COMMENT

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Increased patenting and licensing could lead to pharmaceutical breakthroughs in developing countries such as India, but slow progress in other areas.

Lessons from Bayh–Dole

Developing countries wanting to boost commercialization of their academic research should learn from the mistakes of US patenting legislation, says **Bhaven N. Sampat**.

Thirty years ago this month, the US Congress passed the Bayh–Dole Act. The policy replaced a mishmash of rules that had governed the ownership of patents resulting from publicly funded research. Under the act, grantees and contractors, instead of government funding agencies, hold title to inventions.

Bayh–Dole has been widely celebrated for its effect on US universities. Since its passage, the number of patents that universities have been granted has climbed from fewer than 300 a year to more than 3,000. And, having earned very little from licensing before the act, US universities now earn almost US$2 billion annually[1].

Policy-makers in other countries have taken these trends as evidence that promoting patents and exclusive licensing on the outputs of taxpayer-funded research enhances technology transfer, commercialization and innovation. This has led numerous developing countries — including South Africa, the Philippines and Brazil — to enact Bayh–Dole-style legislation. Others, including India, are considering similar approaches.

Yet countries looking to boost commercialization should be wary of the myth that the act transformed US universities into entrepreneurial institutions capable of generating successful spin-off firms, high-tech jobs and self-sustaining research funds — and all at no cost to the taxpayer. Instead, they should note the problems that have arisen with the act, such as the overly restrictive patenting and licensing mentality it has generated among many technology-transfer offices, and craft their own legislation to avoid these pitfalls.

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The Bayh–Dole legislation was passed in response to a particular set of US problems at a particular time. An important motivation was to give universities the right to patent drug compounds, and to exclusively license them to companies. Before the act, to do either was difficult because of bureaucracy, particularly at the Department of Health, Education and Welfare. Policy-makers were also concerned that aggressive patent policies established in the 1960s by the National Institutes of Health's medicinal-chemistry ▶

programme had reduced collaboration between universities and industry.

Another major concern in the 1970s was the allegedly low rate of commercialization of federally funded research, including that conducted outside universities. Less than 5% of the 28,000 patents owned in 1976 by the government were licensed to industry[2].

The economic argument for allowing companies exclusive access to drug compounds is a strong one. Universities generated nearly one-fifth of the drugs with the greatest clinical impact approved by the US Food and Drug Administration during the past three decades[3]. It is hard to imagine that the profit-oriented companies who developed these drug candidates and put them through clinical trials would have invested the hundreds of millions of dollars needed if competitors could copy and market the drug themselves.

ANTIQUATED ARGUMENTS

Thirty years on, the 1976 licensing figure and the rise of university licensing since 1980 (see 'Technology transfer') form the central arguments used to claim that the Bayh–Dole Act was needed to boost technology transfer for all government-funded research, not just for pharmaceuticals. But these figures are misleading because they downplay the other ways in which universities contribute to economic growth and innovation. Researchers also disseminate their findings and ideas through consulting, publishing and teaching[4]. Indeed, the development of numerous US industries — including chemical engineering, aeronautics, computing and agriculture — relied heavily on academic research, but with little or no university patenting[5].

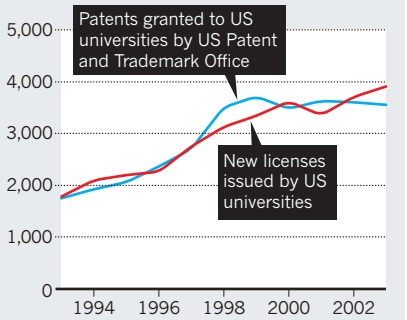
Although universities would probably not have made as much money, many of the non-drug technologies licensed after Bayh–Dole, including some of the most lucrative biotechnology techniques, would have been picked up anyway from academic publications and other traditional channels of dissemination. The Cohen–Boyer patent, for example, which covers recombinant DNA cloning techniques and is held jointly by Stanford University in California and the University of California, has generated more than $250 million, but even Niels Reimers, who managed Stanford University's licensing programme at the time, noted in a 1997 interview that "whether we licensed it or not, commercialization of recombinant DNA was going forward"[6].

In short, Bayh–Dole replaced one set of frictions with another — it eliminatated restrictions on patenting and technology-transfer licensing in favour of promoting excessive patenting and overly restrictive licensing. The growing aggressiveness of some technology-transfer offices in asserting their patents is now souring relationships between universities and industry, especially in information technology. Wayne Johnson, vice-president for university relations at computer giant Hewlett Packard in Palo Alto, California, testified before Congress in 2007 that Bayh–Dole has "fuelled mistrust, escalated frustration, and created a misplaced goal of revenue generation, which has moved universities and industry farther apart than they've ever been"[7].

Developing countries should not follow the United States in enacting policies that undermine traditional ways of commercializing research output. Patents and exclusive licences can boost technology transfer when significant follow-on investment is needed to promote commercialization — for instance, in the development of pharmaceutical compounds or prototypes for medical devices. But outputs that can be used off-the-shelf, such as computer software and biotechnology techniques, can be more effectively transferred by academic publishing, collaborations and teaching.

TECHNOLOGY TRANSFER?

University patents and licences have multiplied in recent decades, but this says little about the amount of technology transfer that is happening.



SOURCES: PATENT BOARD; NSF SRS; AUTM LICENSING SURVEY

In India, a version of Bayh–Dole-type legislation, drawn up in 2008, came close to mandating the patenting of all academic research output; institutions that did not comply would risk having their funding withdrawn. An outcry from academics and others has led policy-makers to soften their approach[8]. But the policy now under consideration still encourages patenting and licensing across the board — for example, for many of the software inventions emerging from Indian laboratories. In the Philippines, the recently passed Bayh–Dole analogue similarly fails to distinguish between inventions that should and shouldn't be patented, although regulations to control how the legislation is implemented are still being developed.

Indeed, policies promoting broad and aggressive patenting may be more of a problem in developing countries now than they were 30 years ago in the United States. More things are legally considered patentable, and under-resourced patent offices may struggle to weed out applications that aren't truly innovative. Legislators in developing countries need to distinguish between, and provide guidance on, the types of research that should be patented and exclusively licensed, and those that should be widely disseminated.

Countries considering Bayh–Dole type legislation should also be prepared to subsidize their technology-transfer offices. Few US universities are making large returns[9] and many make negligible income or even a net loss. One approach to this problem is for funders to allocate grant money for the management of intellectual-property rights for the types of research likely to need it.

A complicated issue for developing countries is whether they should treat academic patents and licences as a way to ensure that domestic firms and consumers, rather than large multinational companies, enjoy most of the benefits of taxpayer-funded research. This is particularly salient in countries without strong indigenous commercial capability, and where companies from developed nations might be better able to exploit innovations. Here again, drugs are a special case. For drug candidates with substantial markets in developed countries — those for 'global' diseases such as HIV or cancer — university licensing policies could be designed to simultaneously promote local access and preserve strong incentives for drug development[3].

There is no one-size-fits-all solution. Given the growing importance of developing-country universities in the global scientific enterprise, and the importance of public sector research for development, it is crucial that nations base their patent-reform laws on a clear-eyed assessment of their own problems and priorities. The choices made today will have profound effects on research, innovation and society for decades to come. ■

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