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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.

The Spirit Of Bayh-Dole

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 mentioned as a precursor to the Act.

The petition relies on a recent article in the Tulane Law Review as the primary authority to justify its march-in request. The article 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 unproven inventions resulting to the marketplace.

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

Put simply, the drafters of the act wanted to ensure that adequate incentives were in place to facilitate invention and to attract private investment into their development and

distribution. We understood that that inventions resulting from government research are mostly unproven and conceptual in nature, requiring significant investment by the private sector to bring them into practical application. The private investment necessary normally exceeds by many multiples the funding of the grants that produced these inventions. This is especially the case with regard to life science inventions, the subject of the march-in requests.

The Petition

The petition estimates that a "modest" $15 million had been invested in the clinical data trials of Ritonovir. But no data is provided regarding the NIH funding which resulted in the invention. I presume that the $15 million investment, if correct, far exceeds that of NIH as that is normally the case when industry pursues development of a composition of matter not known to be either useful or safe.

Imp.

The comparison between the private sector investment vis-à-vis that of the government in specific situations is also not addressed in the Tulane article. On pages 636, the authors reject the Bayh-Dole premise that the life science inventions involved are unproven and only conceptual in nature. Thereafter, they note that the sum of both the federal and state investment in health related R&D exceeds that of the private sector. This is the underpinning throughout the article for a "public equity" beyond that addressed by the Act in unproven inventions that requires reinterpretation of the Act.

On page 634, the authors declare that,

> "One fundamental thematic question that runs throughout this Article is, do American taxpayers, who fund a substantial portion of health-related research and development (R&D) receive a fair return on their investment."

On page 659, the authors apply their "public equity" concept to Bayh-Dole:

> "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."

In comparison, the Bayh-Dole Act addressed the public interest or "equity" by creating the necessary incentives now successfully delivering the unproven inventions made with federal funds to the public in the form of drugs having an established utility and safety record. The total public investment in health R&D has no particular relevancy in determining the appropriate rights of the partners in the equilibrium, as it does not address the industry investment necessary to prove utility and safety.

The Bayh-Dole legislative history establishes that virtually all of the federal investment in health related R&D is directed to thousands of basic research projects to explore the frontiers of the life sciences. A minimal portion of this funding may result in which evidences an unproven medicinal utility. Normally it is only the private sector that is able to prove utility and safety before a drug can be marketed. It was the industry equities in this situation that were addressed by Bayh-Dole and not that of a general comparison between all public and private funding of health R&D.

Our answer to the problem of encouraging industry to prove the utility and safety of the government inventions involved so as to establish their utility and safety was to accord intellectual property rights in full to the innovators, rather than to the government agency that financed their discovery. This permitted the innovators the freedom to leverage their property rights to their advantage in the marketplace as intended by the patent system. Some of 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.

Control Of Drug Prices

What is most disturbing about the subject petition is the attempt to transform this 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 which the Tulane article recognizes on page 648.

Nonetheless, 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.

This authority rests on satisfying the "public equity" as defined in the Tulane article, and the Act's definition of "practical application" which includes a requirement that the invention be made available to the public on "reasonable terms". Even though page 19 of the Tulane article indicates that there is no clear legislative history on what "available to the public on reasonable terms" means, the petitioner argues 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.

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 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 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.

I believe that I have refuted the Tulane article's conclusion that the legislative history of the Act supports its "reasonable price" theory. However, one should take into consideration how the public statements referenced on pages 656-667 as the purported legislative history of Bayh-Dole are used to support the author's conclusions.

My September 27, 1976 statement on government patent policy a House Committee referenced in footnote 157 is used as the source of 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.

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

The comments and quotes made outside the legislative history of the Bayh-Dole Act are referenced in 70 footnotes of the total number of the 82 on pages 656-667. Indeed, 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. Indeed, footnotes 174 and 180 discussed by Senator Bayh references a discussion in the Senate Report limited to the pay-back provision which does not support the article's pricing theory.

20 of the 70 footnotes outside reflect quotes by well-known opponents of contractor ownership of inventions touched by government funding including Admiral H. G. Rickovea, General Russell Long, Congressman Jack Brooks, Ralph Nader and others.

There is nothing in these quotes beyond their objection to contractor ownership that suggests that they would accept a contractor ownership policy if it was conditioned by a reservation in the government to determine a reasonable price after marketing of the government funded invention.

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 action, motivated entirely by a desire to control drug prices and based on a misinterpretation of the law must be denied.