

# Replicating the Bayh-dole Model in India: How to Adapt to Indian Ecosystem?

**Lakshay Adlakha**

*School of Law, Northcap University, Gurugram, Haryana, India.*

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### \*Correspondence:

*alakshay247@gmail.com*

*School of Law, Northcap University, Gurugram, Haryana, India.*

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## Abstract

Under certain terms and conditions, the 1980 statute known as Bayh-Dole permitted small enterprises and non-profit organisations to choose to claim title to innovations that had received government funding. It was passed to offer incentives to encourage the commercialization of technologies supported by federal funding. Even now, the Bayh-Dole Act has had a substantial and long-lasting influence on American economy and innovation. The Act was passed in 1980, and since then, the U.S. economy has grown by more than \$1.3 trillion, more than 4.2 million jobs have been generated nationwide, and more than 11,000 new startups from colleges have found success. Even now, Bayh-Dole promotes American entrepreneurship, strengthening the country's ability for innovation.

On this context, this article discusses the need of Bayh-Dole in United States and given it's success, whether India needs it as well? The article also elaborates upon the protection and utilisation of public supported intellectual property bill of 2008. The article lastly discusses the concerns with regards to Bayh-Dole in Indian Ecosystem while elaborating upon the necessary recommendations.

## What is Bayh-Dole Act?

The bill's sponsors were Bob Dole of Kansas and Birch Bayh of Indiana. The Patent and Trademark Law Amendments Act, popularly known as the Bayh-Dole Act, was passed in 1980. The law governing intellectual property resulting from government funded research is US law. Instead of mandating inventors to assign ideas to the federal government, Bayh-Dole permits companies, non-profit organisations, and federally supported universities like the University of Wisconsin-Madison to pursue ownership of a creation.<sup>1</sup>

## At a glance the Act

Allows universities, small firms, and non-profit organisations to claim ownership of discoveries created during federally financed research and licence them for further applied research and development and wider public usage.

Encourages private-sector investment in basic government-funded

<sup>1</sup> Bayh-Dole Act: Regulations Impacting Ownership of Patent Rights, available at: <https://research.wisc.edu/bayhdole/> (Accessed on 13 September, 2022).

biomedical research that results in tested and approved goods, requires these products to be manufactured in the United States, and assures universities get royalties to advance basic research and education.

Allows the United States government to “march in” under certain conditions, such as when a licenced invention is not made accessible for general use, or during public health or other national emergencies.<sup>2</sup>

## Research Questions

- Why has the US government implemented BDA in federally financed research institutes, and what is the viability of a BDA-type Act in India?
- What exactly is the Protection and Use of Publicly Funded Intellectual Property Bill (PUPFIPB)-2008?
- What were the issues with the 2008 Bill, and how may Indian policymakers mitigate the harmful consequences of this Act in India?

## Objectives

The core objectives of this research paper can be summarised as follows:

- To study the practicality of a BDA-type Act in the Indian context; and
- To develop conclusive policy recommendations to raise awareness of IPRs in Indian research academia.

## The Need and Impact of Bayh-Dole Act in USA

In an effort to remedy the economic downturn of the 1970s, Congress created the Bayh-Dole Act. The US government had acquired 28,000 patents before Bayh-Dole was passed, but only around 5% of those patents had received commercial licences. President Harry Truman desired to continue and even increase government investment on research and development after World War II, which led to the accumulation of these patents.

The fundamental tenet was that inventions would remain the property of the government, which would only award nonexclusive licences

2 BIO-Bayh dole Act, available at: [https://www.bio.org/sites/default/files/legacy/bioorg/docs/BIO\\_Bayh\\_Dole.pdf](https://www.bio.org/sites/default/files/legacy/bioorg/docs/BIO_Bayh_Dole.pdf) (Accessed on 13 September, 2022).

to them. However, none of the government's funding bodies for research had a single patent policy that applied to them all. The Department of Health, Education, and Welfare (HEW) launched an international “Institutional Patent Agreement” in 1968 to allow nonprofit grantee organisations to receive assignment of patentable discoveries made with government help for which the institution had chosen to pursue patents.

By 1978, HEW or the National Science Foundation had negotiated IPAs with more than 70 academic and research institutes. Academics at Purdue University in Indiana made significant discoveries throughout the 1970s with financing from the Department of Energy, which did not grant Institutional Patent Agreements. University authorities protested to Senator Birch Bayh, whose staff investigated into it. Upon learning about concomitant issues at the same time as Senator Robert Dole, the two senators resolved to collaborate on a proposal.<sup>3</sup>

The Bayh-Dole Act has contributed to a \$1.3 trillion increase in the U.S. economy's output, 4.2 million employment, and more than 11,000 new businesses. Since the Act's passage until 2010, more than 200 novel pharmaceuticals and vaccines that were developed through public-private partnerships have been marketed. Before the Act, none had been when the government took away the patent rights from organisations that had developed the products. Research and development spending at universities climbed from 14% of the total in 1980 to 20% in 2001.<sup>4</sup> Due to the extensive commercialization of technology, the Act also gave research groups additional possibilities to preserve the quality of their research.

The Bayh-Dole Act supports the American economy, taxpayers, consumers, and patients, yet some activists oppose the law because they believe it hinders medical innovation, harms small businesses, and even compromises military readiness.

3 Ashley Stevens “The Enactment of Bayh–Dole” 29 Wayback Machine Journal of Technology 93–99(2004).

4 The Bayh-Dole Act: A Guide to the Law and Implementing Regulations, Council for Government relations, Available at: [https://www.umventures.org/sites/umventures.com/files/COGR\\_Bayh\\_Dole.pdf](https://www.umventures.org/sites/umventures.com/files/COGR_Bayh_Dole.pdf) (Accessed on 13 September, 2022).

## Landmark Judgement

The dispute began when a Stanford employee signed a contract with the biotech business promising to assign ideas resulting from his access to PCR to the company. The employee had been brought there by professors to study the proprietary method known as PCR. If Stanford was obliged by law or contract to own a particular innovation, this employee was obligated to assign it to Stanford. Roche later bought the company. Stanford filed patents on the work the employee had done there after he left the firm and returned there. Subsequently, based on the work the Stanford employee (and others) had done there, the business (and later Roche) developed products. When Stanford filed a lawsuit against Roche alleging that the company had violated its rights, Roche answered that it had a stake in the patents due to the agreement that the Stanford employee had made with the company.

The United States Supreme Court ruled on the issue, concluding that even if the inventor works as a researcher at a federally funded facility covered by the Bayh-Dole Act, title in a patent invention belongs to the inventor first. The court supported the generally acknowledged view of US Constitutional law that holds that creators are fundamentally the owners of their ideas and that any contractual obligations to convey such rights to third parties are just incidental.<sup>5</sup>

## The Protection and Utilization of Publicly Funded Intellectual Property Bill, 2008

Promote creativity and harness innovation at the home level in order to compete in the global market. The government has supported numerous academic and research institutions over the years for the purpose of research and development, but the majority of these funds have not resulted in any income for the research institution or the government due to a lack of interest in safeguarding and utilising the resulting intellectual property. This lack of interest is caused by a variety of factors, including a lack of understanding of intellectual

property rights, insufficient inventor incentives, and a lack of institutionalised accountability on the side of research institutes receiving grant money. The legislative aptly wants to address these challenges through the proposed “protection and utilisation of public supported intellectual property bill, 2008” in order to maximise the benefits of public financing to the institutions and to foster innovation at academic and research institutions.<sup>6</sup>

The Bayh Dole Act in the USA is a major source of inspiration and the basis for the Bill. The Bill aims to address the problems in Indian circumstances while largely referencing US legislation. The proposed legislation has a number of stated goals, including the following:

- to promote innovation in small and medium-sized businesses;
- to promote cooperation between the government, private businesses, and non-governmental organisations;
- to make it simpler to commercialise intellectual property resulting from publicly funded research and development;
- to guarantee that all interested parties have access to such innovations for the benefit of the public.

It uses a broad definition of “intellectual property” that include copyrights and trademarks in addition to patents, which were Bayh-primary Dole’s concern. Given this broad interpretation of IP, the Indian bill imposes severe sanctions on recipient organisations and inventors who fail to comply, including the cancellation of all current and future awards as well as other fines and penalties. Institutions would have increased responsibilities in exchange for taking government financing. They would first need to inform the government of any “intellectual property” they possess and declare their intention to keep ownership. Second, organisations receiving government funding must set up a committee to handle their intellectual property. Institutions subject to the act are likewise prohibited from disclosing or publishing research findings prior to IP disclosure. It is essential to share royalties with innovators.<sup>7</sup>

6 Salient features of Indian Bayh-Dole Act. Available at: <https://www.bananaip.com/ip-news-center/protection-and-utilisation-of-public/> (Accessed on 13 September, 2022).

7 UNCTAD - ICTSD Project on IPRs and Sustainable Development, “The Bayh-Dole Model in Developing Countries:

5 Stanford University v. Roche Molecular Systems, Inc., 563 U.S. 776 (2011).

## Comparison with US Bayh-Dole Act

First, the Bayh-Dole Act only sought to protect inventions that were patentable or that could be classified as new plant varieties under their Plant Variety Protection Act. In contrast, the Indian Act deals with intellectual property, which includes the right to trade mark, patent, design, and plant variety as defined under the various Acts.

The Indian Act, however, does not impose any restrictions on the term “utilisation,” just stating that it would include marketing. On the other hand, the US Act specifies that “practical application” would mean making the advantages of the patented discovery accessible to the general public under appropriate conditions.

The Indian Bill has no mention of the “March-in Rights,” which provide the federal government the authority to licence a patented idea in certain situations, such as when it thinks the licensee is not abiding with the rules for public use, health, or safety, although the Bayh-Dole Act does.

Fourthly, according to the Indian Act, the person who created the intellectual property will receive a share of at least 30% of any profits or royalties that result from using the innovation. The US Bayh-Dole Act does not set a minimum amount; it merely stipulates that there should be sharing.<sup>8</sup>

## Concerns with Transplanting Bayh-Dole Act in India

The Bayh-Dole Act was created with the notion that government-funded research was not being properly utilised. More than 28,000 unauthorised patents belonged to the US government in 1980. The Act transferred ownership of these works from the government to the institution or small business that conducted the research, enabling them to apply for patents covering the work’s findings. The researcher in India is the sole owner of their research, regardless of whether it was supported by the government or not. Because of employment agreements, research institutes often already have the right to patent their

ideas. As a result, unlike in the United States, there is now no requirement for enabling legislation in this area.<sup>9</sup>

In actuality, only 222 patents are licenced at this time (with 68 of them being in question), while there are now about 5173 patents held by the Council of Scientific and Industrial Research (CSIR) (including both those in effect and those under dispute).<sup>10</sup> Consequently, there is a “difficult” situation even though the IP is in the hands of the institute, much as the one that made Bayh-Dole necessary in the U.S. Thus, increased patenting will simply result in a scenario of even more unused patents, which is quite counter to the Act’s goals

The impact of the Act and its dynamics will result in the regulation of research and licence hunters, which will severely decrease publishing of research findings and so hamper inputs for various global research initiatives. The Act is based on the assumption that only patenting can encourage innovation, and it ignores other avenues for incentivizing innovation proposed by other experts, such as prize money and open-source models.

Other concerns with 2008 Bill includes:

- The act at question is more complicated and ambiguous because it encompasses all forms of intellectual property, including trademark, patent, design, copyright, geographical indicators, and plant variety. The Bill doesn’t have a clear plan for fostering successful innovation in India.
- The addition of royalties will raise consumer prices in India, where taxpayers provide public funding for R&D. Innovation and new technologies enable industries to produce public goods. These public goods ought to be more reasonably priced and accessible to everyone. While the Bill guarantees that the researchers who created the intellectual property (IP) will receive a portion of 30% of the money from royalties paid to the government. Therefore, societal commitments would receive less attention from scholars. The products would

9 Vivekanandan “Transplanting Bayh-Dole Act- Issues at Stake”, 13 Journal of Intellectual Property Rights 480-485 (2008).

10 Michael S. Mireles Jr., “The Bayh-Dole Act and Incentives for the Commercialization of Government Funded Invention in Developing Countries”, 76 UMKC Law Review 525 (2007).

Reflections on the Indian Bill on Publicly Funded Intellectual Property” (October, 2009).

8 Gina A. Kuhlman “Alliances for the Future: Cultivating A Cooperative Environment For Biotech Success” 11 Berkely Law Journal 311, 330 (1996).

be subject to two taxes, although the primary goal of publicly sponsored research is to promote social and economic development.

- Exclusive and non-exclusive licencing will be provided by this bill. In the domestic market, monopoly will result from exclusive licencing. Monopoly will set the public's price for the products at a high level. The Act does not contain any methods for adjusting product prices for consumers. Therefore, the bill's weak point would be exclusive licencing.
- The Bill will require patenting in Indian academic research, increasing the number of legal actions for scientists and researchers. Every researcher and scientist is required to inform the relevant institutions of the IP that they created during a particular time frame. The government has the right to fine or penalise researchers if they are unable to perform the same task. Penalties rules may cause researchers to conduct fewer studies and pay less attention to ensuring high-quality research.
- How do scientists or researchers decide what intellectual property is? This bill's requirement that all researchers and scientists notify the government of their intellectual property within a certain time frame is another disadvantage. Yet, "how will a researcher or scientist determine what is IP?" The inventor will submit it to the institute's intellectual property committee, as every researcher does on a daily basis. The committee will determine the IP's potential. The IP committee will then forward it to the government for consideration when deciding whether to file an IPR.<sup>11</sup>

## Prospective amendments in the Bill

### **More Discretion to the Researchers**

This greatly increases the power of the individual innovator and enables them to benefit from their innovation. The individual creator, however, has little freedom to choose how to use or market his idea

<sup>11</sup> The Role Of The Bayh-Dole Act In Fostering Technology Transfer And Implications For Innovation, available at: <https://Phrma.Org/-/Media/Project/Phrma/Phrma-Org/Phrma-Org/Pdf/A-C/Bayh-Dole-Whitepaper-Final---21820.Pdf>. (Accessed on 13 September, 2022).

despite the guarantee of a share in the earnings. The Bill grants the technology transfer office of the university or research organisation the ability to decide whether to patent an idea, therefore even if the inventor wishes to release her invention into the public domain, she cannot do so. Additionally, the right passes to the government funding agency if the receiving institution doesn't file a patent within a certain amount of time. Scientists are more likely to file a patent than governmental bodies since they have a greater stake in and understanding of the discovery.

### **Publication in Open-access Repositories**

The law should mandate that publicly financed research findings be published in open-access journals in order to better distribute them. In this regard, India might take a page from the NIH policy and add a "open access" clause stipulating that all content from publicly-funded research that is published in a peer-reviewed journal must be stored in open access institutional repositories.

### **Non-exclusive Licensing**

With more rivals than with one monopolist company, the rate of technological advancement is probably higher. Increased competition will probably result in more options and more affordable costs, which will benefit customers. Take Stanford University's recombinant DNA (rDNA) patents, which Stanford generously licenced to interested parties. Biotechnology might not have developed as quickly as it did if Stanford hadn't employed this cutting-edge method of property protection.<sup>12</sup> In light of this, the Bill ought to establish nonexclusive licencing as the norm.

### **Affordable Pricing Clause**

A clause requiring all licensees to adopt reasonable pricing practises for any patented goods made with public monies should be included in the bill as well. An exclusive licence from Yale University served as the basis for Bristol-Myers' development of the anti-HIV medication Zerit, which is based on the chemical d41. Although the licence had to be utilised

<sup>12</sup> The importance of the Bayh-Dole Act. Available at: <https://catalyst.phrma.org/the-importance-of-bayh-dole-act> (Accessed on 13 September, 2022).



for the benefit of society as a whole, BMS offered the medication in Africa for astronomically high prices<sup>13</sup>.

### **Creation of Nodal Authority**

Despite having extensive measures to control the development and use of publicly-funded intellectual property, the Indian Bill does not establish a nodal entity to manage it. In the Bill, we suggest establishing such a nodal authority.

### **Use of IP by the Government**

The government is only permitted to use intellectual property (IP) for the purpose of complying with international treaties, according to Section 13 of the Bill. This government usage should be expanded to enable it to make non-commercial use of any publicly-funded intellectual property on its own or through a specifically approved third party.

### **Creating Appropriate Research Environment**

Youth populations would develop advanced technological skills in a suitable research environment, enabling them to become entrepreneurs in the future. Additionally, it would provide a forum for academic researchers to offer their findings to businesses through technology transfer for commercialization. The manufacturing industry would then have greater prospects on the global market as a result. The import of advanced technology would be reduced, and local technology would become self-sufficient. India's ability to manufacture high-quality manufacturing goods would thereafter advance on the international market. The domestic market's demand for the goods and services provided by the manufacturing sector would also significantly improve. Thus, private sector involvement in high-tech R&D would be beneficial to foster more innovation and develop technology. The creation of R&D funds for organisations that receive public funding for

13 Basheer "Outsourcing 'Bayh Dole' to India: Lost in Transplantation?" 23(2) Columbia Journal of Asian Law (2010).

research would also be beneficial. As a result, it would increase the financial stability of publicly supported research institutions and lessen their reliance on the R&D budget of the government.<sup>14</sup>

## **CONCLUSION**

If emerging nations adopt legislation resembling the Bayh-Dole Act, they should modify it to fit their local conditions and handle any potential issues discovered by looking at how the Bayh-Dole Act affected the United States. Uncertainty exists regarding whether emerging nations that pass legislation resembling Bayh-Dole will see the same kind of impact as the US. Adopting that legislation, however, might shift government spending in favour of meeting local needs.<sup>15</sup>

In conclusion, it can be said that the Indian Bill, does not seem to have considered all of the negative consequences of the Bayh-Dole Act, despite its lofty objective of ensuring the fullest use of the outcomes of publicly financed research for the welfare of the general public through practical application and commercialization. This is evident from the fact that the public interest is significantly undervalued by the bulk of legislation. Interestingly, the Rajya Sabha's rejection of the Bill and recommendation that the government speak with stakeholders prior to reconsidering it show that the Rajya Sabha cares about the general welfare and human rights.

It would be essential to make the aforementioned changes to this Bill in order to establish a suitable research environment in India. As a result, it would continue India's inclusive growth and sustainable economic development.

14 Amit Shovon Ray, Sabyasachi Saha "patenting public-funded research for technology transfer : A Conceptual-Empirical Synthesis of US Evidence and Lessons for India," Development Economics Working Papers 22918 (2010).

15 Anthony "Is BayhDole Good for Developing Countries? Lessons from the US Experience." 6(10) PLoS Biology 262(2008).