## BioSpectrum

## A Bill full of promises

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The PUPFIP Bill, inspired by the Bayh-Dole Act of the US, proposes to take research being done at universities up to the commercialization stage. However, how much of the impact would play out would depend on the ecosystem for innovation encompassing academics, national int availability

The Protection and Utilization of Public Funded Intellectual Property (PUPFIP) Bill, 2008, commonly known as the proposal for an Indian Bayh-Dole Act, was first tabled in 2008 in Rajya Sabha. Tabled by the then minister of science and technology, Mr Kapil Sibal, the draft was an emulation of the the US Bayh-Dole Act of the 1980s, modelled on the premise that protection and utilization of intellectual property coming out of state-funded research institutions and universities would harness the

wheels of innovation in India and see its fruits in the market.

The biotechnology industry in India at that time recorded a total sales revenue of \$2.57 billior (20) recording a 20 percent growth, and it was hailed as the next big thing for science. It was assumed that like its US counterpart, the biotech industry too would open the floodgates of innovative research, ensure greater interaction between the industry and the academia, incentivize scientists, and above all, bolster growth of the biotechnology industry in India. On paper, it was hailed by all as a progressive piece of legislation.

## The Bill

The Protection and Utilization of Public Funded Intellectual Property Bill, 2008, states that its aim is "to provide incentives

to increase innovations, collaborations, licensing and commercialization in India�. The Bill is an attempt to take research being done at universities up to the commercialization stage, which are otherwise restricted to academic journals and peer reviewed papers.

It throws light on aspects such as funding, disclosure of public funded intellectual property, vesting of title of public-funded intellectual property, assignment of intellectual property, duties of intellectual property creator, constitution of intellectual property management committee and its functions, sharing of royalties or income, protection of action taken in good faith, stoppage of grant and recovery of grant released and penalties for failure to discharge duties of intellectual property creator.

With respect to funding, section 3 of the Bill mentions that any recipient interested in taking a grant from the government for the purpose of R&D shall enter into an agreement with the government before the receipt of such a grant. The recipient shall make disclosure of public funded intellectual property to the government within the time specified under section 4.

A recipient here is a university or an institution of higher education established for research purposes that has entered into an agreement with the government and any organization established by an act of Parliament or a non-profit scientific or educational organization registered under the Societies Registration Act, 1860.

With respect to disclosure of public funded intellectual property, section 4 of the Bill stipulates that the recipient shall, within a period of 60 days of actual knowledge of the public funded intellectual property, make a disclosure to the government. If the grantee institution wishes to patent the said invention, it must make a declaration to the government agency within a period of 180 days of the disclosure under section 4. If the recipient fails to disclose the public funded intellectual property under section 4 or give such intimation within the specified time, the title of the public funded intellectual property, shall vest in the government. Every recipient shall within 180 days of the receipt of the funds under section 3, constitute an intellectual property management committee within its organization.

In terms of royalties and income, section 11 of the draft mentions that royalties or income received by the recipients from the intellectual property shall be shared with the inventor in a proportion of 30 percent of net expenses on IP protection and utilization.

## The Bayh-Dole Act & its Indian version

The PUPFIP Bill is inspired by the US Bayh-Dole Act of 1980s that allows research institutes and universities' ownership of patents on their inventions that are federally funded. The Bill in the US was tabled in the senate as an amendment to the Patent and Trademark Act by Senators Birch Bayh of Indiana and Bob Dole of Kansas. Cascade effects of the law on the US biotechnology industry was huge. It was a spark that accelerated technology transfer between universities and industry. By incentivising inventions and research, the country saw scientists turning towards entrepreneurship and setting up spin-off companies to translate academic research into commercialized marketable products.

Dr Vijay Chandru, chairman and CEO, Strand Life Sciences, and president, Association of Biotechnology Led Enterprises (ABLE), says,  $\hat{a} \in \alpha$ In the US, this act gave the rights for commercializing the output available to the inventors and research institutes. By the early 1980s, institutes such as Stanford and MIT did not need a Bayh-Dole Act as there was already a lot of translational research. The law was actually helpful for state universities, as it gave them a structure for being able to translate research.  $\hat{a} \in ?$ 

Ms Khushboo Baxi, senior member, pharma and IP team, Nishith Desai Associates, says,  $\hat{a} \in \infty$ The Indian Bill provides for greater IP protection to products of public funded research. The most significant difference between the two is that the Indian Bill seeks to protect intellectual property in different forms, such as trademark, copyright and patent, whereas the US Act provides only patent protection to subject inventions. The two have similar objectives, but the US Act covers far more territory than the Indian Bill. $\hat{a} \in ?$ 

Experts from the industry are hopeful that if channelized in the right direction, this Bill can have a similar impact on the biotechnology industry in India as the Bayh-Dole Act had in the US. Mr KV Subramaniam, president, Reliance Life Sciences, says, "The Indian Bill is, by and large, similar to the US Bayh-Dole Act. Going by the stated objective, it should have a positive impact on the innovation scenario in India. How much of this impact would play out would depend on the ecosystem for innovation encompassing academics, national research labs, private research labs, capital and talent availability.�

COMPARATATIVE OVERVIEWS	
PUPFIP Bill 2008 (India)	Bayh-Dole Act 1982 (US)

1. The Bill seeks to provide incentives for creating and commercializing intellectual property from public funded research.	1. The act enables non-profitable organizations, including universities, and small businesses to retain title to innovations developed under federally-funded research programs.
2. The Bill requires the scientist who creates an intellectual property to immediately inform the research institution. The institution shall disclose this information to the government within 60 days.	2. Universities are encouraged to collaborate with commercial concerns to promote the utilization of inventions arising from federal funding.
3. The institution is required to inform the government of the countries in which it proposes to retain the title to the PFIP. The title in all other countries will vest in the government.	3. Universities are expected to file patents on inventions they elect to own.
4. The scientist shall be paid a minimum of 30 percent of net royalties received from the PFIP.	4. Universities are expected to give licensing preference to small businesses.
5. Failure of the scientist to intimate the institution, and of the institution to inform the government carries penalties, which include fines and recovery of grant funds	5. The government retains a non-exclusive license to practice the patent throughout the world.
(Contributed by Dr Ravi Dhar, senior consultant, IP Cell, BIRAP, Department of Biotechnology and former head-IPR, NII, New Delhi.)	

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