

India Enters Product Patent Regime

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Kamal Nath, union minister of commerce and industry, announced in December that there are two significant developments in the world of commerce and industry that would open vast opportunities for India in the New Year. "Both are connected with the world trading order, of which India is a part: one is the final phase-out of the Multi-Fibre Agreement and the other is marked by India's conformity with the international Intellectual Property System in all respects, on terms that are practical and credible," he said.

Important public interest provisions in the Patent Law

The Ordinance on Patents was the same as the Bill introduced last year but with improvements in some significant respects. Elaborating on this, he said, "We have introduced a provision for patenting of software that is embedded in hardware. We have also provided for a definite pre-grant opposition procedure. The earlier Bill had only a post-grant opposition, with a weak pre-grant opposition. After extensive discussions we have decided to have both pre-grant as well as post-grant opposition. The government has rationalized the timelines, so as to not leave everything open-ended, but have a definite time-table within which each of the stages should take place. This would reduce by half the maximum time it takes for the processing of an application, from more than nine years to about four. Another significant modification is the introduction of a provision to protect Indian industry from infringement proceedings with retrospective effect. It has specifically provided that patent rights for mail box applications will only be available prospectively. These changes have been made after wide consultation."

Revocation of patent in public interest [Section 66]: This empowers the Government to revoke a patent when it is found to be mischievous to the State or prejudicial to the public.

The Third Amendment was only the culmination of a process begun 10 years ago. The Bill was introduced in parliament a year ago by the previous government, but it lapsed (owing to the elections). "It was our desire to bring the Bill to parliament first. But it was also necessary to consult with all stakeholders and political parties. Group of Ministers got the feedback from industry associations and experts on December 21, so it was not possible to bring the Bill to this session of parliament. This has necessitated the ordinance. The ordinance will be discussed in detail in parliament in the budget session. The ordinance is an interim measure to fulfil our legal obligations within the stipulated time," Kamal Nath added.

general principles and circumstances for patents of food. Any measures to ensure that the reasonable requirements of the public with respect to availability and affordability are taken into account particularly public health and nutrition is protected and balances intellectual property protection with public health concerns and national security.

The Patents (Amendment) Ordinance, 2013, ensures that the reasonable requirements of the public with respect to availability and affordability are taken into account particularly public health and nutrition is protected and balances intellectual property protection with public health concerns and national security. The provisions check the abuse of patent rights. They can be invoked if the reasonable requirements of the public with respect to patented inventions have not been satisfied and the patented invention is not available for public at a reasonably affordable price, and if the patented invention is mischievous to the State or prejudicial to the public.

It's a mixed bag

There was a mixed response to the government's ordinance from different quarters of the society. The pharmaceutical industry and political parties expressed concern over the government using the ordinance route to effect patent changes. The industry is of the opinion that the Bill would have increased the acceptability provided the government had brought it after the deliberations on it in the parliament.

Note: [Section 92]: This provides for action in case of national emergency, extreme urgency and public non-commercial use, and can be invoked against the hasty passage of the Bill. "as many measures need to be taken to protect the interests of the country. The politburo disapproves of the resort to ordinance to pass such an important legislation. There are whole ranges of issues connected with patent, TRIPS agreement and safeguarding of national interest. The Bill, which has been passed as an ordinance, does not serve the purpose."

Similarly the Center of Indian Trade Unions (CITU) also condemned the ordinance. According to some reports it observed that having opened the door for limitless patenting and patenting of products proves that the government has willingly weakened its position before the powerful economies, which control 99 percent of all patents. India is not on the same platforms. It also noted that this will place India at the receiving end and would pay heavily for everything particularly drugs, biotechnological products and pesticides for public purpose [Section 102]: This

"Definition of patent-ability is vague"
- DG Shah, secretary general, Indian Pharmaceutical Alliance

patented products immediately after expiry of term of patent protection by permitting preparatory action by non-patentees during life of patent.

- Parallel import [Section 107(A) (b)]: This provides for import so that patented product can become available at the lowest international price.

Kamal Nath, union minister of commerce

Dr Swati Piramalai, Director, Nicholas Piramalai India Ltd, participating in

VN Balaji, chief scientific officer, Jubilant Biosys Ltd

Indian pharmaceutical and

Salient features of Third Amendment to the Patent law

Extension of product patent protection to all fields of technology (i.e., drugs, food and chemicals);

- Deletion of the provisions relating to Exclusive Marketing Rights (EMRs) (which would now become redundant), and introduction of a transitional provision for safeguarding EMRs already granted;
- Introduction of a provision for enabling grant of compulsory licence for export of medicines to countries which have insufficient or no manufacturing capacity, to meet emergent public health situations (in accordance with the Doha Declaration on TRIPS and Public Health);
- Modification in the provisions relating to opposition procedures with a view to streamlining the system by having both Pre-grant and Post-grant opposition in the Patent Office;
- Addition of a new proviso to circumscribe rights in respect of mailbox applications so that patent rights in respect of the mailbox shall be available only from the date of grant of patent, and not retrospectively from the date of publication.
- Strengthening the provisions relating to national security to guard against patenting abroad of dual use technologies;
- Clarification of the provisions relating to patenting of software related inventions when they have technical application to industry or are in combination with hardware;

Rationalization of provisions relating to time-lines with a view to introducing flexibility and reducing the processing time for patent applications, and simplifying and rationalizing procedures.

Though the ordinance has been passed by the government, the industry bodies want the government to reconsider the ordinance and include the suggestions made by them in the final Amendment. The government, which is committed to TRIPS agreement, should implement the ordinance by making necessary changes in the existing one while discussing during the budget session of parliament without much delay. Faster implementation will enhance the confidence of the investors and research activities in the country.

Narayan Kulkarni with **Rolly Dureha** in New Delhi and **Srinivas Rao** in Bangalore