When Government Tried March In Rights To Control Health Care Costs

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How universities, one small company and a courageous civil servant changed history.

As we await the decision from the National Institutes of Health (NIH) on the petition backed by Senator Bernie Sanders (D-VT) and others urging that the march in provision of the Bayh-Dole Act be used to control drug prices, it’s worthwhile to recall the time the agency followed similar advice. That resulted in a smack down by Congress and the courts after a band of universities, an innovative small company and a conscientious federal employee refused to be bullied, altering the course of government.
As discussed previously (see here and here) a small, persistent group insists that march in rights allow the government to control prices of products arising from federally supported inventions. That this view was denounced by Senators Bayh and Dole and rejected in all previous march in petitions does not phase them. Perhaps a review of the 70 year history of march in rights— and the disastrous consequences when the government did what the critics recommend — will help.

Towards the U.S. end of World War II, President Roosevelt asked what to do with the impressive research system the government had created to secure the victory. The report delivered to President Truman after Roosevelt's death advised continued support of fundamental research as an important governmental duty. The Attorney General was asked how resulting inventions should be managed. His advice led to a policy of government ownership of federally-supported patents except in special situations where contractors could petition for exclusivity if they worked toward prompt commercialization. If not, the government could march in issuing “nonexclusive licenses at a reasonable royalty to all applicants.”

Note from the beginning the trigger for marching in was a failure to work towards commercialization and the word “reasonable” applied to royalty rates, not the cost of a product.

A month before his assassination, President Kennedy issued a Memorandum on Government Patent Policy providing greater guidance to the agencies. One of the first provisions states:

Whenever the contractor retains more than a non-exclusive license, the policy would guard against failure to practice the invention by requiring that the contractor take effective steps within three years after the patent issues to bring the invention to the point of practical application or make it available for licensing on reasonable terms. The Government would also have the right to insist on the granting of a license to others to the extent that the invention is required for public use by governmental regulations or to fulfill a health need, irrespective of the purpose of the contract.

The Kennedy Memorandum allowed agencies to march in, granting licenses “on terms that are reasonable in the circumstances” if the invention was not being commercialized or if it was required to meet public needs. There was no authority to regulate prices.
In 1971, President Nixon expanded the Kennedy policy, providing “additional authority to permit contractors to obtain greater rights to inventions when necessary to achieve practical application or where equitable circumstances justify such allocations of rights.” Contractors were required to submit reports on their commercialization efforts. If they faltered, the government could march in, issuing additional licenses on reasonable terms. Product availability, not pricing, remained the trigger.

While the Truman, Kennedy and Nixon policies permitted contractors to petition for exclusivity to inventions made with federal funding, the government culture was not sympathetic to such actions. Case by case reviews were time consuming in a system favoring agency ownership. What this meant to successful commercialization soon became apparent.

In 1968, President Johnson asked how many drugs had been developed from NIH supported research. The Comptroller General summarized his bleak findings to Congress:

At that time we reported that HEW (note: the agency is now Health and Human Services) was taking title for the Government to inventions resulting from research in medicinal chemistry. This was blocking development of these inventions and impeding cooperative efforts between universities and the commercial sector. We found that hundreds of new compounds developed at university laboratories had not been tested and screened by pharmaceutical industry because the manufacturers were unwilling to undertake the expense without some possibility of obtaining exclusive rights to further development of a promising product.

President Johnson was appalled that not a single drug had been developed when patents were taken from universities. On the Comptroller General's recommendation, NIH created the Institutional Patent Agreement (IPA) program allowing universities with approved technology transfer capabilities to own patents made under agency grants. The program incorporated the Kennedy/Nixon march in procedures.

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For the first time the management of federally funded inventions was in the hands of those performing the research, not the government. The impact was dramatic.

Agencies licensed less than 5% of the 28,000 inventions they owned and the number of reported inventions was stagnate. The University of Wisconsin testified that prior to the IPA program not one of its NIH funded inventions had ever been licensed. “When the government took title, nothing was happening. They went into publications and they went into the literature, and that was the end of it” Howard Bremer of the Wisconsin Alumni Research Foundation told Congress.

The IPA program unleashed a torrent of innovation. Patent applications increased 300%. Of the 329 inventions managed by universities in the first five years, 122 were licensed, including 78 exclusively. The interagency Committee on Government Patent Policy advised all departments to adopt the program.

But the culture of government control wasn’t giving up that easily. Payback came from a surprising source; a small company with an innovative approach for CAT scanners. What happened next set off a chain reaction damaging all parties.

In 1975, American Science and Engineering, Inc. (AS&E) owned promising inventions in the emerging field of CAT scanners. The National Cancer Institute was so impressed that it awarded AS&E a contract to reduce its inventions to practice. The company made two inventions with NIH funding, petitioning for exclusive licenses. The review involved NIH, the National Cancer Institute, the Assistant Secretary of Health and the agency patent counsel, Norman Latker, who oversaw the IPA program. They supported the request, but because the Carter Administration would shortly be taking office, delayed implementing the agreement. Soon thereafter, a five year exclusive license to AS&E was approved.

Before the deal was signed a critic in NIH objected, triggering a second review. While not required, a notice was published in the Federal Register inviting comments on the licensing request. Seven of AS&E’s competitors objected, but six didn’t submit practical plans for commercialization. The other objection was from the dominant CAT scan company. The decision was made to approve the exclusive license for AS&E, but with a reduced three year term.

But the new HEW Secretary, Joseph Califano, ordered a review of the decision and the IPA program. That same day the department cancelled AS&E’s exclusive license — marching in because of concerns the new technology might increase the costs of health care.

The General Counsel concurred:
Historically, the objectives of our patent policies have been to make inventions developed with government funding available to the public as rapidly and as cheaply as possible, goals which are sometimes incompatible.

While these objectives are basically sound, recent experiences with the high cost of proliferating health care technology suggests that there may be circumstances in which the Department would wish to restrain or regulate the availability of a new invention. Recognizing this objective requires a broader statement of purpose—to influence the availability and cost of inventions made with HEW support, sometimes encouraging rapid, low cost availability, at other times restraining or regulating availability. (emphasis added)

He added that by granting invention ownership to universities, the IPA program gave them, not the department, control over the desirability and pace of innovation. This was termed “conceptually inconsistent with any HEW objective other than rapid commercialization.”

A month after rescinding AS&E’s license, the Department pulled the plug on the IPA program, forcing universities to petition case by case for patent ownership. Norman Latker, who declined to defend the decision before Congress, was fired. While large contractors might have written off the loss of patent rights as the cost of receiving government funding, AS&E filed suit upon learning that its exclusive license was revoked.

The IPA program came to a screeching halt. Promising university inventions were entangled in a lengthy bureaucratic process. Frustrated that important treatments were being delayed, several universities alerted Senators Bayh and Dole. While far apart politically, both saw the Department’s actions as a waste of taxpayer money given its dismal commercialization record.

Bayh and Dole developed legislation giving the IPA program a statutory charter and made it mandatory for all agencies. To protect companies like AS&E, they extended its protections to small businesses. The bill adopted the long existing use of march in rights “if the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to
achieve practical application of the subject invention” or if pressing health, safety or public use requirements specified by federal regulations were not being met. In such cases the government could march in, requiring licenses “upon terms that are reasonable under the circumstances.”

The legislation was unveiled at a press conference identifying thirty delayed inventions ranging from improvements in cancer detection, a revolutionary blood test, and innovative cancer, hepatitis and arthritis treatments. That created a firestorm. Senators rushed to support the bill. Seeing the damage, Sec. Califano directed that all delayed inventions be released, but the genie was out of the bottle.

One of the first topics in the ensuing hearings was the treatment of Norman Latker. Both Senators made their displeasure clear, working behind the scenes to relocate him to another agency. The Bayh-Dole Act was eventually enacted with overwhelming bi-partisan support. Latker wound up at the Department of Commerce, where he would oversee the law’s implementation. (See a tribute to Norman Latker).

Like Latker, AS&E’s day of recompense was fast approaching. In American Science and Engineering, Inc. v. the United States, the U.S. Court of Claims ruled on the lawsuit. Dismissing the government’s contention that the process granting the exclusive license was flawed, the court reviewed in detail how it conformed to the Kennedy/Nixon procedures. The agency’s points were dismissed as “defective” and “sophistry” before the Judge concluded: “All other arguments raised by the government, although not directly addressed in this opinion, have been considered and found to be without merit.” The court upheld the exclusive licensing agreement with AS&E.

The Department’s attempt to march in to control product prices had an ironic result: it undermined the presumption that Washington knew best how to license federally funded inventions. By enacting Bayh-Dole, Congress decentralized patent management from the bureaucracy into the hands of the inventing organizations. The law retained the long established precedent that march in rights were to be used in rare situations when effective efforts are not being made to bring an invention to the marketplace or enough of the product is not being produced to meet public needs.

We’ve previously discussed attempts to reinterpret the march in provision to justify government control of high priced drugs. The pending petition adds a new twist. While defining “practical application” Bayh-Dole includes the phrase “... that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms (emphasis added).” Critics contend available to the public on reasonable terms means available at reasonable prices, as defined by the government.
To understand the original intent, recall that march in rights were designed to prevent companies from licensing federally supported inventions to suppress them. As in the case of seven competitors seeking government licenses to prevent AS&E from commercializing its inventions, this could happen. Thus, “available to the public on reasonable terms” refers to making a legitimate effort to sell the product. Otherwise, the government can march in.

When the theory first appeared that the march in provision allows government to regulate prices, Senators Bayh and Dole replied:

Bayh-Dole did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. This omission was intentional...

The article also mischaracterized the rights retained by the government under Bayh-Dole. The ability of the government to revoke a license granted under the act is not contingent on the pricing of a resulting product or tied to the profitability of a company that has commercialized a product that results in part from government-funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product.

That’s how march in rights have worked since 1947.

Finally, to those who scoff that Bayh-Dole changed the course of history, consider this from The Economist Technology Quarterly: “More than anything, this single policy measure helped to reverse America’s precipitous slide into industrial irrelevance.” Still skeptical? Under Bayh-Dole, more than 300 drugs and vaccines based on federally funded inventions are protecting public health here and abroad. President Johnson would be pleased.

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To say “control drug prices” is a bit misleading- and does a disservice to Americans struggling to pay for medicine. Really about preventing price gouging. Take epi-pens. The device mechanism was invented by the federal government. The device contains about a dollar’s worth of medicine. Yet pricing went from $100 to $600. Tell me why the Feds should not step in to address this.

There’s a real problem when citizens of foreign countries see a greater health and economic benefit from publicly-funded medical inventions than the original investors/underwriters (i.e., US taxpayers/public). I would agree that using march-in for reasons of price is not preferred. That said, I can’t imagine that Bayh, Dole or Johnson would be pleased that the commercialized inventions, seeded with taxpayer dollars, are simply not priced reasonably in America.

Wealthy countries in the ROW have far more rational/evolved healthcare laws/policies re pricing. The best fix IMO is not march-in under B-D, but rather a system-wide change to how prices are set for medical products. In my own licensing deals, I have included the term that, ‘sales to instrumentalities of the USG shall not be at prices higher than those to other parties for the same product sold at similar quantities’.