Wanted A Bayh-Dole Act for India

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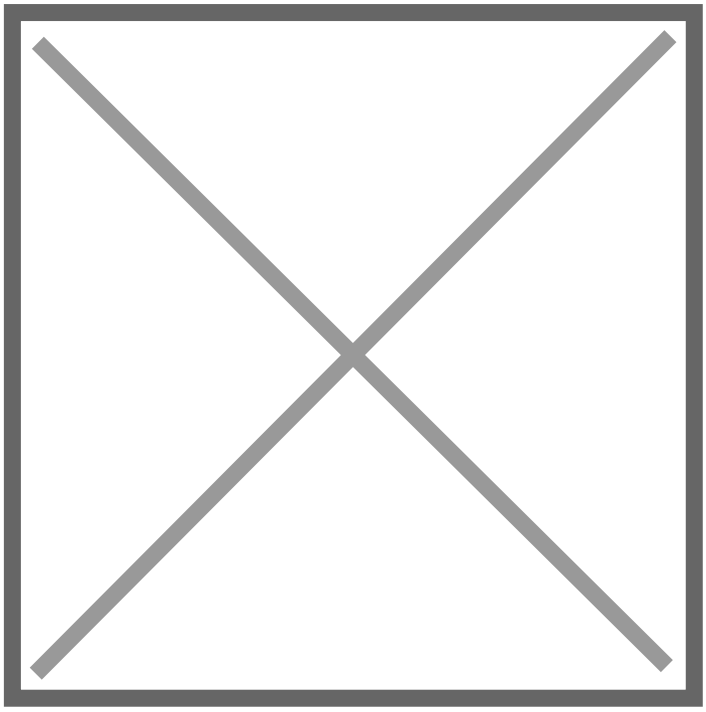


India's fledgling biotechnology industry has entered a critical phase by leaping over the $1-billion revenue mark. Though biotech has been around for over 25 years, the industry took shape in 2000 when dozens of academicians turned entrepreneurs. This is almost similar to the situation in the US 25 years ago, 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. Based on the experience of the 25 years of this Act, most biotech experts believe that India too could benefit from such a legislation to give a further boost to the biotech sector. BioSpectrum Editor Narayanan Suresh reports about the importance of this legislation from Washington DC and Philadelphia.

Major provisions of the Act include

- 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
- Universities are expected to give licensing preference to small businesses
- The government retains a non-exclusive license to practice the patent throughout the world
- The government retains march-in rights.

It was December 1980. Ronald Reagan who had been elected as the President of the US in a landslide election was getting ready to begin the new era of prosperity for Americans.

The US senate was having its last session of the year before adjourning for the Christmas season and a new look house would have taken charge in January 1981. Hours before closing, the Senate approved a small piece of amendment (P.L.96-517) to the Patent and Trademark Act. Little did the sponsors of the amendments - Senator Birch Bayh of Indiana who had lost the elections in the Reagan landslide and Senator Bob Dole of Kansas - realize that they would not only attain immortality for this Act, but also seed the growth of the $91-billion biotechnology industry.

The amendments are no longer referred their identification number. It is simply the Bayh-Dole Act. It created a created a uniform patent policy among the many federal agencies that fund research, enabling small businesses and non-profit organizations, including universities, to retain title to inventions made under federally-funded research programs.

The Act is "perhaps the most inspired piece of legislation to be enacted in America over the past half-century," according to The Economist.

"Innovation's Golden Goose," an opinion piece published in the December 12, 2002 edition of the respected publication, states: "Together with amendments in 1984 and augmentation in 1986, this unlocked all the inventions and discoveries that had been made in laboratories throughout the US with the help of taxpayers' money. More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance."

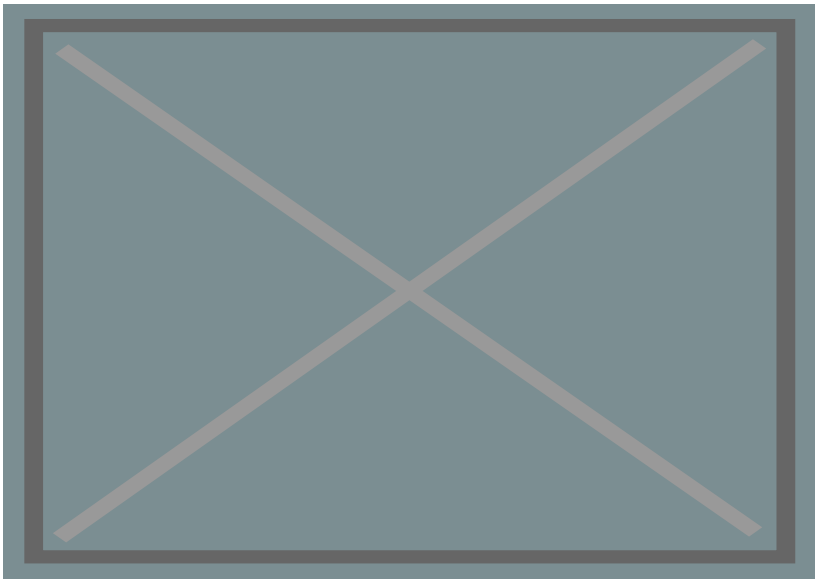
The Act is 25 years old. And the annual convention of the Biotechnology Industry Organization (BIO) hailed Bayh as a visionary and honored him at a special session on June 20, 2005 in Philadelphia.

A new generation of scientist-turned entrepreneurs emerged all over the US, turning their academic research into successful products, backed by the power of the Bayh-Dole Act which specifically permitted such endeavors.

The building of biotech

The Bayh-Dole Act allowed universities and their faculty members to stake patent claims on discoveries they made through research funded by such federal agencies as the National Institutes of Health, instead of leaving ownership of the intellectual property with the government.

That change accelerated the use of academic breakthroughs like gene splicing to develop biotech drugs and other products, giving rise to a three-way partnership of government, universities and startup firms that is "the envy of every nation," said Biogen Idec CEO James Mullen.



Bayh-Dole Act: Success Stories

According to a study by the Council on Government Relations (COGR), University patenting and licensing efforts under the Bayh-Dole Act have fostered the commercialization of many new technological advances that impact the lives of millions of people across the nation.

A recent survey by the Association of University Technology Managers (AUTM) revealed that 70 percent of the active licenses of responding institutions are in the life sciences - yielding products and processes that diagnose disease, reduce pain and suffering, and save lives. Most of the inventions involved were the result of federal government funding.

A few widely known success stories are:

- Artificial lung surfactant for use with newborn infants, University of California
- Cisplatin and carboplatin cancer therapeutics, Michigan State University
- Citracal(r) calcium supplement, University of Texas Southwestern Medical Center
- Haemophilus B conjugate vaccine, University of Rochester
- Metal Alkoxide Process for taxol production, Florida State University
- Neupogen(r) used in conjunction with chemotherapy, Memorial Sloan Kettering Cancer Institute
- Process for inserting DNA into eukaryotic cells and for producing proteinaceous materials, Columbia University
- Recombinant DNA technology, central to the biotechnology industry, Stanford University and University of California
- TRUSOPT(r) (dorzolamide) ophthalmic drop used for glaucoma, University of Florida

These examples of successful new technologies demonstrate that a strong national infrastructure to support technology transfer has been established at academic institutions across the nation since passage of the Bayh-Dole Act. In 1980 there were approximately 25-30 universities actively engaged in the patenting and licensing of inventions. It is estimated that there has been close to a

10-fold increase in institutional involvement since then.

National survey reflects the impact of this growth in activity:

- Academic institutions were granted more than 8,000 US patents between 1993 and 1997 for technologies discovered by their researchers.
- Over 2,200 new companies have been formed since 1980 that were based on the licensing of an invention from an academic institution, including over 330 companies formed in FY 1997 alone.
- Approximately $30 billion of economic activity each year, supporting

In 1980, before the enactment of this Act, there were some 28,000 patents granted to various universities and research centers, developed using government funds. The titles were with the government Less than five percent of these patents were licensed to companies for developing them into successful products or applications.

The government agencies were not keen to part with the licensing of these patents unless forced by legal action. And whenever it did, companies were given non-exclusive licensed. Very few companies took the risk of investing millions of dollars to turn them into products with the threat of competition having the access to the same technologies looming large.

Bayh recalled that policy makers in the 1970 were worried by the declining competitiveness of the US in sectors like steel where the Russians had taken the lead. Discussions at various levels led to the amendments aimed to free the government-held patents for commercialization.

"But I don't think any of us who worked so hard to get that passed had the slightest idea we'd be sitting here 25 years later in the birthplace of our country (Philadelphia where the US constitution was written), with all these people created by it," said Bayh looking at the thousands of biotech leaders who had assembled to listen to him.

At the same time, he recalled, too little commercial use was being made of the thousands of government-owned patents flowing from the billions spent by federal agencies to fund academic research. "Nobody would spend thousands or millions to get it into your medicine cabinet," said Bayh.

The solution, under the Bayh-Dole Act, was to allow universities and their scientists to own the patents and commercialize the inventions themselves. In what was at the time a revolution in academic culture, faculty members founded their own private firms or granted exclusive licenses to biotech company partners.

Biotech CEOs credited the legislation for academic/industry partnerships that have yielded 60 biotech therapies,including Herceptin, a breast cancer drug from Genentech and Nupogen, a remedy for the dip in infection-fighting white blood cells that can result from chemotherapy. Amgen developed this drug.

Of course, the Act is not without critics. The unprecedented co-mingling of the academic and commercial spheres has led to bias in scientific findings, undermined public trust in medical research and tilted universities toward profit-making projects rather than fundamental discoveries, said Sheldon Krimsky, a Tufts University professor and author of the 2003 book "Science in the Private Interest."

Krimsky points to recent industry controversies over the alleged suppression of drug studies with unfavorable results, and disclosures that academics who serve on influential scientific advisory panels to government agencies like the FDA often have extensive ties to industry. Manufacturers who fund academic research have sometimes retained the right to veto publication of a university scientist's results, he said.

During a panel discussion at BIO 2005, an expert panel grappled with the fallout from accusations last year that manufacturers of certain antidepressants had played down or withheld data showing increased risks of suicide linked to the drugs.

It was pointed out that GlaxoSmithKline, settled fraud charges by promising to post all data online, and some others followed suit. Prestigious scientific journals are devising rules to guard against selective publication of favorable studies, to the exclusion of negative results.

There were of course, the potential for a new world of bias or appearance of bias in the new world of academy-industry interactions.

"Conflicts (of interest) are natural products of the system in which we work," said Roger Perlmutter, Amgen's executive VP. But such conflicts can be managed by the disclosure of industry connections, he observed.

India too should have its version of the Bayh-Dole, commented many industry experts at a meeting of the Indo-US High Technology Group Meeting in Washington DC on June 15. The meeting was co-sponsored by the US Chamber of Commerce, Confederation of Indian Industry (CII) and FICCI.

India too has a vast system of government-funded research laboratories and universities. The government has spent over Rs 20,000 crore ($45 billion) since Independence to support scientific research.

In the 1990s, the Council of Scientific and Industrial Research (CSIR) introduced a system to reward scientists who develop with a portion of the royalties. Many other research centers follow different versions of this scheme. However, there is no legislative backup for such which can dramatically alter the way research is conducted and commercialized in India.