Asian Initiatives on Bayh-Dole, with Special Reference to India: How Do We Make It More "Asian?"

Tina K. Stephen

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ASIAN INITIATIVES ON BAYH-DOLE, WITH SPECIAL REFERENCE TO INDIA: HOW DO WE MAKE IT MORE “AMERICAN?”

Tina K. Stephen*

Abstract

With many Asian countries pursuing legislation for managing publicly funded research inventions, the objective of this study is to analyze the adaptability of this type of legislation in several of these countries. Additionally, this study proposes safeguards that governments should build into this legislation in order to make these initiatives more fruitful as this legislation is also capable of causing certain irreversible damage to the public pool of inventions which many countries depend on to meet several public demands, especially relating to health care.

This article analyzes the initiatives made by different Asian countries for the management of publicly funded intellectual property and compares them to the U.S. Bayh-Dole Act. The study especially emphasizes the Indian Protection and Utilization of Public Funded Intellectual Property Bill, 2008¹ and recommends necessary changes to all Asian legislation so as to make it more “Asian.”

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¹ Bill No. LXVI (2008).
Introduction

University research and its resultant outputs have always been great contributors towards technological development in different industries. Certain breakthrough inventions such as Vitamin D fortification, Google, gene-splicing and many more are evidence of the role played by universities in industry research and the use of university research for the greater good of the industry knowledge base. This relationship was made possible by granting proprietary rights in university inventions to the university rather than its funding authority. Once granted proprietary rights, the universities were free to license the commercialization rights to private companies. Universities also realized that gaining proprietary rights over the invention meant raising funds by way of licensing for further research, especially in the backdrop of shrinking government aid. Although universities now had proprietary rights, they nonetheless had difficulty in deciding the terms and extent of commercialization as these were complex issues. In addition, certain scholars suggest that the creation of proprietary rights in university inventions may stifle basic research through the mismanagement of university patent rights. Furthermore, they suggest that certain publicly funded inventions should be readily available to the public, especially in the areas of biotechnology that affect public health.

Universities in the United States have always lobbied for proprietary rights over their inventions and ultimately, the U.S. government enacted the Bayh-Dole Act in 1980. The governments in several developing Asian countries have also started considering the prospects of commercializing innovations of publicly funded research organizations, and these governments are increasingly using the tools of patenting, technology transfer and venture creation for this goal. As many Asian countries are pursuing legislation for managing publicly funded research inventions, the objective of this study is to analyze the adaptability of this type of legislation in several of these countries. Additionally, this study proposes safeguards that governments should build into this legislation in order to make these initiatives more fruitful as this legislation is also capable of causing certain irreversible damage to the public pool of inventions which many countries depend on to meet several public demands, especially relating to health care.

This article analyzes the initiatives made by different Asian countries for the management of publicly funded intellectual property and compares them to the U.S. Bayh-Dole Act. The study especially emphasizes the Indian Protection and Utilization of Public Funded Intellectual

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5 Id.
Property Bill, 2008 and recommends necessary changes to all Asian legislation so as to make it more “Asian.”

Section I describes the U.S. policy for management of publicly funded research, namely the Bayh-Dole Act, and a brief history of its enactment. Section II provides an insight into the diverse European approach followed for the management of publicly funded research. Section III analyzes the legal framework within which publicly funded IP is managed by Asian countries. Section IV attempts to pinpoint the specific issues that need to be evaluated when considering the enactment of a Bayh-Dole type of legislation in different Asian countries, and Section V is a conclusion to the study.

I. The U.S. Policy for Management of Publicly Funded Research

Many countries have recognized university research as a fundamental source of knowledge for various industries. In furtherance of this realization, these countries have also put in place certain mechanisms to facilitate the interaction between universities and industries. The United States is one country where the university-industry research interaction can be very closely studied. The United States has implemented many mechanisms to maintain the exchange of knowledge since the 1950’s. This advanced structure for university-industry collaboration was facilitated by the scientific and application based higher education system that it followed. All of these factors facilitated the universities to be great contributors to the dissemination of applied knowledge. This had provided an impetus to American industry, as the basic research carried on by universities served as a launch pad for product research and product launches by different companies, especially in the field of biotechnology and information technology.

Even before the passage of the Bayh-dole Act, the United States had rules and policies that addressed the issues of publicly funded research innovation management. President John F. Kennedy, in 1960, had issued a policy covering patents that arose out of publicly funded research. But the whole issue regarding ownership of publicly funded research inventions came to light after the Federal Council for Science and Technology (FCST) commissioned the U.S. General Accounting Office (GAO) and Harbridge House to conduct a study on government patent policy as part of a review of this issue by the FCST itself. They published important reports on the National Institute of Health’s (NIH) Medicinal Chemistry program. The GAO and Harbridge House reports criticized the Department of Health, Education, and Welfare’s (HEW) patent policy regarding universities’ signing agreements where the policies prevented

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8 Bill No. LXVI (2008).
10 Id.
firms with NIH funding from patenting technologies which might so arise.\textsuperscript{14} The reports recommended a need for greater clarity in situations when universities could hold patents and when the patents reverted to the government.\textsuperscript{15} In furtherance of these reports, the HEW put into place the Institutional Patent Agreements (IPAs) that gave universities with "approved technology transfer capability" the right to retain title to agency-funded patents.\textsuperscript{16} Thus, there was a steep rise in the number of inventions retained by federally funded universities, but the IPAs did not fully encourage exclusive licensing of these inventions.\textsuperscript{17} Specific regulations and rules were needed because ambiguity still existed regarding the ownership of federally funded inventions and the university licensing of inventions that conflicted with the HEW's interest. Thus, the United States introduced the Bayh-Dole Act to clarify and regulate these issues.\textsuperscript{18}

The increase in university patenting post-1980 has often been attributed to the adoption of the Bayh-Dole Act of 1980, which established a uniform system for universities to license inventions.\textsuperscript{19} Since the introduction of the Bayh-Dole Act, U.S. university research has become more proprietary and commercialized in nature and has also experienced an erosion of the tradition of open science.\textsuperscript{20} Instead of boosting the innovation process at universities per se, the Act mainly facilitated increased licensing of inventions. This was due to the simplification of the complex administrative procedure through which the U.S. universities gained title to the intellectual property created from publicly funded research.\textsuperscript{21}

Some studies have suggested that university patenting would have increased in the 1980's and the 1990's, even without the Bayh-Dole Act.\textsuperscript{22} It has been pointed out that the substantial increase in this period was due to a trend that started back in the 1970's. The percentage of university patenting was almost 0.3\% of the total patents granted in 1964 which rose to 4\% by 1999.\textsuperscript{23} The Bayh-Dole Act nonetheless seemed to have created a sense of encouragement for federally funded inventors to file for and commercialize patents. Such inventions were then

\textsuperscript{14} Harbridge House 1968 a, II-21; General Accounting Office (GAO) Report 1968, at p. 11.
\textsuperscript{17} See Mowery, supra note 15, at 117.
\textsuperscript{18} David C. Mowery & Bhaven N. Sampat, University Patents and Patent Policy Debates in the USA, 1925–1980, 10 INDUS. & CORP. CHANGE 781,814 (2001). Institutional Patent Agreement (IPA) was established by the HEW in 1968 in order to grant permission to universities with "approved technology transfer capability" to retain title to agency funded patents. This grant was based on an application system that allowed the universities to retain the title. These IPA's had to be negotiated between the university and the Federal Agencies.
\textsuperscript{19} See Mowery, supra note 15, at 116.
\textsuperscript{20} Arti K. Rai & Rebecca S. Eisenberg, Bayh-Dole Reform and the Progress of Biomedicine, 66 LAW & CONTEMP. PROBS. 289, 314 (2003).
\textsuperscript{22} David C. Mowery et al., Ivory Tower and Industrial Innovation: University- Industry Technology Transfer Before and After Bayh-Dole, STANFORD UNIV. PRESS, 241 (2004). (The study suggests that a rise in patenting at the universities were due to several reasons and the enactment of the Bayh-Dole was just one among them rather than being the sole reason).
licensed to companies that could now commercialize the inventions. In addition, such commercialization also paved the way for revenue generation that could lead to better research.

However, a very illuminating work by Mowery, Sampat and Ziedonis explains that the rise in patenting by universities during the 1980’s was accompanied by a decrease in patent quality. This work was followed by other literature which brought to light certain drawbacks of the legislation. Some researchers suggested that the Bayh-Dole Act had done too little to ensure the larger availability of university inventions, especially in the field of pharmaceuticals.

Others suggested that the Act does not curb universities’ freedom to patent up-stream research tools and platforms and also criticized the Act’s silence regarding the reasonable pricing of products that are derived from publicly funded research inventions. These university practices can limit invention accessibility, further research, and create patent thickets which run counter to the public interest and the intent of the Act.

The Bayh-Dole Act has also created new hurdles such as high license fees which has in turn hindered university-industry interaction and cooperation. While the Act does permit the funding authorities to intervene in the university’s practice of charging excessive licensing fees in cases such as, where a certain technology is not appropriately commercialized, this interference is very minimal. These problems cannot be neutralized because the U.S. funding agencies have retained little to no control over the licensing practices of the universities. Excessive licensing fees can block access to these inventions and create patent thickets rather than promote dissemination and commercialization of research. Because the purpose of the Act is to facilitate greater access to university inventions through commercialization, this is against the tenor of the legislation. There are also statistics that university patenting and licensing systems in the United States, though quite extensive, have not substantially contributed towards

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24 Bhaven N. Sampat, Changes in University Patent Quality after the Bayh-Dole Act: A Re-Examination, 21 INT’L. J. OF INDUS. ORG. 1371, 1390 (2003). The study was conducted in the backdrop of an accepted notion that the Bayh-Dole Act had contributed to a substantial increase in the patenting trend at universities. The authors have conducted this study to understand the effect of this legislation on the quality of patents and found that there is a substantial decline in the same. The study has very relevant policy implications.

25 See So, supra note 9, at 2080. Upstream research in simple terms is typically conceptual research. They are open-ended and help in knowledge generation and enrichment of public domain. Critics of the Bayh-Dole Act fear deterioration in the culture of upstream research in case more proprietary/IP rights are created on them. Because upstream patents affect follow-on innovations significantly, a proliferation of IP rights in upstream inventions may lead to the stifling of life-saving innovations further downstream in the course of research and product development. It is feared that in case researchers comprehend immense commercial and financial gains from a certain upstream research they might refrain from sharing information and research material and thus this will adversely affect research efficiency and complementarities.

26 Id.


28 Barbara M. McGarey & Annette C. Levey, Patents, Products, and Public Health: An Analysis of The CellPro March-In Petition, 14 BERKELEY. TECH. L. J. 1095, 1116 (1999) (In a case in 1999 a startup company called CellPro petitioned to the United States Department of Health and Human Services to compel National Institutes of Health (NIH) the funding agency of a certain stem-cell separation technology that had been invented at the Johns Hopkins University. CellPro invoked the “March-in” rights clause. CellPro argued that the exclusive licensee in this case had failed to commercialize the invention adequately. The petition by CellPro was rejected.); See Mowery, supra note 15, at 116.

29 Id.

the revenue of universities by accounting for less than 5% of the research funds at AUTM (Association of University Technology Managers) universities.\textsuperscript{31}

There have been mixed conclusions regarding the nature of university inventions post Bayh-Dole in the United States. Henderson concluded that though there has been an increase in the number of patents, there have also been apprehensions regarding the quality of these patents. The study seems to suggest that there has been more applied research rather than basic research.\textsuperscript{32} Mowery in his later research has also come to similar conclusions but has added that in the 1990's the quality seemed to improve.\textsuperscript{33} Thus there is no research that gives us a clear idea regarding the impact of Bayh-Dole on publicly funded research in the United States. Considering such uncertainty on the effects of Bayh-Dole, other countries should be extremely cautious before enacting similar legislations.

II. The European Approach for Management of Publicly Funded Research

Europe has held in-depth discussions about publicly funded research inventions.\textsuperscript{34} They similarly encourage further interaction between publicly financed institutions and private researchers because of the competitive advantage resulting from the knowledge flow from universities into the society and then to business.\textsuperscript{35} The European commission noted that publicly funded institutions and industries should exchange knowledge through licensing agreements, or through the formation of startup and spin-off companies.\textsuperscript{36} Furthermore the Lisbon Strategy was brought out by the European Council in 2000 which aimed to make the European Union "the most competitive and dynamic knowledge-based economy in the world capable of sustainable economic growth with more and better jobs and greater social cohesion" by 2010.\textsuperscript{37} After the adoption of the Lisbon Strategy, the Commission continued to stress the importance of research and innovation.\textsuperscript{38} Even though the European Commission recognizes the importance of research

\textsuperscript{31} See So, supra note 9, at 2080. Upstream research in simple terms is typically conceptual research. They are open-ended and help in knowledge generation and enrichment of public domain. Critics of the Bayh-Dole Act fear deterioration in the culture of upstream research in case more proprietary/IP rights are created on them. Because upstream patents affect follow-on innovations significantly, a proliferation of IP rights in upstream inventions may lead to the stifling of life-saving innovations further downstream in the course of research and product development. It is feared that in case researchers comprehend immense commercial and financial gains from a certain upstream research they might refrain from sharing information and research material and thus this will adversely affect research efficiency and complementarities.

\textsuperscript{32} See Henderson, supra note 23 at, 126.


\textsuperscript{36} See European Commission, supra note 34.

\textsuperscript{37} Demosthenes Ioannouetal, Benchmarking the Lisbon Strategy, ECB OCCASIONAL PAPER No. 85, (June 26, 2008).

\textsuperscript{38} Börje Johansson et al., The Lisbon Agenda from 2000 to 2010, Royal Inst. of Tech., CESIS ECON. & INST. OF INNOVATION WORKING PAPER SERIES No. 106 (2007).
and technology flow, it still does not have a harmonized legislation for IP management of publicly funded research.  

Different countries in the European Union follow different rules for handling publicly funded inventions.  

There are primarily two approaches to university patent ownership. On one hand there are countries such as Finland, Iceland, Sweden, and Italy, where it is common for university-employed inventors to privately hold patents resulting from their work. On the other hand, in countries like Austria, Belgium, Denmark, France, Germany, Ireland, Netherlands, the United Kingdom, Spain, Norway, and Poland, the university, rather than the inventor, generally has a right to own patents on the inventions that result from the research conducted at the university. In the first approach where the inventor holds the rights to invention, the challenge will be to commercialize it, as individual bargaining power in the business context is always weak. Thus there is a risk that due to failed attempts the individual will not try to commercialize it at all. But on the other side of the coin, an inventor with sole rights in the invention can easily transfer them to a relevant company without any delay which can then commercialized. Where the university is given the rights in the invention then there is a possibility that the process may get delayed as it would be difficult for the university to manage individual licensees.

The European approach towards protecting publicly funded research needs further pruning as compared to the United States as there is a need for better understanding among universities regarding inventions that can and cannot be commercialized. A uniform approach on issues of ownership of public funded inventions would give meaning to the Lisbon Strategy, and would facilitate easier use and transfer of technology within the union.

III. Asian Initiatives

Countries like China, Japan, India, Malaysia, and Singapore have enacted certain legislation or other mechanisms for commercializing publicly funded research or are planning to do so. This section analyzes the legislative changes that a few selected Asian countries have enacted regarding publicly funded research and also how other Asian countries are following suit. There are serious issues that need to be considered when enacting such legislation and further analysis is needed on issues regarding the adaptability of the U.S. Bayh-Dole Act in the Asian context. To begin with I shall analyze the position of publicly funded research organizations in certain Asian countries and related legislation.

41 See Verspagen, supra note 35, at 620.
43 Id.
44 See Mowery, supra note 18, at 792.
45 See Graff, supra note 7, at 169.
A. China

In December 2007, the Standing committee of the National People’s Congress in China passed a revision of the 1993 Science and Technology (S&T) Law. This revision is the Chinese counterpart to the U.S. Bayh-Dole Act, which allows scientists of publicly funded organizations to own their inventions. The law provides that the government may not take back a patent, unless the patent holder does not use it within a reasonable period of time. Before the passage of the S&T Law, ownership remained with the State under the Chinese law, but the universities could still use their inventions. Interestingly, China is among those countries where the State Council had passed provisional regulations on technology transfer just five years after the passage of the Bayh-Dole Act in the United States. In China, and similarly in India, the assertion of rights by the universities has only recently started. Previously researchers had to prove that their inventions were non-work related and only in such cases could they pass it on to companies for monetary return. The tendency of university faculty to patent inventions outside the university was very high. However, after the government gave institutions the right to patent their inventions and as the technology transfer offices became more efficient, more universities were granted patents which led to an increase in university-industry contracts.

B. Japan

The Japanese Ministry of Trade and Industry plays an important role in making the right pool of basic scientific and technological knowledge available to entrepreneurial businesses. From the Science and Technology Basic Law of 1995 to the present Japanese Bayh-Dole legislation, Japan has come a long way in university patenting. Since 1988, the Japanese government has been attempting to implement strategies for intellectual property through the establishment of the Technology Transfer Law jointly with the Ministry of Education, Science and Technology and the Ministry of Economy, Trade and Industry. Universities increasingly felt the need to bridge the gap between university and industry research in order to bring

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48 See Graff, supra note 7, at 175.
52 See Graff, supra note 7, at 175.
university inventions to the market and actually commercialize them. To further this purpose, the government established the Technology Licensing Offices (TLOs) and extended appropriate financial support for them.\textsuperscript{56}

The passage of the Japanese Bayh-Dole Act in 1999 was a major step, as the right to patent was now vested with the respective organization where the invention was created.\textsuperscript{57} The Japanese government in 2002, published the “Guidelines on Intellectual Property Strategies,” and thereafter, Intellectual Property Centers were also established. These centers helped strategically implement the creation, management and utilization of intellectual property at universities under the new law that shifted intellectual property rights from individuals to institutions.\textsuperscript{58}

Further study of the Japanese system shows that the Japanese have followed the U.S. Bayh-Dole Act closely. For example, Japan similarly had a systematic growth of university TLOs starting in 1995. The replication of the U.S. model was further facilitated by the inflow of money to the universities when it was required. In recognition of the role played by TLOs in consolidating university inventions in the U.S., the Japanese TLOs were also closely monitored. The government provided everything required for its efficient operation such as the formation of IP management offices which aimed at providing in-house IP management expertise to universities and TLOs. The IP management office has been given the final authority in cases of conflict with the TLOs on issues regarding patenting and licensing.\textsuperscript{59}

Even though Japan is an Asian country, a Bayh-Dole type of legislation can be identically applied and successfully implemented because of the great economic similarities between Japan and United States.\textsuperscript{60} However this is not the case for many other Asian countries.

### C. Malaysia

Malaysia is also among the Asian countries that have made national arrangements for the management of publicly funded research.\textsuperscript{61} The Malaysian government thoroughly discussed finding the best IP rights model for the country and where the rights could be shared between the three parties: the government that funds the research, the university, and the inventor.\textsuperscript{62} In

\textsuperscript{56} Steven Collins & Hikoji Wakoh, Universities and Technology Transfer in Japan: Recent Reforms in Historical Perspective, 25 J. TECH. TRANSFER 213, 222 (2000).
\textsuperscript{58} National Science Foundation, Tokyo Regional Office, TLOs and University Intellectual Property Centers, Report Memorandum #04-05, (July 20, 2004).
\textsuperscript{59} See Kneller, supra note 57, at 20.
addition the Malaysian government had the intention of creating a better incentive scheme in order to attract and retain their scientist. But a striking feature about these discussions was the government’s commitment to maintain the amount of basic research conducted at the universities. For this purpose, the government proposed to split research and development grants into two types: one for fundamental science and the other, called the technology grant, for commercial inventions. Although commercialization was the priority, the government still planned to continue providing grants for scientists and they intended to provide these grants even after the scientists’ retirement, which was seen as quite a laudable suggestion. In 2007, Malaysia adopted the second National Intellectual Property Policy, and further in 2009 the Intellectual Property Commercialization Policy for Research & Development Projects Funded by the Government of Malaysia which intended to promote the management and commercialization of research outputs at public research organizations and universities. Many Malaysian organizations successfully started transferring and commercializing their inventions and they have also setup several TLOs at leading universities and research institutes. The Malaysian IP Commercialization Policy has also included certain provisions that are vaguely similar to the march-in rights as provided under the Bayh-Dole Act.

D. India

In India, publicly funded organizations patent their inventions in accordance with the rules prescribed in the Indian Patent Act and the Department of Science and Technology’s Guidelines for Technology Transfer and Intellectual Property. Although the R&D base is increasingly expanding in India (which has also been of great help to the industry), the commercialization of these inventions is still way below what is desired. Except for a handful of universities and colleges, the majority of Indian universities do not have a Technology Licensing Office, which undoubtedly restricts inventions to the university laboratory. These
inventions in turn are ultimately put into the public domain when the inventions lose their novelty.\textsuperscript{73}

India is now on its way to introduce Bayh-Dole type legislation.\textsuperscript{74} The text of the Indian Protection and Utilization of Public Funded Intellectual Property Bill of 2008 has many provisions that are strikingly similar to the U.S. Act.\textsuperscript{75} The Indian government has introduced this Bill with the aim of taking university inventions to the market through proper commercialization. However, scientists who mainly perform fundamental science research are against commercialization of these inventions claiming that the Act will not result in the increase of patenting at the university level, but will rather hinder the basic research that universities are conducting and will also stifle access to health care.\textsuperscript{76} A very important consideration that the Indian legislators need to remember is the background in which this legislation came into force in the United States. The U.S. Bayh-Dole Act was legislated at a point when there was a total absence of intellectual property rights over inventions that were a product of publicly funded research.\textsuperscript{77} However that is not the case in India. In India such rights are automatically conferred on the inventor, unless a contract to the contrary is signed with the employer institution.\textsuperscript{78} In addition, Indian governmental institutions are already following the revenue model that the Bill suggests.\textsuperscript{79} So the question remains, whether India is actually in need of legislation similar to the U.S. Bayh-Dole Act.

The Indian Protection and Utilization of Public Funded Intellectual Property Bill of 2008 lacks specific clauses that take into consideration the special health care needs of India. The legislation completely ignores provisions for the identification and segregation of basic research inventions from applied research inventions and it does not include any special clauses that provide for access to such inventions. Academia provides the most important criticism of the Indian Bill. They suggest that, rather than passing new laws, universities and other organizations should increase funding for their R&D facilities, which would result in more useful inventions.\textsuperscript{80} On the other hand, some see this Bill as a means for better commercialization of their inventions, which were either dumped in the dark corners of the laboratory earlier or were simply seen as a means of further research. The Bill is expected to introduce some change and clarify issues

\textsuperscript{73} Id. at 25.
\textsuperscript{75} Id.
\textsuperscript{76} Ben Butkus, \textit{As India Mulls Bill Modeled on Bayh-Dole, Critics Claim It May Stifle Innovation}, \textit{BIOTECH TRANSFER WEEK}, (Nov. 12, 2008), http://www.genomeweb.com/biotechtransferweek/india-mulls-bill-modeled-bayh-dole-critics-claim-it-may-stifle-innovation. \textit{See} Kochupillai, supra note 72, at 33. For example as in the case of iodine related disorders, that caused serious problems in some parts of India, was considerably reduced due to basic and chemical research conducted by projects funded by government of India.
\textsuperscript{78} Indian Patent Act (ACT 39 of 1970), Section 6 of the Act allows the true and the first inventor to apply for a patent.
relating to royalty sharing, and thus benefiting the concerned inventor as well as the research
institute.\textsuperscript{81}

\textbf{IV. Issues that Concern Asian Countries}

Even though the Bayh-Dole Act may or may not have been a great success in the United
States (depending on the context), there are many countries that follow it around the globe. As
we make an attempt to study its impact in Asia, we will realize that many countries are very keen
on following it, may it be a developed country, such as Japan, or developing countries such as
China and India. All of them have different goals with regards to the implementation of the
legislation, but the only difference is that a few are doing it with more planning while others
need to further work on certain foundational aspects so that a better framework may be built.\textsuperscript{82}

In most Asian countries, the legislation should contain certain important safeguards to
protect the interest of those who might be directly affected by the enactment of the legislation.
These safeguards, whether they are related to licensing, ownership, or government rights to the
invention, play a very crucial role in important issues such as health care and access to drugs and
pharmaceuticals.\textsuperscript{83}

The legislators need to thoroughly analyze important issues such as: an Expert Committee
decision on the “public use” of invention, the disclosure of inventions, the role of technology
licensing offices, the importance of non-exclusive licensing, “march-in” rights, and the better
commercialization of inventions when enacting initiatives for the management and ownership of
rights in publicly funded research. While I advocate certain general suggestions, some countries
might require variations of my suggestions and customized policies.

\textit{A. Expert Committee Decision on the “Public Use” of Invention}

Asian countries have a particular public need for access to pharmaceuticals and other
inventions related to healthcare. University research and its resultant outputs are typically related
to basic research which become platforms for health care based research.\textsuperscript{84} This type of research
often forms the knowledge base for an industry from which the industry carries forward towards
its commercial application. Only after the invention gets into the hands of a company through
licensing will the invention be commercialized and marketed.

Once patented, these inventions must be commercialized by the university or institute
which has received the funding. Once an invention enters the commercialization process there is
no looking back. But the concern regarding these inventions is whether the public-at-large needs
access to these types of inventions. Who will decide whether the invention serves any public

\textsuperscript{81} Section 18, Indian Protection and Utilization of Public Funded Intellectual Property Bill, 2008 (Bill No. LXVI, 2008).
\textsuperscript{82} David C. Mowery, \textit{The Bayh-Dole Act of 1980 and University-Industry Technology Transfer: A Policy Model for
\textsuperscript{83} See Graff, supra note 7, at 169.
purpose or not? When the invention is identified by the inventor to be of great public importance with a bulk of the population having interest in the invention, what further course of action must be taken? In such situations, I recommend that every Asian country that implements legislation for the protection of publicly funded research inventions should form an expert committee under their respective legislations. After reporting the invention to the government, the government should be obligated to submit the invention to an expert technical committee, which will decide the nature of the invention, the possible public use of the invention, the application of the invention and other related matters. The government should issue guidelines to decide whether the invention is actually useful to the public or not. These guidelines will have significant relevance in the context of pharmaceuticals.

For example, the expert committee would consider these proposed factors before it approves the commercialization of a pharmaceutical invention:

1. The illness being treated,
2. The nature of the affected population (whether the illness will primarily affect poor people),
3. The population density of people who are affected by the disease, and
4. Whether national drug safety may be compromised if the invention falls into private hands.

Only after considering all these factors should an institution have the ability to patent an invention. Say for example an institute has come up with an invention to treat HIV cases which are increasing at an alarming rate. The disease is also of such a nature that the majority of people being infected by it are below the poverty line. In such situations if the invention is licensed to a company for private commercial exploitation then there is a risk that the drug may be priced at such rates that it will be out of reach for the majority of those infected. This can be avoided by preventing private ownership of the drug and increasing public distribution of the drug. There is also a risk that private ownership of drugs may lead to the sale of drugs at extremely high prices because there are no price control mechanisms under either the Bayh-Dole Act or the Indian Protection and Utilization of Public Funded Intellectual Property Bill.

On the basis of these considerations, the committee would submit a report to the government. The government will then decide on whether it needs to retain the rights, whether and how the invention needs to be commercialized, and whether any specific terms need to be applied to the invention. This process will help the authorities make proper use of the invention. But the speed at which the committee studies the application of the invention and submits a report is one aspect that needs to be addressed. The usual administrative delays should be avoided because these delays can have the effect of literally killing the invention by extending the market introduction period required for these products.

An invention is undoubtedly the right of the inventor. The inventor’s sweat and blood goes into the creation of the final research output. This proposition holds well in the case of private institutions, where the inventor or the employer company that has invested financially in the research may have complete rights over the invention. But in the case of publicly funded research organizations the situation is completely different. Any given institute or research
organization does not solely generate its funding for R&D, but rather certain state authorities provide funding to it to develop the knowledge base in a given field of science and technology. Here, the money is generated not from any private source, but from the public-at-large through taxes. So in the scenario where the money comes from the public, it is the government’s responsibility to ensure that the needs of the public are taken care of. Expert committees are needed to protect the public’s interest in publicly funded inventions because ultimately it is the public that supported the creation of the invention. As the Bayh-Dole Act facilitates the creation of private rights over inventions that have been funded by the public-at-large, certain mechanisms should secure the interests of the public so that these interests are not completely sidelined. Thus an expert committee’s opinion with regards to the public use of an invention is indispensable.

B. Disclosure of inventions

In this context it is also important to highlight the significance of proper invention disclosure. As most of the legislation suggests, once an invention is made, the institution is under an obligation to report the invention to its funding authority and the institution then has to apply for a patent. This disclosure aspect is often very vague. In many instances, institutions do not report these inventions and therefore, do not follow the regulations. In order to determine the degree of university compliance with the disclosure requirements under the U.S. Bayh-Dole Act the GAO compared the PTO data with the agency and grants receipt data of about 2000 patents that were related to federal funding. The report stated that:

Federal agencies and their contractors and grantees are not complying with provisions on the disclosure, reporting, retention, and licensing of federal sponsored inventions under the regulations implementing the Bayh-Dole Act and Executive Order 12591. In our review of more than 2,000 patents issued in calendar year 1997 as well as an Inspector General’s draft report on 12 large grantees of the National Institutes of Health, we found that the databases for recording the government’s royalty-free licenses are inaccurate, incomplete, and inconsistent and that some inventions are not being recorded at all. As a result, the government is not always aware of federally sponsored inventions to which it has royalty-free rights.

Thus Asian countries should take special care to insert provisions that require a reporting system that keeps track of all the funds granted and the inventions created from such funds. Therefore, the publicly funded institutions should be required to report their inventions from time-to-time.

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85 See O’Connor, supra note 11, at 7.
86 Indian Protection and Utilization of Public Funded Intellectual Property Bill, 2008 (Bill No. LXVI, 2008) under Clause 4 states that the recipient shall within a period of sixty days of actual knowledge of the public funded intellectual property make a disclosure thereof to the Government in such form and manner as may be prescribed.
89 Id. at 2.
C. The Role of Technology Licensing Offices

Technology licensing offices are pivotal to the success of any policy that promotes a fruitful flow of knowledge from the university or any publicly funded organization to the industry. The transfer of technology and the better utilization of the invention depend on the efficiency of the Technology Licensing Offices (TLOs). That is why, along with the drafting of policies for effective transfer of technology, the establishment of TLOs is also very important. As one tracks the Bayh-Dole Act’s history in the United States, it is important to recognize the simultaneous and systematic development of TLOs. University invention and commercialization got a new face with the creation of specialized TLOs under similar Bayh-Dole like legislations in different countries. In Japan, through the passing of the National University Corporation Law in 1998, the government emphasized the development of TLOs for the licensing of university inventions and the generation of royalties for the inventor. In countries like China, though there have been provisional regulations dealing with technology transfer, only recently have TLOs been established. These TLOs gave institutional support to China’s initiative towards the implementation of public funded research legislations by managing the commercialization of inventions. In countries like Malaysia and India there is still much more to be done in terms of setting up effective technology transfer offices although the government is currently implementing the laws regulating publicly funded research.

There is also a rising concern regarding the over aggressiveness of TLOs in licensing inventions. The officials of Ewing Marion Kauffman Foundation stated very disappointingly that, “Technology Transfer Offices (TLOs) were envisioned as gateways to facilitate the flow of innovation but have instead become gatekeepers that in many cases constrain the flow of inventions and frustrate faculty, entrepreneurs, and industry.” This state of affairs in the United States should be an alarm for the Asian countries with respect to the management of TLOs in their respective countries which will invariably expand with the introduction of Bayh-Dole like legislations. It is thus extremely pertinent to draft rules and regulations for the management of TLOs.

Many countries have drafted special policies that address the different issues of the TLOs. Initially in the United States, the universities individually developed policies governing TLO operation. The large disparity in the licensing and royalty practices between different

90 See Litan, supra note 2, at 35.
92 See Graff, supra note 7, at 169.
93 Law to Promote the Transfer of University Technologies [Daigaku nado gijutsu iten sokushin hou] (Law No.52 of 1998).
94 See Graff, supra note 7, at 175.
96 See Litan, supra note 2, at 40.
97 Wisconsin Alumni Research Foundation (WARF) was founded in 1925 way before the enactment of the Bayh-Dole Act. It has been working on converting university research into real products. The WARF office has developed a technology transfer model for itself over the year and operates on the policy that it had developed. The commercialization by WARF of vitamin D discovery made by Prof. Harry Steenbock was its first success story. It was for the management of this discovery that WARF was initially formed, http://www.warf.org/.
universities made things difficult for industries as they had to discuss and negotiate with each university separately and study the licensing and commercialization pattern of each university every time they proposed a license for a university’s invention. With the implementation of the Bayh-Dole Act in the United States, TLOs started following policies pursuant to the Act. These kinds of rules are inevitable and need to be followed by all countries seeking to establish a system that utilizes publicly funded intellectual property. For example, Section 10 of the Indian Bill provides for the constitution of an intellectual property management committee and its functions. Thus, for the standardization of TLO policies, countries require a detailed set of rules that govern the TLOs. As stated earlier, situations sometimes arise where the TLOs make decisions incompatible with the expectations of publicly funded organizations as well as with industries seeking to commercialize inventions. These policies should also give special emphasis on simplifying the process of technology transfer from public research institutions to the private industries. The policy which will be issued by the government departments should be of such a nature that it enhances the efficiency of technology transfer. The policy should clarify the process regarding the disclosure of the invention by the inventor to the concerned university; the title and ownership of the invention; the details regarding the process of applying for a license of a university invention; and details regarding royalty sharing between the university and inventor.

D. The Importance of Non-Exclusive Licensing

The granting of licenses is the most important means through which the university-industry interaction is facilitated. Prior to the enactment of the Bayh-Dole Act, the Institutional Patent Agreements (IPAs), stressed the granting of non-exclusive licensing, though the granting of exclusive licensing was not altogether prohibited. This made it difficult for companies to commercialize their products because within years or even months of their product launch, there

98 U.S. General Accounting Office, Technology Transfer: Administration of the Bayh-Dole Act by Research Universities, Report to the Congressional committees, GAO/RCED-98-126 (1998). The use of government owned inventions was extremely difficult as there was a maze of rules and regulations that the concerned agencies had drafted for its licensing purposes. This was because there was no uniform federal policy on the transfer of technology from the government to the private sector. For this purpose the Congress passed the Bayh-Dole Act (P.L. 96-517, Dec. 12, 1980). In 1987, the Department of Commerce issued regulations, which are codified in 37 C.F.R. 401, to implement Bayh-Dole. This policy was extended to large businesses by Executive Order 12591, dated April 10, 1987. This helped in bringing in uniformity in, the till then scattered university technology transfer policy.


100 Id.

(1) Every recipient shall, within one hundred and eighty days of the receipt of the funds under section 3, constitute an intellectual property management committee within its organisation.

(2) The intellectual property management committee constituted under sub-section (1) shall,—

(a) identify, assess, document and protect public funded intellectual property having commercial potential;
(b) perform market research and market such public funded intellectual property;
(c) create an intellectual property management fund;
(d) monitor the process of licensing and assignment;
(e) manage revenues from licensed public funded intellectual properties for the organisation;
(f) within one hundred and eighty days of its constitution, establish mechanism to promote the culture of innovation and public funded intellectual property generation within the organisation;
(g) create mechanisms to govern the relations between the recipient and the creator of public funded intellectual property.
were competitors in the market with another license from the same inventor. Over the course of time, companies did not want to collaborate with publicly funded research organizations. But contrary to this policy, the Bayh-Dole Act introduced a provision whereby exclusive licenses could be granted in situations where the substantial production of the product took place in the United States. In this context Eisenberg explained the reasoning for the “substantial production in U.S.” clause as a way to “ensure that U.S. sponsored research discoveries were developed by U.S. firms, rather than by foreign competitors who had too often come to dominate world markets for products based on technologies pioneered in the United States.” But this rule also contained a waiver in situations where a manufacturer is able to prove that by some means the production of a given product is not feasible in the United States.

The Bayh-Dole Act encouraged universities with publicly funded research inventions to retain title to the invention and then collaborate with the industry to give practical application to the invention by way of licensing. The Act gave “considerable discretion” to the inventor/recipients of federal funds with regards to the licensing of his inventions. The licensing of inventions forms the crux of the Bayh-Dole Act as stated in its Statement of the Need for the Legislation:

At the present time U.S. companies desiring to use government funded research to develop new products and processes must confront a bewildering array of 26 different sets of agency regulations governing their rights to use such research. This bureaucratic confusion discourages efficient use of taxpayer financed research and development.

There is a general concern by federal funding agencies regarding exclusive licensing agreements signed between a federal fund recipient and a licensee company because it is argued that this may lead to the creation of monopolies, an increase in product prices, and an unwanted burden on the tax payer with whose money the invention was developed. This presents special concerns for Asian countries because of their high demand for drugs and pharmaceuticals. Although there is a general exception against the granting of exclusive licenses under the Bayh-Dole Act, once granted, the exclusive license is seldom revoked because these kinds of legislations are drafted with the objective of commercialization and revocation of such a license could defeat this objective. From a business perspective, academic research can be transferred to the industry and commercialized; therefore it can generate revenue for the institute for further

107 See O’Connor, supra note 11, at 6.
108 See Vivekanandan, supra note 81, at 485.
R&D. But from a public welfare perspective this approach can be harmful especially in the case of Asian countries. In Asian countries, there is always a risk of universities getting carried away by the over-hyped benefits of the legislation and ultimately ending up attempting to commercialize every minuscule invention that may come their way. In such a scenario these universities should be in a position to differentiate between inventions with industrial application and inventions that are basic in nature or are important from a public welfare perspective. Research organizations/universities also need to explore certain alternate approaches, as earlier stated in the case of research conducted in India by Council for Scientific and Industrial Research (CSIR) on TB through an open-source drug discovery model. In an open-source model the database and other information will be publicly available rather than patenting them and may there by facilitate greater technology and knowledge spill-over, at least in cases of essential and lifesaving drugs and pharmaceuticals. Thus open source can be used as an alternate model to licensing in Asian countries in conditions where inventions cater to needs of large public health issues.

The concerned governments should also thoroughly monitor the granting of exclusive licenses. Exclusive licensing should be granted only in certain cases where a public interest is served or in cases of national emergencies. For this purpose the setting up of an expert committee, as stated earlier, becomes vital. Exclusive licensing can also cause more problems in situations regarding basic scientific inventions that are platform technologies because a patent can block all future research connected to it. On the other hand, granting non-exclusive licenses generates more competition which is in the greater interest of technological development. Thus the Asian legislations should always be in favor of non-exclusive licensing and the granting of exclusive license should be an exception.

E. “March-In” Rights

March-in rights to protect the public’s interest were developed to take care of and address . . . [a] contractor’s windfall profits . . . and detrimental effects to competition.

The United States Congress inserted a provision for “March-in” rights as a safeguard in cases where a company with an exclusive license does not utilize the license in the best possible way. In the United States, the government can exercise its march-in rights and can license the technology to a more responsible producer. The Kennedy Patent Policy had previously made

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110 See Mowery, supra note 15, at 118-119.
111 Council for Scientific and Industrial Research (CSIR) is the premier publicly owned industrial R&D organization in India and also India’s biggest patentee.
similar provisions that addressed the issue of march-in rights in the United States. The
government may use this clause in special public health emergency situations. In the United
States, this clause has never been used, even though Congress has detailed the procedures to be
followed in case judicial and administrative appeals are required for using this clause. From
this it may be derived that the clause is just a “dummy clause” and the government has no desire
to ever use it.

However, Asian legislative bodies should insert the “march-in” clause in their respective
legislation in a more effective way, whereby excessive pricing and other anti-competitive
practices can be checked. As public money is involved in such research, it is absolutely
necessary to insert such clauses so that there are some mechanisms for price monitoring by the
government. Asian governments can prevent these clauses from becoming dummy clauses only
by monitoring such practices. For example in the Indian Protection and Utilization of Public
Funded Intellectual Property Bill, 2008 it has been stated that “[t]he ultimate objective, however,
is to ensure access to such innovation by all stakeholders for public good.” In such a case, all
possible measures should be taken to ensure that the benefits do reach the stakeholders not only
in theory but in practice as well. The grounds relating to the use of “march-in” rights should be
elaborated in the Bill by the government as this will influence the ways in which a licensee
company will conduct business.

F. Better Commercialization of Inventions

Universities have traditionally been the primary source of basic research. But more
often than not, these research outputs are under a risk of getting lost. For example, they may be
lost when universities do not know how to put the basic research into practical use. Efficient
operation of TLOs can solve this problem. But as the TLOs commercialize the inventions, the
universities begin to generate more income by way of royalties. It is now being argued that the
institutions are becoming more commercially aggressive and their research reflects this behavior
very clearly. The general quality of inventions is also diminishing as institutions move away
from basic research.

118 Presidential Memorandum and Statement of Government Patent Policy issued to the Heads of Executive
119 Id.
120 Barbara M. McGarey & Annette C. Levey, Patents, Products, and Public Health: An Analysis of the Cell Pro
121 See Statement of Objects and Reasons, Protection and Utilization of Public Funded Intellectual Property Bill,
2008 (Bill No. LXVI, 2008).
122 Brett M. Frischmann, An Economic Theory of Infrastructure and Commons Management, 89 MINN L. REV. 917,
1030 (2005).
123 R. Stanley Williams, Testimony before the U.S. Senate Commerce Committee’s Subcommittee on Science,
Technology and Space, NANOTECHNOLOGY (September 17, 2002) (“Largely as a result of the lack of federal funding
for research, American Universities have become extremely aggressive in their attempts to raise funding from large
corporations . . . . Large US based corporations have become so disheartened and disgusted with the situation they
are now working with foreign universities, especially the elite institutions in France, Russia and China, which are
more than willing to offer extremely favorable intellectual property terms”).
124 See Henderson, supra note 23, at 121.
Asian countries need to be very cautious about this trend of moving away from basic research as it can be disastrous for them by completely killing their platform technologies which lead to further research. A solution to this problem is to divide the allocated funds under two categories where one category funds basic research and the other funds applied research. The funds shall be allocated in equal proportion so as to solve the problem of moving away from basic research in universities due to lack of commercialization incentives for it and will facilitate a balanced growth between both types of research.

**Conclusion**

The commercialization of publicly funded research outputs is indeed a massive step that will be of great help to the industry and to the public, in terms of dissemination of research in basic and platform technologies. The Bayh-Dole Act put in place a procedure and system for the proper commercialization of inventions.\(^{125}\) The most revolutionary aspect of the Bayh-Dole Act is that the Act granted ownership rights in the invention to the entities that created them.\(^ {126}\) The Act gave an institution the right to claim a patent over an invention but the federal funding agency also had a non-exclusive, royalty free license over the invention.\(^ {127}\) The government can also deny patent rights in the case when a non-U.S. researcher conducts the research.\(^ {128}\)

Legislations similar to the Bayh-Dole Act will have special relevance for Asian countries because many of these countries are witnessing shrinking R&D funds.\(^ {129}\) The institutions constantly search for new funding sources, and at times, many of these attempts are unsuccessful. Laws to commercialize publicly funded research can help address this problem as they suggest a mechanism through which universities can generate money for themselves through royalties by way of licensing their inventions.

But as discussed above, there may be serious repercussions when the universities have money in mind while conducting their research. The commercialization of these inventions may lead to a situation of completely sidelining the public interest in such inventions and may also stunt the growth of an open knowledge base. Thus the risk that Asian countries have in this context is whether the enactment of a Bayh-Dole kind of legislation would hinder the basic research that is conducted, and create a trend towards commercializing of basic research. The legislation may also be a little disappointing because an inventor who wants to put his invention into the public domain may not be allowed to do so because the invention has to be disclosed to a government authority as soon as possible and a patent application has to be filed for the invention.\(^ {130}\) The Asian countries need to keep in mind the task of catering to the increasing

\(^{125}\) Everett M. Rogers et al., *Assessing the Effectiveness of Technology Transfer Offices at U.S. Research Universities*, 12 J. ASSOC. UNIV. TECH. MANAGERS (AUTM), 43, 80 (2000).


\(^{128}\) See Mowery, *supra* note 3, at 7.

\(^{129}\) See Vivekanandan, *supra* note 81, at 482.

\(^{130}\) Protection and Utilization of Public Funded Intellectual Property Bill, 2008 (Bill No. LXVI 2008), Under Section 4 it has been stated that a recipient within 60 days needs to disclose to the government his knowledge regarding any public funded intellectual property. It follows that within a period of 90 he further needs to notify the government whether or not he intends to retain the title to the given IP so generated. The Bill is silent regarding any other option being provided to the recipient.
demand for drugs and pharmaceuticals. Often, when countries blatantly follow foreign legislations without conducting a domestic study on its adaptability, serious consequences can occur, especially in Asian countries.

There has been immense glorification of the Bayh-Dole Act in terms of boosting university inventions and thus facilitating better university-industry relationship. But many studies prove to the contrary and have opined that there has been a decline in the quality of academic patents.\(^{131}\) Asian countries are all set to have similar legislation and many of them already have it.\(^ {132}\) The verbatim adoption of the Bayh-Dole legislation by many Asian countries is quite inappropriate as in the case of the Indian Protection and Utilization of Public Funded Intellectual Property Bill, 2008. The R&D facilities in India are still in its infancy and many of the publicly funded institutes have not yet established a TLO and are unaware of its use in the commercialization process.

Before the enactment of such legislation, it would be wise to consider how it will fit into the domestic requirements of the concerned country. When the U.S. Bayh-Dole Act was enacted, U.S. universities were all ready and capable of commercializing inventions with mechanisms already in place for university technology transfer. But are the Asian universities currently in a similar position? The university-industry collaboration and the R&D facilities in many of the Asian universities are still in their infancy.\(^ {133}\) Without finding out means to first develop the R&D facilities, there is no point in stacking up new legislation.

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\(^{131}\) See Henderson, supra note 23, at 121.

\(^{132}\) See Sampat, supra note 78, at 4.