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## News & Views

# The Bayh–Dole Act: A model for promoting research translation?

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### ABSTRACT

The Bayh–Dole Act of 1980 was passed with the intention of promoting research into cancer and other diseases by providing institutions and researchers with a commercial incentive, even though much of their work was publicly funded. Now, many are questioning whether the system has worked as promised and some warn it may be jeopardizing the pursuit of science with no direct market relevance.

The Bayh–Dole Act of 1980 ([Bayh–Dole Act, 2008](#)) was passed with the intention of promoting research into cancer and other diseases by providing institutions and researchers with a commercial incentive, even though much of their work was publicly funded. Now, many are questioning whether the system has worked as promised. What Bayh–Dole did was to simplify the morass of contradictory guidelines and laws that controlled the ownership of any findings that had received funding from the U.S. government. The idea was that universities and other research institutions should be able to control the patents that resulted from their work, despite that fact that much of it – more than 60 percent currently – is funded by the taxpayer dollars via the National Institute of Health and other branches of the U.S. government. The new law allowed universities, and indeed, researchers themselves, to have ownership and potential profit – sometimes huge – from their scientific work. In the world of cancer research, where the findings may make the difference between life and death, the stakes are even higher.

For years, the Bayh–Dole Act was considered a huge success. In 2002, *The Economist* said that the Act was “[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century.” ([Innovation’s Golden Goose, 2002](#)) Universities had began setting up so-called technology transfer offices in droves to take advantage of the potential profits from their research. Today there are about 300 such offices, which is nearly a tenfold increase from before the law passed, and the number of patents by universities has increased

a hundredfold, according to *The New York Times*. Since Bayh–Dole passed nearly 30 years ago, more than 4500 for-profit firms have sprung up as a result of patents made under the law. The seeming success of the law has caught the attention of other scientific leaders: Germany and Japan have implemented similar rules, and even the University of Cambridge put a Bayh–Dole type system into place in 2005. Developing industrial powers are also implementing patenting laws for publicly funded research, including China, Brazil, and South Africa.

Now though, concerns have arisen that the law, intended to spur research, has created a culture whereby the profit motive often trumps more purely scientific based inquiries. Colleagues have become competitors. Critics say that instead of freely trading information for purely scientific goals, the effect of the law has been to distort the motivations of researchers who once only had science on their minds. Even if individual researchers are still keeping their motivations clean, that may not be true with the institutions for whom they work, which are eager to keep control of their research for potential future sale, and so are motivated to fiercely protect their findings.

“Today’s universities function more like corporate research laboratories,” alleged *The New York Times* in a recent article. “In trying to power the innovation economy, we have turned America’s universities into cutthroat business competitors, zealously guarding the very innovations we so desperately want behind a tangled web of patents and royalty licenses.” Most troubling, said the paper, is that “the kind of basic

experimentation that leads to a greater understanding of how the world works has largely been set aside in favor of projects considered to have more immediate market potential.”

Not everybody agrees with this, of course. The type of research done at his institution is not affected by profit motivations springing from the Bayh–Dole Act, said I. David Goldman, M.D., director of the Albert Einstein Cancer Center of Yeshiva University. It is simply not a factor in their determining what to study, he said. The director of the Mayo Clinic Cancer Center, Robert B. Diasio, M.D., noted that although the Mayo Clinic discovered cortisone, which is an important cancer treatment drug, the clinic chose not to patent it. Most of the institutions patents have come in radiology and diagnostic technology, he said.

Nonetheless, lawsuits between researchers and universities over patent rights have now become commonplace. One of most controversial was in the case of Myriad Genetics, a start up firm that got the exclusive licence for a patent on the gene sequences known as BRCA1 and BRCA2, which are linked to hereditary breast cancer. The sequences were discovered at the University of Utah, which sold them to Myriad. Not only did Myriad have monopoly control on testing to diagnose the disease, for which it charges around \$2300 per test, but it began suing research institutions that wanted to use the gene in further research. This was the experience of Dr. Haig Kazazian, a professor in the genetics department at the University of Pennsylvania, who was threatened with a lawsuit by Myriad after he used the gene tests in his own research for an even cheaper exam, which would cost only \$1800. “This is just the tip of the iceberg,” Kazazian told the Chicago Tribune. “We may end up down the road with a large fraction of the genetic disease testing done under these exclusive kinds of arrangements.”

“That’s generally not good for patients, and it’s not good for the public,” he said. “It’s possible that a lot of people won’t be able to get these tests because of costs or availability. I would consider it a definite threat to clinical medicine.”

The Myriad case gets to an inherent problem in the Bayh–Dole dynamic, said Jennifer Washburn, a fellow at the New America Foundation, who noted that most of the research funding that went into the Myriad gene discovery came from the U.S. government, at a cost of \$4.6 million. The basic science that receives government funding opens the way to many other types of discoveries. If only one company gets the rights to a new technology, that cuts off innovation by other researchers, both public and private. A 2006 study (Hansen et al., 2006) by the American Association for the Advancement of Science found that 35 percent of biotechnology researchers said they had trouble accessing new technologies because they had been patented.

Another case of conflict is over an unusually successful treatment for Chronic Myeloid Leukemia known as imatinib. The drug was developed over decades, beginning with the identification of the Philadelphia chromosome by researchers from the University of Pennsylvania and the University of Chicago. One of the scientists who took that work further was Brian Druker, who is now the chair of Leukemia Research and a professor of medicine at the Oregon Health and Science University Cancer Institute. He is considered the key researcher for what eventually became imatinib, which he

developed primarily from funding from the National Cancer Institute. He worked with the pharmaceutical company Ciba-Geigy (now Novartis) to bring the drug through clinical trials, and in 2001 it was approved. But Druker is concerned that Novartis, which markets the drug as Glivec, is charging far too much for the life-saving cure.

“The price at which imatinib has been offered for sale by Novartis around the world has caused me considerable discomfort,” he wrote in an article last year for [LiveMint.com](#). Dr. Druker expressed concern about the “abuse of these exclusive rights by excessive prices and seeking patents over minor changes to extend monopoly prices. This goes against the spirit of the patent system and is not justified given the vital investments made by the public sector over decades that makes the discovery of these medicines possible.”

But in the world of drug companies, there is no question that profit and public funding go hand in hand – that is true not only in the U.S., but in Europe as well. Such was the case with Novartis’ strategy in the UK, where the drug company was concerned that British health authorities would not provide funding to pay for the drug in a pilot program in which the company gave away the drug for free to 500 patients until it became commercial available (which it just had, due to an expedited European Union approval). Novartis “wanted to secure funding for the new medication and avoid potentially reputation-damaging ramifications,” according to a case study on the website of APCO Worldwide, the public relations and lobbying firm that hired by pharmaceutical giant to liaise with authorities. According to the case study, “strategy was to develop a high-level briefing programme to build personal relationships with a small, focused group of those actually responsible for the decision. It was decided to do this discreetly, avoiding media and public attention.” The drug funding was ultimately approved by the Department of Health, and “the environment became conditioned for the introduction of APCO’s Glivec on a wider scale.”

In fact, many are now questioning whether Bayh–Dole truly fosters new discoveries, rather than just more patents and commercial enterprises. A recently released study in the journal *PLOS Biology* (So et al., 2008) found that “neither overall trends in post-BD patenting and licensing nor individual case studies of commercialized technologies show that BD facilitated technology transfer and commercialization. Empirical research suggests that among the few academic patents and licenses that resulted in commercial products, a significant share (including some of the most prominent revenue generators) could have been effectively transferred by being placed in the public domain or licensed nonexclusively.”

This finding opens up the question of whether providing exclusivity over what was formerly free-flowing academic research is really worth the cost. Proponents of academic patenting say that prior to Bayh–Dole most university research simply sat on the shelf unused. This is untrue, according to the papers authors, who says that in fact, it was largely disseminated to other researchers and transferred to the commercial sector through traditional, open, academic channels such as scientific papers, conferences, and students graduating and going to work in industry.

Part of the inherent problem from which Bayh–Dole sprang is that the pharmaceutical industry does not like to pay for

basic research, said Washburn, the author of the book *University Inc.: the Corporate Corruption of Higher Education*.

The main reason industry doesn't spend a lot of money on basic science is that "it is very difficult to capture the results of that funding in the short term," said Washburn. That means that the federal government has to fund basic research, "because industry will never do enough of it, and the nation as a whole will benefit from this investment in science," she said. The biotechnology revolution was funded mostly by the U.S. government, she notes, because private companies did not think it would be valuable.

The total funding of university research from industry is about 5 percent, compared with 60 percent from the government, said Washburn. Still, she said, even with all of the problems, changing the current system will be difficult. "Every time anybody talks about revising the language of Bayh-Dole the whole university establishment gets all worked up" for fear that the system will be shut down completely.

Even from a financial perspective, it is not at all clear that the current Bayh-Dole system makes sense – at least not for most universities and research institutions. American universities, hospitals and other research institutions earned \$1.85 billion from patents and technology licenses in 2006, according to the PLOS Biology Study. By contrast, they received \$43.86 billion from federal, state and industry funders that same year. The few universities that did pull in significant dollars from patents were limited to the few that produced so-called blockbuster discoveries.

At the same time, oncologists have plenty of complaints about government funders, who also seem at times to be too focused on treatments for cancer rather than preventing cancer in the first place. "The funding people are interested in the magic-bullet research because that's what brings the dollars in," Anthony L. Back, M.D., an oncologist at the Fred Hutchinson Cancer Research Center at the University of Washington recently told *Newsweek*. "It's not as sexy to look at whether broccoli sprouts prevent colon cancer. A reviewer looks at that and asks, 'How would you ever get that to work?'" As a result, studies into preventative tools, like diet, exercise, and stress reduction get relatively short shrift.

The limits and complications of the patent system have been belatedly recognized by the U.S. National Institutes of Health, which issued guidelines saying that exclusive licenses should be granted only when they are necessary to bring

a product to market. That is so open for interpretation, however, that it seems to have had little effect so far.

There are some signs of movement amongst universities themselves. In 2007, a coalition of universities, including Harvard, MIT, Yale, and the University of California, issued a nine-point guide to consider in licensing technology. Among the considerations were limiting the licenses so they did not inhibit future innovation by transferring through to future inventions using the technology or stopping purely educational or scientific research; reviewing conflicts of interest between investigators, institutions, and commercial enterprises; and making special provisions for impoverished or other special needs communities to take advantage of the technology.

There may be reforms on the horizon from the government, although it is not yet clear what form they will take. Dr. John E. Niederhuber, the director of the National Cancer Institute, suggested his agency may take a more active role in a speech at the annual meeting of the American Society of Clinical Oncology in May 2008. "As we move to a more personalized era of oncology, it is clear that we will require multiple agents to target multiple pathways in the same patient. Facilitating that future will challenge how we think of competition, of intellectual property, and even the language of contracts. I believe NCI must step into those areas and become the facilitator between the public, private, and academic sectors," he said.

For now, though, the universities are continuing to line up at the patent office.

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