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PROTECTION AND UTILISATION OF PUBLIC FUNDED INTELLECTUAL PROPERTY BILL 2008 – A CRITICAL ANALYSIS OF THE INDIAN BAYH-DOLE ACT

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On the face of it, The Protection and Utilisation of Public Funded Intellectual Property Bill, 2008 appears to be a progressive piece of legislation. Modelled on the American Bayh-Dole Act of the 1980s, the Act makes it mandatory for institutions to create well-defined intellectual property rights over any innovation arising out of publicly funded research and also to exploit these innovations commercially. Universities, research centres, laboratories etc. would thus be able to reap the financial benefits of their innovative work which, it is hoped, would spur on further innovation. There is, however, much to suggest that the Bill in its present form may not be the panacea that it has been touted to be and there is a need to take a closer look at the apparent success of the Bayh-Dole Act in America and in that context to undertake a rigorous examination of the relative merits and demerits of the Act not only to explore the possibility of improving upon the model but also to better adapt it to the different scenario that India presents. Once the Parliamentary Standing Committee on Science & Technology, Environment & Forests gives its report on the Indian Bill, it will be the prerogative of the Parliament to discuss and debate on the Bill. This article thus seeks to highlight certain issues that the legislature should take into account when considering this Bill.

I. INTRODUCTION

The Protection and Utilization of Public Funded Intellectual Property Bill, 2008 seeks "*to provide incentives to increase innovations, collaborations, licensing and commercialization in India*."[1] The Bill is based on the belief that there should be a uniform legal system for vesting clearly defined property rights

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1 Sam Pitroda, Chairman, National Knowledge Commission, *Letter dated January 16, 2007 to the Prime Minister*, available at http://www.knowledgecommission.gov.in/downloads/recommendations/LegislationPM.pdf (Last visited on September 10, 2009).

with regard to public funded research innovations in universities and research institutions. This coupled with the mandatory direction to take steps to utilize the innovation commercially, it is hoped, would not only increase the probability of transformation of academic research into viable products but also provide impetus for research and development in the country.

It is interesting to note that these were some of the very reasons for which The University and Small Business Patent Procedures Act,1980 (more commonly known as the Bayh-Dole Act) was introduced in the United States of America (*hereinafter* US) over three decades ago. The National Knowledge Commission (*hereinafter* NKC) in fact recommended the modeling of the proposed Indian legislation on the Bayh-Dole Act.[2] This is largely because of the popular perception that the Bayh-Dole Act is the harbinger of innovation, especially in the field of biotechnology, in the US and the perceived possibility of re-creating the model in other countries.[3]

However, there has been criticism against the adoption of a Bayh-Dole styled legislation in India. Critics argue that the Bayh-Dole Act has not really been the success that it has been touted to be in the US and the Act may have in fact worked in detriment to its stated objective of incentivizing innovation.[4] Furthermore, even if the Act was a success, there is the question of the rationality of importing it into India without making adequate modifications to take both changes in the time and place into consideration.[5] Organizations such as Universities Allied for Essential Medicines (*hereinafter* UAEM) have concluded quite emphatically after perusing the text of the proposed Act that *"the current Bill, as written, should not be enacted"*.[6]

In the light of this raging debate, it is important to not treat the Bill as a wonder drug in the first instance. There is need for a rigorous examination of the relative merits and demerits of the Act. This article therefore will try and highlight certain issues that the Parliament should take into account when considering this Bill, following the submission of the report on the same by the Parliamentary Standing Committee on Science & Technology, Environment.

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[2] *Id.*

[3] Helen Davison, *Public-Private Partnership: The Role of IPRs*, available at http://www.stockholm-network.org/downloads/events/HelenDavison.pdf (Last visited on September 10, 2009) (Brazil, South Africa, China are examples of other developing countries that have also adopted Bayh-Dole styled legislations).

[4] Dov Greenbaum, *Academia to Industry Technology Transfer: An Alternative to The Bayh-Dole System For Both Developed And Developing Nations*, FORDHAM INTELL. PROP. MEDIA & ENT. L. J. 311, 318-19 (2009).

[5] *See* Ann Weilbaecher, *Lost In Translation? The Promises and Pitfalls of Enacting US Bayh-Dole Style Legislation In India,* 14 PUB. INT. L. REP. 157.

[6] Annette Lin *et al.*, *UAEM White Paper on the Proposed Indian Bayh-Dole Analogue the Bayh-Dole Act and Promoting the Transfer of Technology of Publicly-Funded Research*, available at http://www.essentialmedicine.org/wordpress/wp-content/uploads/2008/11/uaem-white-paper-on-indian-bd-act.pdf (Last visited on September 10, 2009).

II. BAYH-DOLE ACT IN THE US

The University and Small Business Patent Procedures Act,[7] better known as the Bayh-Dole Act (due to the two senators Birch Bayh and Bob Dole who had introduced the Bill in the Congress) was adopted in the year 1980 by the US Senate. The Act was meant to rectify the lacunae surrounding the federally funded research work in the US as the lack of proper patenting and licensing of the innovations churned out by the universities meant that the successful commercialisation of the innovation was difficult. This was properly identified by the US Congress and they came to the conclusion that it was important to streamline the process of patenting and licensing the innovations which emerged out of publicly funded research activities through mandatory patenting and licensing and became key features of the Bayh-Dole Act.[8]

It was hoped that providing clearly defined property rights in public funded research would not only promote a culture of innovation but also that the mandatory clause on commercialisation would mean that the tax payers would get their due share back as the innovation would be available in the market. It would also herald greater academia-industry linkages which would help increase the revenue of the universities and research organizations and provide incentives to researchers who could make a profit through these new provisions.[9]

The success of the Act however has been the focus of a plethora of discussions. For some observers, the Act has been instrumental in bringing up the level of innovation in the American academia, especially the biotechnology industry and they point to statistical data in support. For example, in 1979 only about 264 patents were obtained by US Universities. In 2003, this number had increased to over 3450 patents. Apart from this, the Act played an important role in the increase of corporate funding for the universities. It increased from 2.3 percent in the early 1970s to almost 8 percent by the year 2000.[10] However the counter argument to this is that the scientific breakthroughs in the life sciences[11] at that time and the dramatic increase in investment in the biotech industry[12] would have ensured a flood of innovation on its own, independent of the Bayh-Dole Act and the impact of the Bayh-Dole Act in the US has been exaggerated.

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[7] The University & Small Business Patent Procedures Act, 1980, 35 U.S.C. §§ 200-212.

[8] *Id.*

[9] Sara Boettiger & Alan Bennett, *The Bayh-Dole Act: Implications For Developing Countries,* 46 IDEA 261, 267 (2006).

[10] Risa L. Lieberwitz, *The Corporatization Of Academic Research – Whose Interests Are Served?,* 38 AKRON L. REV. 759, 765 (2005).

[11] *Supra* note 4 (Such as Paul Berg's success in producing recombinant DNA in 1972, creation of the first monoclonal antibodies in 1975 by Kohler and Milstein, sequencing of strands of DNA by Maxam and Gilbert, and Sanger in 1977).

[12] For example, equity investments in biotechnology companies increasing from $50 million to over $800 million between 1978 and 1981.

Critics also feel that the Bayh-Dole Act may, in the long run, in fact have impeded innovation rather than stimulated it. This is based on the concept of 'Tragedy of the Anticommons' which sets out that if a large number of people are given the right to exclude others from making use of a single property, then there could arise a situation in which the property will be underutilized.[13] Thus, the proliferation of property rights on basic research tools necessary for any further innovation in the biotechnology field may prevent any single party from being able to innovate as it would involve the difficult task of consolidation of property rights disseminated over multiple parties. Furthermore, the transaction costs involved in this process of patenting and licensing may take away any real benefit of the Act and it has been observed that transaction costs may prove higher than the gains obtained by the universities from those providing corporate funding.[14]

There has also been much backlash against the phenomenon of 'double-paying'[15] which is seen as a flaw in the Act. This theory sets out that that the public had to pay twice: once, while funding the research activity that resulted in the innovation and then again when paying a supra-competitive price that the private companies usually charge using their monopolistic position as exclusive licence holders.

There has also been criticism regarding what is seen as the changing nature of the university from that of a public institution with a goal to achieving public interest to that of a private research and development (*hereinafter* R&D) laboratory serving the interest of its corporate partners and aimed at filling its own coffers. It has been alleged that the Act goes against the fundamental nature of universities which is rooted in principles of 'knowledge sharing'.[16] A 1996 study, for example, found that nearly 60 percent of agreements between academic institutions and life sciences companies required that universities keep information confidential for more than six months. Thus dissemination of publicly funded research is stifled by these prohibitions to publication of research results for extended periods of time[17] even though the National Institute of Health (*hereinafter* NIH) has suggested that the universities should not allow commercial enterprises to restrict the publishing of research beyond a period of one or two months.[18] In this regard, it has been alleged that the drive for commercialization has resulted in research activities getting limited to the

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[13] Gary Pulsinelli*, Share and Share Alike: Increasing Access to Government-Funded Invention Under the Bayh- Dole Act,* 7 MINN. J. L. SCI. & TECH. 393 394, 395 (2006).

[14] Clovia Hamilton, *University Technology Transfer and Economic Development: Proposed Cooperative Economic Development Agreements under the Bayh-dole Act,* 36 JOHN MARSHALL L. REV. 397, 407 (2003).

[15] *Supra* note 13.

[16] *Supra* note 14.

[17] *See generally,* Eyal Press & Jennifer Washburn, *The Kept University*, THE ATLANTIC MONTHLY (Boston) Vol. 285, No. 3, March 1, 2000, 39.

[18] *Supra* note 14.

development of commercially viable products with public funds being diverted to activities likely to result in commercial products rather than towards basic research. Thus, it is felt that the freedom of universities and research organizations has been stifled with the increasing domination of commercial interest both from within and outside the universities. There is need therefore to address these concerns even if assuming that the Bayh-Dole Act enabled the American research institutions to develop as never before.

III. THE BAYH-DOLE ACT IN INDIA

A. REASONS FOR INTRODUCTION

The National Knowledge Commission had felt that for greater levels of knowledge creation and application in India, there was a need to provide an impetus to government-funded research and to translate this knowledge into applicable products for the public. It was suggested that making a clearly-defined and uniform system of property rights and licensing would hopefully help in the translation of R&D to viable products.[19] The rationale behind this is that patent law helps to prevent others from free-riding on the efforts of the inventors thus helping to retain the value of innovation and spurring further such activities. It provides a right to prevent others from making, selling, or using an invention which is an incentive for capitalists to invest in commercialization of an invention as they are guaranteed exclusive control over it.[20]

This is not to suggest that before the proposed Bill, such an understanding did not exist in India. Some notable universities and research labs in India such as the Indian Institute of Technology, Jawaharlal Nehru University and the research laboratories of the Council of Scientific and Industrial Research (*hereinafter* CSIR)[21] have had patenting policies and transfer technology offices in place even before the Bill. CSIR, for example, has encouraged a policy of '*Patent, Publish and Prosper'* and is considered as one of the leading patenting organizations from the developing countries.[22] IIT Kharagpur, through its Transfer Technology Group, has already several new technologies in the pipeline for commercialization – which were promoted at their annual workshop Ind'Ac – for academia-industry interaction.[23]

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[19] *Supra* note 1.

[20] *Supra* note 13, 394 -95.

[21] The Council of Scientific and Industrial Research is a grouping of 37 public funded laboratories across India engaged in diverse fields of research – from agriculture to aircraft parts.

[22] Rekha Chaturvedi, *Conference on Publicly Funded Patents and Technology Transfer: A Review of the Indian "Bayh-Dole" Bill,* NUJS, held on September 12, 2009. *See also Potent Patents*, BUSINESS WORLD, May 19, 2003, available at http://www.ncl-india.org/aboutncl/Potent_Research.pdf (Last visited October 20, 2009).

[23] *A Report on IndAc'2008 Industry and Academia Interaction,* available at http://www.ttg-sric.iitkgp.ernet.in/indac/indac.pdf (Last visited on October 20, 2009).

However there has been debate as to whether initiatives taken up at the level of universities or research laboratories alone would be enough to bridge the gap between research and commercialisation. CSIR itself is a classic example of the proverbial slip between the cup and the lip, since, even though it holds a record for the highest number of patents, yet successful commercialisation has only been possible in a handful of cases.[24] Also, success stories seem restricted to a few specialised institutions which have had the capability and infrastructure to follow a policy of patenting and licensing, while most research and development in other institutions languishes.[25] Academia-industry linkages, though welcomed by both academia and industry, have never been actively pursued due to what is perceived to be a lack of incentives. It was hoped that conferring ownership rights of innovation to universities, subject to product commercialisation, would render research not only more attractive but also make available to the public, the practical results of their funding.[26] The Bayh-Dole Act was considered as a guiding piece of legislation for the Indian Bill, as its core aim of streamlining the process of patenting and licensing the innovations which emerged out of publicly funded research activities was the key feature that was hoped to be emulated by the Indian Act. The apparent stellar success of the Act in America also seems to have played a large role in inspiring the Indian government in recreating the same model.[27]

B. THE INDIAN BILL VIS-À-VIS THE BAYH-DOLE ACT

The Indian Bill's provisions are based largely on the Bayh-Dole Act and contain almost similar stipulations. The provisions of the Bill require that a potential recipient of public funds for research must enter into an agreement with the government prior to receiving a grant by which it agrees to make disclosures of any public-funded innovation that is created. It must then decide within a stipulated period of time whether to retain the title of the intellectual property. If it decides to retain it, then it is under a duty to file for intellectual property right and to take all steps to protect it. Furthermore, it must also work towards utilization of the intellectual property. The recipient is also expected to set up Intellectual Property Management Committees which would be in charge of these activities.[28] In its basic structure, the Indian Bill thus resembles its American counterpart; yet, a comparative perusal of the provisions of the Indian Bill as opposed to the Bayh-Dole Act brings to light some interesting deviations.

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[24] *Supra* note 10.

[25] Dr. Vivekananda, *Conference on Publicly Funded Patents and Technology Transfer: A Review of the Indian "Bayh-Dole" Bill*, NUJS held on September 12, 2009.

[26] *Supra* note 1.

[27] *Supra* note 5,157-58.

[28] *See* The Protection And Utilization Of Public Funded Intellectual Property Bill 2008, available at http://www.prsindia.org/docs/bills/1229425658/1229425658_The_Protection_and_Utilisation_of_Public_ Funded_Intellectual_Property_Bill_2008.pdf (Last visited on September 10, 2009).

First, while the Bayh-Dole Act sought only to protect inventions which were patentable or could be classified as new plant varieties under their Plant Variety Protection Act,[29] the Indian Act deals with intellectual property which is inclusive of the right to trade mark, patent, design, and plant variety as defined under the various Acts.[30] Thus, as regards scope of IPR, the Indian Act seems to have a wider coverage. On the other hand, the Bayh-Dole Act seems to allow more extensive funding arrangements as the contractor with whom a Federal Agency may have a funding agreement may not be only universities or non profit organizations, but also persons and firms.[31] The Indian Bill, in this case, only talks of funding arrangements with universities, non-profit institutions and organizations set up by Parliamentary Acts.[32] Thus with regard to contracting parties, the Indian Act is restricted in its application.

Second, while dealing with the utilization of the patented innovation, the US Act provides that "practical application" includes that its benefits are to be made available to the public on reasonable terms;[33] the Indian Act, however, provides that "utilization" would involve commercialization and it does not attach any terms and conditions to this term.[34]

In this regard it is important to note thirdly that while the Bayh-Dole Act has a substantial clause dealing with the "March-in Rights"[35] wherein the Federal Agency may step in and license a patented innovation in certain circumstances which include: when it feels that the requirements for public use, health or safety are not being satisfied by the licensee, the Indian Bill is silent in this regard.

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[29] *Supra* note 7, § 201 **"**(d) The term "invention" means any invention or discovery which is or may be patentable or otherwise protectable under this title or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321 et seq.)."

[30] *Supra* note 28, § 1 "(c) "intellectual property" means any right to intangible property, including trade mark, patent, design, and plant variety as defined under the Copyright Act, 1957, the Patents Act, 1970, the Designs Act, 2000, the Semiconductor Integrated Circuits Layout-Design Act, 2000, and the Protection of Plant Varieties and Farmers' Rights Act, 2001."

[31] *Supra* note 7, § 1 "(c) The term "contractor" means any person, small business firm, or nonprofit organization that is a party to a funding agreement."

[32] *Supra* note 28, § 1 "(e) "recipient" includes a University or institution of higher education established for research purposes which has entered into an agreement with the Government under §3, and includes an organisation established by an Act of Parliament or a non-profit scientific or educational organisation registered under the Societies Registration Act, 1860;"

[33] *Supra* note 7, § 1 "(f) The term "practical application" means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms."

[34] *Id.*, § 1 "(h) "utilisation" means the manufacture of a composition or product, the practice of a process or method, operation of a machine or system, or commercialisation thereof."

[35] *Supra* note 7, § 203.

Fourthly, the Indian Act provides that the intellectual property creator will be given a share of not less that thirty percent of the income or royalty generated by utilization of the invention.[36] The US Bayh-Dole Act only has the requirement that there should be sharing; however, it does not specify a minimum amount.[37] Thus the Bill only deviates in some details from the US Act and the effects of these similarities as well as deviations will be analyzed in the next part.

IV. THE IMPACT OF AN INDIAN BAYH-DOLE ACT – A CRITICAL ANALYSIS

The purported success of the Bayh-Dole Act in the US has been a contentious issue and it is important, when trying to look at the impact of the Act in India to examine at the reasons why the Act may fail to meet its stated objectives if passed in its current form. The arguments for the same are manifold. First, it is sought to be shown how the high transaction costs involved might mean that the universities may run this model in loss. Second, these transaction costs are likely to increase even more due to this Act creating a 'Tragedy of Anticommons' which may stifle the very innovation that is hoped for. Third, even if the innovations were to reach the market, they may be prohibitively expensive in case the companies charge supra-competitive prices by exercising their position as exclusive licensors under the Act and thus adversely affecting the public which had paid for the innovation in the first place. Lastly, it is debatable whether the industry-university linkages that is hoped to be built up through this Act may cause a larger adverse impact on the society at large. The reasons substantiating such an analysis are as follows.

A. THE TRANSACTION COSTS INVOLVED ARE HIGH

Prior to the Bayh-Dole Act in the US, less than four percent of all government funded research was ever commercialized, which has since increased substantially.[38] Furthermore, between 1991 and 2000, the revenue earned through royalties in universities had increased by over 520 percent.[39] It is, however necessary, to put these statistical leaps in figures in their right context. It has been argued that only a few universities have actually made much money after Bayh-

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[36] *Supra* note 28, § "11. (1) The income or royalties arising out of the public funded intellectual property shall be shared as under:— (a) subject to the provisions of any agreement which may be entered into between the intellectual property creator and the recipient, not less then thirty per cent of such income or royalties, after deducting the expenses incurred in protection and utilisation, shall be given to the creator of intellectual property: Provided that where such agreement has a provision for a lesser amount than thirty per cent. of the net income, the provisions of this section shall prevail;"

[37] *Supra* note 7.

[38] Gina A. Kuhlman, *Alliances for the Future: Cultivating A Cooperative Environment For Biotech Success*, 11 BERKLEY L. J. 311, 330 (1996).

[39] *Supra* note 10, 765.

Dole,[40] most only making enough to cover expenses while others not even able to recoup their costs.[41] This is, in part, due to the high transaction costs involved in technology transfer. The two contracting parties may have differences in perception as to the likely results of a project, the potential commercial value of an innovation and the benefits of the patent, which make it difficult for the parties involved to agree on a price for the licence, driving up transaction costs.[42] The incomplete nature of information available to the negotiating parties regarding the future commercial potential of an invention may result in exaggeration of the likely value of the innovation which also adds to the costs.

The Indian Act is likely to drive up these costs even further. The Indian universities through their Intellectual Property Management Committees (comparable to the Technology Transfer Offices (*hereinafter* TTO) of the US universities) are expected to undertake the patenting, protecting, marketing and licensing of intellectual property. However, the Indian Act places shorter time constraints on the performance of these actions when compared to the US Act. Within sixty days of knowledge of a publicly funded intellectual property, the university has to intimate the government about it.[43] After this, within ninety days, the university has to decide whether to retain the title or not. Once the university has retained the title, it is bound by law to apply for protection of IPR, which has to be followed immediately by steps to commercialize the product – a written report of which has to be filed in less than six months from the date of filing for protection.

Thus the Indian universities are given very little time to balance out the costs (involved in patenting and licensing) and potential commercial value of the public funded intellectual property created by them. They have to, almost immediately, retain the title of the intellectual property or risk losing it altogether. This may result in rampant patenting of academic research and innovation with no thoughts as to its commercial viability. This problem is faced already by CSIR where many patents are obtained on research which is later stalled as there is need for further research and development before the product can be made commercially available.[44] Furthermore, the fact that the Universities are time bound to show results regarding commercial utilization of inventions, may place them at an unequal bargaining position vis-à-vis the industries during negotiations as they may be forced to prefer a bad deal over a no-deal situation.

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[40] *Supra* note 9.

[41] *Supra* note 4, 319-20.

[42] Michael S. Mireles, *An Examination of Patents, Licensing, Research Tools, And The Tragedy Of The Anticommons In Biotechnology Innovation*, 38 Univ. Mich. J. L. Ref. 141, 171 (2004).

[43] *Supra* note 28.

[44] *Supra* note 22

The Bayh-Dole Act in US, on the other hand, gives the universities up to two years to decide whether to obtain IPR for their innovation, thus giving them time to make the necessary cost-benefit analysis. Even then, as already suggested, the universities' cost of transferring technology is high, raising the pertinent question as to how much higher it is likely to be in the Indian scenario and whether the universities will actually be benefited.

Furthermore, the Intellectual Property Management Committees are essentially meant to be self-financed institutions that will have funds arising out of the royalties generated by the university innovations. However it has been seen that most Technology Transfer Offices run in losses[45] and thus may not be able to have the capacity and attract the expertise needed for successful commercialization. In addition, TTOs have been found to sometimes add further impediments to actual commercialization with delays, ad-hoc basis of deciding as to which products to patent and commercialize.[46] It is thus doubtful as to how successful the Intellectual Property Management Committees are likely to be in commercializing public funded innovations, especially as the Act is silent on any form of capacity-building measures for these Committees.

B. THE TRAGEDY OF ANTICOMMONS THAT IS LIKELY TO RESULT

The Tragedy of Anticommons is a phenomenon which is the inverse of the well-known economic principle of the Tragedy of Commons. A Tragedy of Anticommons is said to occur if too many people own private property rights in a piece of property and no one person is able to exercise his right as it is blocked by the rights of the others.[47] In the field of biotechnology, it has been suggested that a patent thicket has emerged, wherein a large number of parties own multiple patent rights especially on basic research tools which create impediments to further research and development.[48] In a patent thicket, it becomes necessary for new researchers to bargain with multiple patent holders in order to incorporate a number of innovations into one product or even to utilise the various research tools necessary in order to produce an innovation. There is no surety that such bargaining will be successful. Furthermore, the cost of bargaining with several different parties is likely to be substantial.[49] The need for multiple pieces of property rights is likely to also create the problem of strategic hold-out among research tool patent holders thus driving up costs. Survey data from the American Association for the Advancement of Science has, in fact, shown that many

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[45] *Supra* note 4, 319-20.

[46] Dr. V Premnath, *Conference on Publicly Funded Patents and Technology Transfer: A Review of the Indian "Bayh-Dole" Bill*, NUJS held on September 12, 2009.

[47] Michael S. Mireles, *Adoption of The Bayh-Dole Act In Developed Countries: Added Pressure For A Broad Research Exemption In The United States?*, 59 ME. L. REV. 259, 261 (2007).

[48] *Supra* note 42, 148.

[49] *Supra* note 6.

researchers have been forced to modify or abandon research altogether due to patent barriers.[50] For example, the presence of several private patents on the HFE gene and the tests for the HFE gene mutations has created a severe impediment to further research and diagnostic testing for the HFE gene which is central to the serious illness of hemochromatosis.[51]

This negative externality was not foreseen at the time of the Bayh-Dole Act, in the fledgling biotechnology industry of the day.[52] There were not that many cumulative innovations, nor so many patented basic research tools. The public interest today would be better protected if greater access to research tools is made possible as it is likely to result in the creation of more innovations that benefit the public. Thus it is important, today when incorporating such an Act into India to take steps to prevent such a tragedy from occurring wherein the Indian Act may result in hindering the very innovation it was supposed to stimulate.

C. THE SOCIAL COST OF PRIVATISING PUBLIC INNOVATION

1. Issues of Access

Commercialisation of innovations especially in the sphere of biotechnology is riddled with costs. At the time of licensing an innovation, the private party would have already invested substantial amounts in obtaining that licence. Even after the creation of the innovation such as a drug, it would still have to undergo rigorous clinical trials and several rounds of testing before it can be introduced commercially.[53] Furthermore, it may take further investment to market such an innovation. When a private company begins commercially producing a product, it will therefore try to recoup these costs and make a profit. In such a case, it is more likely than not, to use the monopoly power it derives from the exclusive license.[54] Armed with this monopoly power, the private company is likely to price an innovation higher than the competitive market price and this monopoly pricing is likely "to make access to socially beneficial products cost-prohibitive."[55]

There are a large number of examples which support such a position. "Fuzeon" – a treatment which was touted as making the difference between life and death for patients suffering from HIV was developed after decades of research in public funded labs of Duke University and University of California. The two

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[50] *Id.*

[51] Risa L. Lieberwitz, *Confronting The Privatization And Commercialization Of Academic Research: An Analysis Of Social Implications At The Local, National, And Global Levels,* 12 INDIANA J. GLOB. LEG. STUDIES 127, 127-28, (2005).

[52] *Supra* note 6.

[53] *Supra* note 42, 164

[54] *Id.*,152.

[55] *Supra* note 6.

Universities chose to license the drug exclusively to a Swiss private pharmaceutical Roche which then proceeded to market the drug at 22,000 US dollars a year making it the most expensive HIV medicine ever. Roche's pricing not only makes it almost impossible for lower/middle income countries around the world to access this treatment, but it is also prohibitive for patients in the US who being taxpayers had in fact funded the initial research.[56] Another such example is the case of Myriad Genetics a company which charges up to 2700 US dollars to conduct a screening test for the presence of two breast cancer causing genes. It has been calculated that if it were not for the private company's attempt to cover its licensing fees, the cost for the test would have been 50 US dollars. The discovery of the two breast cancer genes in this case was again based in part on public funding.[57] The two cases described above further bring to light one of the greatest criticisms of the Bayh-Dole Act which is likely to be also the case with the Indian Act – though the taxpayer pays for research and development of the innovation, she is not likely to get adequate returns from it.[58] The public ends up paying twice – once by funding the research and development of the innovation through taxes and later by paying supra competitive prices for the end product innovation.[59]

A perusal of the Indian Act has already revealed how, unlike the US Bayh-Dole Act, there have been no stipulations made as to the nature of commercialisation that is to be undertaken. There are no provisions which at least promise that the benefits are to be made available to the public on reasonable terms as is the case in the US Act. There are also no provisions for intrinsic march-in-rights in the Act which raises the question as to how issues of access and benefit to the public will be ensured. It may be argued that the provisions relating to '*compulsory licensing*' found in the Indian Patents Act 1970 would be applicable to the inventions patented under this new Act as well; however there are differences between the sort of power granted to the Indian government and the federal agency in US While the federal agency march-in rights are not time bound, in India, a request for compulsory license can only be made three years after the time of sealing of the patent[60] which, in the ever-growing and dynamically changing biotechnology industry may, in fact, be more than the life of the drug in the biotechnology market. Furthermore, in cases of life saving or essential medicines, this stipulation of a three-year waiting period could prove fatal for many. Although, it is true that the fear of monopoly pricing is slightly alleviated due to the presence of control measures such as The Drug (Prices Control) Order of 1995 and the Essential Commodities Act 1955, they will apply only to a smaller extent of innovations and will take time to take effect.

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[56] *Id.*

[57] *Supra* note 51, 128.

[58] *Supra* note 38, 335.

[59] *Supra* note 47, 260.

[60] *Supra* note 5, 160.

There is also the fear that dissemination of publicly funded research may be stifled by the Indian Act under the guise of confidentiality agreements. A classic case in this regard is the tie up between University of California, Berkeley University and the pharmaceutical giant Novartis in 1998 by which the research work was kept unpublished for over four months.[61]

Thus the pertinent question asked in this regard, is what the use of this innovative product is, if its access is limited to only a few.

2. Changing Nature of Research

Furthermore, as suggested by UAEM, undue stress on market incentives for innovation may end up in vitiating the more important goal of maximizing public interest. The Act creates the impression that it must be possible to equate public funded innovations to commercially viable products and aims at 'rewarding' universities which are able to do the same. However, research and development in basic sciences may be of equal if not paramount importance in the long term even if they do not produce commercially viable innovations at the moment. Furthermore, the potential of an innovation may not be revealed until much later on and the commercial value of an innovation should not be taken as an indicator of its success or failure. It is important to ensure that universities do not channel these public funds into what it perceives are the only commercially successful products to the detriment of other research.[62] For example, it is commonly understood that the lack of medical attention towards medicines for "neglected diseases" which affects more than 90 percent of the world's population but receives just 10 percent of funding is largely because there is no commercial market for these drugs.[63] India, which has many of these neglected diseases and also the capability to research for possible treatments and drugs, should not allow its funds to be directed away from such socially beneficial research.

V. CHANGES THAT NEED TO BE EFFECTED TO KEEP THE BILL ALIVE

From the discussion above, it may be inferred that there are several problems in implementing the Bayh-Dole Model in India. However, this is not to suggest that the situation is entirely unsalvageable. When the National Knowledge Commission recommended a Bayh-Dole styled legislation, it did add that the US Act will have to be altered to meet Indian specifications.[64]

For example, one way of reducing transaction costs that has been suggested is that of having regional or national TTOs as opposed to multiple TTOs

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[61] *Supra* note 14, 408-09.

[62] *Id.,* 406-07.

[63] *Supra* note 6.

[64] *Supra* note 1.

at the university or research laboratory levels.[65] Individual TTOs generally lack the expertise and the funding for carrying out successful commercialisation which is even more likely to be the case for the smaller universities in the country. A centralized or a larger TTO would be able to take advantage of economies of scale in spinning out commercially viable products. As the larger TTO would be the single negotiating body for a number of patented innovations, it would also be possible to bundle rights of multiple patentable and interrelated research innovations, thus reducing transaction costs of negotiating for each and every patented bit of research which may otherwise be spread over a number of institutions.[66]

In order to avoid the Tragedy of Anticommons, there may also be need to explore the possibilities of alternative systems of patenting such as the open source patenting initiative Biological Open Source by which a common pool of protected research tools are created which are available to all for further research and development.[67] Another alternative would be to incorporate an experimental-use exception clause in connection to public-funded research which would prevent the stifling of further innovation.[68]

In India, CSIR and other institutions have largely always given non-exclusive licenses to the companies during the commercialization of innovations.[69] The Bayh-Dole Act provides for exclusive licensing, something companies are always keen upon. It is necessary to incorporate certain minimum safeguards to ensure that such licenses are not abused. Although, there exist compulsory licensing provisions and drug pricing control measures, they would only apply to certain drugs and would not be applicable to other innovations. CSIR, for example, has many innovations in other fields – steel, rubber, polymers among others and the lacunae in the Bayh-Dole Act regarding their protection need to be addressed.

Also, although the Indian Act through Clause 12, in effect, gives preference to the domestic industries – as it lays down that the exclusive licensing should only be granted to the industries that manufacture in India;[70] however, there exists the fear that India may end up subsidizing R&D for foreign companies and hence a clearer distinction needs to be made between domestic and foreign parties.

It is also necessary to ensure that there is public dissemination of academic research for which there might be need to ensure that all publicly funded research is published within a certain specified period. Examples to emulate would be the case of NIH, which has the Pubic Access Plan by which public research

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[65] *Supra* note 4, 239.

[66] *Id.,* 341.

[67] *Supra* note 9, 268.

[68] *Supra* note 6.

[69] *Supra* note 22.

[70] *Supra* note 28.

findings (funded by NIH) have to be made available to the US public within a year of its publication in a private journal. A proposed Act – the Federal Research Public Access Act (FRPAA) (which has been introduced in the Senate) is also worth noting as it would require eleven of the biggest public funded agencies in the US to publish their papers online within 6 months from publication in a journal.[71]

Thus considering that there exists a US model in place with all its flaws and successes, there is an opportunity to pick, choose and modify the draft Bill so that the success and not the faults of the Act are imported.

VI. CONCLUSION

The Bayh-Dole Act in America has been heralded as the Magna Carta of university technology transfer and the harbinger of innovation in the biotechnology industry. Many countries have, because of the apparent success of the Bayh-Dole Act, tried to recreate this model. India, in this regard, cannot be faulted in trying to create more incentives for research and development in universities as well as providing incentives for the private companies to bring viable commercial innovations to the market. However, this push to provide incentives and commercialise public funded research needs to be always seen not as the goal but as the way forward to achieve pubic interest goals. An analysis of the text of the proposed Act reveals that many of the objectives of the Act will not be met if the Act is passed in its present form. The patenting licensing system meant to increase the revenue of universities may actually result in losses for it; the Tragedy of Anticommons that is likely to result due to the Act is more likely than not to stifle innovation than stimulate it and further even if there is innovation there remain the fundamental question of who will receive the benefits and who is likely to be able to have access to this innovation. It is hoped that when the Parliament will sit to discuss this Bill, it will take these fundamental concerns into consideration and modify the Bill accordingly so as to ensure that the protection and utilisation of public funded intellectual property will result in benefit for all.

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[71] Jenifer Reinhardt*, Bill Aims to Provide Taxpayers Access to Publicly Funded Research*, July 21 2009, available at http://ohmygov.com/blogs/general_news/archive/2009/07/21/bill-aims-to-provide-taxpayers-access-to-publicly-funded-research.aspx (Last visited on October 25, 2009).