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

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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 [9]. 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 [5] has argued, that figure is misleading because the sample largely comprised patents (funded by the Department of Defense) to which firms had already declined the option of acquiring exclusive title. 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, where 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 [18]. 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
explore alternatives to the BD model, officials from the Ewing Marion Kauffman Foundation (the
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.
The problems that BD has raised for the biopharmaceutical industry are dwarfed by the
shoring” research to countries with fewer patent restrictions [128]. 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 cell lines [26–28]). Biotechnology firms eager to do research on stem cells have complained
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provisions that call for royalties on any product developed from research on embryonic
stem cell lines, 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, “Whether we licensed it or not,
commercialization of recombinant DNA was going forward…a nonexclusive licensing program,
recombinant DNA licensing at Stanford quipped, “[W]hether we licensed it or not,
revenue as evidence that BD facilitated commercialization in the US. And it is little more than a
leap of faith to conclude that similar legislation would automatically promote commercialization
and technology transfer in other, very different, socioeconomic contexts.

Sources of Concern

What have we learned from the US experience with BD? Because the Act gives recipients of
government research funds almost complete discretion to choose what research to patent,
universities can patent not only those inventions that firms would fail to commercialize or use
without exclusive rights, but also upstream research tools and platforms that do not need patent
protection and exclusive licensing to be adopted by industry [6, 9, 10].

For example, while the patented technologies underlying recombinant DNA were fundamentally
important for biotechnology and generated ample revenues for Stanford, the University of
California, Columbia University, and City of Hope Medical Center [6], the patenting and licensing
of these research platforms and technologies were not necessary for commercialization. Both
the Cohen-Boyer patents for recombinant DNA and the Axel patents on cotransformation were
rapidly adopted by industry even though neither invention came with the BD “carrot” of an
exclusive right. The Cohen-Boyer patents reportedly contributed to 2,442 new products and
US$35 billion in sales. Its licensing revenues to Stanford University and the University of
California San Francisco were US$255 million [23]. With 34 firms licensing the technology, the
Axel patents earned US$790 million in royalties for Columbia University over the patent period
(Colaianni and Cook-Deegan, unpublished data). While the patenting and licensing of these
inventions clearly enriched the universities involved, there is no reason to believe that
nonexclusive licensing (as opposed to simple dedication to the public domain) deterred
commercialization of the invention(s). In fact, Columbia University justified efforts to extend the
life of its Axel patents not because such extension would improve commercialization, but rather
because it protected royalty income that would be channeled back into its educational and
research mission.

While BD gave those conducting publicly funded research the discretion to patent fundamental
technologies, changes in US patent law since 1980 provided the means, by expanding eligibility
standards to include basic research and research tools. These trends have been notable in the
biotechnology and information technology sectors [24, 25]. A widely watched, recent
consequence of this shift involves the suite of University of Wisconsin patents on embryonic
stem cell lines [26–28]. 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”
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recombinant DNA licensing at Stanford quipped, “Whether we 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’” [23].

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
downbreaks 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 [9, 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 [37]. 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

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explore alternatives to the BD model, officials from the Ewing Marion Kauffman Foundation (the
importance, at a minimum, of considering a variety of safeguards (see Box 1). Nonetheless, even those who decide to implement similar laws, the US experience suggests the crucial importance of considering a variety of safeguards (see Box 1). For those countries that nonetheless decide to implement similar laws, the US experience suggests the crucial importance of considering a variety of safeguards (see Box 1).

Based on our review above, we believe it is doubtful that the benefits of legislation would outweigh their costs in developing countries. 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).
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.

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. 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, but they have never been granted, and because of the administrative disincentives built into BD, this power is unlikely ever to be used. 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” 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. Governments may choose to use patented inventions to promote public health, national security, 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. 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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