

Public Funded R&D Bill, 2007, a legal perspective

06 May 2009 | News



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India's biotechnology industry has entered into a critical phase. Though biotech has been around for some time now, the industry took shape in the late 1990's when dozens of academicians turned entrepreneurs. This is almost similar to the situation in the US, when a remarkable piece of legislation, called Bayh-Dole Act opened the floodgates of research centers and led to the emergence of the biotechnology industry as we know today.

It was indeed rightly timed, the Indian Government came out with the bill to encourage the scientific community in India whose rights is otherwise not recognized. The US was the pioneer in this regard by enacting the Bayh-Dole Act, 1980, that sought to empower universities for protecting their intellectual property rights (IPRs). Many in the industry too feel the time is conducive since we already have venture capitals in technology development and once the bill is passed and takes the form of an act, it will generate infrastructure as well.

At present, the universities and research institutions in India that manage to get government funding lack the mandate to commercialize their research results, which is largely done by the industry. Innovations also get wasted as they belong to the funding agency. The proposed legislation is expected to provide a legal framework to the research institutions that would develop an active interface between the funding agencies, academia and the industry, which has been lacking so far.

Scientists are not expected to have profits on their mind when they involve themselves in laboratory work. This is set to change, with the Public Funded R&D (Protection, Utilization and Regulation of Intellectual Property) Bill, 2007, drafted by the Central Government and apparently being circulated among the ministries. The bill is expected to commercialize research from public-funded institutions as they have been largely insulated from the challenges of the competitive environment in which private-funded research operates. Companies typically get their research patented, following which they try to leverage the research into a viable commercial product.

The bill seeks to encourage public sector research organizations to patent their inventions and offer them to the industry for commercialization on a revenue-sharing basis quite like how the Bayh-Dole Act did for American universities. The bill will

provide the enabling mechanism to permit research institutes to own IP on publicly-funded research projects. Government funded R&D bodies like CSIR among others are set to be covered under the proposed law. The legislation should be a broad guiding framework and specifics should be left to the rules that are made later taking into account in the changing environment.

Questions for consideration

Will the legislation bring institutions and corporations too close to each other for public comfort? Is there a way to get the best research on board and not just that of a high profile researcher or scientist? And, most importantly, what happens to national interest, in terms of pricing and access to a medicine developed through public-funded research and subsequent commercialization?

It would be useful to incorporate penalty provisions in the proposed bill if not included which may act as a deterrent for scientists from infringing their rights to reap profits out of their inventions. Scientists need to put their protected work in the public domain.

Various agreements will take place between the public and private sectors and the technology that bears fruit from the research should be evaluated properly with the appropriate commercial yardstick.

Some of the major features of the Bayh-Dole Act, 1980 (BDA) are, non-profits, including universities, and small businesses may elect to retain title to innovations developed under federally-funded research programs; universities are encouraged to collaborate with commercial concerns to promote the utilization of inventions arising from federal funding; universities are expected to file patents on inventions they elect to own and universities are expected to give licensing preference to small businesses.

The BDA was part of the attempts of the US Congress during the 1980s to create a unified government patent policy pertaining to inventions made with federal support, to promote invention-related activities among the academia. The bill has triggered another global debate on the impact of IPRs on development and access to public health that have occupied the centre-stage in the last decade, starting with the Doha Declaration. The introduction of the IP bill now in India perhaps also typifies the confused mindset of most developing countries whether to adopt or adapt the western models of IP protection regimes for development given the complexity of the issues.

Supporters of the IP bill, largely the government functionaries and some section of the Indian industry, chant the IP mantra – innovate, patent and prosper. At the other end are the academics, civil society groups both from India and abroad – voicing serious concern on both the bill itself and the way it is being rushed through the Indian Parliament.

There are numerous opportunities in the biotechnology sector in India. With enough scientific manpower, India has the vital ingredients for success in biotech and pharmaceutical R&D. However in order to harness this talent, care must be taken to address the above issues in an enabling business environment with a pragmatic, entrepreneurial mindset. The Public funded R&D bill in India should be debated far and wide in order to make it a realistic and effective piece of legislation.

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