Journal of Intellectual Property Rights
Vol 21, May 2016, pp. 140-148

The Indian Protection and Utilisation of Public Funded Intellectual Property Bill, 2008: Does it Secure Access to Medicines?

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Received 19 October 2015; accepted 15 March 2016

In the last decade, governments of different countries have promulgated or considered legislation aimed at promoting collaboration between research institutions, namely, universities and other national research councils and industries to ensure that public or government-funded research conducted at these research institutions feeds into industries' needs, and lead to the manufacture of tangible products. These laws require research institutions to transfer technologies they develop to industry for further development, translation into tangible products, and commercialisation. In India, given the high level of research and development (R&D) and manufacturing capacity in the biopharmaceutical technology sector, this model could play a significant role in boosting local innovation and entrepreneurship. Furthermore, considering the high burden of communicable and non-communicable diseases currently prevalent in India, the need for such a strategic approach to optimise research output cannot be overemphasised. This paper therefore examines the Protection and Utilisation of Public Funded Intellectual Property Bill, 2008 (the Bill) tabled before the Rajya Sabha in 2008 and its potential impact on access to medicines manufactured out of government-funded research, by analysing some of its main provisions. The paper posits that some of these provisions do not seem to tally with the laudable aim of the Bill.

Keywords: Intellectual property, technology transfer, public (government)-funded research, research institutions, access to medicines, India

The Protection and Utilisation of Public Funded Intellectual Property Bill (the Bill) was tabled before the Rajya Sabha (Upper House of Parliament in India) in 2008 for consideration and possible endorsement. The idea of enacting such a law was first discussed in 2004 during a meeting of the National Knowledge Commission (NKC).[1] In a letter written by the chairman of the NKC to the Prime Minister in 2007, the NKC recommended that government needed to introduce a new approach to government-funded research in order to ensure knowledge creation and to ensure that government-funded research is transformed into commercially relevant and useful applications that will benefit the Indian community.[2] According to the chairman, conferring ownership rights of such research to universities and linking such ownership with the patent system and the market was the way to make research more attractive, and bring about a radical change in the research landscape in India.[2] This would also 'create wealth for Indian academic institutions and wean them off government support.'[3] The chairman in his letter further briefly highlighted what some of the main provisions of such legislation could be, and a number of public welfare safeguards that could be introduced in the law.[2]

Drafted in 2005, the Bill was only made available by the government to key stakeholders for inputs and to the public at large for public viewing and comments in 2008 when it was introduced in the Rajya Sabha and to the Standing Committee.[4] According to Shamnad Basheer and Shouvik Guha, the Indian Institute of Science, which is a leading public scientific and technological research and higher education institution in the country and therefore a key stakeholder to involve in the drafting of such a Bill, was only consulted about the Bill in January 2010.[4] After the Bill was tabled before the Rajya Sabha, it was widely criticised by the media and stakeholders. A conference was organised by the National University of Juridical Sciences and attended by representatives from public-funded laboratories, industry, prominent scientists from academia, and civil society to discuss the Bill. During the conference, the Bill was severely criticised by most

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of these stakeholders.[5]

Very importantly, and perhaps for the first time in Indian history, the Standing Committee returned the Bill to the Government for review in consultation with the different stakeholders involved before it would consider it.[6] The Rajya Sabha felt that Government had failed to take into account the interests of the various stakeholders.[4]

The following paragraphs analyse the provisions of the Bill, paying particular attention to whether or not, if passed in its current form, the Bill will promote research, facilitate technology transfer from academia to industry, and the possible implications of the Bill with respect to access to medicines developed out of, or incorporating, publicly funded research.

Analysis of Key Provisions of the Bill

Objective of the Bill

The stated objective of the Bill is to provide for the protection and utilisation of intellectual property originating from government-funded research and to enable India compete in global markets, thereby ensuring that products manufactured through government-funded research are accessible to all stakeholders for the public good.[7] The Bill also aims to promote collaboration between government and private enterprise; promote the culture of innovation; enhance awareness about intellectual property, within public academic and research institutions, so as to increase the responsibility of these institutions to encourage students and faculty scientists to innovate.[7] Innovation will raise revenue for the universities and promote self-reliance, hence, minimising their reliance on government funding.[7] In spite of these ambitious objectives, and as noted by Shamnad Basheer and Shouvik Guha, 'there is a serious disconnect between the Bill's objectives and the proposed method for achieving them.[8]

Retention of Title, Patenting and Licensing

The question of who retains title to intellectual property in the case of government-funded research and how the intellectual property is licenced to industry is critical as this determines whether or not the fruits of this intellectual property can actually be transformed into finished products and how accessible the products would be. This is particularly so in the case of pharmaceutical products like medicines where access or lack thereof could be a question of life or death. The Bill grants title to recipients and requires them to seek intellectual property protection on intellectual property arising from such research. The relevant provision stipulates that recipients shall[9]

> … within ninety days … intimate … to the Government, its intention to retain the title of the … intellectual property with respect to the designated countries and … apply for … protection … [and] … initiate the process for utilisation of the public funded intellectual property immediately after the application for protection … is filed … and submit a written report within six months and biannually thereafter … specifying the steps to take for utilisation …

The word utilisation as used above is defined by the Bill to mean[10] 'the manufacture of a composition or product, the practice of a process or method, operation of a machine or system, or commercialisation thereof.'

Most frequently, commercialisation is achieved through the granting of a licence to industry interested and specialised in the development of the particular technology. With respect to licensing, the Bill provides that[11]

> … no recipient … and no assignee of such recipient shall grant, to any person, the exclusive right to use or sell any public funded intellectual property in India …, unless such persons manufacture such products … substantially in India … Provided that the Government may, for reasons to be recorded in writing allow such sale or use for manufacture in countries other than India.

Based on this provision research institutions can, after obtaining intellectual property protection over public-funded research, grant an exclusive licence thereon to industry for commercialisation provided that the licensee manufactures the product involved substantially in India.

The above provison provides clarity as to who may hold title to intellectual property resulting from government-funded research, which clears any inconsistences or uncertainty which may have existed before. Institutions are sometimes better placed and may have a higher bargaining power in licence negotiations with industry compared to individual scientists. Unlike scientists, institutions

are also more likely to be able to afford prosecution fees in legal actions against infringers. In addition, based on the United States experience examined in Chapter Two, if title is held by the government without the ability of the government to transfer exclusive rights, private industry might be deterred from investing in product development and commercialisation for fear of not being able to recoup their investment costs.

The above patenting and licensing provisions does raise a number of concerns. Firstly, the Bill provides for rather strict deadlines, namely ninety days for recipients to indicate intention to retain title to inventions and immediate commercialisation of the intellectual property. The provision on immediate commercialisation may place universities in an unequal bargaining position *vis*-a-*vis* industry during licensing negotiations as it gives universities very little time to balance the costs of patenting and licensing and establishing the potential commercial value of the intellectual property before engaging in negotiations with industry. This also gives universities limited time to assess and decide on whether patenting is indeed the most appropriate means of ensuring that society benefits from publicly funded research before deciding whether or not to do so.[12] As a result, universities may accept a bad deal over a no-deal situation for compliance purposes, and to avoid losing title to the intellectual property all together.[13] Kathy Nair and Balu Nair note that the Council for Scientific and Industrial Research (CSIR) currently faces a number of challenges resulting from hasty patenting of basic research as several patents have been obtained on upstream research at very early stages of research processes. As a result, further research that must be carried out before any product can be developed and made available commercially is blocked.[14] Rather than making patenting compulsory, the Bill should require each recipient to assess each invention to first determine what is the best way of exploiting it from a public interest point of view would be before deciding whether to patent, how widely to patent, and on what terms to licence the patent to industry[15]. It may also be important to explore the commercial prospects and the benefits of patent exclusivity in other countries.

Secondly, the near mandatory requirement to patent and commercialize places undue emphasis on market incentives for innovation, which may end up vitiating the more important goal of maximizing public and user interests.[16] Market incentives have been prioritised in the Bill, giving the impression that whenever funds are provided to universities for research, commercialisation must ensue. This is a rather false impression because most of the research done in universities is basic research, which sometimes fails to produce commercially viable innovations at least in the short or medium term, yet may prove to be of paramount importance in the long run.[17] In addition, not every single intellectual property held by a research institution needs to be commercialised. In fact, in most research institutions involved in technology transfer, the majority of the inventions are never licensed for commercialisation.[18] Even in India, the CSIR (which is also a leading public research institute and involved in technology transfer) generates only approximately $1 million in licensing revenue, while it spends more than twice this amount in filing and licensing processes. Although it may be argued that the limited profit can be attributed to the fact that the CSIR just recently started pursuing aggressive patenting,[19] Stanford University (a leading United States university in terms of technology transfer) sometimes successfully patents and licences only about 50% of its inventions. In fact, in 2011 only 101 inventions out of the 504 generated by the University were licensed to industry.[20]

Furthermore, the importance accorded to commercialisation in the Bill gives the impression that commercialisation is the only benchmark for measuring the success or failure of technology transfer. This may be very dangerous as it may result in a situation where universities channel public funds to research that only has promising commercial prospects to the detriment of research that would ensure greater public welfare or academic advancement. The success of technology transfer can also be measured in terms of social and humanitarian contributions, such as level of patient access to the end pharmaceutical products; the degree to which university knowledge was useful in creating further innovations; and the number of new jobs generated from patented research.[21]

Given that intellectual property is based on secrecy, over-emphasis on commercialisation may result in research silos as there may be limited collaboration and mistrust among researchers resulting in inefficiencies and lost opportunities. In a bid to avoid the negative effects of market forces,

the CSIR is using an open source drug discovery model to research a cure for tuberculosis in order to mitigate the research gap on the disease.[22] The Bill as it currently stands does not support this kind of venture.

In addition, when it comes to biopharmaceutical technology and considering the public health challenge relating to access to medicines faced by developing countries generally and India in particular, the above provision on immediate licensing could be problematic. The granting of an exclusive licence as allowed by the Bill will prevent competition, which is usually the main force behind lower prices.[23] With exclusive licences come high unaffordable prices, which may, in the case of medicines, be equated to death as was true in the early years of the HIV/AIDS pandemic. By authorising the granting of exclusive licences with no further restrictions designed to increase affordability or to ensure access, the Indian government basically gives away tax payers' money to industry with no consideration of the public's wellbeing because pharmaceutical companies are out for profit and would use their exclusive monopoly rights to charge high prices.

India is the principal supplier of generic medicines to sub-Saharan Africa. India has stringent laws on what constitutes novelty in pharmaceutical patent applications, and unlike other developing countries, has made reasonable progress in utilising some of the flexibilities of the TRIPS Agreement to promote access to medicines both at home and abroad. India also has a robust pharmaceutical manufacturing industry that produces medicines at global standards of quality. It is somewhat surprising that the Indian Bill does not prioritise non-exclusive licenses on government-funded intellectual property.

Moreover, for purposes of commercialisation, while the United States Bayh-Dole Act provides that the fruits of research originating from government funding shall be made available to the public on 'reasonable terms' which courts have interpreted in non-Bayh-Dole related cases to mean reasonable pricing,[24] the Indian Bill is silent on the terms upon which proceeds of government-funded research shall be commercialised.[25] Given that pharmaceutical companies are out for profit, the absence of such an express provision gives way for industry to charge high prices on products manufactured from research that was initially funded by the government with taxpayers' money. Were this to happen, taxpayers will be paying both for the research and the proceeds of the research at exorbitant prices. The fact that the 'reasonable terms' provision is not enforced in the United States does not serve as justification for India not to have it in its laws.

Manufacture Substantially in India

With respect to manufacturing, the Bill provides that[26]

> … no recipient … and no assignee of such recipient shall grant, to any person, the exclusive right to use or sell any public funded intellectual property in India …, unless such persons [manufacture] such products … substantially in India … Provided that the Government may, for reasons to be recorded in writing allow such sale or use for manufacture in countries other than India.

The word substantially as used in the above provision has not been defined. Borrowing from the interpretation under United States policy as discussed earlier under a similar provision in the United States Bayh-Dole Act. This requirement will be met, if, for example, the cost of the components mined, produced or manufactured in India exceed 50% of the cost of all components required by the licensee to make the product.[27] The Bill provides that a government authorisation can however be obtained to allow an exclusive licensee to not manufacture substantially in India but fails to prescribe under what circumstance the authorisation may be granted. This means that a foreign pharmaceutical company having a branch in India can obtain an exclusive licence on inventions originating from intellectual property emanating from government-funded research and be allowed to manufacture more than 50% of the compounds required to manufacture the said product outside India.

March-in Rights

A march-in right is a safeguard measure available to the government whenever an exclusive licensee or an assignee of intellectual property emanating from government-funded research fails to develop or commercialise the intellectual property, or does so in a manner that does not meet the public's need. This intervention can either take the form of compelling the exclusive licensee or assignee to develop and

commercialise the invention, or granting a licence to a third party who can develop the invention and make it available for use in a manner that meets the public's need. While this safeguard measure is included in the United States Bayh-Dole Act,[28] the South African Intellectual Property Right from Publicly Financed Research and Development Act No 51 of 2008,[29] and the Brazilian Innovation Law,[30] it is lacking in the Indian Bill. Under appropriate legislation, government can resort to march-in rights whenever necessary to ensure the development of a technology or to alleviate health, military, security or safety needs in a country. It may be important to note that in his recommendations of this legislation, the Chairman of the NKC expressly mentioned that it would be important to include safeguards like march-in rights.[2]

In the specific case of bio-pharmaceutical technology, the absence of march-in rights results in a dangerous lacuna. Borrowing from the United States where similar legislation has been in place for over 30 years, the practice has been for some pharmaceutical companies that are exclusive licensees of intellectual property emanating from government-funded research to not develop and commercialise the intellectual property if so doing will not be profitable. For example, a pharmaceutical company which obtained a licence on an invention may decide not to develop the treatment or cure because very few people suffer from the disease it is meant to treat or cure, which means that the company will make little or no profit from developing the treatment or cure.[31] A pharmaceutical company may also obtain an exclusive licence on an invention simply to prevent other companies from obtaining the licence where this can be used to develop commercially competing products. Even though the march-in provision has never been used by the United States government or courts when such situations arose, the mere fact that the Bayh-Dole Act provides for this has provided a legal basis for CSOs to bring actions against, pressurise, name and shame pharmaceutical companies exclusive licensees of intellectual property emanating from government-funded research which failed to develop and commercialise inventions, or which did so in a manner that was detrimental to the public's interest. Again, because the Bayh-Dole Act provides for march-in rights, CSOs have been able to advocate for march-in rights, which has sometimes contributed to exclusive licensees granting licences to other companies to develop inventions on their behalf.[32]

Government-Use Rights

This refers to the right of the government to obtain an unrestrictive and royalty free licence to intellectual property resulting from piggybacking on research it has funded. With respect to government-use rights, the Bill provides that[33]

> Notwithstanding anything contained in this Act, the Government shall have the right to practice and to assign any … intellectual property to carry out its obligations under any international treaty or agreement.

This is an important safeguard measure as it confers onto the government an irrevocable royalty free right to exploit the intellectual property to meet its obligations. This provision is particularly important because unlike the government, industry to which universities licence intellectual property, mainly seek profit and sometimes do not necessarily care about the public's interest. Because of this difference in objectives, it is important for government to retain powers to intervene whenever the public interest so requires.

Government-use rights may also be used by the government to allow for broad research, educational, and experimental use of intellectual property and research results between public research institutions and researchers involved in government-funded research. Enabling such research collaboration between researchers is very important as it prevents duplication of research, wastage of resources and time. Particularly in the context of biopharmaceutical technology, where research is often very costly and spans a long duration, experimental use exception is critical as collaboration between researchers may play a great role in curbing unnecessary spending, and ensuring that research actually moves forward. In the absence of research and experimental use exceptions, the tragedy of the anti-commons situations may arise.[34]

Disclosure and Reporting

With respect to disclosure, the Protection and Utilisation of Publicly Funded Intellectual Property Rights Bill provides that the intellectual property creator shall[35]

> … immediately after the creation of publicly funded intellectual property, make a disclosure to the recipient … [and] shall not publish, exhibit or publicly disclose the public funded intellectual property …

Once notified by the inventor, the recipient shall also not publicly disclose, publish or exhibit the intellectual property till an application for the protection of the same in designated countries is made.[36]

With respect to reporting, the recipient shall:[37]

> … submit a written report within six months and biannually thereafter to the Government, specifying the steps taken for utilisation … [and] maintain proper accounts and other relevant records and prepare an annual statement of accounts … [the recipient] shall be audited by the Comptroller and Auditor-General of India … The accounts … together with the audit report thereon shall be forwarded to the Government …

With respect to the disclosure provision, it is important that recipients do not disclose inventions for which they opt to seek intellectual property protection until patent applications are filed. This is because once the invention is disclosed it becomes public knowledge – part of the prior art, thus not novel – and is no longer eligible for patent protection. Globalisation and the advent of the TRIPS Agreement have brought along rather selfish modes of knowledge creation and management, which developing countries have to embrace to avoid being exploited and robbed as is sometimes the case through biopiracy. Not only does concealing intellectual work until a patent application is filed prevent third parties from claiming ownership over the intellectual property and excluding others from using it, it also secures exclusive rights (patents) to recipients which they can then licence to industry in return for royalties.

Equally as important is the need for these inventions to be published and made available to the public on an open and accessible basis. This is not addressed by the Bill. In the United States for instance, the NIH has a Public Access Plan through which research funded by the federal government through the NIH is made available to the public in a private journal within a year of publication. In addition there is a proposed law, the Federal Research Public Access Act (FRPAA), which has been introduced in the United States Senate to require eleven of the biggest public-funded agencies of the country to publish their research online within six months from publication in a journal.[38] The idea is to make publicly funded research available to the public on an open source basis.[39] It should be noted that secrecy comes at some social cost. The lack of collaboration between university researchers results in inefficiencies and lost synergies. Plus, the pace of incremental, follow-on, or translation innovation might also be affected.

Reporting on intellectual property created from government-funded research is also very important as it notifies government about such inventions. In the case of biomedical research, knowledge by government of such patents is even more crucial because government can facilitate or support the further development of the invention into pharmaceutical products to meet emergency health related crises through march-in rights or government-use rights. In addition, reporting is a form of accountability to the government and to the tax paying public. Reporting is also important for monitoring and evaluation purposes.

Apart from having this reporting provision in the text of the legislation, appropriate measures need to be put in place to ensure that recipients actually report on eventual inventions arising from government-funded research. The onus should not only be on recipients to report with no mechanism in place to ensure compliance. As is frequently the case in the United States,[40] recipients may fail to report on intellectual property created and commercialised, and government will not know which intellectual property protected products result from the research it has funded. Also, without knowledge of which products incorporate or have been developed using intellectual property emanating from government-funded research, government will not be able to exercise march-in or government-use rights in the interest of the public if the need arises.

Other Provisions of the Act

The Intellectual Property Management Committee

Under the Bill, the intellectual property management committee is the TTO that will be responsible for the management of intellectual property emanating from the research institution. The relevant provision reads as follows[41]

> Every recipient shall, within one hundred

> and eighty days of the receipt of the funds … constitute an intellectual property management committee within its organisation. The intellectual property management committee … shall identify, assess, document, and protect public funded intellectual property having commercial potential; perform market research and market the intellectual property; create an intellectual property management fund; monitor the process of licensing and assignment; manage revenues from licensed … intellectual property for the organisation … establish mechanisms to promote the culture of innovation …

While it is important for research institutions to have efficient and effective intellectual property management structures, the above provision raises serious concerns. Firstly, the Bill makes it mandatory for each and every research institution to have its own TTO. Experience from the United States Bayh-Dole Act indicates that running an efficient TTO in each university is very costly as it also requires recruiting and maintaining expert technology transfer staff members. Research indicates that while some TTOs in the United States are barely able to break even, others operate on a net loss.[42] For example, according to a survey conducted to determine how TTOs at United States academic institutions are organised, tasked, financed, and motivated, researchers found that these institutions spend on average 0.6% of their research budgets on transferring technology resulting from their research programs, and split 45% on patent protection and 55% on operating costs. Over half of the technology transfer programs bring in less money than the costs of operating the program, and only 16% of institutions are self-sustaining, bringing in enough income that, after distributions to inventors and for research, there are sufficient funds to cover the operating costs of the program.[43] In addition, research also indicates that the bottom 50% of all universities in the United States operate at a loss, and only the 50% to 95% group are operating at a break-even or slightly profitable level, while only the top 5% are very profitable.[44]

An option could be to have a single TTO in each state, or for a number of universities in each state to jointly establish a single TTO. This will cut the cost of negotiating for each and every patented bit of research as it will be possible to bundle rights of multiple patentable and interrelated research innovations, and involve fewer negotiations with perhaps fewer industries.[45]

Royalty Sharing and Reinvesting

Under the Bill recipients of government funds for research are required to share royalties derived from the commercialisation of intellectual property originating from government-funded research with the researchers, and to reinvest some of these royalties in ongoing research. The relevant provision reads as follows:[46]

> … subject to any agreement which may be entered into between the intellectual property creator and the recipient, not less than thirty per cent of such income or royalties, after deducing 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 provision of this section shall prevail:

In addition, the Bill provides that from the remaining royalties, another 30% shall be paid into a fund created by the intellectual property management committee,[47] and any other amount left shall be used for further research and other fees necessary for the protection and maintenance of the intellectual property.[48]

Conclusion

To sum up one may say that the Indian Bill, though ambitious in trying to secure maximum use of the outcome of government-funded research for public welfare through practical application and commercialisation, does not seem to have taken into account some of the negative impacts of the Bayh-Dole Act. This is evident from the fact that most of the provisions are seriously lacking in terms of public interest prioritisation. Interestingly, the fact that the Rajya Sabha has rejected the Bill and requested the government to consult with stakeholders before it is reconsidered, is indicative of the Rajya Sabha's concern for public interest and human rights.

This is particularly because this is the first time in Indian history that the Rajya Sabha rejects a Bill asking government to review it.

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