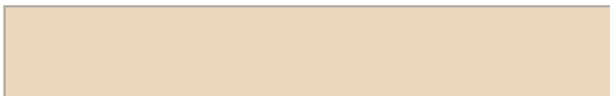


## Patents Act 1970 amended

11 April 2005 | News



The Rajya Sabha finally passed the Patent (Amendment) Bill 2005 on March 23, 2005, with little public debate. Succumbing to pressure from the Left, the government made amendments to the Ordinance (the new Patent Bill 2005) with no discussions to determine the effects of the amendments that have been made to it. Given the compulsions of the coalition government, the UPA government handled the Patent Bill very effectively in the Parliament for its smooth passage, thus honoring the country's commitment to comply with the TRIPS requirement.



With the passing of the Patents Amendment Bill, Kamal Nath, Union minister of commerce and industry, said that the much awaited product patent era had dawned. India now has product patents for pharmaceuticals, agricultural chemicals and special food products. Welcoming the Patents Bill, the Indian Pharmaceutical Alliance (IPA) noted that it has struck a balance between the consumers' interest and that of innovators.

Kumar & Sridharan, a Delhi-based law firm, talks about the salient features of the Bill. Building operations in India, would now confidently take the plunge. Indian companies, on the other hand, need to fine tune their strategies. Foreign companies would be looking at launching their patentable products in India with the hope of a high volume driven growth in India. Indian companies in areas like biotechnology and herbal products may look now to expand their product portfolio. Indian companies will have to adopt a multi-pronged strategy to fully exploit the challenges of the new regime", the minister said.

### What are the key highlights of the third amendment to the Patents Act in relation to biotechnology?

The Patents Act, 1970 has been recently amended to comply with the TRIPS agreement. One of the salient features of the amended Act is that it provides for product patents, which were hitherto not available. The potential for outsourcing opportunities such as clinical trials, contract manufacturing, custom synthesis and technical services is also tremendous.

Shripad Patil, President, Haridharan & Associates, a Mumbai based law firm, said, "The changes in the definition of patentability, restoration of pre-grant opposition and grant of compulsory licensing would help to maintain supply and prices of medicines currently manufactured in India. It would also allay the fears of developing countries about the continuity of supply of low-cost medicines from India."

Still to look at of patentability in relation to However, some NGOs, industry bodies such as the OPPI and IPA have some reservations over the Bill. Khora Kulkarni said "There are still some concerns about the new Bill that needed 'correction', such as Indian residents not being allowed to file patents overseas without the approval of the Controller of Patents, the three-year cooling period which was not required under the TRIPS. The Bill has also provided the option of early publication of patent applications."

Naturally occurring microorganisms are likely to be excluded from patentability. For instance, narrowing the definition of Patentability and broadening the scope of Compulsory Licensing will not be in our interests. As far as Patentability is concerned, India's strength lies in its natural characteristics. We are not yet very proficient in discovery research, which is lengthy, risky and requires deep pockets. Hence the low hanging fruits of innovation such as NDDS (Novel Drug Delivery Systems), polymorphs, esters, isomers etc. should have been grabbed with both hands. Compulsory Licensing is understandable for national emergencies but expanding its scope to cover a wide range of drugs will make mockery of the Patent Law. Also, granting pre-grant opposition will increase frivolous objections delaying the patent granting process. However, we are hopeful that over a period of time these issues could be resolved." SAJ D (Sri Ajit Dangi)

Such as vaccines, enzymes, hormones and Treatment Campaign (AMTC), Alternative Law Forum and Lawyers Collective, which have been raising voice against the Patent Bill, said in a press release that "now the real fight begins". "We will do everything to ensure that dubious patents are not granted by challenging them at all levels," said Leena Menghaney of the Lawyers Collective. HIV/AIDS writer "When legitimate patents are granted, we will ensure that when necessary we will push for compulsory licensing with fair royalties that reflect industry norms."

Chandigarh, is the IDA in India for some of the developing countries to access affordable medicines," said Anand Grover, convener of the Affordable Medicines and Treatment Campaign. Expressing similar views, Loon Gangte, president of the Delhi Network of People Living with HIV/AIDS said, "Today I am using generic AIDS drugs because I can afford the price. The Bill has passed, severely restricts drug patenting of software. This is likely to negatively impact research in bio-informatics."

Reacting to these observations, Dr Ajit Dangi said that the public perception that product patents will have a negative impact on medicine prices is untrue, as 97 percent of the medicines in the WHO List of Essential Drugs are out of patent and will continue to be available at current prices. Also several therapeutic equivalents are available for patented drugs. These therapeutic equivalents are already out of patent. We also have the Drug Price Control Order (DPCO), which is monitored by National Pharmaceutical Pricing Authority (NPPA) to control medicine prices. The government should aggressively privatize health insurance so that patients will get reimbursed for medicine expenses as in most developed countries. The Doha Declaration also takes care of emergencies such as medicines for HIV/AIDS etc.

By passing the Patents Bill, India has sent a message to the global community that the nation is open for business.

Narayan Kulkarni