(except as against the
>> Government)] rights to an invention are acquired by the contractor,
>> the Government shall have the right to require the granting of a
>> nonexclusive or exclusive license to [an] a responsible applicant(s)
>> [royalty?free or] on terms that are reasonable in the circumstances
>> (i) to the extent that the invention is required for public use by
>> governmental regulations, or (ii) as may be necessary to fulfill
>> health or safety needs, or (iii) for other public purposes stipulated
>> in the contract.
>>
>> COMMENTS: The Federal Council for Science and Technology has
>> recommended the deletion of the phrase "royalty?free" in view of the
>> fact that the application of this section is not predicated on the
>> fact that the contractor himself is not using the invention. In
>> extreme cases, however, the Federal Council believed that the phrase
>> "on terms that are reasonable in the circumstances" could be
>> interpreted* broadly enough to include a royalty?free license. This
>> section has also been amended to require licensing only to
>> "responsible" applicants. The addition of "safety" needs was made to
>> clarify the application of this provision to purposes of safety. The
>> parenthetical phrase "except as against the Government" has been
>> deleted in view of the amendments to Section 1(h).
>>
>> SECTION 1(h)
>>

>> (h) Whenever the principal or exclusive rights in an invention remain
>> in the contractor, the Government shall normally acquire, in addition
>> to the rights set forth in Section 1(e), 1(f), and 1(g),
>>
>> (1) at least a nonexclusive, nontransferable, paid up license to
>> make, use, and sell the invention throughout the world by or on
>> behalf of the Government of the United States (including any
>> Government agency) and States and domestic municipal governments,
>> unless the agency head determines that it would not be in the public
>> interest to acquire the license for the States and domestic municipal
>> governments; and
>>
>> (2) the right to sublicense any foreign government pursuant to any
>> existing or future treaty or agreement if the agency head determines
>> it would be in the national interest to acquire this right; and
>>
>> (3) the principal or exclusive rights to the invention in any country
>> In which the contractor does not elect to secure a patent.
>>
>> COMMENTS: The license rights of the Government and the contractor
>> originally set forth in Sections I(a), (b), (c), (e), (f), (g), and
>> (h) are now set forth in Sections 1(h) and (i). Section 1(h) covers
>> the situation where the principal or exclusive rights remain in the
>> contractor.
>>
>> Section 1(h) has been amended to include the minimum rights to be
>> retained by the Government in all cases where the contractor has been
>> given principal or, exclusive rights to an invention.
>>
>> Section 1(h)(1) defines the scope of the license that the Government
>> shall normally acquire both for its own use as well as for use by
>> States and municipal governments. A license for use by the States and
>> domestic municipal governments is normally acquired, unless the
>> agency head determines that it is not in the public interest to do
>> so. Section 1(h)(1) as amended spells out the meaning of the
>> definition of "governmental purposes," and therefore, that phrase no
>> longer appears in the Policy Statement.
>>
>>
>>
>> ---
>> Techno-L archives are available on UVentures.com.
>> Techno-L is a free service provided by UTEK Corporation
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>
>

From: "Sullivan, Kristi" <kristi@warf.org>
To: "Norman Latker" <NJL@browdyneimark.com>
Date: 4/12/04 4:49PM
Subject: RE: Draft Letter To N.I.H.

Norm:
My reaction to your proposed letter to NIH on the Love March-in rights effort is as follows:
I believe the first portion dealing with the intent of the drafters and the purpose of the Bayh-Dole Act is strong but the latter portion tends to be more argumentative and a bit like a "he says, she says" situation. My suggestion is to keep the first portion intact and then under the heading "Control of Drug Prices" have the letter read:

Control of Drug Prices

"Bayh-Dole is not an instrument to control drug prices. What I find most disturbing about the subject petitions is the attempt to transform a fundamental piece of intellectual property law into an administrative mechanism to control drug prices, with no regard for the consequences.

The drafters of Bayh-Dole never envisioned that the law could authorize government funding agencies to compel private entities to divulge internal accounts or pricing information, which is why the Act lacks any functional criteria specifying how this could be done.

If the drafters had intended such an interpretation, we would have inserted specific criteria into the law to enable the funding agency to assess exactly what a reasonable price might be. No such criteria are found, precisely because controlling patent rights on the basis of price was antithetical to what the drafters had in mind. Moreover, attempting to set the price of a product in the market place having only the knowledge embraced by an embryonic invention prior to any knowledge of the cost of its development and even acceptance in the market defies logic and would only defeat the policy and objectives of the Bayh-Dole Act and deprive the public of benefiting from valuable inventions."

This is a view from the university position leaving pricing to the province of the drug company.

I was really concerned about your sentence in the Scalia Rule portion, namely, "Property rights are inherently invested with the ability to set prices" as giving Love and company another basis for their position.

Best Regards,
Howard

-----Original Message-----
From: Norman Latker [mailto:NJL@browdyneimark.com]
Sent: Friday, April 09, 2004 3:43 PM
To: sheldon_steinbach@ace.nche.edu; astevens@bu.edu; kphillips@cogr.edu; rhardy@cogr.edu; niels@comcast.com; Michael.Remington@dbr.com; P_harsche@fccc.edu; Owen_C_Hughes@groton.pfizer.com; ahammer@mit.edu; jallen@nttc.edu; Sullivan, Kristi; jon.soderstrom@yale.edu

From: "Norman Latker" <NJL@browdyneimark.com>
To: <Techno-l@lists.uventures.com>
Date: 5/13/04 3:49PM
Subject: [techno-l] Essential Inventions Petitions and Sanders' Amendments to DHHSAppropriations Bill

Below is a site to an undated news release from Cong. Sanders office regarding his unsuccessful efforts to amend the DHHS appropriation bill to require that all drugs developed with taxpayer dollars be marketed at a "reasonable price"

He supports this on the mistaken fact that, "Almost all of the health care research and development dollars in the United States, both public and private, is spent on the development of prescription drugs" and that the dominant public portion of this funding demands a public equity in establishing a "reasonable price" for sale of drugs touched by the public R&D portion.

This is incorrect on its face as any investigation (no matter how modest) will establish that virtually all the public funding involved is directed to thousands of basic research grants to explore the the frontiers of the life sciences. Most likely none of these grants involve creating the clinical data nessary in the development of a drug for FDA licensure. At most, a minor portion of this funding will result in identification of a composition of matter which evidences a medicinal utility which could be pursued through the FDA with private capital. Even the private R&D funding identified is not used for producing the clinical data nessary to bring potential drugs discovered during such R&D to the marketplace.

In short, there is no basis to presume that any of the research funding identified has anything to do with paying for the clinical data necessary for FDA licensure.

Of course, it quite clear that it is the private sector that funds substantfally all the clinical data necessary whether the potential drug involved is derived from public or private research. It is also clear that if public research is the source, the private funding for clinical data far exceeds by many multiples the funding for the grants that produced the potential drug.

Cong. Sanders unsuccessful efforts have now morphed into a Tulane law article which falsely maintains that the Bayh-Dole Act provides NIH with the authority to set a reasonable price without a Sanders amendment. The Tulane article clearly crosses the line from academic objectivity into a 62 page polemic act on the Bayh=Dole Act. Essential Inventions uses this article as the primary basis for their march-in petitions at NIH either without review or disregarding its contrived conclusion.They are further pursuing congressional support for this position with some success.

The time has come for technology transfer people to alert their congressional representatives about the misrepresentations used to support these petitions and the Sanders amendments

http://www.netmagic.net/~franklin/AHC07b.html

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

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

James Love wrote:

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

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

>> maintains that the Bayh-Dole Act provides NIH with the authority to
>> set a reasonable price without a Sanders amendment. The Tulane
>> article clearly crosses the line from academic objectivity into a 62
>> page polemic act on the Bayh=Dole Act. Essential Inventions uses this
>> article as the primary basis for their march-in petitions at NIH
>> either without review or disregarding its contrived conclusion.They
>> are further pursuing congressional support for this position with
>> some success.
>> The time has come for technology transfer people to alert their
>> congressional representatives about the misrepresentations used to
>> support these petitions and the Sanders amendments
>>
>> http://www.netmagic.net/~franklin/AHC07b.html
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>> ---
>> Techno-L archives are available on UVentures.com.
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statute. Williams v. Taylor, 529 U.S. 420, 431 (2000). A court derives the plain meaning of the statute from its text and structure. Alexander v. Sandoval, 532 U.S. 275, 288 (2001). If the language is clear and fits the case, the plain meaning of the statute generally will be regarded as conclusive. Sullivan v. Stroop, 496 U.S. 478, 482 (1990); see also VE Holding Corp. v. Johnson Gas Appliance Co., 917 F.2d 1574, 1579-80 (Fed. Cir. 1990) (noting that unambiguous statutory language controls, unless legislative intent is clearly contrary or when its application produces a result so unlikely that Congress could not have intended it). rÇÿWe have stated time and again that courts must presume that a legislature says in a statute what it means and means in a statute what it says there.rÇÖ Conn. NatrÇÖl Bank v. Germain, 503 U.S. 249, 253-54 (1992).rÇ¥

> Reversing the Court of Federal Claims, the Federal Circuit held that rÇ£[t]he language of the statute at issue in this case is clear and unambiguous, and absent extraordinary circumstances our inquiry must end here. See VE Holding, 917 F.2d at 1580. Thus, it is unnecessary to seek clarification in the admittedly sparse legislative history. ***rÇ¥

From: <jraubits@doc.gov>
To: <NJL@browdyneimark.com>
Date: 8/18/04 10:08PM
Subject: Fw: Norfolk Dredging v. United States: Statutory Interpretation Principles

Here's the quote. Thought we had a great conversation today.

****

John H. Raubitschek
Patent Counsel
U.S. Department of Commerce
Room 4835
14th and Constitution Avenue, N.W.
Washington, D.C. 20230
voice (202) 482-8010; fax (202) 482-0253

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----- Forwarded by John Raubitschek/HCHB/Osnet on 08/18/2004 03:59 PM -----

"Wegner, Harold C." <hwegner@foley.com> To
cc
07/07/2004 02:09 PM Subject
Norfolk Dredging v. United States: Statutory Interpretation Principles

Norfolk Dredging Co. v. United States, __ F.3d __ (Fed. Cir. July 7, 2003)(Linn, J.), revГÇÖg 58 Fed. Cl. 741 (2003), contains an excellent summary of the principles of statutory interpretation and the controlling importance of the wording of the statute
Regards
Hal

ГÇ£Statutory interpretation begins with the language of the

5432593309

My name is Norman Latker. I am here as a private citizen to speak in the defense of the Bayh-Dole Act as it was intended to be read and how it has been practiced for 25 years. The Act has fostered the development of a potent four-way partnership between researchers, their institutions, government and industry. This partnership has become a powerful engine of innovation, generating more practical advances than the rest of the world combined. Nowhere is this more true than in the fields of medical technology and pharmaceuticals.

NORMAN LATKER

Should the petitioner succeed in subverting one of the key precepts of Bayh-Dole - that of according broad marketplace prerogatives to the developers of government-funded inventions - the equilibrium of the partnership will be broken and this marvelous engine of innovation will stall.

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

The petition relies entirely on a recent article in the Tulane Law Review to support its contention that federal agencies have the authority to end the exclusive right of a developer of a government funded invention, if the invention is being sold at an unreasonable price. This article unfortunately paints a highly distorted picture both of the Act itself and the legislative process leading to its passage in order to support its conclusion.

Before the enactment of Bayh-Dole, an enormous amount of government-sponsored health research went to waste, as there was no incentive to invest in establishing the utility ~~and~~ or, if necessary, the safety to bring resulting inventions to the marketplace.

~~The drafters of~~ The Act ~~understood that~~ recognized that inventions resulting from government research are mostly conceptual in nature, having no established utility or safety. To bring these inventions into practical application required a significant investment by the private sector. The private ~~investment necessary to prove utility and safety normally~~ exceeds by many multiples the government funding that produced these inventions. This is especially the case with regard to life science inventions, ~~the subject of the march-in petition~~ requiring licensure by FDA..

The Act recognized that the contribution by the American public to support health research was a public equity that should be, and would be, rewarded by the Act's success in extending and improving the lives of American taxpayers, creating new jobs and generating tax receipts beyond the government's R+D investment.

Our answer to the problem of encouraging industry to make this investment was to accord intellectual property rights in full to the inventing organization, rather than to the government agency that financed their discovery. This allowed them to use the patent system as it has always been used: to leverage their rights to attract the capital to prove the inventions' safety and utility. Their freedom was not unlimited. The March-in provisions were conceived as extraordinary measures to be used only when there was overwhelming need to protect the public against non-use or unreasonable use of inventions as called for in §200 of the Act.

In comparison, neither the Tulane article or the petition takes into account the developer's investment compared to that of the government in specific situations. Instead, the article's conclusion is justified by the fact that the total sum of government funded health research exceeds that of industry. This they submit creates "a public equity" beyond that addressed

by the Act and supports their march-in concept (see "Thematic Question" on page 634).

Even though the "public equity" defined by the authors is different from that addressed in the Bayh-Dole legislative history, it is used to incorrectly identify the motive for the Act's march-in provisions on page 659 as follows:

> "The march-in provisions became the linchpin of the entire enterprise because Congress wanted to balance the demands of private industry against the "public equity" that resulted from the massive public investment of funds to produce these patented inventions."

This is supported nowhere in the legislative history of the Act. The authors then point out that the Act's definition of "practical application" in §203(a) of the march-in provisions includes a requirement that the invention be made available to the public on "reasonable terms". From there, the article and petition argue that "reasonable terms" can be interpreted, in an ordinary context, as including a "reasonable

price", and that the funding agency is therefore authorized to assess what a "reasonable" market price might be.

A plain reading of §203(a) itself without any reference to any legislative history establishes that the petitioner and the authors are absolutely wrong.

Section 203(a) only applies to contractors and assignees. Licensees are not included. The contractors are non-profit organizations and small businesses, and the assignees are limited to patent management organizations. In comparison, the next two sections of 203 apply to contractors, assignees and licensees, and the last section applies only to licensees.

In 1980, it was clear that health inventions made by the non-profit organizations and small businesses subject to Section 203(A) had to be licensed to larger businesses to bring their inventions to practical application, because they did not have the resources necessary to obtain FDA clearance.

These contractors and assignees clearly do not set the sales price of an invention marketed by their licensee, and there is nothing in the Act that requires them to do so. If they attempt to do so on their own initiative it would

predictably kill any chance to negotiate a license. The sales price is set only by the licensee who as indicated is not subject to Section 203(A).

Since no party subject to Section 203(A) in 1980 set market prices, it is clear that there is no reason whatever to assume that "reasonable terms" include a "reasonable price".

Well then, what did "reasonable terms" mean in the context of Section 203(A) in 1980? The term referenced are directed to those contractors subject to Section 203(A) are required to negotiate into their license contracts. This makes perfect sense, since the word "terms" is normally used in the context of a contract. It makes no sense as applied to the licensee (who is not subject to Section 203(A)), because there are no "terms" attached to the sale of a product in the open market.

The most obvious "term" to address in a license contract is the royalty rate. There is an extensive history in government patent law that "reasonable terms" and "reasonable royalties" synonymously. There is no necessity to address in detail the petition's claim that case law and the Scalia test

establishes that "reasonable terms" must include a "reasonable price", because the findings in these cases and the Scalia test are out of context with the fact that the contractor in 1980, under Section 203(a), did not set the price on licensed health products, as that was the function of the licensee and was not subject to Section 203(a).

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

If the rights-holder were not given the freedom to set prices, it would not be willing to commit resources required to ensure an invention's delivery into the marketplace, thereby obviating the requirement that it be widely available. No commercial concern would invest in the commercial development of any invention knowing that their contribution in proving utility and safety would be ignored and the government could challenge their sales price after marketing.

~~Again,~~ If the drafters had intended such an interpretation, we would have inserted specific criteria into the law to enable the funding agency to assess exactly what a

reasonable price might be. As ~~the Tulane article agrees,~~ no such criteria are found, precisely because controlling patent rights on the basis of price was antithetical to what the drafters had in mind.

~~It is important to examine~~ The Tulane article's purported legislative history of the Act on pages 656-667 of the article ~~to demonstrate what the author's are willing to do to support their theory.~~ The Bayh-Dole legislative history includes only the law itself, the committee report on the bill, and the floor debate on that particular bill. The Act's legislative history does not include debates on other bills that were not enacted.

Notwithstanding, 70 of the footnotes of the total number of the 82 on pages 656-667 reference statements that are clearly outside of the Bayh-Dole legislative history. The petition's footnotes 10, 12 and 14 are among these 70 footnotes. Only 12 footnotes of the total 82 are directed to comments or quotes from the hearings and Senate Report on the Act. Not one of these 12 explicitly or by implication addresses the issue of pricing. Of the 12, footnotes 174 and 180 discussed by Senator Bayh reference a discussion in the senate hearings and report

limited to a pay-back provision which has nothing to do with the article's pricing theory.

20 of the 70 footnotes reflect quotes by well-known opponents of contractor ownership of federal inventions including Admiral H. G. Rickover, General Russell Long, Congressman Jack Brooks, Ralph Nader and others. Twelve of the 20 quote Admiral Rickover who's expertise in patents was derived from observing R&D contracts designed to fully build nuclear submarines entirely at government expense. There is nothing in these statements beyond their well-known objection to such contractor ownership that suggests that they would accept the contractor ownership policy found in the Act if it was only conditioned by a reservation in the government to determine a reasonable price after marketing of the government funded invention.

My September 27, 1976 statement on government patent policy before a House Committee is referenced in footnote 157 and used as the source of only the following comment on page 657:

> "There was also some testimony indicating that the pharmaceutical industry acted as a bloc to extort a favorable government patent policy and boycotted government patents in order to gain greater rights."

My actual comments makes no reference whatsoever to the pharmaceutical industry acting as "a bloc to extort" greater rights.

More disconcerting, however, is the fact ~~that my statement was directed to the Administration's progress to extend to all the federal R&D agencies the administrative policy referenced by Senator Bayh.~~ that my The statement provided an extensive justification for the need for a government-wide administrative policy which was later reflected in the Act. ~~The statement went well beyond those upon which the author's focused.~~ This kind of ~~selectivity is evidenced throughout pages 656-667 of the~~ article.

we not give any consideration to

~~Control Of Drug Prices~~

What is most disturbing about the subject petition is its attempt to transform this fundamental and successful piece

of intellectual property law into an administrative mechanism to control drug prices, with no regard for the consequences.

The drafters of Bayh-Dole never envisioned that the law could authorize government funding agencies to compel private entities to divulge internal accounts or pricing information, which is why the Act lacks any functional criteria specifying how this could be done.

Based on the Tulane article, the petition holds that the government should issue multiple licenses for a drug because the industry owner is charging too much, and quite falsely assert that the Act invests funding agencies with the authority to approve the pricing of inventions after they have been developed and distributed in the marketplace by private sector initiatives.

Beyond the author's purported legislative history, the authors argue that the Act's definition of "practical application" includes a requirement that the invention be made available to the public on "reasonable terms". However, on page 649 of the article the authors indicate that there is no clear legislative history on what "available to the public on

reasonable terms" means. Further, on page 651 they agree that the term applies to conditions other than "reasonable prices". The article and petitioner then argue that it can be interpreted, in an ordinary context, as including a "reasonable price", and that the funding agency is therefore authorized to assess what a "reasonable" market price might be.

The Scalia Rule

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

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

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

Healthcare Policy

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

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

Accordingly, I feel strongly that the petitioners' request for march-in under §203(a) of the Act, motivated entirely by a desire to control drug prices and based on a contrived interpretation of the law must be denied.

WRITTEN PAPER
May 22, 2004 - 1:32 PM
Page 1

My name is Norman Latker. I am here as a private citizen to speak in the defense of the Bayh-Dole Act as it was intended to be read and how it has been practiced for 25 years. The Act has fostered the development of a potent four-way partnership between researchers, their institutions, government and industry. This partnership has become a powerful engine of innovation, generating more practical advances than the rest of the world combined. Nowhere is this more true than in the fields of medical technology and pharmaceuticals.

Should the petitioner succeed in subverting one of the key precepts of Bayh-Dole - that of according broad marketplace prerogatives to the developers of government-funded inventions - the equilibrium of the partnership will be broken and this marvelous engine of innovation will stall.

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

The petition relies entirely on a recent article in the Tulane Law Review to support its contention that federal agencies have the authority to end the exclusive right of a developer of a government funded invention, if the invention is being sold at an unreasonable price. This article unfortunately paints a highly distorted picture both of the Act itself and the legislative process leading to its passage in order to support its conclusion.

Before the enactment of Bayh-Dole, an enormous amount of government-sponsored health research went to waste, as there was no incentive to invest in establishing the utility and safety to bring resulting inventions to the marketplace.

The drafters of the Act understood that that inventions resulting from government research are mostly conceptual in nature, having no established utility or safety. To bring these inventions into practical application required a significant investment by the private sector. The private investment necessary to prove utility and safety normally exceeds by many multiples the government funding that produced these inventions. This is especially the case with regard to life science inventions, the subject of the march-in petition.

The Act recognized that the contribution by the American public to support health research was a public equity that should be, and would be, rewarded by the Act's success in extending and improving the lives of American taxpayers.

Our answer to the problem of encouraging industry to make this investment was to accord intellectual property rights in full to the inventing organization, rather than to the government agency that financed their discovery. This allowed them to use the patent system as it has always been used: to leverage their rights to attract the capital to prove the inventions' safety and utility. Their freedom was not unlimited. The march-in provisions were conceived, as extraordinary measures to be used only when there was overwhelming need to protect the public against non-use or unreasonable use of inventions as called for in §200 of the Act.

In comparison, neither the Tulane article or the petition takes into account the developer's investment compared to that of the government in specific situations. Instead, the article's conclusion is justified by the fact that the total sum of government funded health research exceeds that of industry. This they submit creates "a public equity" beyond that addressed

by the Act and supports their march-in concept (see "Thematic Question" on page 634).

Even though the "public equity" defined by the authors is different from that addressed in the Bayh-Dole legislative history, it is used to incorrectly identify the motive for the Act's march-in provisions on page 659 as follows:

> "The march-in provisions became the linchpin of the entire enterprise because Congress wanted to balance the demands of private industry against the "public equity" that resulted from the massive public investment of funds to produce these patented inventions."

This is supported nowhere in the legislative history of the Act. The authors then point out that the Act's definition of "practical application" in §203(a) of the march-in provisions includes a requirement that the invention be made available to the public on "reasonable terms". From there, the article and petition argue that "reasonable terms" can be interpreted, in an ordinary context, as including a "reasonable

price", and that the funding agency is therefore authorized to assess what a "reasonable" market price might be.

A plain reading of §203(a) itself without any reference to any legislative history establishes that the petitioner and the authors are absolutely wrong.

Section 203(a) only applies to contractors and assignees. Licensees are not included. The contractors are non-profit organizations and small businesses, and the assignees are limited to patent management organizations. In comparison, the next two sections of 203 apply to contractors, assignees and licensees, and the last section applies only to licensees.

In 1980, it was clear that health inventions made by the non-profit organizations and small businesses subject to Section 203(A) had to be licensed to larger businesses to bring their inventions to practical application, because they did not have the resources necessary to obtain FDA clearance.

These contractors and assignees clearly do not set the sales price of an invention marketed by their licensee, and there is nothing in the Act that requires them to do so. If they attempt to do so on their own initiative it would

predictably kill any chance to negotiate a license. The sales price is set only by the licensee who as indicated is not subject to Section 203(A).

Since no party subject to Section 203(A) in 1980 set market prices, it is clear that there is no reason whatever to assume that "reasonable terms" include a "reasonable price".

Well then, what did "reasonable terms" mean in the context of Section 203(A) in 1980? The term referenced are directed to those contractors subject to Section 203(A) are required to negotiate into their license contracts. This makes perfect sense, since the word "terms" is normally used in the context of a contract. It makes no sense as applied to the licensee (who is not subject to Section 203(A)), because there are no "terms" attached to the sale of a product in the open market.

The most obvious "term" to address in a license contract is the royalty rate. There is an extensive history in government patent law that "reasonable terms" and "reasonable royalties" synonymously. There is no necessity to address in detail the petition's claim that case law and the Scalia test

establishes that "reasonable terms" must include a "reasonable price", because the findings in these cases and the Scalia test are out of context with the fact that the contractor in 1980, under Section 203(A), did not set the price on licensed health products, as that was the function of the licensee and was not subject to Section 203(A).

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

If the rights-holder were not given the freedom to set prices, it would not be willing to commit resources required to ensure an invention's delivery into the marketplace, thereby obviating the requirement that it be widely available. No commercial concern would invest in the commercial development of any invention knowing that their contribution in proving utility and safety would be ignored and the government could challenge their sales price after marketing.

Again, if the drafters had intended such an interpretation, we would have inserted specific criteria into the law to enable the funding agency to assess exactly what a

reasonable price might be. As the Tulane article agrees, no such criteria are found, precisely because controlling patent rights on the basis of price was antithetical to what the drafters had in mind.

It is important to examine the Tulane article's purported legislative history of the Act on pages 656-667 of the article to demonstrate what the author's are willing to do to support their theory. The Bayh-Dole legislative history includes only the law itself, the committee report on the bill, and the floor debate on that particular bill. The Act's legislative history does not include debates on other bills that were not enacted.

Notwithstanding, 70 of the footnotes of the total number of the 82 on pages 656-667 reference statements that are clearly outside of the Bayh-Dole legislative history. The petition's footnotes 10, 12 and 14 are among these 70 footnotes. Only 12 footnotes of the total 82 are directed to comments or quotes from the hearings and Senate Report on the Act. Not one of these 12 explicitly or by implication addresses the issue of pricing. Of the 12, footnotes 174 and 180 discussed by Senator Bayh reference a discussion in the senate hearings and report

limited to a pay-back provision which has nothing to do with the article's pricing theory.

20 of the 70 footnotes reflect quotes by well-known opponents of contractor ownership of federal inventions including Admiral H. G. Rickover, General Russell Long, Congressman Jack Brooks, Ralph Nader and others. Twelve of the 20 _____ Admiral Rickover who's expertise in patents was derived from observing R&D contracts designed to fully build nuclear submarines entirely at government expense. There is nothing in these statements beyond their well-known objection to such contractor ownership that suggests that they would accept the contractor ownership policy found in the Act if it was only conditioned by a reservation in the government to determine a reasonable price after marketing of the government funded invention.

My September 27, 1976 statement on government patent policy before a House Committee is referenced in footnote 157 and used as the source of only the following comment on page 657:

> "There was also some testimony indicating that the pharmaceutical industry acted as a bloc to extort a favorable government patent policy and boycotted government patents in order to gain greater rights."

My actual comments makes no reference whatsoever to the pharmaceutical industry acting as "a bloc to extort" greater rights.

More disconcerting, however, is the fact that my statement was directed to the Administration's progress to extend to all the Federal R&D agencies the administrative policy referenced by Senator Bayh. The statement provided an extensive justification for the need for a government-wide administrative policy which was later reflected in the Act. The statement went well beyond those upon which the author's focused. This kind of selectivity is evidenced throughout pages 656-667 of the article.

Control Of Drug Prices

What is most disturbing about the subject petition is its attempt to transform this fundamental and successful piece

of intellectual property law into an administrative mechanism to control drug prices, with no regard for the consequences.

The drafters of Bayh-Dole never envisioned that the law could authorize government funding agencies to compel private entities to divulge internal accounts or pricing information, which is why the Act lacks any functional criteria specifying how this could be done.

Based on the Tulane article, the petition holds that the government should issue multiple licenses for a drug because the industry owner is charging too much, and quite falsely assert that the Act invests funding agencies with the authority to approve the pricing of inventions after they have been developed and distributed in the marketplace by private sector initiatives.

Beyond the author's purported legislative history, the authors argue that the Act's definition of "practical application" includes a requirement that the invention be made available to the public on "reasonable terms". However, on page 649 of the article the authors indicate that there is no clear legislative history on what "available to the public on

reasonable terms" means. Further, on page 651 they agree that the term applies to conditions other than "reasonable prices". The article and petitioner then argue that it can be interpreted, in an ordinary context, as including a "reasonable price", and that the funding agency is therefore authorized to assess what a "reasonable" market price might be.

The Scalia Rule

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

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

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

Healthcare Policy

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

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

Accordingly, I feel strongly that the petitioners' request for march-in under §203(a) of the Act, motivated entirely by a desire to control drug prices and based on a contrived interpretation of the law must be denied.

I am here as a private citizen. I do not wish to use any ofmy 15 minutes to identify my credentials, so I attached my C.V. to my written testimony.

Drug pricing is a serious problem that affects everyone and needs to be addressed. But this is not the forum for its resolution.

As one of the draftsman of the Bayh-Dole Act, I am here today in its defense.

What is most disturbing about the subject petition is its attempt to transform this fundamental and successful piece of intellectual property law into an administrative mechanism to control drug prices, with no regard for the consequences.

The Act has fostered the development of a potent four-way partnership between researchers, their institutions, government and industry. This partnership has become a powerful engine of innovation, generating more practical advances than the rest of the world combined. Nowhere is this more true than in the fields of medical technology and pharmaceuticals.

Should the petitioner succeed in subverting one of the key precepts of Bayh-Dole - that of according broad marketplace prerogatives to the developers of government-funded inventions -

the equilibrium of the partnership will be broken and this marvelous engine of innovation will stall.

The basis for the petition is the allegation that the march-in provisions of Bayh-Dole gives NIH the authority to determine whether the price of a drug is unreasonable, and if so, permits NIH to grant multiple licenses.

To support this, the petition maintains that the entire government investment in health research and development demands this interpretation of the march-in provisions, and that the term "reasonable terms" in Section 203(A) of the Act must be interpreted in its ordinary context to mean "reasonable prices". None of this is supported by a correct reading of the Act and its legislative history.

The drafters of Bayh-Dole never envisioned that the law could authorize government funding agencies to compel private entities to divulge internal accounts or pricing information, which is why the Act lacks any functional criteria specifying how this could be done.

Only a very small portion of the government's health R&D investment is directed to drug research. Most is directed

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Only a very small portion of the government's health R&D investment is directed to drug research. Most is directed to grant funding to investigate the frontiers of the life sciences.

The Act is directed to creating an incentive for industry development of compositions of matter discovered during grant research that have no proven utility and safety. The Act's incentives were considered necessary because the government does not develop drugs for the marketplace It is the private sector that must prove the utility and safety necessary to obtain FDA approval for marketing. The private sector investment necessary to obtain FDA approval always exceeds by many multiples the government funding that produced the composition of matter being developed.

The Act's legislative history makes clear that the public equity in funding the grants in question will be significantly rewarded by the delivery of drugs that improve and extend the lives of millions of their countrymen that otherwise would not have been available.

With regard to the petitions' argument that "reasonable terms" must include "reasonable prices", a simple reading of Section 203(A) without regard to any legislative history clearly shows such interpretation to be incorrect.

Section 203(A) only applies to contractors and assignees as defined by the Act. Licensees are not included by design as shown by the next two sections application to contractors, assignees and licensees, and the last section only to licensees.

In 1980, it was clear that most of the health inventions made by the small business and non-profit contractors of Section 203(a) could be developed only under licenses with the drug industry.

As the licensor, the contractors do not set the price of the drugs ultimately marketed. In fact, there is nothing in the Act that requires the contractors subject to 203(a) to set the price of the marketed drug. That would be inconsistent with the incentive to gain the licensee's cooperation. Accordingly,

the sales price, as would be expected, was left to the discretion of the licensee who as indicated is not subject to Section 203(a).

Since the contractors subject to Section 203(a) in 1980 had no responsibility or authority to set market prices it is clear that there is no reason whatever to assume that the "reasonable terms" they were responsible to implement included "reasonable prices". If the drafters had wanted a drug resulting from contractor research to be sold at a reasonable price that condition would have been required as part of the contractors license agreement as they are the only ones subject to 203(a)

How then should "reasonable terms" be specifically interpreted in the context of Section 203(a) in 1980? The "reasonable terms" that the contractors of Section 203(a) were obligated to observe in their license agreements has had a long history of meaning "reasonable royalties". This makes perfect sense since the word "terms" is normally used in the context of a contract. A license agreement is a contract and in the context of the Act includes the terms for royalties which as required must be reasonable. In comparison, Essential Inventions definition of "reasonable terms" suggests that the sale of a drug by the licensee is a contract with the purchaser which has a term imposed by Sec.203(a) requiring that their sales be at a

reasonable price. Frankly that makes no sense since the licensee is not subject to sec.203(a) and a sale is not a contract.

There was some possibility in 1980 that a small business contractor subject to 203(a) could bring an invention to the market with its own resources without licensing. In these limited situations "reasonable terms" could not mean "reasonable royalties". What "reasonable terms" specifically means in this situation I will leave to others. But the Essential Inventions definition cannot be applied as that would clearly be inconsistent to how licensees are handled under Sec. 203(a)

If the drafters had intended the petition definition of "reasonable terms", we would have inserted specific criteria into the law to enable the funding agency to assess exactly what a reasonable price might be. No such criteria are found, precisely because controlling patent rights on the basis of price was antithetical to the Act.

The petition relies on a purported legislative history of the Act on pages 656-667 of a Tulane Law article cited in the petition.

The Bayh-Dole legislative history includes only the law itself, the committee report on the bill, and the floor debate on that particular bill. The Act's legislative history does not include debates on other bills that were not enacted.

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20 of the 70 footnotes outside the Act's legislative history reflect quotes by well-known opponents of contractor ownership of federal inventions including Admiral H. G. Rickover, General Russell Long, Congressman Jack Brooks, Ralph Nader and others. Twelve of these 20 footnotes reference statements made by Admiral Rickover. There is nothing in the opponents statements beyond their well-known objection to

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

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The Act's legislative history makes clear that the public equity in funding the grants in question will be significantly rewarded by the delivery of drugs that improve and extend the lives of millions of their countrymen that otherwise would not have been available.

With regard to the petitions' argument that "reasonable terms" must include "reasonable prices", a simple reading of Section 203(A) without regard to any legislative history clearly shows such interpretation to be incorrect.

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Drug pricing is a serious problem that affects everyone and needs to be addressed. But this is not the forum for its resolution.
As one of the draftsman of the Bayh-Dole Act, I am here today in its defense.

What is most disturbing about the subject petition is its attempt to transform this fundamental and successful piece of intellectual property law into an administrative mechanism to control drug prices, with no regard for the consequences.

The basis for the petition is the allegation that the march-in provisions of Bayh-Dole gives NIH the authority to determine whether the price of a drug is unreasonable, and if so, permits NIH to grant multiple licenses.

To support this, the petition maintains that the entire government investment in health research and development demands this interpretation of the march-in provisions, and that the term "reasonable terms" in Section 203(A) of the Act must be interpreted in its ordinary context to mean "reasonable prices".

The petition relies entirely on a recent article in

Amendments To The Claims

the Tulane Law Review to support its contention that federal

This listing of claims will replace all prior

agencies have the authority to end the exclusive right of a

versions, and listings, of claims in the application:

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Listing of Claims

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Claims 1-8 (Canceled)

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To support this, the petition maintains that the entire government investment in health research and development demands this interpretation of the march-in provisions, and that the term "reasonable" in Section 304(A) of the Act must be interpreted in its ordinary context to means "reasonable prices". None of this is supported by a correct reading of the Act and its legislative history.

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In 1980, it was clear that most of the health inventions made by the small business and non-profit contractors

of Section 203(A) could be developed only under licenses with the drug industry.

In this situation, the contractors did not set the prices of the drugs ultimately marketed under their licenses. In fact, there is nothing in the Act to require them to do so, which would be inconsistent with the incentive to gain industry cooperation. The sales price is set only by the licensee who is ~~indicated as~~ not subject to Section 203(A).

Since no party subject to Section 203(A) in 1980 set market price, it is clear that there is no reason whatever to assume that "reasonable terms" must include a "reasonable price".

Well then - how can "reasonable terms" be more specifically interpreted in the context of Section 203(A) in 1980? That's easy. Negotiating "reasonable terms" is a responsibility that the contractors of Section 203(A) must ~~answer to~~ pursue when assuming a license with a prospective licensee.

My name is Norman Latker. I am here as a private citizen to speak in the defense of the Bayh-Dole Act as it was intended to be read and how it has been practiced for 25 years. The Act has fostered the development of a potent four-way partnership between researchers, their institutions, government and industry. This partnership has become a powerful engine of innovation, generating more practical advances than the rest of the world combined. Nowhere is this more true than in the fields of medical technology and pharmaceuticals.

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

Subject: Fw: Avery Bonds
From: "Latker, Carole (NIH/NIGMS)" <LATKERC@nigms.nih.gov>
Date: Thu, 22 Apr 2004 17:49:00 -0400
To: "'latkerc@bellatlantic.net'" <latkerc@bellatlantic.net>

Fyi

Sent from my BlackBerry Wireless Handheld

-----Original Message-----
From: pristine@netvigator.com <pristine@netvigator.com>
To: Latker, Carole (NIH/NIGMS) <LATKERC@nigms.nih.gov>
CC: jyotilatker@hotmail.com <jyotilatker@hotmail.com>
Sent: Thu Apr 22 05:38:14 2004
Subject: Avery Bonds

Hi:

Hope you had a good trip.

Thought you might want to know more about Avery Bonds, the hot new investment idea that doubles as a social welfare fund. Here's how it works:

* Avery Bonds are sold to investors who might otherwise buy fixed deposits. They are guaranteed an interest rate return somehwat higher than they would get from a fixed savings deposit, say 2.5%.

* The Avery Bond portfolio acquires securitisation instruments and other high-yield products that are normally only available to large institutional investors, achieving a yield of say 4%.

* The expenses for the fund manager, who is working pro-bono, are written off as a tax-deductible contribution to Avery Bonds (501c3). The work is minimal, because the invrestments parallel other portfolio products already in existence. Maintaining the avery Bond investor database also helps the fund manager establish goodwill & market other investment products.

* The 1.5% in excess Avery Bond interest is used for a) a medical fund for all children with tuberous sclerosis in Hong Kong (presently numbering perhaps 100), and b) selective donation towards TSC research.

* The 1.5% interest foregone by Avery Bond investors is also, of course, tax deductible.

* Avery Bonds would target an initial investor base of about 1,000, with a minimum investment of US$500 and an average investment of US$2,000. That would yield US$2 million, interest on which would come to US$30,000 per year.

* Should the model prove successful and attain an investor base similar to the average portfolio fund in Hong Kong, total investment would reach US$50m, generating US$750,000 per year for medical care and research for children with TSC.

R---

public accountability and social responsibility in the conduct of science. I need the help of those many politicians who care about the NIH mission and our devotion to advancing the health of the American public. It is time to make those who are abusing power and political influence feel as uncomfortable as we feel when they trample on our mission and vision. I urge you not to remain neutral on this frontal attack on myself, my dedicated staff, and science itself.

I cannot fulfill my mission when leading scientists must pass a series of political litmus tests in order to work with me. I cannot fulfill my mission when politicians target grants for topics they deem unworthy of funding, despite scientific peer acclaim. I cannot fulfill my mission when my workers must constantly look over their shoulder to see if they are on a list for "outsourcing" or a victim of "consolidation." I cannot fulfill my mission when web sites providing health information are consciously and deliberately altered to fit ethical and/or religious beliefs. The NIH should be about the open celebration of the scientific enterprise, not a target for political agendas to be played out on a national stage. The stakes are far too high.

I encourage all of my friends to contact the NIH Director, Dr. Elias Zerhouni, to express concern for science and for the staff of the NIH. I plead with you to contact your Congressman or Congresswoman to express your fears about what happened on the House floor on July 11th. This is likely not the last time that targeting individual grants in this fashion will be attempted. Those in support of such actions must be buoyed by the narrow margin of defeat. I ask that you inform the DHHS and those in the Senate and House of the daily impact that misguided administrative and personnel policies such as A-76 have on the hearts and minds of my workers.

Why am I asking for your help now? This is now the 2004 election season. It is time to become even more involved in the political process, and much more vigilant about the influence of politics on our science. On an individual and professional organizational level, let us be more diligent. Question motives. Challenge values. Keep political agendas far removed from the noble mission of the NIH.

I am the NIH . . . and I need your help.

Dear Dr. Rohrbaugh:

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

While the subject of delivering affordable health care is certainly a serious issue, the provisions of the Bayh-Dole Act do not provide for governmental actions such as those requested by Essential Inventions.
Indeed, such actions were never contemplated by the Congress and are not reflected in the legislative history of the law.

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

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

Regrettably, Mr. Love and several others making the same case mix up the legislative history of the Bayh-Dole Act

My name is Norman Latker. I am here as a private citizen to speak in the defense of the Bayh-Dole Act as it was intended to be read and how it has been practiced for 25 years. The Act has fostered the development of a potent four-way partnership between researchers, their institutions, government and industry. This partnership has become a powerful engine of innovation, generating more practical advances than the rest of the world combined. Nowhere is this more true than in the fields of medical technology and pharmaceuticals.

Should the petitioner succeed in subverting one of the key precepts of Bayh-Dole - that of according broad marketplace prerogatives to the developers of government-funded inventions - the equilibrium of the partnership will be broken and this marvelous engine of innovation will stall.

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

The petition relies entirely on a recent article in the Tulane Law Review to support its contention that federal agencies have the authority to end the exclusive right of a developer of a government funded invention, if the invention is being sold at an unreasonable price. This article unfortunately paints a highly distorted picture both of the Act itself and the legislative process leading to its passage in order to support its conclusion.

Before the enactment of Bayh-Dole, an enormous amount of government-sponsored health research went to waste, as there was no incentive to invest in establishing the utility and safety to bring resulting inventions to the marketplace.

The drafters of the Act understood that that inventions resulting from government research are mostly conceptual in nature, having no established utility or safety. To bring these inventions into practical application required a significant investment by the private sector. The private investment necessary to prove utility and safety normally

exceeds by many multiples the government funding that produced these inventions. This is especially the case with regard to life science inventions, the subject of the march-in requests. The "public equity" for supporting health research was to be recognized by the Act's success in extending and improving the lives of American taxpayers.

Our answer to the problem of encouraging industry to make this investment was to accord intellectual property rights in full to the innovators, rather than to the government agency that financed their discovery. This provided to the developers the freedom to leverage their property rights to their advantage in the marketplace as intended by the patent system. The conditions attached to this freedom are found in the march-in provisions of §203 of the Act. The march-in provisions were conceived, as extraordinary measures to be used only when there was overwhelming need to protect the public against non-use or unreasonable use of inventions as called for in §200 of the Act.

In comparison, neither the Tulane article or the petition takes into account the developer's investment compared to that of the government in specific situations. Instead, the article's conclusion is justified by the fact that the total sum of government funded health research exceeds that of industry. This they submit creates "a public equity" beyond that addressed by the Act which supports a march-in based on unreasonable pricing (see "Thematic Question" posed on page 634).

Even though the "public equity" defined by the authors is different from that addressed in the Bayh-Dole legislative history, it is used to interpret the Act's march-in provisions on page 659 as follows:

> "The march-in provisions became the linchpin of the entire enterprise because Congress wanted to balance the demands of private industry against the "public equity" that resulted from the massive public investment of funds to produce these patented inventions."

To support this conclusion, the authors present a purported legislative history of the Act on pages 656-667 of the article. The Bayh-Dole legislative history includes only the

law itself, the committee report on the bill, and the floor debate on that particular bill. The Act's legislative history does not include debates on other bills that were not enacted.

Notwithstanding, 70 of the footnotes of the total number of the 82 on pages 656-667 reference statements that are clearly outside of the Bayh-Dole legislative history. The petition's footnotes 10, 12 and 14 are among these 70 footnotes. Only 12 footnotes of the total 82 are directed to comments or quotes from the hearings and Senate Report on the Act. Not one of these 12 explicitly or by implication addresses the issue of pricing. Of the 12, footnotes 174 and 180 discussed by Senator Bayh reference a discussion in the senate hearings and report limited to a pay-back provision which has nothing to do with the article's pricing theory.

20 of the 70 footnotes reflect quotes by well-known opponents of contractor ownership of federal inventions including Admiral H. G. Rickover, General Russell Long, Congressman Jack Brooks, Ralph Nader and others. There is nothing in these statements beyond their well-known objection to such contractor ownership that suggests that they would accept the contractor ownership policy found in the Act if it was only conditioned by a reservation in the government to determine a reasonable price after marketing of the government funded invention.

My September 27, 1976 statement on government patent policy before a House Committee referenced in footnote 157 is used as the source of only the following comment on page 657:

> "There was also some testimony indicating that the pharmaceutical industry acted as a bloc to extort a favorable government patent policy and boycotted government patents in order to gain greater rights."

My actual comments makes no reference whatsoever to industry "extortion" to gain greater rights. ✓as a "bloc"

More disconcerting, however, is the fact that the entire statement is directed to the Administration's progress to extend to all the Federal R&D agencies the administrative policy referenced by Senator Bayh as ~~the~~ ✓being the precursor to the Act. The

statement provided an extensive justification for the need for Bayh-Dole type legislation well beyond those upon which the author's focused. This kind of selectivity is evidenced throughout pages 656-667 of the article.

Control Of Drug Prices

What is most disturbing about the subject petition is the attempt to transform this fundamental and successful piece of intellectual property law into an administrative mechanism to control drug prices, with no regard for the consequences.

The drafters of Bayh-Dole never envisioned that the law could authorize government funding agencies to compel private entities to divulge internal accounts or pricing information, which is why the Act lacks any functional criteria specifying how this could be done which the ~~Tulane~~ article ~~recognizes~~ acknowledges on page 648.

Based on the Tulane article, the petition holds that the government should issue multiple licenses for a drug because the industry owner is charging too much, and quite falsely assert that the Act invests funding agencies with the authority to approve the pricing of inventions after they have been developed and distributed in the marketplace by private sector initiatives.

Beyond the author's purported legislative history, the authors argue that the Act's definition of "practical application" includes a requirement that the invention be made available to the public on "reasonable terms". However, on page 649 of the article the authors indicate that there is no clear legislative history on what "available to the public on reasonable terms" means. Further, on page 651 they agree that the term applies to conditions other than "reasonable prices". The article and petitioner then argue that it can be interpreted, in an ordinary context, as including a "reasonable price", and that the funding agency is therefore authorized to assess what a "reasonable" market price might be.

The Scalia Rule

That "reasonable terms" must include the notion of price, they maintain, is evidenced by a number of court

decisions supporting that definition. They also cite the Scalia rule:

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

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

In context, therefore, "reasonable terms" cannot be interpreted to mean a limitation on the developer's ability to set prices in the marketplace, but can be interpreted to apply to other conditions as noted by the authors on page 651.

If the rights-holder were not given the freedom to set prices, it would not be willing to commit resources required to ensure an invention's delivery into the marketplace, thereby obviating the requirement that it be widely available. No commercial concern would invest in the commercial development of any invention knowing that their contribution in proving utility and safety would be ignored and the government could challenge their sales price after marketing.

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

Healthcare Policy

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

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

Accordingly, I feel strongly that the petitioners' request for march-in under §203(a) of the Act, motivated entirely by a desire to control drug prices and based on a contrived interpretation of the law must be denied.

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

While the subject of delivering affordable health care is certainly a serious issue, the provisions of the Bayh-Dole Act do not provide for governmental actions such as those requested by Essential Inventions. Indeed, such actions were never contemplated by the Congress and are not reflected in the legislative history of the law.

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

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

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

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

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

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

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

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

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

The article also mischaracterized the rights retained by government under Bayh-Dole. The ability of the government to revoke a license granted under the act is not contingent on the pricing of a resulting product or tied to the profitability of a company that has commercialized a product that results in part from government-funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product. (Emphasis added).

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

Birch Bayh/Bob Dole

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

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

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

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

Sincerely,

Joseph P. Allen

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Sincerely,

Joseph P. Allen
President
National Technology Transfer Center

--
James Love, Director, Consumer Project on Technology http://www.cptech.org, mailto:james.love@cptech.org tel. +1.202.387.8030, mobile +1.202.361.3040

President
National Technology Transfer Center

Ms. Luk, I have recieved the forms and will fax them back to you in about 12 hours (our morning) with a copy of the charge card (back side) and a copy of my passport. Everything looks in order. Also can you tell me if there is an airport shuttle that goes to this hotel and where in the airport I pick it up. I will be arriving around 6:30 PM April 16 and departing the morning of April 22.

Thank you for your assistance. Carole Latker

Latker, Carole (NIH/NIGMS) wrote:

-----Original Message-----
From: Tiglion Travel [mailto:tvlraina@tiglion.com]
Sent: Tuesday, April 13, 2004 12:05 AM
To: Latker, Carole (NIH/NIGMS)
Subject: * URGENT * Invoice for Hotel reservation (Regal Oriental Hotel 16-22Apr04)

Dear Mrs Latker,

I have attached herewith the Invoice and the credit card authorization froms for you (Invoice no. 767), pls print it out and check all details, if all in order, pls first of all, return email to indicate all details shown
are ok and you accept the Invoice and terms & condition by return email to us tonight your time (before 13Apr04 1500 hrs Hong Kong time), and I will guarantee the booking and settle the payment for you first, and then pls sign on the invoice and fill the forms and fax it back to me together with the credit card copy back side and passport copy to me on or before 14Apr04 1200 noon Hong Kong time.

Pls click and read the following for the information of important notice --

http://www.tiglion.com/form/importan.htm

Pls make sure passenger have proper visa(s) or document(s) for the countries you enter into or transit.

Thank you.

Please bookmark travel.com.hk to check news on the early bird promotions for air fares, packages, hotels, cruises:

http://www.travel.com.hk

Regards.

Raina Luk (Ms)
Senior Travel Executive
13 Apr 2004
****
Tiglion Travel Services Company Limited
902 Yue Xiu Building 160-174 Lockhart Road
Wanchai, Hong Kong
Tel: 852-25117189 Fax: 852-25197296 Lic.350005
Email: travel@tiglion.com
Website: http://www.travel.com.hk
****

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Sincerely,

Joseph P. Allen

I am here as a private citizen. I do not wish to use my 15 minutes identifying my credentials, so I attached my C.V. to my written testimony.

Drug pricing is a serious problem that affects everyone and needs to be addressed. But this is not the forum for its resolution.

I am here today only to defend Bayh-Dole. The basis for the petition is the allegation that the march-in provisions of Bayh-Dole gives NIH the authority to determine whether the price of a drug is unreasonable, and if so, permits NIH to grant multiple licenses.

To support this, the petition maintains that the entire government investment in health research and development demands this interpretation of the march-in provisions, and that the term "reasonable terms" in Section 304(A) of the Act must be interpreted in its ordinary context to mean "reasonable prices". None of this is supported by a correct reading of the Act and its legislative history.

First, only a very small portion of the government's health R&D investment is directed to drug research. Most is directed to grant funding to investigate the frontiers of the life sciences.

The Act is directed to creating an incentive for industry development of compositions of matter having no proven utility and safety found which is discovered during grant research. This is based on the fact that government does not develop drugs for the marketplace and that it is the private sector that must prove the utility and safety necessary to obtain FDA approval for marketing. The private sector investment necessary to obtain FDA approval always exceeds by many multiples the government funding that produced the composition of matter being developed.

The Act's legislative history makes clear that the public equity in funding the grants in question will be significantly rewarded by the delivery of drugs that improve and extend the lives of millions of their countrymen that otherwise would not have been available.

With regard to the petitions' argument that "reasonable terms" must include "reasonable prices", a simple reading of Section 203(A) without regard to any legislative history clearly shows such interpretation to be incorrect.

Section 203(A) only applies to contractors and assignees as defined by the Act. Licensees are not included by design as the other of 203 sections apply to contractors, assignees and licensees, or to only to licensees.

In 1980, it was clear that most of the health inventions made by the small business and non-profit contractors of Section 203(A) could be developed only under licenses with the drug industry.

In their license agreements the contractors do not set the price of the drugs ultimately marketed. In fact, there is nothing in the Act that requires the contractors subject to 203(A) to set the price of the marketed drug. That would be inconsistent with the incentive to gain the licensee's cooperation. Accordingly, the sales price as one would expect was left to the discretion of the licensee who as indicated is not subject to Section 203(A).

Since the contractors subject to Section 203(A) in 1980 had no responsibility or authority to set market prices it is clear that there is no reason whatever to assume that the "reasonable terms" they were responsible to implement included "reasonable prices". If the drafters had wanted to require that a drug resulting from their research be sold at a reasonable price that condition would have had to be made part of the contractors license agreement as they are the only ones subject to 203(A)

Well then - how were the "reasonable terms" specifically interpreted in the context of Section 203(A) in

1980? That's easy. The "reasonable terms" that the contractors of Section 203(A) were obligated to observe in their license agreements has had a long history of meaning "reasonable royalities". This makes perfect sense since the word "terms" is normally used in the context of a contract. A license agreement is a contract and in the context of the Act includes the terms for royalty payment which as required must be reasonable. In comparison Essential Inventions definition of "reasonable terms" suggests that the sale of a drug by the licensee is a contract with the purchaser having a term requiring that sale be at a reasonable price. Frankly that makes no sense.

"There was also some testimony indicating that the pharmaceutical industry acted as a bloc to extort a favorable government patent policy and boycotted government patents in order to gain greater rights."

My actual comments makes no reference whatsoever to the pharmaceutical industry acting as "a bloc to extort" greater rights.

More disconcerting, however, is the fact that my statement provided an extensive justification for the need for a government-wide administrative policy ~~which~~ was not given any consideration. ✓ which was later reflected in the ACT but

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

Obviously any healthcare reform effort could face resistance from vested interests, and it is tempting for some to

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Accordingly, I feel strongly that the petitioners' request for march-in under §203(a) of the Act, motivated entirely by a desire to control drug prices and based on a contrived interpretation of the law must be denied.

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C:\My Documents\NJL\ORAL SPEECH.doc

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Drug pricing is a serious problem that affects everyone and needs to be addressed. But this is not the forum for its resolution.

As one of the draftsman of the Bayh-Dole Act, I am here today in its defense.

What is most disturbing about the subject petition is its attempt to transform this fundamental and successful piece of intellectual property law into an administrative mechanism to control drug prices, with no regard for the consequences.

The Act has fostered the development of a potent four-way partnership between researchers, their institutions, government and industry. This partnership has become a powerful engine of innovation, generating more practical advances than the rest of the world combined. Nowhere is this more true than in the fields of medical technology and pharmaceuticals.

Should the petitioner succeed in subverting one of the key precepts of Bayh-Dole - that of according broad marketplace prerogatives to the developers of government-funded inventions -

the equilibrium of the partnership will be broken and this marvelous engine of innovation will stall.

The basis for the petition is the allegation that the march-in provisions of Bayh-Dole gives NIH the authority to determine whether the price of a drug is unreasonable, and if so, permits NIH to grant multiple licenses.

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The drafters of Bayh-Dole never envisioned that the law could authorize government funding agencies to compel private entities to divulge internal accounts or pricing information, which is why the Act lacks any functional criteria specifying how this could be done.

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design as shown by the next two sections application to contractors, assignees and licensees, and the last section only to licensees.

In 1980, it was clear that most of the health inventions made by the small business and non-profit contractors of Section 203(a) could be developed only under licenses with the drug industry.

As the licensor, the contractors do not set the price of the drugs ultimately marketed. In fact, there is nothing in the Act that requires the contractors subject to 203(a) to set the price of the marketed drug. That would be inconsistent with the incentive to gain the licensee's cooperation. Accordingly, the sales price, as would be expected, was left to the discretion of the licensee who as indicated is not subject to Section 203(a).

Since the contractors subject to Section 203(a) in 1980 had no responsibility or authority to set market prices it is clear that there is no reason whatever to assume that the "reasonable terms" they were responsible to implement included "reasonable prices". If the drafters had wanted a drug resulting from contractor research to be sold at a reasonable price that condition would have been required as part of the contractors license agreement as they are the only ones subject to 203(a)

How then should "reasonable terms" be specifically interpreted in the context of Section 203(a) in 1980? The "reasonable terms" that the contractors of Section 203(a) were obligated to observe in their license agreements has had a long history of meaning "reasonable royalties". This makes perfect sense since the word "terms" is normally used in the context of a contract. A license agreement is a contract and in the context of the Act includes the terms for royalties which as required must be reasonable. In comparison, Essential Inventions definition of "reasonable terms" suggests that the sale of a drug by the licensee is a contract with the purchaser which has a term imposed by Sec.203(a) requiring that their sales be at a reasonable price. Frankly that makes no sense since the licensee is not subject to sec.203(a) and a sale is not a contract.

There was some possibility in 1980 that a small business contractor subject to 203(a) could bring an invention to the market with its own resources without licensing. In these limited situations "reasonable terms" could not mean "reasonable royalties". What "reasonable terms" specifically means in this situation I will leave to others. But the Essential Inventions definition cannot be applied as that would clearly be inconsistent to how licensees are handled under Sec. 203(a)

If the drafters had intended the petition definition of "reasonable terms", we would have inserted specific criteria into the law to enable the funding agency to assess exactly what a reasonable price might be. No such criteria are found, precisely because controlling patent rights on the basis of price was antithetical to the Act.

The petition relies on a purported legislative history of the Act on pages 656-667 of a Tulane Law article cited in the petition.

The Bayh-Dole legislative history includes only the law itself, the committee report on the bill, and the floor debate on that particular bill. The Act's legislative history does not include debates on other bills that were not enacted.

Notwithstanding, 70 of the footnotes of the total number of the 82 on pages 656-667 reference statements that are clearly outside of the Bayh-Dole legislative history. The petition's footnotes 10, 12 and 14 are among these 70 footnotes. Only 12 footnotes of the total 82 are directed to comments or quotes from the hearings and Senate Report on the Act. Not one of these 12 explicitly or by implication addresses the issue of

pricing. Of the 12, footnotes 174 and 180 discussed by Senator Bayh reference a discussion in the senate hearings and report limited to a pay-back provision which has nothing to do with the article's pricing theory.

20 of the 70 footnotes outside the Act's legislative history reflect quotes by well-known opponents of contractor ownership of federal inventions including Admiral H. G. Rickover, General Russell Long, Congressman Jack Brooks, Ralph Nader and others. Twelve of these 20 footnotes reference statements made by Admiral Rickover. There is nothing in the opponents statements beyond their well-known objection to contractor ownership that suggests that they would accept the contractor ownership policy found in the Act if it was only conditioned by a reservation in the government to determine a reasonable price after marketing of the government funded invention.

My September 27, 1976 statement on government patent policy before a House Committee is referenced in footnote 157 and used as the source of only the following comment on page 657:

Subject: Re: [techno-l] My May 25 Statement at NIH meeting on the Essential Inventions Petition
From: James Love <james.love@cptech.org>
Date: Wed, 02 Jun 2004 18:09:04 -0400
To: Norman Latker <NJL@browdyneimark.com>
CC: Techno-l@lists.uventures.com

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

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

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

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

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

You say, "When reading the march-in clauses, it is important to understand that Section 203a only applies to contractors-that is, the original researchers -and assignees," further that "it cannot mean "reasonable prices," because contractors, in the view of the drafters, would not normally be setting prices."

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

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

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

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

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

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

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

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

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

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

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

Jamie

Norman Latker wrote:

> As I indicated earlier Essential Inventions contention that "reasonable terms" must mean "reasonable prices" is no longer credible based on the correct reading of the Act set out in my May 25 statement below. If Jamie does not agree he is free to make his case on this board. I do not believe he will do so because he has committed himself to his misrepresentation of the Act all over capitol hill. As I suggested earlier, the most effective way to undue the damage he has done is request that the appropriate official at your institution make know to your state's representatives on capitol hill the importance of the Act to your state's economy and the damage that will be done if they buy into Jamie's misrepresentation of the Act. You and the public are the Act"s direct beneficiaries. While we in Washington are doing the best we can, It is you that must step forward to defend the Act. If you can convince yourselves that this is someone else's responsibility, be assured that Jam
> ie is still on capitol hill misrepresenting the Act.
>
> Norman J. Latker
> Statement Before NIH On
> Essential Inventions Petition Regarding Norvir
> May 25, 2004
>
> Hello. I'm Norm Latker, and I'm here to address the petition sponsored by Mr. James Love of Essential Inventions, which asks NIH to end the exclusive title held by Abbott Laboratories for the AIDS drug Norvir.
>
> I thank you for the opportunity to address this issue today.
>
> While I am sympathetic to the efforts of Mr. Love, which I believe are motivated by a desire to enhance the quality of life for the millions of Americans living with AIDS, I must oppose his petition, which, if successful, would undermine the integrity of the Bayh-Dole Act, which I helped to draft back in the 1970s.
>
> Although there was spirited opposition to Bayh-Dole when it was brought before Congress in 1980, a broad political consensus was ultimately built around the notion that market forces would do a far better job of disseminating government-sponsored inventions than bureaucracies ever could.

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

That may sound like hyperbole, but the impact of the Act has indeed been astounding-and overwhelmingly positive.
It has fostered a potent four-way partnership between researchers, their institutions, government and industry. That partnership has evolved into the most powerful engine of practical innovation in the world, producing innumerable advances that have extended life, improved its quality and reduced suffering for hundreds of millions of people.
Of course, the law isn't perfect. No law is. There have been changes in the three decades since Bayh-Dole's passage-changes that no one could have predicted. But overall it has stood the test of time.
While I feel I can provide some perspective on the Act, there is very little I can say with authority on the underlying issues that have prompted Mr. Love's petition.
Frankly, there are a number of things that I simply do not know.

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

Nor can I pretend to know what impact the price hike will have on those who need the drug to stay healthy, or on the healthcare finance system. I do not know if some people who need Norvir will now not have access to it. I don't know whether Abbott's promise to provide the drug for free to those who cannot afford it should be taken at face value.
It is worth noting that Senator John McCain has called on the Federal Trade Commission to investigate Abbott Laboratories for possible abuse of its monopoly power with respect to Norvir. Attorneys General in Illinois and New York are also looking into the matter. Again, I do not know precisely what criteria these organs of government might use to determine whether corrective action is warranted.
But I do know this: the Bayh-Dole Act is not an arbiter of healthcare policy or drug pricing, and was never intended to be.
Bayh-Dole defines critically important aspects of intellectual property law, while ensuring that viable government-sponsored research does not go to waste. It is decidedly ill-suited for any other purpose.

Simply put, the legal philosophy of Bayh-Dole is this: if the government accords broad marketplace prerogatives to the developers of government-funded inventions, such inventions are far more likely to be developed and disseminated to the public.
The law holds that intellectual property rights should be accorded in full to the innovators, rather than to the government agency that financed their research, and that developers should be free to leverage their property rights to their advantage in the market place as intended by the patent system.
There were a few conditions placed on this freedom-conditions which are now the subject of dispute. In layman's terms, the conditions provided that:

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

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

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

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

These conditions were translated into the legal language found in section 203 of the Act-what we now refer to as the "march-in" clauses, because they give the government the power to "march-in" and reassign intellectual property rights.

These were conceived as extraordinary measures to be used only when there was overwhelming evidence to show that the public resources invested into an innovation were being wasted or abused.
Obviously, Abbott Laboratories has been enormously successful in bringing the benefits of Norvir to the public at large. The drug may be expensive-perhaps intolerably expensive, given the critical importance it holds for people with AIDS. But by the criteria established by Bayh-Dole, Abbott has complied with the law.

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

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

The petition points out that one march-in clause, section 203a, specifies that the invention in question must be made available on "reasonable terms", which the authors interpret to mean "reasonable prices".
None of this is supported by a correct reading of the Act and its legislative history.
In fact, if the drafters of Bayh-Dole had intended such an interpretation, we would have inserted specific criteria into the law to enable NIH-or any government funding agency -to assess what a reasonable price might be. No such criteria are found, because controlling patent rights on the basis of price was antithetical to what the drafters had in mind.

Nor did we envision that the law could authorize government funding agencies to compel private entities to divulge internal accounts or pricing information. If we had foreseen such a process, the Act would have contained enabling language specifically empowering it.
It must be admitted that the law is written in the arcane legalese of the period, and many sections are quite easy to misinterpret unless armed with the correct definitions.
Let me provide some of those definitions now.
The Bayh-Dole Act refers to three key entities involved in the government-sponsored research and subsequent development of an invention.
1) Contractors: These are the organizations that originally used government research funds to make fundamental discoveries

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

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

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

Section 203a does not apply to licensees.

This was not an accidental omission. That licensees are consciously excluded from 203a is obvious, because the next three sections -203b--d explicitly apply to all three entities: contractors, assignees and licensees.
Back in 1980, it was clear that most health inventions could only be practically developed under licenses with the drug industry. Bayh-Dole granted the property rights to the contractor, who would then negotiate a license agreement with the licensee. Of course, drug pricing played no role in these negotiations. Pricing a drug which has not yet been tested, approved and marketed is, of course,

impossible.

As the phrase "reasonable terms" found in 203a applies to contractors, and not to licensees, it cannot mean "reasonable prices," because contractors, in the view of the drafters, would not normally be setting prices. Further, they are not required to do so under the defined contractor obligations under the Act. The phrase clearly refers to the terms of the agreement between the contractor and the licensee.
Bayh-Dole wants government-sponsored inventions moved to the marketplace. Towards that end, it obligates the contractor to transfer the invention to the licensee without demanding exorbitant, or unreasonable, royalties.

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

After explaining all that, I must now point out that Norvir has never been licensed, and that Abbott Laboratories is not a licensee. It is, in fact, a contractor who obtained title to its invention directly through a contract with NIH.
Again, when the law was written, we thought that in most cases, a contractor would be an academic, research institute or small business that would not have the resources to develop and market the invention on their own. Bayh-Dole therefore emphasizes the licensing process, as is abundantly evident throughout the Act and its implementing regulations.

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

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

In closing, I'd like to return briefly to the broader issues that have prompted Mr. Love's petition.
It must be plainly understood that medical access problems in the United States stem not from the research and development regime, but from the way healthcare entitlements are ascribed and healthcare resources are distributed.
I confess that I am no fan of price controls, because I believe that they could stifle innovation and drastically reduce the amount of money the drug industry pumps into pharmaceutical research every year. Contrary to what has been published in recent weeks, only a very small portion of the government health research and development funds are channeled directly into drug research and clinical studies. Most is used to sponsor investigations into the life sciences.

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

In the absence of government price controls, drug companies will seek to maximize their profits by balancing prices with the need for market penetration

- and that is exactly what the drafters of Bayh-Dole expected. Pricing freedom is one reason often cited by the pharmaceutical industry for concentrating their research and development activities in the U.S. It is why the U.S. remains the world leader in medical research, and why so many drugs are made available here first.

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

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

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

A sober reading of the Bayh-Dole Act will leave no doubt that retail drug pricing has nothing to do with the march-in provisions of the Act. Mr. Love's petition must therefore be denied.

Thank you again for the opportunity to be here today.

--
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Subject: Spam Alert: [techno-l] Pres. Reagan
From: "Norman Latker" <NJL@browdyneimark.com>
Date: Wed, 09 Jun 2004 17:25:43 -0400
To: <Techno-l@lists.uventures.com>

Dear Colleagues:

I would like to say a few words on behalf of President Reagan.

From the beginning, the Reagan White House embraced the Bayh-Dole Act as their own. It fit exactly into the Reagan agenda of deregulation and decentralization of decision-making as an incentive for invention and innovation. President Reagan frequently reminded us that the Soviet Union would ultimately fail because it suppressed exactly these kinds of incentives.

The White House was actively involved in enhancing the Act's incentives and their implementation as part of the President's effort to relight America's entrepreneurial spirit. OMB Circular A-124 implementing the Act was issued in 1982; his 1983 memorandum expanded the Act to additional contractors; the Administration's 1984 amendments to the Act and their 1987 implementing regulations expanded the Act's incentives to encourage greater involvement in invention and technology transfer, and their 1986 Federal technology Transfer Act expanded the prerogatives provided to non-profit organizations under Bayh-Dole to the Federal Laboratories. His 1987 Executive Order restated and emphasized all of his earlier actions.

In addition, the Administration supported creation of the small business set-aside program (SBIR) and the two-tier Patent Office fee schedule to assist small business, non-profit organizations and independent inventors.

These completed the Bayh-Dole body of laws, regulations and executive actions that are now your legacy.

There may always be contention on whether President Reagan was primarily responsible for ending the cold war and/or inflation. Decades from now there should be no debate on the amazing contribution the Reagan White House made to the rebirth of innovation in this country.

Thank you, Mr. President.

More Speeches

Early Speeches (1964 - 1980)
First Presidential Term (1981 - 1984)
Second Presidential Term (1985 - 1988)
Post-presidential Speeches (1992 - 1994)

Address to the British House of Commons

London
June 8, 1982

Considered by some to be the original "evil empire" speech, Reagan takes on totalitarianism and the Soviet Union. In it he says " military strength is the prerequisite to peace," a theme he would repeat throughout his presidency.

We're approaching the end of a bloody century plagued by a terrible political invention -- totalitarianism. Optimism comes less easily today, not because democracy is less vigorous, but because democracy's enemies have refined their instruments of repression. Yet optimism is in order because day by day democracy is proving itself to be a not at all fragile flower. From Stettin on the Baltic to Varna on the Black Sea, the regimes planted by totalitarianism have had more than thirty years to establish their legitimacy. But none -- not one regime -- has yet been able to risk-free elections. Regimes planted by bayonets do not take root.

The strength of the Solidarity movement in Poland demonstrates the truth told in an underground joke in the Soviet Union. It is that the Soviet Union would remain a one-party nation even if an opposition party were permitted because everyone would join the opposition party....

Historians looking back at our time will note the consistent restraint and peaceful intentions of the West. They will note that it was the democracies who refused to use the threat of their nuclear monopoly in the forties and early fifties for territorial or imperial gain. Had that nuclear monopoly been in the hands of the Communist world, the map of Europe--indeed, the world--would look very different today. And certainly they will note it was not the democracies that invaded Afghanistan or suppressed Polish Solidarity or used chemical and toxin warfare in Afghanistan and Southeast Asia.

If history teaches anything, it teaches self-delusion in the face of unpleasant facts is folly. We see around us today the marks of our terrible dilemma--predictions of doomsday, anti-nuclear demonstrations, an arms race in which the West must, for its own protection, be an unwilling participant. At the same time we see totalitarian forces in the world who seek subversion and conflict around the globe to further their barbarous assault on the human spirit. What, then, is our course? Must civilization perish in a hail of fiery atoms? Must freedom wither in a quiet, deadening accommodation with totalitarian evil?

Sir Winston Churchill refused to accept the inevitability of war or even that it was imminent. He said, "I do not believe that Soviet Russia desires war. What they desire is the fruits of war and the indefinite expansion of their power and doctrines. But what we have to consider here today while time remains is the permanent prevention of war and the establishment of conditions of freedom and democracy as rapidly as possible in all countries."

Well, this is precisely our mission today: to preserve freedom as well as peace. It may not be easy to see; but I believe we live now at a turning point.

In an ironic sense Karl Marx was right. We are witnessing today a great revolutionary crisis, a crisis where the demands of the economic order are conflicting directly with those of the political order. But the crisis is happening not in the free, non Marxist West but in the home of Marxism-Leninism, the Soviet Union. It is the Soviet Union that runs against the tide of history by denying human freedom and human dignity to its citizens. It also is in deep economic difficulty. The rate of growth in the national product has been steadily declining since the fifties and is less than half of what it was then.

The dimensions of this failure are astounding: a country which employs one-fifth of its population in agriculture is unable to feed its own people. Were it not for the private sector, the tiny private sector tolerated in Soviet agriculture, the country might be on the brink of famine. These private plots occupy a bare 3 percent of the arable land but account for nearly one-quarter of Soviet farm output and nearly one-third of meat products and vegetables. Over-centralized, with little or no incentives, year after year the Soviet system pours its best resources into the making of instruments of destruction. The constant shrinkage of economic growth combined with the growth of military production is putting a heavy strain on the Soviet people. What we see here is a political structure that no longer corresponds to its economic base, a society where productive forced are hampered by political ones.

The decay of the Soviet experiment should come as no surprise to us. Wherever the comparisons have been

made between free and closed societies -- West Germany and East Germany, Austria and Czechoslovakia, Malaysia and Vietnam -- it is the democratic countries that are prosperous and responsive to the needs of their people. And one of the simple but overwhelming facts of our time is this: of all the millions of refugees we've seen in the modern world, their flight is always away from, not toward the Communist world. Today on the NATO line, our military forces face east to prevent a possible invasion. On the other side of the line, the Soviet forces also face east to prevent their people from leaving.

The hard evidence of totalitarian rule has caused in mankind an uprising of the intellect and will. Whether it is the growth of the new schools of economics in America or England or the appearance of the so-called new philosophers in France, there is one unifying thread running through the intellectual work of these groups -- rejection of the arbitrary power of the state, the refusal to subordinate the rights of the individual to the superstate, the realization that collectivism stifles all the best human impulses....

Chairman Brezhnev repeatedly has stressed that the competition of ideas and systems must continue and that this is entirely consistent with relaxation of tensions and peace.

Well, we ask only that these systems begin by living up to their own constitutions, abiding by their own laws, and complying with the international obligations they have undertaken. We ask only for a process, a direction, a basic code of decency, not for an instant transformation.

We cannot ignore the fact that even without our encouragement there has been and will continue to be repeated explosion against repression and dictatorships. The Soviet Union itself is not immune to this reality. Any system is inherently unstable that has no peaceful means to legitimize its leaders. In such cases, the very repressiveness of the state ultimately drives people to resist it, if necessary, by force.

While we must be cautious about forcing the pace of change, we must not hesitate to declare our ultimate objectives and to take concrete actions to move toward them. We must be staunch in our conviction that freedom is not the sole prerogative of a lucky few but the inalienable and universal right of all human beings. So states the United Nations Universal Declaration of Human Rights, which, among other things, guarantees free elections.

The objective I propose is quite simple to state: to foster the infrastructure of democracy, the system of a free press, unions, political parties, universities, which allows a people to choose their own way to develop their own culture, to reconcile their own differences through peaceful means.

This is not cultural imperialism; it is providing the means for genuine self-determination and protection for diversity. Democracy already flourishes in countries with very different cultures and historical experiences. It would be cultural condescension, or worse, to say that any people prefer dictatorship to democracy. Who would voluntarily choose not to have the right to vote, decide to purchase government propaganda handouts instead of independent newspapers, prefer government to worker-controlled unions, opt for land to be owned by the state instead of those who till it, want government repression of religious liberty, a single political party instead of a free choice, a rigid cultural orthodoxy instead of democratic tolerance and diversity.

Since 1917 the Soviet Union has given covert political training and assistance to Marxist-Leninists in many countries. Of course, it also has promoted the use of violence and subversion by these same forces. Over the past several decades, West European and other social democrats, Christian democrats, and leaders have offered open assistance to fraternal, political, and social institutions to bring about peaceful and democratic progress. Appropriately, for a vigorous new democracy, the Federal Republic of Germany's political foundations have become a major force in this effort.

We in America now intend to take additional steps, as many of our allies have already done, toward realizing this same goal. The chairmen and other leaders of the national Republican and Democratic party organizations are initiating a study with the bipartisan American Political Foundation to determine how the United States can best contribute as a nation to the global campaign for democracy now gathering force. They will have the cooperation of congressional leaders of both parties, along with representatives of business, labor, and other major institutions in our society. I look forward to receiving their recommendations and to working with these institutions and the Congress in the common task of strengthening democracy throughout the world.

It is time that we committed ourselves as a nation -- in both the public and private sectors -- to assisting democratic development....

What I am describing now is a plan and a hope for the long term -- the march of freedom and democracy which will leave Marxism-Leninism on the ash heap of history as it has left other tyrannies which stifle the freedom and muzzle the self-expression of the people. And that's why we must continue our efforts to strengthen NATO even as we move forward with our zero-option initiative in the negotiations on intermediate-range forces and our proposal for a one-third reduction in strategic ballistic missile warheads.

Our military strength is a prerequisite to peace, but let it be clear we maintain this strength in the hope it will never be used, for the ultimate determinant in the struggle that's now going on in the world will not be bomb sand rockets but a test of wills and ideas, a trial of spiritual resolve, the values we hold, the beliefs we cherish, the ideals to which we are dedicated.

The British people know that, given strong leadership, time, and a little bit of hope, the forces of good ultimately

rally and triumph over evil. Here among you is the cradle of self-government, the Mother of Parliaments. Here is the enduring greatness of the British contribution to mankind, the great civilized ideas: individual liberty, representative government, and the rule of law under God.

I've often wondered about the shyness of some of us in the West about standing for these ideals that have done so much to ease the plight of man and the hardships of our imperfect world. This reluctance to use those vast resources at our command reminds me of the elderly lady whose home was bombed in the blitz. As the rescuers moved about, they found a bottle of brandy she'd stored behind the staircase, which was all that was left standing. And since she was barely conscious, one of the workers pulled the cork to give her a taste of it. She came around immediately and said, "Here now -- there now, put it back. That's for emergencies."

Well, the emergency is upon us. Let us be shy no longer. Let us go to our strength. Let us offer hope. Let us tell the world that a new age is not only possible but probable.

During the dark days of the Second World War, when this island was incandescent with courage, Winston Churchill exclaimed about Britain's adversaries, "What kind of people do they think we are?" Well, Britain's adversaries found out what extraordinary people the British are. But all the democracies paid a terrible price for allowing the dictators to underestimate us. We dare not make that mistake again. So, let us ask ourselves, "What kind of people do we think we are?" And let us answer, "Free people, worthy of freedom and determined not only to remain so but to help others gain their freedom as well."

Sir Winston led his people to great victory in war and then lost an election just as the fruits of victory were about to be enjoyed. But he left office honorably and, as it turned out, temporarily, knowing that the liberty of his people was more important than the fate of any single leader. History recalls his greatness in ways no dictator will ever know. And he left us a message of hope for the future, as timely now as when he first uttered it, as opposition leader in the Commons nearly twenty-seven years ago, when he said, "When we look back on all the perils through which we have passed and at the mighty foes that we have laid low and all the dark and deadly designs that we have frustrated, why should we fear for our future? We have," he said, "come safely through the worst."

Well, the task I've set forth will long outlive our own generation. But together, we too have come through the worst. Let us now begin a major effort to secure the best -- a crusade for freedom that will engage the faith and fortitude of the next generation. For the sake of peace and justice, let us move toward a world in which all people are at last free to determine their own destiny.

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Subject: Spam Alert: [techno-l] Pres. Reagan
From: "Norman Latker" <NJL@browdyneimark.com>
Date: Wed, 09 Jun 2004 17:25:43 -0400
To: <Techno-l@lists.uventures.com>

Dear Colleagues:

I would like to say a few words on behalf of President Reagan.

From the beginning, the Reagan White House embraced the Bayh-Dole Act as their own. It fit exactly into the Reagan agenda of deregulation and decentralization of decision-making as an incentive for invention and innovation. President Reagan frequently reminded us that the Soviet Union would ultimately fail because it suppressed exactly these kinds of incentives.

The White House was actively involved in enhancing the Act's incentives and their implementation as part of the President's effort to relight America's entrepreneurial spirit. OMB Circular A-124 implementing the Act was issued in 1982; his 1983 memorandum expanded the Act to additional contractors; the Administration's 1984 amendments to the Act and their 1987 implementing regulations expanded the Act's incentives to encourage greater involvement in invention and technology transfer, and their 1986 Federal technology Transfer Act expanded the prerogatives provided to non-profit organizations under Bayh-Dole to the Federal Laboratories. His 1987 Executive Order restated and emphasized all of his earlier actions.

In addition, the Administration supported creation of the small business set-aside program (SBIR) and the two-tier Patent Office fee schedule to assist small business, non-profit organizations and independent inventors.

These completed the Bayh-Dole body of laws, regulations and executive actions that are now your legacy.

There may always be contention on whether President Reagan was primarily responsible for ending the cold war and/or inflation. Decades from now there should be no debate on the amazing contribution the Reagan White House made to the rebirth of innovation in this country.

Thank you, Mr. President.

Hello. I'm Norman Latker, and I'm here to address the petition sponsored by Mr James Love of Essential Inventions, which asks NIH to obviate the exclusive title held by Abbot Laboratories for the AIDS drug Retonavir.

I'd like to thank the organizers of this meeting for the opportunity to address this issue today.

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

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

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

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

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

Of course, the law it isn't perfect. No law is. There have been many 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 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 reasoned its decision to raise the price of Retonavir. I don't know whether it was based on legitimate business issues, or as AIDS activists allege, on unmitigated 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 Retonavir will now not have access to it. I don't know whether Abbot'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 Retonavir . Attorneys General in Illinois and New York are also looking into the matter. Again, I do not know precisely what criteria these organs of government might use to determine whether corrective action is warranted.

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

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

It is decidedly ill suited for any other purpose.

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

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

There were a few conditions placed on this freedom—conditions which are now the subject of dispute. In layman's terms, the rights were transferred 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 inventions should be developed 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, Abbot Laboratories has been enormously successful in bringing the benefits of Retonavir 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, Abbot has complied with the law.

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

They assert that Bayh-Dole invests NIH with the authority to determine whether the price of Retonavir is too high and, if so, to terminate the exclusivity of Abbot's property rights.

They point out that one March-in clause, section 203a, specifies that the invention in question must be made available on "reasonable terms", which they 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 individuals or organisations that originally used government research funds to make fundamental discoveries
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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 licencsees are consciously excluded from 203a is obvious, because the next two sections —203b and 203c—explicitly apply to all three entities: contractors, assignees and licensees. The last section—203e—*only* applies to 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." The phrase refers to the terms of the contract 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 with section 203a. 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 ownership rights over the invention.

After explaining all that, I must now point out that Retonavir has *never* been licensed, and that Abbot Laboratories is *not* a licensee. It is, in fact, a contractor who possesses direct title to the invention.

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

Abbot Laboratories, by contrast, had no need to license its invention. It had the resources to bring the invention to market without any assistance.

This exposes an ambiguity in Bayh-Dole, and renders section 203a meaningless. Obviously, "reasonable terms" in this particular case cannot mean "reasonable royalties." But neither can it mean "reasonable pricing", as that was not conceived of or elaborated anywhere in the legislation.

In other words, we cannot spontaneously reinterpret 203a to mean that when contractor brings a drug to market itself, it must price the drug "reasonably." The intent of 203a is obvious enough, even if it fails to address the case at hand.

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Dad: from here the conclusion isn't crafted. I'll make use of the two paragraphs below. I will also try to reinsert your passage about how most government research money isn't spent on drug development, as EI asserts.

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terms," as Senators Bayh and Dole wrote in reply to your article in the **Washington Post** several years ago, it was not their intent that this phrase would include the ability of the Government to oversee prices of resulting products.

While drug pricing is a serious issue, attempting to read into the law an intent missing in the words of the statute and the accompanying legislative history, would be a mistake.

"Michael H. Davis" <michael.davis@law.csuohio.edu>

04/19/2004 01:11 PM

To jallen@nttc.edu

cc

Subject [Fwd: [ip-health] Nat'l Tech Transfer Ctr on March-in]

Dear Mr. Allen:

I found your statement puzzlilng. Can you tell me whether or not the Bayh-Dole Act does mandate that Bayh-Dole inventions must be offered to the public "on reasonable terms?"

M. Davis

-------- Original Message --------

Subject: [Ip-health] Nat'l Tech Transfer Ctr on March-in
Date: Mon, 19 Apr 2004 12:27:39 -0400
From: Sean Flynn <sean.flynn@cptech.org>
Organization: http://www.cptech.org
To: ip-health@lists.essential.org

March 31, 2004

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

Dear Dr. Rohrbaugh:

Subject: RE: Latest round on Bayh-Dole
From: "Adler, Reid" <Reid.Adler@venterscience.org>
Date: Tue, 20 Apr 2004 16:02:15 -0400
To: <jallen@nttc.edu>, <armbrecht@iriinc.org>, <alfred.berkeley@cos.com>, <Louis_Berneman@nttc.edu>, <hwbremer@warf.org>, <RLD1@msn.com>, <kofaley@venable.com>, <henry.fradkin@comcast.net>, <Larry_Gilbert@nttc.edu>, <randolph.j.guschl@usa.dupont.com>, <P_Harsche@fccc.edu>, <whendee@mcw.edu>, <jhill@mcw.edu>, <latkerc@bellatlantic.net>, <chris.mckinney@vanderbilt.edu>, <jmuir@ufl.edu>, <lita@mit.edu>, <laura.nixon@morganstanley.com>, <kphillips@cogr.edu>, <loripressman@mediaone.net>, <preston@mit.edu>, <Jay_Rappaport@nttc.edu>, <robinlr@umich.edu>, <niels@leland.stanford.edu>, <BAReres@venable.com>, <rriddell@promaxrealtors.com>, <jas@purdue.edu>, <Larry_Udell@nttc.edu>, <John_Weete@nttc.edu>, <Deborah_Wince-Smith@nttc.edu>, <rich.wolf@caltech.edu>, <smsheehan@mail.wvu.edu>

As another historical footnote, I had the same discussion with Prof. Davis back in 1989-1990 when NIH was developing its technology transfer policies to implement the FTTA. At that time, Joe Allen, Deborah Wince-Smith and Lita Nelson were also in that loop. Health and energy permitting, we should probably look forward to having the same discussion in 2020!

Reid A.

From: jallen@nttc.edu [mailto:jallen@nttc.edu]
Sent: Tuesday, April 20, 2004 12:20 PM
To: Adler, Reid; armbrecht@iriinc.org; alfred.berkeley@cos.com; Louis_Berneman@nttc.edu; hwbremer@warf.org; RLD1@msn.com; kofaley@venable.com; henry.fradkin@comcast.net; Larry_Gilbert@nttc.edu; randolph.j.guschl@usa.dupont.com; P_Harsche@fccc.edu; whendee@mcw.edu; jhill@mcw.edu; latkerc@bellatlantic.net; chris.mckinney@vanderbilt.edu; jmuir@ufl.edu; lita@mit.edu; laura.nixon@morganstanley.com; kphillips@cogr.edu; loripressman@mediaone.net; preston@mit.edu; Jay_Rappaport@nttc.edu; robinlr@umich.edu; niels@leland.stanford.edu; BAReres@venable.com; rriddell@promaxrealtors.com; jas@purdue.edu; Larry_Udell@nttc.edu; John_Weete@nttc.edu; Deborah_Wince-Smith@nttc.edu; rich.wolf@caltech.edu; smsheehan@mail.wvu.edu
Subject: Latest round on Bayh-Dole

Thought you might be interested in my recent e-mail exchange with Prof. Davis, co-author with Prof. Arno of a **Washington Post** op-ed piece in 2001 "Paying Twice for the Same Drug," alleging that NIH is remiss in enforcing Bayh-Dole with regard to march-in rights on resulting drug prices. This is the philosophical underpinning of the recent petition to NIH. I quoted Senators Bayh and Dole's subsequent rebuttal that Davis and Arno misinterpreted the law in my recent letter to NIH .

----- Forwarded by Joe Allen/NTTC on 04/20/2004 11:57 AM -----

Joe Allen/NTTC

04/20/2004 11:54 AM

To "Michael H. Davis" <michael.davis@law.csuohio.edu>

cc

Subject Re: [Fwd: [Ip-health] Nat'l Tech Transfer Ctr on March-in] Link

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

While the subject of delivering affordable health care is certainly a serious issue, the provisions of the Bayh-Dole Act do not provide for governmental actions such as those requested by Essential Inventions. Indeed, such actions were never contemplated by the Congress and are not reflected in the legislative history of the law.

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

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

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

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

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

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

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

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

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

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

The article also mischaracterized the rights retained by government under Bayh-Dole. The ability of the government to revoke a license granted under the act is not contingent on the pricing of a resulting product or tied to the profitability of a company that has commercialized a product that results in part from government-funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product. (Emphasis added).

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

Birch Bayh/Bob Dole

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

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

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

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

Sincerely,

Joseph P. Allen

Thanks for your e-mail. When the Bayh-Dole Act states 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," as Senators Bayh and Dole wrote in reply to your article in the **Washington Post** several years ago, it was not their intent that this phrase would include the ability of the Government to oversee prices of resulting products.

While drug pricing is a serious issue, attempting to read into the law an intent missing in the words of the statute and the accompanying legislative history, would be a mistake.

"Michael H. Davis" <michael.davis@law.csuohio.edu>

04/19/2004 01:11 PM

To jallen@nttc.edu

cc

Subject [Fwd: [Ip-health] Nat'l Tech Transfer Ctr on March-in]

Dear Mr. Allen:

I found your statement puzzlilng. Can you tell me whether or not the Bayh-Dole Act does mandate that Bayh-Dole inventions must be offered to the public "on reasonable terms?"

M. Davis

-------- Original Message --------

Subject: [Ip-health] Nat'l Tech Transfer Ctr on March-in
Date: Mon, 19 Apr 2004 12:27:39 -0400
From: Sean Flynn <sean.flynn@cptech.org>
Organization: http://www.cptech.org
To: ip-health@lists.essential.org

March 31, 2004

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

Dear Dr. Rohrbaugh: