Transplanting Bayh-Dole Act- Issues at Stake

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The Intellectual Property Regime in India is in the midst of transition with TRIPS mandated provisions finding their way into the existing laws and also looking at comparative regimes for newer legislations. One of the serious issues is that of public funded research and its direction in terms of protection. The dominant argument is that to reap the benefits through licensing these rights to create resources for themselves, a protection system is needed. It is argued that such rewards will fund their activities in an environment where State funding is shrinking. In this context there have been efforts to bring in a legislation on the lines of the Bayh-Dole Act of US to push forward ‘patenting efforts’ of public funded research and also to bring in academic–industry linkage. The Act in US itself is 25 years old and has come under the scanner of various critiques. In the Indian context it needs a critical analysis whether such a transplant will work. This article focuses on the issues at stake in bringing in such a transplant. It also traces the background of Bayh-Dole Act in US, its impact in the last two decades, its appropriateness in the Indian scenario and critical issues involved with such efforts to transplant.

Keywords: Bayh-Dole Act, Indian Patents Act 2005, Public Funded Research & Development (Protection, Utilization & Regulation of Intellectual Property) Bill 2007

To transplant (transitive) to uproot (a growing plant), and plant it in another place.

1 (transitive) To remove (something) and establish its residence in another place; to resettle or relocate.

2 (transitive, medicine) To transfer (tissue or an organ) from one body to another, or from one part of a body to another.

The Organ

The Bayh-Dole Act came into force in 1980 in United States with the aim of creating a uniform patent policy among the many federal agencies funding research to universities. The Act came into being with the efforts of the Federal agencies of Health and Human Services (HHS) and National Science Foundation due to various pressure groups which included universities like University of Wisconsin. The universities and non profit organizations primarily wanted to retain the titles of the inventions which hitherto went to the Government. They wanted autonomous patent policies to deal with their inventions. Prior to the Act these organizations had to deal with around 26 agencies to decide about the IP created by them. At a point of time, the US federal government had around 30,000 patents accrued by the efforts of the universities and non profit organizations. The effort to bring in Bayh-Dole Act is based on the aim to have a greater say in the patent policies and inventions though they were funded by the federal agencies like the National Science Foundation.

The Act basically aimed to empower universities to hold the title of the inventions funded by the Federal agencies. They in return have to protect them by patenting and to commercialize the same through licences. The money received through the form of royalties was allowed to be shared with inventors, the department/college or university and also to allocate a part to the technology transfer process.

From a historical perspective, there was a need for reliable technology transfer mechanisms and for a uniform set of federal rules to make the process work. It was tough for the federal government to transfer...
technologies for which it had assumed ownership. In 1980, the federal government had approximately 30,000 patents of which only 5% led to new or improved products. Many patents were not being used as the government did not have the resources to develop and market the inventions. Thus, Bayh-Dole gave universities control of their inventions. The salient provisions of the Act in US can be summarized as:

• The provisions apply to all inventions conceived or first actually reduced to practice in the performance of a federal grant, contract, or cooperative agreement. This is true even if the Federal government is not the sole source of funding for either the conception or the reduction to practice. The provisions do not, however, apply to federal grants that are primarily for the training of students and postdoctoral scientists.

• The university is obligated to have written agreements with its faculty and technical staff requiring disclosure and assignment of inventions.

• The university has an obligation to disclose each new invention to the federal funding agency within two months after the inventor discloses it in writing to the university.

• The decision whether or not to retain title to the invention must be made within two years after disclosing the invention to the agency. This time may be shortened, if, due to publication of research results or public use, the one-year US statutory patent bar has been set in motion. Under such circumstances, the university must make an election at least sixty days before the end of the statutory period. If the university does not elect to retain title, the agency may take title to the invention.

• Upon election of title, the university must file a patent application within one year, or prior to the end of any statutory period in which valid patent protection can be obtained in the United States. The university must, within ten months of the US filing, notify the agency whether it will file foreign patent applications. If the university does not intend to file foreign applications, the agency may then file on its own behalf in the name of the United States.

• Universities must include within the specification of the patent a notification of government support of the invention and government rights in the invention.

• If the university elects to retain title, the university must provide the government, through a confirmatory license, a non-exclusive, non-transferable, irrevocable, paid-up right to practice or have practiced the invention on behalf of the US throughout the world.

• The university must submit periodic reports regarding the utilization of the invention as requested by the funding agency, but no more often than annually.

• Any company holding an exclusive license to a patent that involves sales of a product in the United States must substantially manufacture the product in the US. Waivers of this rule may be granted by the Federal agency upon a showing that reasonable but unsuccessful efforts had been made to find a company that would manufacture the product in the US, or that manufacture in the US would not be economically feasible.

• In their marketing of an invention, universities must give preference to small business firms (fewer than 500 employees), provided such firms have the resources and capability for bringing the invention to practical application. However, if a large company has also provided research support that led to the invention, that company may be awarded the license.

• Universities may not assign their ownership of inventions to third parties, except to patent management organizations.

• Universities must share with the inventor(s) a portion of any revenue received from licensing the invention. Any remaining revenue, after expenses, must be used to support scientific research or education.

• Agencies may decide, for compelling reasons, that title should be vested in the federal government. Such decisions must be consistent with provisions within the Bayh-Dole Act and made in writing before entering into a funding agreement with a university. The agency must also file a Determination of Exceptional Circumstances (DEC) with the Department of Commerce. The NIH, for instance, has issued several DECs for programmes where NIH determined it was necessary to protect rights in intellectual property obtained from third parties.

• Under certain circumstances, the government can require the university to grant a license to a third party or the government may take title and grant licenses itself (these are called ‘march-in rights’). This might occur if the invention was not brought
to practical use within a reasonable time, if health or safety issues arise, if public use of the invention was in jeopardy, or if other legal requirements were not satisfied.  

The Arguments for Transplant

In India since independence the thrust of R & D and innovation has been a public initiative. In the emerging IPR paradigm, there is a major thrust for these institutions to capitalize the IPR regime to create rights for their creations and innovations. They are urged to reap the benefits through licensing these rights to create resources for themselves. It is argued that it will fund their activities in an environment where State funding is shrinking.

Advocacy for such a thrust is based on the following reasoning:

1. If these innovations and creations are not claimed as ‘rights’ but placed in public domain, it will only help other players to use it freely to commercialize this knowledge. Hence there will be a loss for the efforts of the publicly funded knowledge resources.

2. The creations of IP rights for Public funded institutions will also increase the direction of applied research which will help in creating essential technologies which otherwise is imported at a huge cost and also at times is denied by the technology holders in other countries by their respective trade policies.

To illustrate in Indian context - The national investment on R&D activities attained a level of Rs 18000.16 crores (450 million USD) in 2002-03. The same is estimated to be Rs 19726.99 crores in 2003-04 and Rs 21639.58 crores in 2004-05. Of these sector-wise percentage share of national R&D expenditure during 2002-03 was from Central Government 62.0%, State Government 8.5%, Higher Education 4.2%, Public Sector Industries 5.0% and Private Sector Industries 20.3%.

During the year 2002-03, 84.1% of the R&D expenditure incurred by Central Government sources came from 12 major scientific agencies CSIR, DRDO, DAE, DBT, DST, DOS, DOD, ICAR, ICMR, MICT, MNEs, MoEn and rest came from other central ministries/departments/public sector industries. Amongst the major scientific agencies, Defence Research & Development Organisation (DRDO) accounted for 30.2% of the expenditure. It is a clear factor that the funding and institutions and human resources involved in innovation is from the Government funded research base constituting around 80%.

The IP Protection of Public Research in India

The IP protection of public research output has taken a major route of filing patents in India and abroad. However, commercialization of the patents when analysed has not resulted in any significant incentive. A calculation based on the years 2001-2006 released by the Department of Science and Technology shows that a total of 612 patents granted to CSIR funded by the department but resulted in the licence of 92 patents -15% were commercialized. The Department which patented directly through its labs was around 22 in the same period resulting in 0% licensing.

On the cost spent on the IP protection for the patents for CSIR stood at 41.69 crores (and maintenance of the same stood at 25.29 lakhs total 44.22 crores and the revenue granted during the period through these assets stood at 12.64 crores –approximately 28.58 % (One crores is approximately 2.48 million USD)

The details of the patenting activity of the CSIR and DST are given in table 1. Department of Science and Technology (DST), through its Patent Facilitating Centre (PFC), has been facilitating filing of patent applications on behalf of educational institutions and governmental R&D agencies and government departments.

Table 2 gives the amount spent in various heads by DST/CSIR and table 3 gives the total money realized on licensing of US patents by DST.

### Table 1—Patenting activities of CSIR and DST

<table>
<thead>
<tr>
<th>Year</th>
<th>Patents filed</th>
<th>Patents granted</th>
<th>Patents licensed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CSIR</td>
<td>DST</td>
<td>CSIR</td>
</tr>
<tr>
<td>2001-2002</td>
<td>236</td>
<td>9</td>
<td>69</td>
</tr>
<tr>
<td>2002-2003</td>
<td>255</td>
<td>5</td>
<td>149</td>
</tr>
<tr>
<td>2003-2004</td>
<td>201</td>
<td>2</td>
<td>141</td>
</tr>
<tr>
<td>2004-2005</td>
<td>135</td>
<td>-</td>
<td>142</td>
</tr>
<tr>
<td>2005-2006</td>
<td>115</td>
<td>6</td>
<td>111</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>942</td>
<td>22</td>
<td>612</td>
</tr>
</tbody>
</table>

### Table 2—The amount spent in various heads by DST/CSIR

<table>
<thead>
<tr>
<th>Year</th>
<th>Filing and prosecution fees</th>
<th>*Attorney charges Maintenance fees</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001-2002</td>
<td>557.60</td>
<td>19.30</td>
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<tr>
<td>2002-2003</td>
<td>953.37</td>
<td>42.77</td>
</tr>
<tr>
<td>2003-2004</td>
<td>953.64</td>
<td>41.80</td>
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<tr>
<td>2004-2005</td>
<td>916.61</td>
<td>56.56</td>
</tr>
<tr>
<td>2005-2006</td>
<td>806.18</td>
<td>92.50</td>
</tr>
</tbody>
</table>

* included in filing fees and maintenance fees—total
The total money realized on licensing of US patents by CSIR during the period was Rs 1264 lakhs and by DST is given in table 3.

In this context, the advocates for a transplant of Bailey-Dole type of transplant are aiming for a repeat of the US experience in India context which will unleash autonomy of institutes to collaborate with industry and also incentivise the researcher to give a fillip to patents.

To Transplant or not to Transplant?

The original Act in US has completed 20 years of its inception and impact and there are contradictory audit results emanating at this point of time. Prior to Bailey-Dole, fewer than 250 patents were issued to universities per year. In the year 2000, there were over 330 US and Canadian institutions and universities engaged in technology transfer. Technology transfer has helped to spawn new businesses, create industries and open new markets. In fact, core technologies, likely to spark new industries, often result from university patents. University-industry collaborations have helped to move new discoveries from the lab to the marketplace faster and more efficiently than ever before ensuring that products and services based on federally funded research reach the public (Fig.-1).

The reason that the Bailey-Dole Act is so instrumental to university technology transfer that it speeds up the commercialization process of federally funded university research and helps new industries to develop quicker. Examples range from Stanford’s Cohen-Boyer patent on the basic gene splicing tools - to the Axel patents, from Columbia University which provided a completely new process for inserting genes into mammalian cells to make protein. Bailey-Dole has also enabled laboratory advances to become a significant factor in US and Canadian industrial growth. The Bailey-Dole Act is also vital to the university as a whole. University gross licensing revenues exceeded $200 million in 1991 and by 1992 that number had risen to $250 million. In the year 2000, US and Canadian institution and universities gross licensing income is reported in the AUTM survey at $1.26 billion. The Association of University Technology Managers in its statement to the Senate Committee on the Judiciary on the ‘Role of Federally Funded University Research in the Patent System’ on October 2007 submitted the following in favouring the act and it’s working as:

University research helped create whole new industries like biotechnology and is now a leader in the rapidly growing field of nanotechnology.

- More than 5,000 new companies have formed around university research, the majority locating in close proximity to the university. Such companies are vital to continued economic growth.
- University patenting exploded from just 495 issued patents in 1980 to 3,278 in 2005.
- In the latest AUTM survey, universities helped create 527 new products in 2005 alone and 3,641 new products since 1980. 4,932 new licenses were signed in one year alone.
- 28,349 current licenses were in place, each representing a one on one partnership between a company and a university. The great majority of these licenses are going to small companies.
- 628 spin-off companies were created or 1.7 new companies every day of the year. This represents 1.25 new products based on academic inventions introduced every single day over the last eight years.

The Percentage of Patents Granted to Research Universities

According to the National Science Foundation, industry support for academic research has grown faster than any other funding source. Industry

<table>
<thead>
<tr>
<th>Year</th>
<th>Filing fees</th>
<th>Attorney charges</th>
<th>Maintenance fees</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001-2002</td>
<td>4.08</td>
<td>6.07</td>
<td>-</td>
</tr>
<tr>
<td>2002-2003</td>
<td>1.60</td>
<td>3.60</td>
<td>-</td>
</tr>
<tr>
<td>2003-2004</td>
<td>0.90</td>
<td>2.47</td>
<td>-</td>
</tr>
<tr>
<td>2004-2005</td>
<td>-</td>
<td>-</td>
<td>1.23</td>
</tr>
<tr>
<td>2005-2006</td>
<td>2.40</td>
<td>3.52</td>
<td>-</td>
</tr>
</tbody>
</table>

* No patent was licensed by DST
financing expanded from 3.9% of university R&D in 1980 to 7.2% in 2000, although by the year 2003 industry support had dropped to 5.2% of academic R&D due to market conditions. In 1980, federal financing comprised 67.5% of the total academic undertaking; by 2000 federal support declined to 58.2% of university funding, yet increasing to 60.8% in FY2003.7

On the flip side, the recent studies question the impact of Bayh-Dole Act where in the arguments range from the coincidence of the stimulus and response to that of fundamental argument against the Act itself. In a study conducted by Professor David Mowery (University of California, Berkeley) and his colleagues concluded “...little impact on the content of academic research.” The pursuit of patenting and licensing at universities has expanded because of changes in biomedical and biotechnology R&D, not because of the act.8

The above authors went on to publish a much sited work of ‘Ivory Tower’ and Industrial Innovation: University-Industry Technology Transfer Before and After the Bayh-Dole9 which argued that the Act will impede the progress of science and technology itself. However other critics questioned the analysis of their work on the ground that it does not clearly counter the reason for the rapid growth in university patenting and further the growth percolated to middle level universities from the toppers in the matrix. The critics further argued about the collateral effect of the Act which provided the impetus for venture capital industry to bet upon start-up companies and the commercialization of the same.10 Bruce Lehman, President of the International Intellectual Property Institute opines ‘Bayh-Dole caused a whole mind-set change in academic and technology communities so now there is a culture to commercialize,’ says Lehman. ‘All these countries go to the same conferences and meetings. They have been persuaded that this [change] is in their interest, and they want to become technological powers.’11

Arguments Against Transplant

The Indian Patent Act of 1970 was amended in 1999 and 2001 in response to the TRIPS Agreement and went through the final change in 2005 through to usher in product patent for drugs, food and chemicals.12 The amendment itself created a huge debate among the various stakeholders of the civil society before it got its assent. The amended act also resulted in a major litigation challenging certain provisions which attracted wide attention in the country and outside. Amidst these issues the public policy choice of steering the public funded research has gained momentum.

One such move is to bring a Bayh-Dole type of Act in Indian context to effect speed and incentive to public funded research in terms of granting titles to research institutions and researchers involved. The draft of the bill referred as Public Funded Research and Development (Protection, Utilization and Regulation of Intellectual Property) Bill, 200713 which has been in circulation and consultation has not been made public for discussion resulting in various speculations among the media, civil society groups and IP blogs.14

The concerns of such a transplant can be summarized as follows:

1. The thrust of a Bayh-Dole type of Act will shift the research focus from traditional fundamental and basic research to that of ‘market oriented short term research’ due to the thrust on patenting and licencing to private players. The private players are driven by its stock stake holders who expect quarterly results of the scrips and may be constrained to prioritize the long term issues of health and vulnerable groups of society.

2. The impact of the Act and its dynamics will result in the control of the research and licence hunters and thereby will drastically reduce publishing of the research findings and thereby will hamper the inputs for various research efforts of the world.

3. The Act is premised on the hypothesis that only the patenting route can spur innovation and ignores other routes for incentivising innovation mooted by various scholars through prize money and open source models15

4. The Act will arm the Technology Transfer Office to go for exclusive licences which will be demanded by industries to safeguard their monopoly and will deprive other start-ups or public interest entities and thereby will deprive the consumers of a wider choice of manufacturers.16

5. The Act will not motivate the title holding entities to ‘march in’ for effecting price controls which will benefit consumers as the ‘pricing mechanism’ will be determined by the exclusive licencee which predominantly will be private players.
Conclusion

The arguments against the transplant can be divided into two polarities—those who are ideological against the ‘Patent route of innovation’ and those who are ‘OK with patent—but one size does not fit all’. The first school of advocates argue for a ‘minimalist approach’ where the act if transplanted will subject public funded research to the market machinations and will fundamentally alter the focus and flow of research to ‘profit’ agenda. The second school is per se not opposed to such a type of act with a ‘mixed approach and argues for a modified organ to be transplanted than the original organ to include the issues of accommodating non-exclusive licences, clear provisions of compulsory licences, ‘public domain’ discretion.

One of the major concerns is that of the legislative process which does not have an effective participation of stake holders which may end up putting the cart before the horse. The success of any transplant certainly requires the in depth study of the patient in the theatre. This requires the consultation of many specialists and the surgery is the last act.

References

2  The Bayh-Dole Act or University and Small Business Patent Procedures Act is the United States legislation dealing with intellectual property arising from federal Government-funded research. Adopted in 1980, Bayh-Dole is codified in 35 U.S.C. § 200-212, and implemented by 37 C.F.R. 401. Among other things, it gave US universities, small businesses and non-profits intellectual property control of their inventions and other intellectual property that resulted from such funding. The Act, sponsored by two senators, Birch Bayh of Indiana and Bob Dole of Kansas, was enacted by the United States Congress on 12 December, 1980.
3  http://www.ucop.edu/ott/faculty/bayh.html (1 August 2008).
4  www.nstmis-dst.org .
13  Note : The name of the bill is not officially confirmed by the Government and is often quoted in media and blogspots .
14  spicyipindia.blogspot.com.
17  http://www.business-standard.com/india/storypage.php?autono=328187, Dinesh Abrol, senior scientist with the National Institute of Science, Technology and Development Studies (NISTADS) of Delhi who says universities must be allowed to maintain their mission of diffusing knowledge independent of state and market and without subordinating them to corporate interests (2 August 2008).