

view from the top joseph allen

When it comes to inventions, just don't mess with success

A PETITION THAT SOUGHT to use the authorities of the Bayh-Dole Act to force Abbott Laboratories to lower the price of Norvir, an important part of the AIDS "cocktail" used by many patients, was rejected on August 4 by the National Institutes of Health. Since Abbott had discovered Norvir at least in part with NIH funds, was the agency correct to reject the petition? The answer is yes.

The research alliances between US universities, federal laboratories and private industry are essential to our economic growth. However, it must be realized that commercializing federally funded inventions is a high-risk endeavor. It is clear that allowing the government to come in years later and second-guess product pricing would destroy the system.

Although it is little known by the general population, the Bayh-Dole Act of 1980 has been an essential part of the American economic renaissance. As *The Economist Technology Quarterly* said on September 14, 2002: "Possibly the most inspired piece of legislation to be enacted in America over the past half century was the Bayh-Dole Act of 1980....More than anything, this single policy measure helped reverse America's precipitous slide into industrial irrelevance."

Before the law's enactment few inventions were commercialized from the billions of dollars invested in federal R&D at our research universities. This is because they were warehoused in Washington and typically offered to private industry non-exclusively. The commercial sector was not interested without strong patent protections that justified significant development risks.

A study in the Johnson Administration was unable to find a single instance where any drug had been developed when the government owned the patent. Bayh-Dole provided incentives for schools and small companies to nurture inventions they make with federal funds. University inventors must receive a share of royalties and the remainder must be invested in research. Preference is given in licensing to small firms and those who will develop the resulting products in the US.

The basis for the petition to NIH, filed by the Washington-based consumer advocacy group Essential Inventions, was a misunderstanding of the rights of the funding agencies. A great fear when Bayh-Dole was debated in Congress was that companies might license university discoveries to stop their development when

the discovery might threaten a company's existing products. Therefore, agencies were given the right to "march-in" if a licensee was not making good faith efforts to move the product toward market.

Because the universities are serving as stewards of the public interest, additional language required them to make their licenses available on "reasonable terms" for subsequent commercial development.

Through a misreading of the law and its legislative history (the hearings, committee report and floor debate leading to enactment) the public interest group developed a theory that somehow the university's requirement to license on "reasonable terms" provides federal agencies with the right to make sure that resulting products are available at reasonable prices.

Despite a joint letter to *The Washington Post* by former senators Bayh and Dole decrying such a misreading of their bill, a petition was filed to NIH asking the agency to "march-in" and regulate the price of Norvir.

If Congress had intended for government to regulate prices of resulting discoveries, surely it would have offered some guidance on how to define a "fair price." Senators Bayh and Dole would have been poor legislators, indeed, if they hid such an intent for almost 25 years. Legislation is not archeology!

If further clarification was required, Bayh spoke at the NIH meeting considering the petition again clearly explaining how the law worked. Ultimately NIH agreed, rejecting the petition. Trying to combine technology transfer legislation with product price controls would again doom federally funded inventions to the dustbin. As NIH reported to Congress, about 75 percent of licensed university patents were little more than a proof of concept. The vast majority of such patents are licensed to small firms.

Thomas Edison said invention is 1 percent inspiration and 99 percent perspiration. In the case of publicly funded R&D, government is typically financing the inspiration and industry the perspiration.

The Economist Technology Quarterly rightly concluded about Bayh-Dole: "A goose that lays such golden eggs needs nurturing, protecting and even cloning, not plucking for the pot."

If Congress had intended for government to set discoveries' prices, it would have offered some guidance on how to define a 'fair price,' says Allen