

## The Bayh-Dole Act and Promoting the Transfer of Technology of Publicly Funded-Research

### *UAEM White Paper on the Proposed Indian Bayh-Dole Analogue*

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The government of the Republic of India is considering implementation of legislation that would encourage the patenting of publicly funded research. The Indian Protection and Utilization of Public Funded Intellectual Property Bill of 2008 (“the Indian Bayh-Dole Bill”) is modeled on a piece of legislation passed in the United States commonly known as the Bayh-Dole Act of 1980.<sup>1</sup> Proponents of the Indian Bayh-Dole Bill have introduced it as a mechanism to encourage the commercialization of publicly funded research, yet the bill also has the potential to reduce access to the outputs of publicly funded research while harming future innovation.

### Executive Summary

While the Bayh-Dole Act of 1980 led to a dramatic increase in patenting and licensing of publicly funded research, there is little evidence that the legislation was necessary for or successful in accomplishing the goals which inspired its drafting. The practice of licensing at universities in the US has raised serious concerns regarding the application of similar legislation in India:

- **The Bayh-Dole Act too narrowly focuses on patenting and licensing**, ignoring the fact that public sector research institutions contribute economy in multiple ways, through publishing in journals, collaboration with other scientists, consultations with industry, and the teaching of students. As patenting increases, it has the potential to reduce the contribution made by these economic inputs by reducing free access to knowledge. India was recently party to WHO negotiations that developed a Global Strategy and Plan of Action to address the dual challenges of access and innovation. The final Global Strategy, building off of findings of a report issued by the Commission on Intellectual Property Rights, Innovation and Public Health, recommended a number of agreed upon strategies for improving access and innovation that do not rely solely on the patent system.
- **The Bayh-Dole Act has failed to generate consistent revenues.** While a few universities have profited from “blockbuster” discoveries, overall, technology transfer offices at universities often barely breaking even, and many operate at a net loss.
- **The exclusive use of the patent model, without appropriate public health safeguards, threatens access to life-saving drugs.** The act encourages research

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<sup>1</sup> Bayh-Dole University and Small Business Patent Procedures Act of 1980, 35 U.S.C. § 200 (2006).

- institutions to obtain patents on publicly funded research to the exclusion of other methods that could in many situations be more beneficial to access and encouraging future innovation. Such rights allow the institutions and their licensees to charge monopoly prices that may place life-saving medicine out of the reach of India's poorest consumers, denying them the opportunity to benefit from publicly-funded research.
- **The Bayh-Dole Act contains only weak access safeguards.** Critics of the original Bayh-Dole Act point out that the safeguards the act contained to allow for public access in case a publicly funded innovation was not made available on reasonable terms have never been successfully used. Instead of fixing this problem, the Indian Bayh-Dole Bill currently includes *fewer safeguards* aimed at preserving public access. Under proposed legislation, the government loses its opportunity to preserve access to publicly funded research just *90 days* after learning of the new technology.
  - **The patenting model is a bad fit for many forms of publicly funded research.** Much of the research done at universities is upstream research, often related to research tools that are critical for developing further innovations. Patenting is not only unnecessary for these basic tools; it can inhibit further downstream research and development by placing a costly “tax” on tools for innovation.
  - **The Bayh-Dole model is increasingly out of date.** Bayh-Dole was designed for the innovation climate of 1980, when most medical innovations involved a small number of patents on individual chemicals. Modern research, particularly in the area of biotechnology, is more likely to require a large number of basic tools, and as more of these tools are patented, researchers will be blocked from investigating promising areas of research by the transactional and other costs of patent licensing.
  - **The Indian Bayh-Dole Bill is being pushed forward without public debate.** Drafts of the bill were made public only recently, leaving little time for the public and civil society to voice concerns or have any input in crafting positive, pro-health legislation.

## I. History and Limitations of Bayh-Dole

Bayh-Dole became law in the United States in 1980 due to the perception that federally-funded research was not moving efficiently from the lab to the marketplace.<sup>2</sup> The Act sought to facilitate this movement of technology by providing clear ownership of intellectual property arising from taxpayer-funded research.<sup>3</sup> The Act provided a uniform framework to encourage institutions performing the research, such as universities, to obtain patents on the discoveries resulting from such work.<sup>4</sup> Such patents allowed the institution to grant exclusive licenses on patented inventions, licenses that were argued to be necessary in some cases to encourage the commercialization of publicly funded research.<sup>5</sup>

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<sup>2</sup> Thomas A. Massaro, Innovation, Technology Transfer, and Patent Policy: the University Contribution. 82 Virginia Law Review 1729, 1729 (1996). Available from: <http://www.jstor.org/pss/1073687>

<sup>3</sup> *Id.* at 1731

<sup>4</sup> Bhaven N. Sampat, Patenting and US academic research in the 20th century: The world before and after Bayh-Dole. 35 Res. Po'ly 772 (2006).

<sup>5</sup> Carolina Rossini, *Innovation and Patent Ownership Policies and the Role of Universities as Public Spaces*, IQsensato Studies. (forthcoming) [http://www.iqsensato.org/?page\\_id=71](http://www.iqsensato.org/?page_id=71)

*Was Bayh-Dole Really Necessary?: Other Routes to Economic Success*

Proponents of Bayh-Dole point to an increase of patenting and licensing of public sector inventions to show that the legislation has been successful at contributing to economic growth in the United States. This narrow focus on licensing ignores the fact that public sector research institutions can and have contributed to the economy in multiple ways, through the free and open disclosure of knowledge by publishing in journals, collaboration with other scientists, consultations with industry and the teaching of students.

Much of the technological growth America experienced over the past century depended on the basic and applied research carried out in universities and shared widely through the public domain. These mechanisms of knowledge exchange remain the key ways in which universities contribute to technological growth: an industry survey taken in 2005 revealed that for most industries, patents and licenses involving inventions from university or public laboratories remain of little importance compared with publications, conferences, and interaction with university researchers.<sup>6</sup>

Bayh-Dole may not have been necessary to commercialize public research. Before Bayh-Dole, public research was often commercialized without patents. In cases where patents were necessary, institutions could and did obtain them without additional legislative encouragement.<sup>7</sup> While patenting and licensing of public research increased dramatically following Bayh-Dole, empirical research indicates that many of these innovations could have effectively transferred to commercial use through non-exclusive means, by being placed in the public domain or licensed nonexclusively.<sup>8</sup>

While patenting and licensing have increased under Bayh-Dole, arguments that Bayh-Dole has increased the economic contribution of publicly funded research overall remains a speculative and untested claim.

*Below Expectations: Low Revenues from Patent Licenses*

While the overall benefits of Bayh-Dole remain debatable, data does exist showing that the legislation has failed to generate anticipated high levels of licensing revenue for research institutions. Though the purpose of the Act was not focused on increasing university funding, many institutions were encouraged to patent by a few isolated examples of “blockbuster” inventions that originated from public research.<sup>9</sup>

Yet overall, the university returns on patenting and licensing have been quite modest. According to the a report by the National Institutes of Health, “[g]iven the investment in

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<sup>6</sup> David Mowery & Bhaven Sampat, *The Bayh-Dole Act of 1980 and university-Industry Technology Transfer: A Model for other OECD Governments?* 30 J. Tech. Transfer 115 (2005).

<sup>7</sup> Jeannette Colyvas, et al, "How Do University Inventions Get Into Practice?" 48 Mgt. Sci. 61 (2002) (demonstrating that patenting of publicly funded research was on the rise before 1980 and that Bayh-Dole only magnified the trend)

<sup>8</sup> Anthony So et al. *Is Bayh-Dole Good for Developing Countries? Lessons from the US Experience*, 6 PLoS Biol., e262, available at <http://biology.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pbio.0060262>.

<sup>9</sup> David Mowery et al., *The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980*, 30 Res. Pol'y 99 (2001).

patent prosecution costs, operating expenses, and revenue sharing with inventors as provided by law, many universities operate their technology transfer programs at a net loss.”<sup>10</sup> While a handful of successful patents have brought in millions, these numbers are concentrated on a few institutions and are dwarfed by other sources of funding for academic research. In 2006, for example, licensing brought in less than 5% of total funding for academic research.<sup>11</sup> Success for individual institutions is also an uncertain gamble, with only a handful of “blockbuster” inventions accounting for most of the gains.<sup>12</sup> As the former head of technology transfer at MIT described in 1998, after subtracting the costs of patent management, most university licensing offices “barely break even.”<sup>13</sup>

## II. Costs of the Bayh-Dole Model: Reducing Innovation and Access

### *Failings of the Model*

In considering whether the Bayh-Dole model should be exported to India, policy-makers should take into account the costs of patenting in addition to its claimed benefits. The patent framework lets the commercial developers of the patent determine the terms on which the product is made available to the public. Such a system contains no guarantee that the products that come from public research be made available to the public at a reasonable or affordable price, with the end result that some consumers are prevented from making use of the innovations developed with taxpayer money.

Government march-in rights included in the Bayh-Dole Act, a safeguard meant to ensure access to the fruits of federally funded research on reasonable terms, have never been exercised. Despite taxpayer subsidies, publicly funded medicines remain subject to monopoly pricing, often too expensive for even those in the United States to have access.<sup>14</sup>

Fuzeon, a therapy developed in part by both Duke and the University of California, San Francisco (“UCSF”), offers one stark example of how patenting without safeguards can reduce access to public research. Scientists in publicly funded labs at these schools synthesized a novel therapy for treating HIV. Fuzeon is called a “salvage therapy”: a treatment used when all other methods have failed to treat HIV. Professor Dr. Jay Lalezari, a UCSF professor and one of the drug’s researchers, praised the therapy as marking “a great day for people with HIV infection who are in trouble...For these individuals, it can mean the difference between life and death.”<sup>15</sup>

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<sup>10</sup> National Institutes of Health, NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers’ Interests are Protected (2001), available at [http://ott.od.nih.gov/policy/policy\\_protect\\_text.html](http://ott.od.nih.gov/policy/policy_protect_text.html).

<sup>11</sup> Anthony So et al. *Is Bayh-Dole Good for Developing Countries? Lessons from the US Experience*, 6 PLoS Biol., e262, available at <http://biology.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pbio.0060262>.

<sup>12</sup> David Mowery et al., *The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980*, 30 Res. Pol’y 99 (2001).

<sup>13</sup> Quoted from the former head of licensing office at MIT (and former President of the Association of University Technology Managers), in Nelsen L., *The Rise of Intellectual Property Protection in the American University*, 279 Science 1460 (1998).

<sup>14</sup> Peter Arno & Michael Davis, *Why Don’t We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research*, 75 Tul. L. Rev. 631 (2001).

<sup>15</sup> Sabin Russell, *AIDS drug gets quick approval: Fuzeon geared toward failing patients; \$20,000 price dismays activists*. San Francisco Chron. Friday, March 14, 2003



This difference – that between life and death – comes after decades of research and public grants, in tax-exempt space. UCSF and Duke, however, licensed the Fuzeon patents exclusively to Roche, a Swiss conglomerate, which then marketed the drug in the US for an eye-popping \$22,000 a year. It was, and is, the most expensive HIV medication ever. Fuzeon is so costly that over 30% of American states have at some point refused to include it as part of their Aids Drug Assistance Programs.<sup>16</sup> Residents of North Carolina, the birthplace of Fuzeon, felt this harm close to home: Evelyn Foust, the head of HIV/STD Prevention at North Carolina’s Division of Public Health, greeted the introduction of Fuzeon by announcing that her state would not purchase the medicine.<sup>17</sup> As of July 2008, Roche has no plans to reduce the drug’s cost to make it available in low- or middle-income countries.<sup>18</sup> If the drug had been commercialized through other channels without a patent, or patented with access protections in place, Fuzeon would now be available for patients in Durham, where it was invented with the support of taxpayer dollars.

Yet another infamous case in which exclusive licensing has hindered access to an urgently needed healthcare tool developed with public funding has been the imanitib mesylate, marketed by the multinational pharmaceutical firm Novartis under the brand name Gleevec. A therapy for chronic myeloid leukemia, imanitib was given orphan drug status; several public-funded research institutions were thus able to collaborate using US tax credits, grants for clinical trials, and FDA fee waivers to develop the much-needed drug. Yet Novartis, imanitib’s exclusive licensee, priced Gleevec at US\$2500 per month to accrue US\$7.5 billion in the span of less than five years while prohibiting access to treatment for thousands of patients. Novartis obtained monopoly over imanitib in Korea, Brazil and several other developing countries, in spite of outcry from public health advocates. In India, exclusive marketing rights over imanitib granted to Novartis in 2003 caused generic producer Natco—who had been selling the drug, along with several other generic producers, for as low as Rs 9000 as compared to Novartis’s Rs 120000 price tag—to challenge Novartis in the Delhi High Court.<sup>19</sup> While Novartis claimed that its secondary patent granted for a beta-crystal formulation of imanitib, a modification on earlier versions, justified renewed IP protection, its chief inventor Dr. Brian Druker, professor of medicine at the Oregon Health and Science University Cancer Institute, lamented the impact of exclusivity on access: “the price at which imatinib has been offered for sale by Novartis around the world has caused me considerable discomfort. Pharmaceutical companies that have invested in the development of medicines should achieve a return on their investments. But this does not mean 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 make the discovery of

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<sup>16</sup> See National Association of State and Territorial Aids Directors (NASTAD), ADAP-Watch (updated monthly), available at <http://www.nastad.org/Publications/adapwatch.aspx>; Kaiser Foundation, ADAP Monitoring Reports, available at <http://www.nastad.org/Publications/adapwatch.aspx>.

<sup>17</sup> Florida Department of Health, Division of Disease Control Surveillance Report 5 (2003).

<sup>18</sup> Médecins Sans Frontières, Untangling the Web of Antiretroviral Price Reductions 16 (11<sup>th</sup> ed., July, 2008) available at <http://www.accessmed-msf.org/main/hiv-aids/untangling-the-web-of-antiretroviral-price-reductions-11th-edition/>. Accessed November 6, 2008.

<sup>19</sup> Chaudhuri, Sudip. “TRIPS and Changes in Pharmaceutical Patent Regime in India,” Working Paper 535, Indian Institute of Management Calcutta (2005), available at [http://www.who.int/hiv/amds/IDA\\_India-Patent-amendments-Sudip.pdf](http://www.who.int/hiv/amds/IDA_India-Patent-amendments-Sudip.pdf).



these medicines possible.”<sup>20</sup> The proposed legislation aids action contrary to the spirit of publicly-funded research endeavors by placing access control under profit incentives for non-profit entities created to serve the public good. It furthermore undermines scientists’ autonomy in determining the degree to which their innovations are globally accessible.

In addition to blocking access to expensive drugs, such models also fail to promote biomedical research and development in areas of dire public health concern. The dearth of medicines for “neglected diseases,” which affect 90% of the world’s population but receive 10% of all health research funding, is generally caused by the lack of an adequate market to buy commercially-developed therapies.<sup>21</sup> Bayh-Dole provides no real added incentive for production of technologies for which a commercial interest believes it will not recuperate the costs of production.

#### *A “Tax” on Innovation*

While proponents of Bayh-Dole would argue that such stark profits are necessary to encourage investment into further research, evidence is mounting that – at least for publicly-funded university research – patents can form barriers to innovation as well. Numerous reports demonstrate an increase in university patenting. Yet much of the patenting is not related to a potential product per-se, but rather to research tools that are critical for further research.<sup>22</sup> Patenting of research tools is not only unnecessary; it can inhibit further downstream research and development.

The “carrot” of exclusivity offered by patenting and licensing is unnecessary for these upstream products. For example, the patented technologies underlying recombinant DNA were important innovations for biotechnology and generated large licensing revenues for Stanford, University of California, Columbia University, and City of Hope Medical Center, but patenting was not necessary for commercialization of these research technologies.<sup>23</sup> The technologies were rapidly adopted by industry even though each was licensed non-exclusively to multiple companies, meaning that the exclusivity incentive and accompanying monopoly pricing were not necessary to encourage development of these research tools.<sup>24</sup>

These rare successes in licensing brought in hundreds of millions for the institutions who executed them, yet because the licenses were not necessary to promote commercialization, they constituted an unnecessary expense for downstream researchers. As the manager of recombinant DNA licensing at Stanford put it, “[W]hether we licensed it or not,

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<sup>20</sup> Druker, Brian. “Don’t abuse patents: scientists.” August 15, 2007. *available at* <http://www.livemint.com/2007/08/15003521/Don8217t-abuse-patents-sci.html>.

<sup>21</sup> Global Forum for Health Research, 10/90 Report on Health Research 2003-2004, *available at* [http://www.globalforumhealth.org/Site/002\\_What%20we%20do/005\\_Publications/001\\_10%2090%20reports.php](http://www.globalforumhealth.org/Site/002_What%20we%20do/005_Publications/001_10%2090%20reports.php). Accessed November 4, 2008.

<sup>22</sup> Stephen Hansen, et al. “The Effects of Patenting in the AAAS Scientific Community.” *American Association for the Advancement of Science*. Second Edition. 2006.

<sup>23</sup> Anthony So, et al. *Is Bayh-Dole Good for Developing Countries? Lessons from the US Experience*, 6 PLoS Biol., e262, *available at* <http://biology.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pbio.0060262>.

<sup>24</sup> Anthony So et al. *Is Bayh-Dole Good for Developing Countries? Lessons from the US Experience*, 6 PLoS Biol., e262, *available at* <http://biology.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pbio.0060262>.



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.'"<sup>25</sup>

Such a "tax" acts as a deterrent to innovation. Aggressive profit-seeking by public institutions can exacerbate the problem, as has been the case with the excessive licensing fees that University of Wisconsin charges for patents on embryonic stem cell lines. These basic research platforms and others like them would be widely used in the absence of cost-prohibitive intellectual property protection.<sup>26</sup>

*Bayh-Dole in a Changing Landscape of Innovation: the Rise of Patent Thickets*

In some cases, upstream patents can actually block innovation entirely through the rise of patent thickets. Patent thickets develop when downstream researchers are forced to bargain with multiple patent holders to incorporate many innovations into one product.<sup>27</sup> Such complicated bargaining structures raise transaction costs and can lead to breakdown in bargaining, which can deter downstream innovators from combining and improving on initial innovations.<sup>28</sup>

The rise of such thickets was not considered by policy-makers who passed Bayh-Dole, because this legislation took place before the advent of biotechnology and the accompanying dramatic increase in the number of patentable innovations necessary to produce any one product. Scientists today are often prevented from engaging in research by inability to obtain the rights to research tools and materials. Survey data from the American Association for the Advancement of Science has shown that many researchers have changed or dropped research due to patent barriers.<sup>29</sup>

*Hidden Consequences?: A Chilling Effect on Knowledge Exchange*

As mentioned previously, the primary contribution universities make to society is in the creation and dissemination of knowledge for the public good. A legal infrastructure that promotes research linkages and knowledge networks can facilitate socially beneficial innovation. Intellectual property protection has the potential to stifle the free exchange of ideas that characterizes an academic environment free of commercial incentives. Recognition and esteem, not financial gain, are the traditional currency upon which the value of intellectual property relies in the scientific community.<sup>30</sup> Critics of Bayh-Dole in the United States point to mounting evidence that patents have a chilling effect on this exchange of ideas.<sup>31</sup> As one vocal commentator put it, "[S]omething alarming has been happening over

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<sup>25</sup> N. Reimers, Stanford's Office of Technology Licensing and the Cohen/Boyer cloning patents: An oral history conducted in 1997 by Sally Smith Hughes, Ph.D. Regional Oral History Office, (The Bancroft Library, University of California, 1998)

<sup>26</sup> Arti K. Rai and Rebecca S. Eisenberg, *Bayh-Dole reform and the progress of biomedicine*, 66 *Law Contemp. Pros.* 289 (2003).

<sup>27</sup> Michael A. Heller & Rebecca S. Eisenberg, *Can patents deter innovation? The anticommons in biomedical research*, 280 *Science* 698 (1998).

<sup>28</sup> *Id.*

<sup>29</sup> Matthew Herder & E. Richard Gold, *Intellectual Property Issues in Biotechnology: Health and Industry*. OECD Multi-Disciplinary Issues, International Futures Programme (2007).

<sup>30</sup> Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*. 94 *NW. U. L. REV.* 77, 90-93 (1999).

<sup>31</sup> Clifton Leaf, *The Law of Unintended Consequences*, *Fortune* 75 (2005), available at



the past 25 years: Universities have evolved from public trusts into something closer to venture capital firms. What used to be a scientific community of free and open debate now often seems like a litigious scrum of data-hoarding and suspicion.”<sup>32</sup>

One study showed that the patent system reduces dissemination of academic research by making academics more likely to withhold research results and data until the project is substantially completed.<sup>33</sup> Ties with industry also increase the pressure for secrecy: a 1996 study found that nearly 60% of agreements between academic institutions and life sciences companies required that university investigators keep information confidential for more than six months.<sup>34</sup> In a survey of life sciences facilities receiving NIH funding, almost a third of respondents who received a research-related gift from corporate donors stated that the donor wanted pre-publication review of any research generated.<sup>35</sup>

Pressure for secrecy prevents other scientists from building on the knowledge generated through research. A recent study found that one in four university geneticists and life scientists reported they had denied requests for post-publication information, data, or materials because they had been required to do so by an industrial sponsor.<sup>36</sup> Excessive patenting plays a central role in this cultural shift. A recent survey of US medical school faculty showed that researchers who had chosen to withhold their own research or had patented or licensed their own inventions were more likely to report being denied research results by others.<sup>37</sup>

## II. The Indian Bayh-Dole Bill Replicates and Magnifies the Mistakes of the US Bayh-Dole Act

### *Lack of Input from the public and civil society*

Issues of access to publicly funded research are hotly contested because of their implications for public health and access to scientific knowledge. As illustrated in the Fuzeon and imanitib examples, the patenting rules laid down by the government today have the potential to dramatically impact patients’ ability to access the fruits of publicly funded research years down the road.

In spite of the public interest at stake in the management of publicly funded innovations, the public and civil society were not allowed to view or comment upon the legislation during the

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<http://lists.essential.org/pipermail/ip-health/2005-September/008305.html> (originally published at: <http://www.fortune.com/fortune/fortune75/articles/0,15114,1101810,00.html>)

<sup>32</sup> *Id.*

<sup>33</sup> Jeremy M. Grushcow, *Measuring Secrecy: A Cost of the Patent System Revealed*, 33 J. Legal Stud. 59 (2004), available at <http://www.journals.uchicago.edu/doi/abs/10.1086/381288>

<sup>34</sup> D. Blumenthal et al., *Relationships between academic institutions and industry in the life sciences: An industry survey*, 334 New Engl J Med 368–374 (1996).

<sup>35</sup> E.G. Campbell et al., *Looking a gift horse in the mouth: Corporate gifts supporting life sciences research*, 279 JAMA 995 (1998).

<sup>36</sup> E.G. Campbell et al., *Data withholding in academic genetics: Evidence from a national survey*. 287 JAMA 473 (2002).

<sup>37</sup> E.G. Campbell et al., *Data withholding in academic medicine: Characteristics of faculty denied access to research results and biomaterials*, 29 Res. Pol. 303 (2002).



drafting process, which was conducted largely in secret. Details of the draft were made available to the public only recently.

#### *Overly Broad Scope*

The Indian Bayh-Dole Bill is designed to cover all forms of intellectual property, “including trademark, patent, design, and plant variety.”<sup>38</sup> By encouraging patenting across such a broad range, the bill offers no recognition of the difference between applied research that can benefit from exclusive licensing and upstream research that does not require exclusive licenses to encourage use. As a result, it has the potential to discourage a broad range of productive research activity that has previously thrived under a system of free and open academic exchange.

#### *Lack of experimental-use exception*

The Indian Bayh-Dole contains no exception for experimental or research use. A robust research exemption would do much to mitigate upstream patenting that has inhibited innovation and development in the United States. This exception should apply at minimum to all future publicly funded research. Such an exception may also work to preserve the academic norms of free and open exchange, and collaboration by discouraging propriety behavior within the research community.

#### *Lack of an effective access provision*

The United States example illustrates the need for an effective access provision. The Bayh-Dole Act recognized the need to ensure public access to publicly-funded inventions, stating the need to “ensure the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions.”<sup>39</sup> In order to meet this objective, Bayh-Dole retained for the government 1) a nonexclusive license to practice the invention on behalf of the United States,<sup>40</sup> and 2) the right to require that the holder of the patent grant an additional license on reasonable terms if such a step is necessary to develop the technology or alleviate health and safety needs (the so-called “march-in” right). While march-in rights have never been exercised to increase access in the United States<sup>41</sup> and must therefore be considered weak protection at best, the fact that the legislature included such provisions testifies to the importance of access in setting public policy. Indeed, Sam Pitroda, the Chairman of the National Knowledge Commission, who originally recommended that India adopt Bayh-Dole style legislation in January 16<sup>th</sup>, 2007, described these rights as “important safeguards,” and lists both the right to retain a license and the march-in rights as several key incentives for government to enact the new policies contained in the Indian Bayh-Dole Bill.<sup>42</sup>

The drafters of the Indian Bayh-Dole have failed to respond to these well-founded concerns over access. The only provision regarding public access gives the Indian government the right to refuse title to a research institution receiving the grant within ninety

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<sup>38</sup> The Protection and Utilization of Public Funded Intellectual Property Bill §2(c)

<sup>39</sup> 35 U.S.C. § 200 (2006)

<sup>40</sup> 35 U.S.C. § 202 (c)(4) (2006)

<sup>41</sup> Russell Korobkin, *The Taxpayers’ Stake in Stem Cell Profits*, in *Stem Cell Century* 130 (2007).

<sup>42</sup> Letter to the Prime Minister from Sam Pitroda, Chairman of the National Knowledge Commission, January 16, 2007.



days of learning of the research institution's intention to retain a patent.<sup>43</sup> In contrast to the licensing and march-in rights contained in Bayh-Dole, which are perpetual and automatic, this provision is available only for a brief, ninety-day window occurring immediately after the research institution announces its intent to retain title to a patent. The governments' rights of refusal are further limited to the grounds the refusal is "in the public interest and in exceptional circumstances."<sup>44</sup>

Such access provisions will be far less effective even than the weak protections contained in Bayh-Dole. Under the Indian analogue of the bill, the government is asked to any future public health concerns within 90 days of learning of the research institution's intent to retain title, a decision which by its nature must come at early stages of the drug's development process.<sup>45</sup> Even if the government were to somehow become aware of the implications of granting a patent during the brief ninety-day window, it is unlikely to be able to meet the burden of showing that the refusal is both "in the public interest" and "in exceptional circumstances" when the drug is in this nascent patenting stage.

#### *Undue pressure to patent*

Sections 4, 5, 7, 9, and 10 of the Indian Bayh-Dole Bill put a pressurized timeline on research institutions to decide whether or not to apply for titles to patents of IP. Section 9 requires inventors to disclose to the research institution receiving the grant "immediately" upon learning of the patent right,<sup>46</sup> and §4 requires the research institution to disclose the invention to the government within 60 days after learning of the patent.<sup>47</sup> Section 5(1) then requires the research institution to inform the government of its intention to take title to the invention within 90 days of discovery. This timeline is stricter than that contained in the Bayh-Dole Act, which only requires that recipients disclose the invention to the government within a "reasonable time,"<sup>48</sup> and offers a 2 year window in which to disclose its intentions to the government.<sup>49</sup>

The Indian Bayh-Dole Bill also requires the research institution receiving the public grant to establish IP management committees to evaluate the commercial potential for their

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<sup>43</sup> The Protection and Utilization of Public Funded Intellectual Property Bill, 2008, § 5

<sup>44</sup> The Protection and Utilization of Public Funded Intellectual Property Bill, 2008, § 5(b). Section 5 also gives the right of refusal on the grounds that the researchers are outside of India, (a discriminatory provision potentially in violation of the TRIPS agreement), that it is necessary to do so in the interest of national security, or that the property is related to atomic energy.

<sup>45</sup> Section 4 of the Indian Bayh-Dole Bill gives the researcher sixty (60) days to disclose the patent to the government after the researcher themselves receives knowledge of the patent, and § 5 gives the researcher ninety (90) days after that to inform the government of intent to retain title. At most then, the government must make a final decision on all future public health needs within eight months of patenting. Such a window is too early to establish the clinical effectiveness of the drug, a process that can take an upwards of 6 years.

<sup>46</sup> The section states "The intellectual property creator shall, immediately after the creation of public funded intellectual property, make a disclosure to Government." It is unclear from this section whether the requirement to disclose is triggered by discovery of the patentable innovation itself, which would occur at some point during the research, or creation of the patent right when the patent is granted. The definition in § 2 suggests the later in stating that the term "intellectual property" means the "*right* to intangible property, including... patent." (italics added).

<sup>47</sup> In practice, the research institution itself may often assist the inventor/employee in filing for the patent right, rendering the reporting requirements of § 9 unnecessary.

<sup>48</sup> 35 U.S.C. §202(c)(1)

<sup>49</sup> 35 U.S.C. §202(c)(2)

publicly-funded research,<sup>50</sup> regardless of whether they intend to retain title. Such provisions, enforceable through fines or loss of funding,<sup>51</sup> create unnecessary financial burdens for research grant recipients engaged in basic research that is without commercial application. Through strict timelines and other requirements, the Indian Bayh-Dole Bill puts undue pressure on researchers to patent all research, and encourages over-patenting that could impede both innovation and access.

#### *Perverse Research and Development Incentives*

In requiring research institutions receiving grants to establish and maintain IP management committees and report on licensing and revenues,<sup>52</sup> the Indian Bayh-Dole Bill creates a set of perverse incentives for research and development. Licensing is only one measure of a successful technology transfer program, which can also be measured in terms of broader social and humanitarian contributions, such as level of patient access to end products, degree to which university knowledge was useful in creating further innovations, and number of new jobs generated from patented research. Using commercial revenues to measure the success of publicly funded research ignores these other potential avenues.<sup>53</sup> Such a one-dimensional focus distorts incentives for research institutions and has the potential to detract from these other economic inputs.

Further, available empirical evidence as cited above strongly indicates that the incentive structure put forth by the proposed legislation unnecessarily sets the National Knowledge Commission's policy objectives in opposition to one another. In its 2007 *Report to the Nation*, the National Knowledge Commission claims an aim "to promote the use of knowledge capabilities in making government an effective, transparent, and accountable service provider to the citizen and to promote widespread sharing of knowledge to maximize public benefit" as a guiding principle for action. Yet it further states that Bayh-Dole legislation "is necessary to help scientific research develop far reaching innovations, generate employment, and function as a vehicle of economic growth."<sup>54</sup>

By resorting exclusively to market incentives for innovation, the Indian Bayh-Dole Bill unnecessarily sets economic growth in competition with maximized public benefit. Publicly funded innovations with healthcare implications exemplify the ramifications of such a tension, which directs innovative efforts away from current research gaps and stands to make access to socially beneficial products cost-prohibitive. Innovation policies such as those recommended by the World Health Organization's Commission on Intellectual Property Rights, Innovation and Public Health and in a recent World Health Assembly resolution 61.21, represent viable alternatives to exclusive licensing as a means of spurring

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<sup>50</sup> § 10

<sup>51</sup> § 20-22

<sup>52</sup> § 10 (d) requires that the IP management committee identify and monitor the licensing process and § 10 (e) requires that it manage revenues from the licensed property.

<sup>53</sup> Michael S. Mireles, *The Bayh-Dole Act and Incentives for the Commercialization of Government-Funded Inventions in Developing Countries*, 76 UKMC L. Rev. 525, 544 (2007).

<sup>54</sup> Government of India National Knowledge Commission, "Report to the Nation 2007" available at <http://knowledgecommission.gov.in/reports/report07.asp>.



research and development.<sup>55</sup> Patent pools and prize funds direct attention to urgent gaps in research, encourage unique research partnerships, and provide incentives for technology transfer while also promoting public access to the fruits of such endeavors. Further, current laws and regulations do not in any way prohibit the commercialization of Indian publicly-funded innovations. The implication is that in the absence of Indian Bayh-Dole legislation, intellectual property protection can be exercised in appropriate cases. The Indian government should therefore consider incentivizing innovation in needed areas using policy models which promote both innovation and access.

### **Conclusion**

The Indian Bayh-Dole Bill has serious flaws which need to be addressed in an open and public setting to determine whether any legislation should be enacted and if so what kind. Given the track record of Bayh-Dole in the United States, policy makers need to seriously consider what they hope to accomplish by enacting similar legislation, its suitability for a different country context and whether the measures adopted will accomplish the stated goals of the legislation while protecting the public interest. The current Bill, as written, should not be enacted.

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<sup>55</sup> WHO Commission on Intellectual Property Rights, Innovation and Public Health (2006) “Public health, innovation, and intellectual property rights” available at <http://www.who.int/intellectualproperty/report/en/>.