

## Plucking the Golden Goose Won’t Help Patients Dec. 3, 2012

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Several public interest groups recently filed a march in petition under the Bayh-Dole Act asking NIH to force Abbott Laboratories to license its competitors for the production of Ritonavir, a drug used to treat AIDS.  Abbott used federal funding in making the invention.  The complaint is that Ritonavir is more expensive for private users in the US than it’s priced abroad. This is a repetition of a similar action dismissed by NIH in 2004 as regulating prices is not a trigger for march in’s under the law.

Hopefully the Obama Administration agrees with the prior dismissal and again denies this latest effort.

The new petition also lays a trap for other drug developers. It proposes that any drug derived from federal funding also be subjected to march in licensing if it’s sold at a higher price in the US than in seven  ”comparison countries,” or if US prices are higher than median prices abroad.

While making drugs affordable is certainly a laudable goal, this burden is simply not one that can be borne by the Bayh-Dole system. If adopted the proposal could  be the death knell for university/industry drug development partnerships that have done so much to protect public health worldwide.

Companies would be whipsawed for selling drugs in foreign markets with price controls over which they may have little say.  With this added burden, what company would license embryonic academic inventions already requiring billions of private development dollars, and more than a decade of testing and regulatory hurdles, with few drug discoveries ever returning any revenue? How many investors would fund university life science start-up companies?

Drug developers face a daunting task. For every 5,000 drugs tested, about five proceed to clinical trials. Perhaps one is eventually approved.  That one must not only pay for itself, but for all the company’s other drugs that died along the way. This grim math eludes the petitioners.

The proponents seem to believe that the golden goose of US drug development will continue producing as a matter of course. But US leadership in the field is anything but assured.  High-tech start-up companies form and grow where patent rights are strongest, and governments don’t arbitrarily change the rules penalizing success. In an era of globalization and multi-national companies, continued US dominance cannot simply be assumed.

The commercialization system unleashed by the Bayh-Dole Act is a marvel.  Previously 28,000 federally funded inventions were taken from their creators, mostly wasting away on government shelves.

Congress was particularly concerned with the impact of this failure on public health. In its report endorsing Bayh-Dole, the Senate Judiciary Committee said that under the previous patent policies “***not one drug*** *(*emphasis in original) had been developed and marketed from HEW (now HHS) research because of a lack of incentives to the private sector to commit the time and money needed to commercialize these inventions.”

Senators Bayh and Dole held a press conference identifying promising medical technologies not being developed because the intended incentives of the patent system had thus been destroyed. This is not what the US Constitution had in mind when it established intellectual property rights to promote innovation.

Now fast forward thirty years.  An article in The New England Journal of Medicine found 153 FDA approved drugs, vaccines, or new indications for existing drugs currently fighting human suffering around the world as a result of Bayh-Dole.

The march in provision of the law ensures that companies do not license government supported technologies to suppress them.  March in’s also provide that in times of emergency adequate supplies of the product will be made available to meet public needs. That price control is no trigger for forced march in licensing was attested to by Senators Bayh and Dole when this theory first arose.

And we have clear evidence that such approaches simply do not work.

In 1989 Congress pressured NIH to include in its own R&D partnerships with industry language mandating that resulting inventions must demonstrate “a reasonable relationship between the pricing of a licensed product, the public investment in that product, and the health and safety needs of the public.”

However, the result was not the increased availability of new drugs at lower prices.  Instead industry collaborations collapsed. NIH finally rescinded the requirement finding “this policy had the effect of posing a barrier to expanded research relationships and, therefore was contrary to the Bayh-Dole Act.”

Rather than meekly accepting the proposed terms of the new march in petition, companies are likely to just walk away from commercializing federally supported inventions as they did before Bayh-Dole.  The US life science industry would suffer a serious blow, shifting even more research abroad to our competitors now actively courting them. But the real suffering would fall on those desperately seeking new therapies to alleviate their pain.

At the 30 year celebration of Bayh-Dole, cancer survivor Betsy de Parry looked Senator Bayh in the eye and said: “Because of your law, I’m alive today.”  There was not a dry eye in the house, including mine. If the current petitioners are successful, those suffering in the future may not be as lucky as Betsy.