

## NIH Gets It Right: Bayh-Dole is not for Price Controls November 24, 2013

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The National Institutes of Health recently made its long anticipated ruling on a petition seeking to use the “march in” provisions of the Bayh-Dole Act as a mechanism for the government to control prices on drugs derived from federally-funded research by issuing compulsory licenses.

NIH correctly ruled that such actions are not sanctioned under the law. Three succeeding NIH directors have reached the same conclusion: the march in rights provision was never intended as a price control mechanism.  Hopefully, the third time is the charm.

The petition was a reiteration of one dismissed in 2004 seeking to have the government march in to control the price of Norvir, part of the AIDS “cocktail.”  Norvir was invented by Abbott Laboratories with partial NIH funding, thus it falls under the Bayh-Dole Act which grants ownership of federally funded inventions to universities and industry contractors so they can be developed for public use.

Before Bayh-Dole not a single drug was commercialized when the government took patent rights away from inventing organizations. Under the law at least 153 new drugs and vaccines are now alleviating human suffering world-wide.

The revised petition proposed a formula triggering a government march in against any federally supported drug sold more expensively in the U.S. than abroad. The petitioners charged NIH was failing in its public duty to use the authorities of Bayh-Dole to control drug prices.  They alleged that since no march in petition had ever been granted, what was intended as a public protection was essentially toothless.

In dismissing the petition, [**NIH Director Francis Collins concluded**](http://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir2013.pdf):

The NIH is sensitive to the impact of the pricing of drugs and their availability to patients. As in 2004, when similar pricing and availability issues were raised and discussed at public hearings, the NIH’s role in the present case is limited to compliance with the Bayh-Dole Act, including its march-in criteria, outlined and discussed in detail.

Drug pricing and patient access are broad and challenging issues in the United States.  The NIH continues to agree with the public testimony in 2004 that the extraordinary remedy of march-in is not an appropriate means of controlling drugs broadly available to physicians and patients.

In conclusion, as set forth in this determination, the information and justification provided in the Request, as well as publicly available information, do not support re-consideration of the NIH determination to decline to initiate a march-in proceeding… As stated in previous march-in considerations the general issue of drug pricing is appropriately addressed through legislative and other remedies, not through the use of the NIH’s march-in authorities.

So what was the march-in provision intended to do?

At the time Bayh-Dole was enacted the fear was expressed that dominant companies might license promising university inventions to suppress them so they couldn’t compete with existing products.  The march-in provision was added so if this were to happen agencies could act on public petitions alerting them to the problem, investigate the situation, and, if warranted, compel the university to grant additional licenses “upon terms that are reasonable under the circumstances.”  If the university refuses, the government can itself issue new licenses to bring the product to market.

The procedure can also be used if the licensee cannot produce enough products to meet public health or safety needs, or to satisfy the requirements for public use specified by federal regulations.

Years later through misleading interpretations of the statute and its legislative history critics announced that the “reasonable circumstance” wording in Bayh-Dole actually meant that the government should insure that resulting drugs were made available at “reasonable” prices.

When an op-ed appeared in the Washington Post touting this theory, Senators Bayh and Dole immediately wrote to say it was a complete misinterpretation of their statute. Nevertheless, the advocates began filing a series of petitions to NIH asking it to march in to control drug prices.

Appearing before a 2004 NIH meeting on the first Norvir petition, Senator Bayh pointed out his law was never intended to control prices, but to make sure that federally funded inventions were developed for public use.  He added:

*If Congress does decide to amend Bayh-Dole someone must clearly define what is a “reasonable price.” Congress must keep in mind that the vast majority of technologies developed under the law are commercialized by small companies that “bet the farm” on one or two patents.  Copycat companies are always waiting until an entrepreneur has shown the path ahead.  They can always make things cheaper since they have no significant development cost to recover.*

What will happen to the start-up companies arising from Bayh-Dole that are driving our economy forward with this sword hanging over their heads? What evidence is there that large drug companies will not simply walk away from collaborations with our public sector?

Norman Latker (former NIH patent counsel who wrote the regulations and oversaw implementation of Bayh-Dole) testified that the “reasonable circumstance” language simply means that if universities are forced to issue additional licenses they must be done on terms conducive to development. In other words, “no sulking” by including provisions intended to undermine the compulsory licensee.

Now let’s consider the frequently made charge that the non-use of the march in provision is an indictment of Bayh-Dole.  There are only a handful of cases where march ins were sought.  One was from a company being sued for infringement of a university patent.   Then NIH Director Harold Varmus dismissed the petition stating:

We are wary, however, of forced attempts to influence the marketplace for the benefit of a single company, particularly when such actions may have far-reaching repercussions on many companies’ and investors’ future willingness to invest in federally funded medical technologies. The patent system, with its resultant predictability for investment and commercial development, is the means chosen by Congress for ensuring the development and dissemination of new and useful technologies. It has proven to be an effective means for the development of health care technologies. In exercising its authorities under the Bayh-Dole Act, NIH is mindful of the broader public health implications of a march-in proceeding, including the potential loss of new health care products yet to be developed from federally-funded research.

Three attempts were made to use the march in provision as a means for controlling drug prices. Each was rejected on the same grounds—that was not the intent of the law. Then NIH Director Elias Zerhouni dismissed the first petition saying: “*the extraordinary remedy of march-in rights is not an appropriate means of controlling prices…”*

However, one petition did meet the criteria of Bayh-Dole.  Genzyme obtained an exclusive license to develop Fabrazyme, a treatment for patients suffering serious enzyme deficiencies.  Genzyme  encountered quality control problems in its plant and was forced to halt production.  This caused a serious problem for those depending on the drug, and a march in petition was filed at NIH.

This case fell under the march in trigger of a licensee unable to meet public health requirements.  After considering the situation NIH declined to force the issuance of additional licenses reasoning that it would take new companies longer to obtain FDA approval to get into production than it would take Genzyme to get their factory back on line.  However, NIH reserved the right to revisit the decision until production was restored.  Genzyme got its new facility running and the needs of Fabrazyme’s patients are again being met.

But why have there been so few march in petitions if the inability or unwillingness of university licensees to meet their obligations is really as serious a problem as the critics allege?  The answer is not hard to find.

The march in provision was designed as a fail-safe if universities proved unable to effectively monitor their licensees.  This has not proven to be a problem. Universities include milestones and benchmarks for product development in their agreements.  In cases where the licensee cannot or will not comply, the university terminates the license and seeks another partner.  As royalties are keyed to success in the marketplace, there is a very real incentive for universities to monitor their deals. Thus, there has been no need for the government to march in.

The trust Bayh-Dole placed in those making federal funded inventions as the most effective stewards of the public interest has been amply rewarded.  We are very fortunate that those heading NIH have refused to bow to considerable political pressures and continue to maintain the integrity of the law.

So Dr. Collins, you got it right. Millions of patients are alive and well because of federally funded inventions. Millions more will be saved in the future. They all owe you a heart-felt thank you.