

## Moving ahead...or just moving on?

*The Bayh-Dole Act of 1980, upon its introduction, was responsible for a sea change in university patenting in the US. Almost three decades later a policy remodelled on the same Act is awaiting discussion and clearance in the Indian Parliament. No doubt it will unleash the innovation bottled in our research institutes, but is the time right? **Aashruti Kak** finds out*

Academic research has a vast social, economic and cultural impact. But all over the world it is still unclear as to how much of this research, which is funded mostly by governments through taxpayer money, is benefiting the population. The main goal of institutional research is not necessarily to achieve economic wealth through their findings; it is to pursue the controversial, neglected and unanswerable questions. There needs to be a concrete link between public investments made in university research and the final successes for the simple reason that if the public does not see and understand the need and importance of university research then governments and policy makers will not and one would argue, should not support it.



If we look back at the last decade, technology has evolved tremendously and has played a significant role in transforming a scientific discovery into an industrial application and then translating it into products useful to the society. For years we have heard about how the industry and academia need to be more proximate to each other and avail the mutual advantage of knowledge and its translation to benefit society and economic growth of the country. In India, this needed alliance has been progressing, but at a snail's pace.

### Patents transfer made easier...

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- **Dr Ajit Dangri**  
President and CEO  
Danssen Consulting

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Following the cue from Japan, in 1980 the US introduced the Patents and Trademarks Amendments (known as the Bayh-Dole Act) in the country to promote the distribution and commercialisation of discoveries and inventions resulting from public-funded university research. The Act led to an extraordinary escalation of the number of filed patents and their translation into beneficial products, thereby improving the industry-academia collaboration. Although it took years for the pharma industry to actually bear the fruits of academic research, the success of it is for all to see.

It is a known fact that universities are far ahead in knowledge than their industrial counterparts, but it is the industry that is ahead of universities and institutes in terms of technologies and processes, and only the industry can impart an economic value to academic knowledge. The main concern that surfaces in solidifying this needed linkage is the immense difference between the work philosophies of institutes and industry. Therefore, to further facilitate existing links between industry and academia, our country needs a formal policy that would encourage co-operation between the two.

As a research hub, our country has no dearth of talent or innovation, but it is due to the lack of adequate government resources to commercialise the precious research, and various bureaucratic complexities, university/laboratory research has still to see the light of day. In other words, we are at a juncture where the US was 30 years ago.

### Of 'Bills', banes and boons...

On December 15, 2008, there was a glimpse of hope for academic research, when the Protection and Utilisation of Public Funded Intellectual Property Bill was introduced in the Rajya Sabha. According to Gowree Gokhale, Co-Head, Pharma

Practice, Nishith Desai Associates, various reports suggest that the Bill has been referred to the Parliamentary Standing Committee on Science and Technology, Environment and Forest for further consideration.

Gokhale explains the basic gist of the introduced Bill, "The Bill attempts to regulate 'public funded intellectual property (IP)'. At present, there is no specific law that lays down who shall own IP in such a scenario and consequently inventors may not get their dues from commercialisation of the IP."

The Bill also aims to regularise the system and lay down a process from the stage of funding to the stage of commercialisation of the IP generated, if any. Gokhale elaborates, "It sets down duties and rights for the three stakeholders in the system of government funded research—the Government, the recipient of the grant of funds and the creator of the IP (scientist)." She continues, the Bill seeks to create clarity on the ownership of publicly funded IP, incentivises research in universities by creating industry out-licensing model, and helps inventors get their dues from the commercialisation. However, she says, "It is silent on whether the scientist gets his due share of revenue/royalty if the recipient chooses not to retain title in the IP and the IP then vests with the Government."

Dr Ajit Dangi, President and CEO, Danssen Consulting, agrees that the Bill is in line with the Government's commitment to policy reforms, but it still needs to be widely debated with all the stakeholders and should not be rushed through. And he is right in saying so as there are many aspects of the Bill that are not clear or well formed, for example, although the Bill is largely based on the US Bayh-Dole Act, with similar provisions in relation to funding, disclosure, retention of title, and national preference for utilisation of IP, it does not have provision for 'march-in rights' which would enable the Government to step in and license the invention to a third party without the consent of the patent holder or original licensee, if it determines that an invention is not being made available to the public on a reasonable basis, says Gokhale.

Also, there are certain issues in the Bill that could create hiccups in the smooth functioning of the envisaged system. "For instance, the Bill envisages (that) the Central Government (will) perform all functions of funding and dealing with IP that shall vest in it when the recipient chooses not to retain title in it," says Gokhale. "The Government would be able to play this role more effectively if it were to create a body of technical experts to assist it to take decisions in relation to the IP that shall vest in it, and while invoking penal provisions of the Bill, decide if steps being taken by recipients are in conformity with the law." There should also be an authority/body created that shall monitor the utilisation of IP that shall vest in the Government, she adds.

"Another issue is that the recipient is expected to bear all expenses in relation to protection of IP. The Bill could also provide for a situation wherein a recipient is not capable of bearing such expenses, since prosecution and maintaining patents is an expensive proposition," suggests Gokhale. "In the Bill, there is a mention that the recipient should 'having regard to its financial capability' bear all expenses for protection and enforcement. It appears that having no funds would be a valid defence for penal provisions of non-compliance," she adds. Lastly, she proposes that the Bill should set down the minimum standard of the composition of the IP Management Committee in the organisation.

All of the above reasons raise questions about whether the Bill will provide a smooth path for university-generated patents and whereby it can further play a crucial and consequential role in corporate-generated patents.

### **Need versus want**

The issues discussed above do not stop here; there are other matters that require urgent attention as well. Dangi says that the Bill needs to be evaluated from an Indian perspective because there is a vast difference in the functioning of the two countries. "The quality of research carried out in Indian academic institutes, barring few exceptions, has still not reached the standards prevalent in the US and other developed countries. Presently most academic research in India is focused on theoretical aspects and on publishing papers, which also shows the gap between the processes of a commercial organisation and a research institute. We are still into chemistry, while the whole world has already moved on to biology. Even China has overtaken India in biotechnology," he says.

But that is just one way of looking at it because there are a lot of talented professors, students (graduates and post-graduates) brimming with innovative ideas and projects. Sadly, the fact that we have segregated institutes for research and teaching, is a deterrent. So, other than stepping up the research quality, we also need to turn our education system around by amalgamating the research institutes with teaching institutes,

thereby giving them better hands on training and work experience, all in one.

Another factor that demands a re-draft of the Bill is our patent laws. Because of lack of data protection/exclusivity, large companies are bound to be reluctant to share projects with universities in order to maintain confidentiality. Dangi explains, "While we claim that our Patent Act passed in 2005 is TRIPS compliant, it still requires correction of few ambiguities to make it compatible with global standards, specifically with respect to the definition of 'patentability' (restricted only to New Molecular Entities (NMEs)) and lack of provision for data protection." He continues, "Our strength lies in incremental innovation. But if you see the Indian Patent Act under Section 3(d), it does not allow patenting anything other than New Chemical Entities (NCEs)." For instance, Biocon is working oral insulin, which is not only an incremental innovation, but is also a major breakthrough for anti-diabetic therapy as it has helped patients tremendously. And yet under Section 3(d) it did not get a patent.

"Unless we harmonise our IPR with global requirements in developed countries, which incidentally even China has done now, I do not think we can go ahead with this bill," says Dangi. Enforcement of the Act and expertise in patent examination also needs dire improvement before rushing in to passing the bill; we should focus on these areas and also implement Dr Mashelkar Committee's report (revised) which is a priority.

Dangi says that the Bill will definitely spur R&D activities in academic institutes due to funding available from the industry and help our scientists to explore newer areas such as biotech, nanotechnology etc. However, he believes that the industry is unlikely to come forward with enthusiasm unless the points mentioned above are addressed. "The Bill is likely to change the direction towards commercial aspects of research. Both these aspects of R&D are important and need to be balanced by incorporating appropriate safeguards in the bill," he adds.

#### Key provisions of 'the Bill'

- Funds for R&D are granted only pursuant to an agreement between the recipient and the Government, the model agreement shall be provided in Rules post the enactment of the Bill.
- The scientist working on a Government funded R&D project must immediately disclose the creation of IP to the recipient
- The recipient must make a disclosure of the same to the Government within 60 days of actual knowledge of the generation of the IP to the recipient.
- The recipient must within a further period of 90 days inform the Government its decision on the countries in which the recipient wishes to retain title (ownership).
- The Government shall be the owner in respect of the countries in which the recipient does not wish to retain title.
- The Bill puts an obligation on recipient of funds to protect and maintain the IP, and utilise the IP by either manufacturing the product itself or by out-licensing it. The recipient has to submit a report to the Government within six months of making an application for protection of IP on steps taken for utilisation of IP and details of licensees, if any.
- Similar obligation is placed on the Government in respect of the IP that shall vest in it.
- The recipient cannot assign the IP to a third party unless it gives the Government information at least 45 days prior to such assignment.
- The recipient cannot grant exclusive licence to sell/use the IP unless substantial manufacturing will be done in India post such licence. This is in consonance with the requirement of local working under the Indian Patents Act.
- The recipient must set up an IP Management Committee within its organisation that is responsible for assessing commercial potential of IP generated from Government funds and manage the protection and commercialisation and also create a fund for the purpose.
- The proportion in which revenue generated/ royalty received from exploitation of IP (minus expenditure incurred in its protection and utilisation) is as follows: minimum of 30 percent to the creator, 30 percent of the rest to the IP

Management Committee and the remaining to the recipient.

- Penalties for contravening any duties imposed on the recipient include fine to the tune of 50 percent of the grant received as well as bar from future grants

*Source: Gowree Gokhale, Co-Head, Pharma Practice, Nishith Desai Associates*

## Being hasty?

The Bayh-Dole Act in the US has been quite successful so far and has rapidly gained popularity in many countries, including ours. But as per many critics of the Act, its rewards have spurred a lot of changes in the researchers' agendas as they increasingly incline towards commercially viable research, leaving behind the unexplored. Considering this, and the fact that 'march-in' clause of the Act has rarely been invoked to punish those who abused the privileges granted under the Act, one wonders if it is a good idea to implement a policy modelled on the Act in India.

"It is too early for us to be introducing this bill because it was only in 2005 that the product patent regime was introduced; and we have immense pressure from World Intellectual Property Organisation (WIPO) to amend the Act because many Indian companies have started taking international patents. Hence, we need to get our IPR in place and harmonise it with the global trade, along with enforcement of the same, training of the judiciary, the patent attorneys and so on," avers Dangi.

According to him, the Bill should not be a priority for the Government at this juncture. "If you see the Government's track record, doing commercial research has never been their forte. So it is better that all is left to the universities and the industry to work on this model. The Government, in my opinion should only give the policy environment that is conducive for research, rather than actually conducting research," he says. Giving the example of Mumbai's Haffekine Institute being shut down for not complying with Good Manufacturing Practice (GMP) norms, Dangi says that the very fact that a government institute is being closed down for non-compliance to norms does not reflect well upon the government itself. The pharma industry, in general, is reasonably profitable, but government units like for example, Hindustan Antibiotics, Indian Drugs and Pharmaceuticals Limited (IDPL) have turned sick because of mis-management, mostly on grounds of incompetence, political interference and rampant corruption.

Coming back to patenting, Dangi says that institutes and national laboratories can get international patents for their inventions/discoveries and license them to big companies and earn money. "Council of Scientific and Industrial Research (CSIR) has been doing that; being the number one patent filer in India, it holds the maximum number of patents in the country. That was possible because Dr R A Mashelkar internally reformed all the CSIR laboratories. So if you look at National Chemical Laboratory (NCL) in Pune, which was a sleeping giant, it has been transformed over the last 20 years. Everything has been changed," he says. "Policies should encourage innovation incentivised through tax benefits and so on, eg National Institute Of Pharmaceutical Education And Research (NIPER) is coming out with six to seven facilities all over the country, which is good. Government should develop research and teaching institutes, and focus on healthcare rather than taking direct charge of the R&D," he adds.

Gokhale opines that inspite of the criticism of the US Bayh-Dole Act, the Indian Bill is a positive step for R&D in the country in view of the many advantages it offers. Once practical issues are taken care of, the system of public funded research is anticipated to function in accordance with the legislative intent of the Bill.

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