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India needs to introduce sensible data exclusivity regulations

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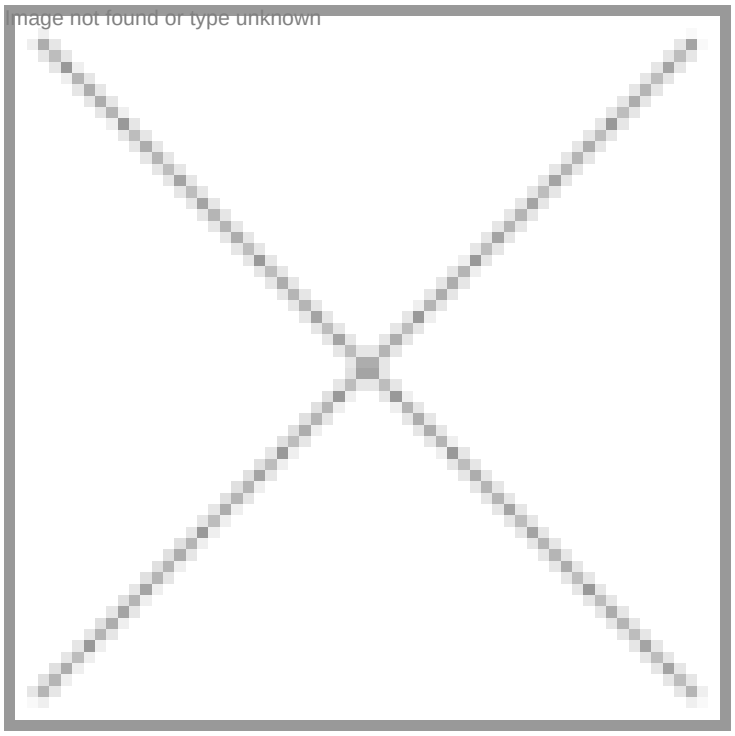

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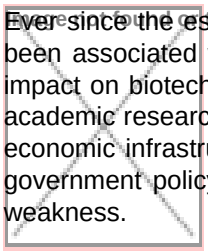

Prof. Ananda M. Chakrabarty

Prof. Chakrabarty is attached to the University of Illinois.

Ever since the establishment of the National Biotechnology Board and then the Department of Biotechnology (DBT), I have been associated with this unique governmental agency for over two decades and have observed with awe its tremendous impact on biotechnology development in India. Yet, in spite of its many successes in fostering biotechnology education and academic research, it has lagged in its mission in technology development and marketing, an important area of industrial and economic infrastructure development in India. While the reasons are many, there are two important areas within the Indian government policy where a direct comparison with the policies of the US will shed light on the reasons for this perceived weakness.

Emerging Indian patent laws and their potential impact

In 1970, the Indian Patents and Designs Act of 1911 was amended to exclude pharmaceutical and agrochemical products as patentable subject matters, thus helping a thriving generics industry to take root. An undesirable consequence was that making new and innovative products no longer merited protection, thus making innovation a major casualty and Indian pharmaceutical industry basically a copycat industry.

A sea change occurred in 1994-1995 when India signed the TRIPS agreement, bolstered by the information technology, as part of India's entry to the WTO. To meet the TRIPS mandates, India had to change her patent laws to recognize product patents of the other WTO member countries. India was given 10 years until January 2005, to make this legal change effective. In response, the Indian Parliament passed the Second Patents Amendments Act in 2002 that recognized a 20-year patent term but diluted certain protections, particularly in the area of traditional knowledge and benefit sharing as well as allowing compulsory licensing on grounds of public health emergency and legally allowing to make patented drugs for export to countries with insufficient or no manufacturing capacity.

In December 2004, the President of India promulgated an ordinance amending the patent laws to be effective from January 1, 2005. The Indian Parliament finally passed the Patent Amendments Act in April, 2005, thus making Indian patent laws largely TRIPS-compliant, although a few obscure issues such as patentability of new use (or mere new use as used in the 2004 ordinance) of a known substance, and whether salts, esters and polymorphs comprise the same substance or not, remain to be fully settled.

Two somewhat contentious issues that are being addressed may play a role in future biotechnology development in India. One is the issue on data exclusivity where the TRIPS Article 39.3 mandates India to protect clinical dossiers submitted to the regulatory authority for marketing approval of a candidate drug for a fixed period of time. The protection of the clinical data from unfair competition is of paramount importance for promoting clinical trials in India and a five-year period of protection of the submitted data is considered useful. India had no such data protection guidelines in place, although efforts are being made to change these guidelines.

The traditional knowledge and access to benefit sharing is more contentious. In the absence of documented benefits and use, and what constitutes traditional knowledge, this issue, which is of great significance, particularly for the indigenous populations who traditionally generate and use the fruits of such knowledge, needs resolution. At the Hong Kong WTO Ministerial Conference in December 2005, India pushed hard for disclosure of the origin or source of genetic resources, proof of prior informed consent, and some form of benefit sharing, for patentable inventions to be adopted by the WTO. The idea is to prevent what's popularly known as biopiracy, that is, the utilization of Indian tropical flora and fauna by the multinational corporations for patented drug development.

Since in most cases, medicinal plants or their products or extracts are used as drugs without any written or legally valid documentation on their efficacy, the Indian government has embarked on digital library construction for proof of their usage and efficacy. As a follow up of the 1993 Convention on Biological Diversity, the Indian Biodiversity Act mandates registration of the patent applications with the National Biodiversity Authority for their approval, particularly with regard to identification of genetic resources, informed consent and benefit sharing. While they will certainly slow down the pace of utilization of Indian genetic resources for drug development by the foreign corporations, they will similarly negatively affect the use of these genetic resources by Indian inventors in India.

Having recognized product patent to encourage product development by young Indian inventors, why would the Indian government put major roadblocks on their inventive approaches? While multinational corporations have many other places to go, such as Thailand, Costa Rica and others, where would the young Indians go to look for appropriate medicinal plants and other genetic resources without much time consuming paperwork with the National Biodiversity Authority? The attitude of the Indian government and the pharmaceutical industry that Indian inventors and entrepreneurs are incapable of innovation and therefore their job is to prevent foreign enterprises to use Indian genetic resources is self-defeating, short-sighted and counter-productive.

US patent laws giving rise to a vibrant economy

In contrast to the Indian Patents Act of 1970, the US patent laws are part of the US Constitution framed in 1790 (Art.1, cl.8) and clearly state that "The Congress shall have the power to promote the progress of science and useful arts by securing for limited times to authors and inventors the exclusive rights to their respective writings and discoveries". Indeed, in language written by Thomas Jefferson in 1793, the US patents could be obtained for "any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement thereof". The purpose was to protect innovation in all its forms and to attract innovators to the US from countries where their inventions could not be protected.

This was emphasized by President Abraham Lincoln, holder of a patent, on February 11, 1859 in his second lecture on discoveries and inventions "in absence of protection, any man might instantly use what another had invented, so that the inventor had no special advantage from his own invention. The patent system changed this; secured to the inventor, for a limited time, the exclusive use of his invention, and thereby added the fuel of interest to the fire of genius, in the discovery and production of new and useful things". Today, a patent issued by the US PTO (Patent and Trademark Office) is generally signed electronically by the PTO Director.

In contrast, in an effort to add the fuel of interest to the fire of genius, President George Washington personally reviewed and signed each successful patent application, which were also signed by the Secretary of State, Thomas Jefferson. It was not just an empty gesture. US Patent No.3 was granted to Oliver Evans who invented an automated flourmill for continuous milling of flour. As a mill owner and operator, President Washington, and many others, adopted Mr Evans's patented technology, providing a clear example of technology promotion and transfer in the early days of the US government. It is no wonder then that the US has developed and nurtured such sustained technological capability and industrial productivity resulting in an economy that is second to none.

Public financing of education and the Bayh-Dole Act

Simply having a great patent policy is not enough. If innovation is to be encouraged, the government must encourage education in what is described in the Constitution as "science and useful art". The Land Grant Act of 1862, sponsored by congressman Morrill and hence known as the Morrill Act, helped found innumerable colleges for agriculture and mechanic art throughout the country. I work in one such land grant university. It was also apparent that patenting was a costly process and it was harder for individual inventors to transfer a patented invention to the marketplace. As early as in 1912, research corporations were set up for managing patents from various institutions and in 1925, Wisconsin Alumni Research Foundation (WARF) was set up to manage university intellectual property.

Since then, WARF has distributed more than $750 million to the university. As the US government became more and more concerned about the state of science and technology in the country, in 1945, Vannevar Bush, in the famous document, Science: The Endless Frontier, stipulated the importance of the government funding for scientific and technological research and development. Thus began the emergence of major funding agencies such as NIH, NSF and ONR. A downside was that the patents from government funding belonged to the government and fewer than five percent of the approximately 28,000 government-held patents were licensed for commercial use.

In 1980, two US senators, Birch Bayh of Indiana and Robert Dole of Kansas, sponsored legislation known as the Bayh-Dole Act, that stipulated that government funded research can be owned by academic institutions and small businesses. To allay the fear that the taxpayers' money was going to enrich private people, there was a march-in clause that allowed government takeover of the intellectual property if it was not licensed or marketed in a timely manner. This partnership among the government, the academic institution and private industry has catalyzed significant transfer of technology to the market place. Total funding including private funding in academia, as a result, has grown from about $6.0 billion in 1980 to about $33.0 billion in 2001 and the patented innovations licensed for commercial application have climbed from about five percent to about 30 percent. While in 1980, less than 250 patents were issued to the US universities, in 2003, 3,933 patents were issued. Only a few start-up companies existed in 1980. Today there are more than 4,000 such companies from academic research, 70 percent of which are in biotechnology.

An example that India can follow

It is clear that scientific and technological innovations, intellectual property generation and its legal protection, and licensing such intellectual property for business development to bring new products to the global market, are key to the economic success of a country. The 1970 Patent Act of India was a far cry from such a policy. The lack of product patents provided no incentives to innovative product development in India. The 2005 amendment to the Patent Act is likely to change this scenario, although major impediments remain. For India to become part of the global knowledge economy, it is important that

the Indian government provides explicit clarification for the patentability criteria, removes pre-grant opposition and softens wordings on compulsory licensing.
India also needs to introduce sensible data exclusivity regulations to encourage clinical trials of drugs and pharmaceuticals, reduce hurdles on the use of genetic resources by young Indian inventors and set up appropriate courts of law to adjudicate patent infringement cases in a fair and timely manner. Training of patent attorneys and judges to write broad-based but legally acceptable claims and to help understand and strengthen the emerging patent laws for rapid and fair adjudication by the Indian Judiciary is critical to the development of a thriving biotechnology industry in India.

Even when the Indian Parliament enacted the new patent laws in 2005, there are nagging uncertainties regarding the patentability criteria and patenting of higher life forms are not allowed. In contrast, the US Supreme Court ruled as early as in 1980 that "anything under the sun that is made by man is patentable" in the US. Nothing much will happen if young Indian researchers are not encouraged to be aware of the spirit of innovations and intellectual property creation, and to be actively involved in initiating start-up companies within the academic or small business infrastructures, as the US has done. Thus the future of biotechnology development in India depends largely on a combined partnership between the government, the academia and the business sector, all joining hands for this common goal.

NOTE: Prof. Ananda Chakrabarty, the celebrated scientist, now an American citizen, drew world attention in December 1979 when he applied for the first patent on a living organism - a genetically engineered bacterium able to digest oil spills. The case ended up in the US Supreme Court (US Patent Office Vs Ananda Chakrabarty, December 13, 1979). Prof. Chakrabarty obtained his patent in 1981 and paved the way for many successive patents for genetically modified living organisms in the US. Prof. Chakrabarty is attached to the University of Illinois and visited India in December 2006 for a lecture tour in Kolkata, New Delhi, Mumbai, Chennai and Bangalore. This was organized by the Healthcare and Industry Information Centre along with the respective regional chambers of commerce and industry.