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See pgs 5-7

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I would like to comment on recent petitions filed by Mr. James Love and Mr. Sean Flynn of Essential Inventions, Inc, requesting the National Institutes of Health to invoke the march-in provisions of the Bayh-Dole Act to invalidate exclusive drug patents held by Abbott Laboratories and Pfizer Corporation.

While the authors of the petition might be commended for embarking on such an innovative approach to controlling drug prices, it must be clearly understood that Bayh-Dole was enacted to define critically important aspects of intellectual property law, and is decidedly ill suited for any other purpose. Any attempt to use it as a weapon in the political debate over drug prices will meet certain failure, as the enabling language required for such use is wholly — and intentionally — absent from the legislation.

In the unlikely event that NIH were to grant the request of the petition's authors, the decision would have virtually no chance of surviving judicial review.

Nonetheless, I feel compelled to speak out in defense of Bayh-Dole, which has allowed for the development a potent four-way partnership between researchers, their institutions, government and industry. This partnership has become 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's succeed in subverting one of the key precepts of Bayh-Dole — that of according broad marketplace prerogatives to the developers of government-funded inventions — this marvelous engine of innovation could stall.

The spirit of Bayh-Dole

I believe 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 frequently refer.

The authors have woefully misrepresented the spirit and purpose of the legislation, which was intended to enlist the marketplace to develop and distribute government-supported innovations. Judging from the petition, they appear to have been informed primarily by a

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recent article in the Tulane Law Review, penned by Peter S. Arno & Michael H. Davis, which unfortunately paints a highly distorted picture both of the Act itself and the legislative process leading to its passage.

Before the enactment of Bayh-Dole, an enormous amount of government-sponsored research and innovation went to waste, as there were no clear mechanisms in existence to transfer the resultant inventions to the marketplace.

Although there was spirited opposition to the bill at the time, a powerful bipartisan consensus was built around the basic notion that market forces would do a far better of disseminating such inventions to society than bureaucracies ever could.

Put simply, the drafters of the act wanted to ensure that adequate incentives were in place to facilitate innovation and to attract corporate investment into their development and distribution. We understood that that inventions resulting from government research are conceptual in nature, and require significant investment by the private sector to bring them into practical application. This is especially the case with regard to life science inventions, the subject of the march-in requests.

Our answer to the problem was that intellectual property rights should be accorded in full to the innovators, rather than to the government bureaucracies 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. The only conditions to be attached to this freedom were envisioned as follows:

A) Reasonable efforts were required to develop the inventions to practical application;

B) The inventions should be readily available to society;

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

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

E) The inventions should be manufactured within the United States.

These conditions were translated into the legal language found in section 203a of the Act, which is reproduced in the subject petitions. The march-in clauses 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. This is clearly

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not the case with either Retonavir or Latanoprost, both of which have been successfully developed and are readily available to the public at large.

Bayh-Dole cannot be used 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.

Nonetheless, the petition's authors hold that the government should issue multiple licenses for the drugs because the companies are charging too much for them, 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.

They also assert that because the Act defines practical application" as including whether the invention is made available to the public on "reasonable terms", a phrase which they apparently interpret to mean a low price, and that the funding agency is therefore authorized to assess what a "reasonable" market price might be.

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 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.

In fact the opposite is true: if the rights-holder were not given the freedom to set prices, it would not be willing to commit the resources required to ensure an invention's dissemination

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through 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 sales price could be challenged by the government after marketing..

Again, if the drafters had intended the government to arbitrate prices, we would have inserted criteria into the law to enable the funding agency to do so. No such criteria are found, precisely because controlling patent rights on the basis of price was antithetical to what the drafters had in mind.

Of course it could be argued that extremely high prices might prevent an invention from achieving widespread application, and the petition authors attempt to show that this is the case with Retonavir or Latanoprost.

However, while the authors might show that the drugs are expensive, they fail utterly to substantiate the notion that high prices have curtailed their availability, or their continued improvement by the developer. For example, the authors fail to show that the 600-800 people nationwide who do not have access to Retanovir would necessarily be granted access if the price of the drug were reduced. They also fail to mention the many thousands of people who do have access to the drug, and that many of these individuals receive it for free.

That is not to say that the needs of the minority who do not have access should be ignored. But it must be plainly understood that medical access problems in the United States stem from the way healthcare entitlements are ascribed and healthcare resources are distributed.

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.

Price comparison with other countries are of dubious value
Another specious argument offered by the authors is that since the companies offer the same drug at lower prices in other countries, this somehow violates the notion of reasonable terms. Not only do they fail to substantiate this assertion logically, they also fail to point out that the average prices paid for drugs overseas are often reduced by means of government subsidies and/or price controls — neither of which could be effected through intellectual property law.

The authors also imply that since the drug was developed in the United States, it is unfair that

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Europeans are getting it cheaper:

"Prices in the U.S. are generally 2-5 times the price in most European countries, despite American taxpayers funding its early development."

Even if one accepts the prices the authors provide for Latanoprost in various countries at face value — although one must wonder about the methodology used, and how representative the data really are — they provide no insight into how or why drug prices come to be lower in other countries.

Note that prices are lower not only in low income countries like Nicauragua, where weak spending power would compel lower prices — but also in countries like Germany and Sweden, where per capita spending power is roughly equivalent to that in the US. The obvious reason is that the vast majority of drug purchases in such countries are financed by governments, which use their monopoly power to keep the price of medications low.

There are also experiments in the US — notably in the State of Maine — in which state and local governments are seeking to leverage their own market power to force down drug prices. Presumably, they have the constitutional authority and popular support to do so.

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 Bahy-Dole expected. Pricing freedom is one reason often cited by the pharmaceutical industry for concentrating their research and development activities in the US. It is why the US remains the world leader in medical research, and why so many drugs are made available here first.

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.

Accordingly, I feel strongly that the petitioners' request for a March-in action, which is motivated entirely by a desire to control drug prices, must be denied.

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Conclusion

It is important to reiterate that if the authors of Bayh-Dole had intended to grant funding agencies the authority to challenge the pricing of an invention, such an extraordinary measure would have resulted in explicit discussion, especially with regard to any

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requirement to provide proprietary pricing data.

Going back to the article in the (date, etc) *Tulane Law Review*, from which the petitions' authors derive the legal justification for their March-in requests, one finds that the "legislative history" presented is in fact a compilation of quotes from oversight or legislative hearings either preceding, concurrent with or after the introduction of S.414 directed to legislative hearings on issues outside of Bayh-Dole. As such, these quotes are made in the context of legislative language and issues different from that of the Act and cannot be considered to be relevant to the Act.

The comments and quotes made outside the legislative history of S.414 are found in footnotes 146-151, 153, 154, 157-169, 175-179, 181-195, 197-199 and 202-227 of the total number of 81 footnotes (146 to 227) on pages 656-667. Indeed, only 11 footnotes, 152, 155, 156, 170-174, 180, 196, and 200-201 of the total 81 are directed to comments or quotes from the 1979 hearing or Senate Report 96-480 on S:414. Not one of these explicitly or by implication addresses the issue of pricing. Indeed, footnote 180 references a discussion in Senate Report 96-48 limited to the "pay-back" provision of the S:414 which was deleted before passage of the Act. The author's comment on this maintains that this discussion somehow supports their thesis of pricing.
The preponderance of the comments and quotes identified to be outside of what is commonly known as a legislative history, are chosen from well-known opponents of the Act, i.e. Adm. H. G. Rickover, Sen. Russel Long, Hon. Jack Brooks, Ralph Nader, etc. etc. Adm. Rickover's positions are found in 7 of the 81 footnotes. If indeed these positions represented an accurate legislative history of the Act, one needs to wonder how the Act could have been promulgated in the face of such critical comments. Of course, the answer is quite simply that the authors have assiduously and systematically excluded from their history the most salient positions in support of the Act.

Instead, as noted from 35 U.S.C. 200, the general description of the authorities reserved to the government are limited "...to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against non-use or unreasonable use of the

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invention..." (underlining added). This general reservation of rights in the Government is specifically implemented in the march-in provision of 35 U.S.C. §203, which we submit cannot be read to be any broader than intended in the general reservation of 35 U.S.C. §200, which would be necessary to grant the requested march-in request.

In addition to the fact that there is no expressed authority in the Act permitting the government to challenge a developer's pricing determination or require delivery of proprietary data establishing such pricing, practice over twenty years clearly supports the fact that these authorities were not provided by the Act.