Is Bayh-Dole Good for Developing Countries? Lessons from the US Experience

Anthony D So, Bhaven N Sampat, Arti K Rai, Robert Cook-Deegan, Jerome H Reichman, Robert Weissman, Amy Kapczynski

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Recently, countries from China and Brazil to Malaysia and South Africa have passed laws promoting the patenting of publicly funded research [1, 2], and a similar proposal is under legislative consideration in India [3]. These initiatives are modeled in part on the United States Bayh-Dole Act of 1980 [4]. Bayh-Dole (BD) encouraged American universities to acquire patents on inventions resulting from government-funded research and to issue exclusive licenses to private firms [5, 6], on the assumption that exclusive licensing creates incentives to commercialize these inventions. A broader hope of BD, and the initiatives emulating it, was that patenting and licensing of public sector research would spur science-based economic growth as well as national competitiveness [6, 7]. And while it was not an explicit goal of BD, some of the emulation initiatives also aim to generate revenues for public sector research institutions [8].

We believe government-supported research should be managed in the public interest. We also...
believe that some of the claims favoring BD-type initiatives overstate the Act's contributions to growth in US innovation. Important concerns and safeguards—learned from nearly 30 years of experience in the US—have been largely overlooked. Furthermore, both patent law and science have changed considerably since BD was adopted in 1980 [9, 10]. Other countries seeking to emulate that legislation need to consider this new context.

Overstating Claims

On a positive note, the BD Act required different agencies that funded US research and development to adopt more consistent policies about ownership of patents arising from federal funding [3]. One of BD's intended virtues involved transferring default patent ownership from government to parties with stronger incentives to license inventions. BD assigned ownership to institutions, such as universities, nonprofits, and small businesses, although it could just as easily have opted for individual grant and contract recipients.

Nevertheless, many advocates of adopting similar initiatives in other countries overstate the impact of BD in the US. Proponents note The Economist's 2002 claim that the Act was “[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century” [11]. They also cite data (originally used by US proponents of the Act) on the low licensing rates for the 28,000 patents owned by the US government before BD to imply that the pre-BD legal regime was not conducive to commercialization [12]. But as Eisenberg [13] has argued, that figure is misleading because the sample largely comprised patents funded by agencies of the Department of Defense to which firms already had declined the option of acquiring exclusive licenses. Moreover, these figures are of questionable relevance to debates about public sector research institutions, because most of the patents in question were based on government-funded research conducted by firms, not universities or government labs [13]. Finally, and most importantly, the narrow focus on licensing of patented inventions ignores the fact that most of the economic contributions of public sector research institutions have historically occurred without patents—through dissemination of knowledge, discoveries, and technologies by means of journal publications, presentations at conferences, and training of students [6, 14, 15].

Throughout the 20th century, American universities were the nation's most powerful vehicles for the diffusion of basic and applied research results [16], which were generally made available in the public domain, whereas industry and other public sector researchers could use them. These activities were central to the rise of American technological success broadly and to the growth of knowledge-based industries, such as biotechnology and information technology, in particular.

Public sector research institutions also relied on generous public funding for academic research—from a highly diverse group of federal funding agencies—which grew dramatically after the Second World War, and on the availability of venture capital to foster the development of early-stage ideas [6]. These and other unique features of the US research and development system explain much more about innovation in the US after BD than the rules about patenting that BD addressed.

In the pre-BD era, discoveries emanating from public research were often commercialized without patents, although academic institutions occasionally patented and licensed some of their publicly funded inventions well before BD, and these practices became increasingly common in the 1970s [17]. Since the passage of the Act in 1980, US academic patenting, licensing, and associated revenues have steadily increased. BD accelerated this growth by clarifying ownership rules, by making these activities bureaucratically easier to administer, and by changing norms toward patenting and licensing at universities [6]. As a result, researchers vested with key patents sometimes took advantage of exclusive licenses to start spin-off biotechnology companies. These trends, together with anecdotal accounts of "successful" commercialization, constitute the primary evidence used to support emulating BD in other countries. However, it is a mistake to interpret evidence that patents and licenses have increased as evidence that technology transfer or commercialization of university technology has increased because of BD.

Although universities can and do patent much more in the post-BD era than they did previously, 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 [6, 18].

Another motivation for BD-type legislation is to generate licensing revenues for public sector research institutions. In the US, patents are indeed a source of revenues for some universities, but aggregate revenues are small. In 2006, US universities, hospitals, and research institutions derived US$1.85 billion from technology licensing compared to US$43.58 billion from federal, state, and industry funders that same year [19], which accounts for less than 5% of total academic research dollars. Moreover, revenues were highly concentrated at a few successful universities that patented “blockbuster” inventions [20].

A recent econometric analysis using data on academic licensing revenues from 1998 to 2002 suggests that, after subtracting the costs of patent management, net revenues earned by US universities from patent licensing were "on average, quite modest" nearly three decades after BD took effect. This study concludes that "universities should form a more realistic perspective of the
leading US foundation supporting entrepreneurship research) recently argued that "Technology
other university partners, often outside the US [126]
product development and university–industry collaboration, which encouraged companies to find
information technology firm complained that aggressive university patenting impeded both
than they do in the pharmaceutical sector [127]
exclusive licensing play a much more limited role in the development of information technology
all" approach to patenting research results, notwithstanding the evidence that patents and
problems it has raised for information technology. Universities may too often take a "one size fits
The problems that BD has raised for the biopharmaceutical industry are dwarfed by the
pharmaceutical firms may be able to avoid thickets through secret infringement or by "off-
thickets over time [36]. Biotechnology firms eager to do research on stem cells have complained
about the excessive licensing fees that Wisconsin charges (as well as about "reach through"
provisions that call for royalties on any product developed from research on embryonic stem
cells, and impose restrictions on use) [29]. Rather than promote commercialization, these
patents on basic research platforms constitute a veritable tax on commercialization [30]. Nor
were these efforts to tax future innovation unprecedented, as the example of recombinant DNA
shows. The Wisconsin Alumni Research Foundation's extension of licensing terms to academic
research institutions [31] and its imposition of restrictions on use became especially controversial
because these measures went beyond the Cohen-Boyer precedent. The manager of
recombinant DNA licensing at Stanford quipped, "When it was licensed it or not,
commercialization of recombinant DNA was going forward…a nonexclusive licensing program,
at its heart, is really a tax…But it's always nice to say 'technology transfer"' [32].
The broad discretion given to publicly funded research institutions to patent upstream research
raises concern about patent thickets, where numerous patents on a product lead to bargaining
breakdowns and can blunt incentives for downstream research and development (R&D) [33, 34].
Barriers to bundling intellectual property necessary for R&D become higher in frontier
interdisciplinary research areas, such as synthetic biology, microarrays, and nanobiotechnology,
because they draw upon multiple fields, some of which may be likelier than others to form
thickets over time [6, 10, 32-35]. Although there is some evidence that biotechnology and
pharmaceutical firms may be able to avoid thickets through secret infringement or by "off-
shoring" research to countries with fewer patent restrictions [36], secret infringement and the
transfer of R&D to other countries are hardly tactics that government policy should encourage.
The problems that BD has raised for the biopharmaceutical industry are dwarfed by the
problems it has raised for information technology. Universities may too often take a "one size fits
all" approach to patenting research results, notwithstanding the evidence that patents and
exclusive licensing play a much more limited role in the development of information technology
than they do in the pharmaceutical sector [57]. In testimony to the US Congress, a prominent
information technology firm complained that aggressive university patenting impeded both
product development and university–industry collaboration, which encouraged companies to find
other university partners, often outside the US [38]. Expressing similar concerns in a proposal to
explore alternatives to the BD model, officials from the Ewing Marion Kauffman Foundation (the
leading US foundation supporting entrepreneurship research) recently argued that "Technology
Instituting Safeguards

Countries seeking to enhance the contributions of universities and public sector laboratories to social and economic development have numerous policy options. Many of these policies do not involve intellectual property rights at all, but rather look to provide funds for basic and applied research, subsidize scientific and engineering education, strengthen firms’ ability to assimilate university research, and invest in extension, experimentation, and diffusion activities [39, 54, 55]. But even policies focused on intellectual property management need not presume that patenting and exclusive licensing are the best options. For example, they may instead focus on placing by default or by strategy government-funded inventions into the public domain, creating a scientific commons, enabling collective management of intellectual property, or fostering open-source innovation [56–60]. Where greater commercial incentives seem necessary, the benefits of nonexclusive licensing should always be weighed against the social cost of exclusive licenses.

The appropriate array of policies will vary from country to country: there is no “one size fits all” solution. Based on our review above, we believe it is doubtful that the benefits of legislation closely modeled on BD would outweigh their costs in developing counties. For those countries that nonetheless decide to implement similar laws, the US experience suggests the crucial importance, at a minimum, of considering a variety of safeguards (see Box 1).
Access to End Products

Box 1: Safeguards Serving the Public Interest

Governments adopting laws styled after the US BD Act should be vigilant to ensure that the public’s interests are served. In commercializing publicly funded research, a number of safeguards on patenting and licensing practices should be built into any law or its regulatory implementation.

**No Exclusive Licensing Unless Necessary for Commercialization**

Any BD-style legislation should be founded on the principle that publicly funded research should not be exclusively licensed unless it is clear that doing so is necessary to promote the commercialization of that research. Public sector institutions should not, for example, exclusively license research tools that were developed with public funding if those tools can instead be used off the shelf by others. Where exclusive licenses are not required for commercialization, one may ask whether universities and public sector labs should be patenting research at all. Will encouragement of patenting and nonexclusive licensing, as in the Cohen-Boyer model discussed above, help or hurt researchers, firms, and the public in developing countries? Even nonexclusive licenses will tax downstream users, although presumably with lower rents and transaction costs and more procompetitive effects. As suggested above, revenues from licensing academic inventions are likely to be minuscule for most institutions, and aggressive university patenting can have other deleterious effects. A robust research exemption can ward off some of the problems potentially associated with restrictive licensing of upstream inventions [62].

**Transparency**

The legislation should ensure transparency in the patenting and licensing of publicly funded research. Public accountability should follow public funding. Institutions that engage in patenting and licensing should be required to report or make public all information that is necessary to determine whether they are reasonably serving the public interest. Such information may include the number of patents and licenses obtained, the funds expended on patenting and licensing activities, licensing revenues, and the key terms (e.g., exclusive or nonexclusive, humanitarian access, research exemption, definition of market segmentation or field of use, performance milestones, and march-in rights) of licenses. The lack of a transparency mandate is a key flaw of the BD Act that should not be replicated.

**Government Authority To Issue Additional Licenses**

Where licensing arrangements for publicly funded research do not achieve public interest objectives, governmental authorities must have power to override such licenses and to grant licenses to additional or alternative parties [9,10,43]. In the US, this authority is formally embodied in the government’s “march-in” rights under BD, but this power has never been exercised. Petitions to invoke it have been made a few times [46,47,63,64], but they have never been granted, and because of the administrative disincentives built into BD, this power is unlikely ever to be used [30]. To avoid this result, legislatures must develop standards to ensure that march-in rights or comparable authority will be exercised when public interest objectives are not otherwise attained.

In evaluating licensing options, those receiving government research funding could also be required to consider the option of licensing patented inventions to a “technology trust,” that is, a commons that would ensure designated inventions remained available to all interested parties on predetermined terms. Such a commons could enable the pooling of socially useful bundles of technology, particularly research tools and health technologies for neglected or rare diseases. Governments might also consider reducing or waiving patent application and maintenance fees for such inventions when they are made broadly available for research and humanitarian application, without royalty, for a specific geographical area or field of use.

**Government Use Rights**

The government should retain an automatic right to use any invention arising from its funding. Under BD, the US government has an automatic “nonexclusive, nontransferable, irrevocable, paid-up license” [65] to use any invention developed with government funds. Typically, however, it does not invoke such a license and often pays monopoly prices for products that it funded. The US experience shows the importance both of establishing that the government should be provided with an automatic license in products resulting from its funding and of elaborating standards to ensure such licenses are actually exercised in appropriate circumstances.

From a broader perspective, governments retain the right to use any invention, whether or not it arises from public funding, under international law [66]. Governments may choose to use patented inventions to promote public health [67], national security [66], or comparable objectives, while public-interest compulsory licenses may sometimes be granted to avoid abusive licensing practices or to ensure access to patented research products on reasonable terms and conditions [43,66]. Where publicly funded grantees fail to commercialize a technology appropriately or to foster its availability, the trigger for government use—under any enabling provision adopted in domestic law—must work better than the march-in right has under BD.

**Access to End Products**
Besides promoting commercialization, the government must ensure consumer access to end products. The public is entitled to expect that the inventions it paid for will be priced fairly. The US experience shows that a BD system that lacks mandatory rules concerning the affordability of end products will not deliver on this reasonable expectation [43–47]. As a condition of receiving a license to a government-funded invention, parties should be required to ensure that end products are made available to the public on reasonable terms and conditions. What constitutes “reasonable” will vary by national context, but it is important to ensure that the term is defined with enough precision to be enforceable.

Licenses to government-funded inventions should presumptively include access-oriented licensing provisions that address humanitarian needs in other countries [68]. One such provision is an open license for production and sale of end products in (or to) developing countries in exchange for a fair royalty [69]. At the very least, when inventions have foreseeable applications in resource-poor regions, a plan for access in those regions should be explicitly incorporated into technology licensing.

Conclusion

While policies supporting technological innovation and diffusion contribute to economic growth and development, the appropriate sets of policies to harness public sector R&D are highly context-specific. Much depends on factors such as the level of publicly funded research, the focus of such research on basic versus applied science, the capabilities of industry partners, and the nature of university–industry linkages [54, 55].

Recognizing these difficulties, reasonable minds may disagree about the likely impact of BD-type legislation elsewhere. Nevertheless, the present impetus for BD-type legislation in developing countries is fueled by overstated and misleading claims about the economic impact of the Act in the US, which may lead developing countries to expect far more than they are likely to receive. Moreover, political capital expended on rules of patent ownership may detract from more important policies to support science and technology, especially the need for public funding of research. Given the low level of public funding for research in many developing countries, for example, the focus on royalty returns at the expense of public goods may be misplaced [61]. Furthermore, it is unclear whether any of the positive impacts of BD in the US would arise in developing countries following similar legislation, absent the multiagency federal pluralism, the practically oriented universities, and other features of the US research system discussed above.

In any event, both the patent laws and patterns of scientific collaboration have changed substantially since BD was passed in 1980. To the extent that legislation governing the patenting and licensing of public sector research is needed in developing countries at all, it should reflect this new context rather than blindly importing a US model that is 30 years old.

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ADS is a Member of the Advisory Board for Universities Allied for Essential Medicines and has conducted commissioned research for the World Health Organization Commission on Intellectual Property Rights, Innovation and Public Health (2005).

BNS is a Member of the Advisory Board for the Initiative for Medicines, Access & Knowledge and has testified before the Secretary’s Advisory Committee on Genetics, Health, and Society, Task Force on Impact of Patents and Licensing Practices on Clinical Access to Genetic Testing (July 10, 2007).

AKR is a Member of the Scientific Advisory Board for Science Commons and the Advisory Board for the Peer-to-Patent Project. She has testified before the Senate Committee on the Judiciary hearing on “The Role of Federally-Funded University Research in the Patent System” (October 24, 2007) and has conducted commissioned research for the World Health Organization Commission on Intellectual Property Rights, Innovation and Public Health (2005).

RC-D is a Member of the National Research Council Committee on Management of University Intellectual Property and the Task Force on Patent Reform of the Association of American Universities, Council on Government Relations, Council on Education, National Association of State Universities and Land Grant Colleges, and Association of American Medical Colleges (joint committee). He has also conducted commissioned research for the Secretary’s Advisory Committee on Genetics, Health, and Society, Task Force on Impact of Patents and Licensing Practices on Clinical Access to Genetic Testing (ongoing) and for the World Health Organization Commission on Intellectual Property Rights, Innovation and Public Health (2005).

JHR is a Member of the Editorial Board for the *Journal of International Economic Law*. He has testified before the NIH Public Hearing on March-In Rights under the Bayh-Dole Act, National Institutes of Health (May 25, 2004).
RW is the Director of Essential Action. He is also Counsel to, and Member of the Board of Directors of, Essential Inventions, which has petitioned for the issuance of march-in licenses for two government-funded pharmaceutical products, ritonavir and latanoprost. He is also a Member of the Board of Directors for Health GAP (Global Access Project) and the Board of Directors for Union for the Public Domain. He has testified before the Senate Committee on the Judiciary hearing on “The Role of Federally-Funded University Research in the Patent System” (October 24, 2007).

AK is a Member of the Board of Directors for Universities Allied for Essential Medicines.

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Developing countries wanting to boost commercialization of their academic research should learn from the mistakes of US patenting legislation, says Bhaven N. Sampat. Do you want to read the rest of this article? Request full-text. India is currently considering implementing a Bayh-Dole-like policy as well.309 Nevertheless, countries need to do much more to encourage innovative approaches to technology transfer from universities. Localization Barriers to Trade: Threat to the Global Innovation Economy. Article. countries? lessons. 4. bayh-dole good. 4. experience. 1. countries? 1. developing. 1. bayh-dole. 1. lessons. Lessons from the US experience. To: Anthony D So, Bhaven N Sampat, Arti K Rai, Robert Cook-Deegan, Jerome H Reichman, Robert Weissman, Amy Kapczynski. From (Name): E-mail: Only shared with authors of paper. Please enter a personalized message to the authors. More detailed explanations for your need are more likely to get a response. Send Request. Load Form Load Form. Request PDF from Authors. We can help you find this article by emailing the authors directly. Follow us on Twitter to stay on top of the latest in scientific research. Press proceed to send the authors a message. Follow PubFacts. Task 1 Lessons. Task 2 Lessons. Reading Lessons. Moreover, experts from the developed countries can also help with the vaccination programmes in the developing countries. This will led to decrease in infant mortality rate. Secondly, assistance in the field of education should be provide to the poorer nations. The developed countries can provide funds to open new schools and polytechnic institutions. Furthermore, the rich governments should provide the students of poor countries an opportunity to study in the prestigious institutions by giving. To conclude, if we want to live in a better world with peace and harmony, we should always help each other. The pandemic teaches us that human health, economic wellbeing and the natural environment are deeply connected. While governments and people are coping crisis, we now have a unique opportunity to learn lessons that will prepare us for the future. This is a BETA experience. You may opt-out by clicking here. Edit Story. | Apr 11, 2020, 08:53pm EDT. Four Lessons We Should Learn From The Pandemic. Georg Kell Contributor. Opinions expressed by Forbes Contributors are their own.