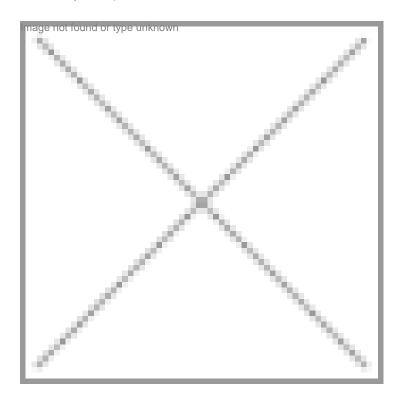


India Enters Product Patent Regime

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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 space significant response consultation of patent in public interest [Section 66]: This empowers the

Elaborating on this, he said, "We have introduced a provision for patenting of software that is embedded in hardware." have alscoptified and of the reference of the procedure. The earlier Bill had only a post-grant opposition, with a weak pre-grant hirepresentation thatter extensive telescussions we have decided to have both pre-grant as well as post-gran opposition of the government of the property of the first of the first of the state of the property of the first of the fi time-table within which each of the stages should take place. This would reduce by half the maximum time it takes for the processing in 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 afte

Kamal Nath, union minister of commerce

The Thire the Thire that the compate the compated where the control of a process begun 10 years ago. The Bill was introduced the partial partial own first. But it was also necessary to consult with all stakeholders and political parties. Group of Ministers got the feedback from <mark>industry associations and experts on Decemb</mark>er 21, so it was not possible to bring the Bill to this ses<mark>s</mark>ion of parliamen has necessitateൾdhe usdinancece lise തുരിളുള്ള will be discussed in detail in parliament in the budget session. The ordinance i<mark>s an interims measwaeteo fw/full ode aegawoobligaeti</mark>ons within the stipulated time," Kamal Nath added.

The Paternats (The iron) Asquestisensones that the reasonable requirements of the public with respectively. affordability eare universe optional adultion is protector, Nicholas Stramal balances and canbratest Mellecta Property protection with public health concerns and national sec<mark>urity participatin</mark> the interflationale system of patent cights properly protection, India has unlocked itself for vast opportunities in both exports as

well as its properties to the presentable in the area of R&D based clinical research outsourcing, particularly in the area of R&D based clinical research outsourcing, particularly in the area of biotechnologyed inventions have not been

general principles and circumstances for

satisfied, and the patented invention is t's a mixedalag for public at a reasonably affordable price, and if the patented

There was enaicom is each trespose to the the rigory entrement's ordinance from different quarters of the society, and he pharmace was known industry ladial political parties expressed condern over the government using the ordinance rouse 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 for Note: I Section 921: This provides for

does not serve the purpose."

A coalitied to be taken to protect the interests of the country. The against the massing passes of national emergency of coalities and the country. The against the massing passes age of the belling any measures need to be taken to protect the interests of the country. The politburow<mark>alisapprovescefpthe reservitore</mark>nce to pass such an important legislation. There are whole ranges of <mark>connect**e**chwithpեReRS agreement and safegl</mark>iarding of national interest. The Bill, which has been p<mark>leased as an ordi</mark>

VN Balaji, chief scientific

officer, Jubilant Biosys Ltd

Similarly Here **erinterniting the aderpresens** (CITU) also condemned the ordinance. According to some reports it observed that having property Sections of the comment 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, biotechnംവിളമുള്ളപ്പെട്ടെയുട്ടുള്ള കൂരു pasticides tor

"Definition of patent-ability is vaque"

- DG Shah, secretary general, Indian **Pharmaceutical Alliance**

> patented products immediately after expiry of term of patent protection by permitting preparatory action by nonpatentees during life of patent.

> public purpose [Section 102]: This

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

Section Editinat are not inventions.

Record of Discussions of the ৰিজ্ঞান্তৰিলিপ্ৰিটেউটোউ<mark>ৰা ক্ষাব্যস্তৰ বিচাইলাম্ভৰিটোলক্ৰা</mark> the patents ordinance has been issued to fulfil In**qua's commitments and** wh

However, this leaves definition of patent-ability towever, big pharmace the patents interiored to polymorphs, hydrates, isomers, metabolites, blicholaso real, ndia Ltd, said, "I'm happy that the government has done it on time." **litigratiatins**na**lli**ke. Government seemed to have abdicated its responsibility to jurisprudence.

lepsanologgaces Twelliaad Differithe reveral benefit and growth of Indian agriculture."

เอ**ย์อยู่ผลาประ**cTi**hrs**ta**หญ่อย** t**he governer eatevand** ude the suggestions in the rules when enacted. for defence purposes, etc.

them patient plate of the filing, speed and the given the compared to price structure so far when many parties were producing them is any poor of the filing, speed and the

Consultant in the ordinance. Hopefully, these will be covered in Rules TRIPS Council decision and will expose LDCs to whose pressure out soon.

oխnidations visitider <mark>law TRIPS agreemeine Biorl</mark>it does not cover all necessary safeguards. Although it provides an opportunity fevergreening of patents use it prohibits patents of the government of the government of the prohibits patents in the law when enacted, the concern among the industry people is if no promise for a known substance. on mere new use for a known substance substance ansaes in parliament what well happen, as the ordinance will lapse (ordinance's life being only six months).

Nicholas Piramal, which believes in its scientists and scientific strength and

obc.Andliweoare hope éuleandroptimistice that tolle parliament will also ratify it. It is a positive and futuri <mark>Sucest G Kares compete</mark>

<mark>\$haring his excitement VN Balaji, chief s</mark>¢ientific officer, Jubilant Biosys Ltd, said, "This pro<mark>௸ssociation dou</mark> Section 14's PHEIRATION of Parlications global village and provides a great opportunity for the Indian pharmaceutical and option for early publication of the tabplication of line ovation in the global market place. It gives an opportunity for the multinationals to make privileges and also developing the value of early in the date of enriching the credibility of the Indian companies and also developing the value of the invention has been granted or the date of enriching the credibility of the Indian companies and also developing the value <mark>bdsd arod wrtshe his hill den erate poor hampl</mark>eyment opportunities and support R&D activities in the country."

abusive practices wherein the applicant for a supplicant for a supplicant

<mark>চিহুংটোবাৰিইন্ Opposition to graph জাকুৰালয়ে. also l</mark>brought in some cheer among the stocks of the pharma multinationals on p<mark>େଝେଖା୪etଦୁ ମୃତ୍ୟୁଷ୍ୟାତ୍ୟୟ୍ୟ ହେଜାବେଥି और ସେ</mark> ସେ ପ୍ରଥମେ investors felt that the pharma multinationals may launch newer drugs in the l<mark>acal Recruding Piscussions at the regritice of its the</mark>t so easy as the ordinance has to get clearance of the parliament in the budget Group of Ministers the Stedinarios is slight oction to hit the Indian market only after 2007, as viability of the new drugs has to be the composite order and mentions have to continue with their existing product portfolio.

Sevencer, the pharmaticularity badies expuested some concern saying that the ordinance does not cover all the necessary

<mark>StriesbaGirkare visiosida et conditional Engage Manuf</mark>acturers' Association, (IDMA) said, "The expected Patents' Ordinance has been i<mark>lseueldtelwithantbliatsnep ewergyavelytuthilteds ouwl</mark>entire set of obligations and commitments under the TRIPS Agreement. The <mark>pbeiducexpartsled ito phearmanyeandialsijohoodtsidal</mark> agro-chemicals is now operative. The era of inexpensive medicines due to elarlier Thiscesis batereisdisectening insteret the new-patented medicines now will be sold at the monopoly price laid down by

need for confidentiality.

The further noted, We were expecting that the Patents' Ordinance (in lieu of the Third Amendment Bill), which would <mark>ന്റോഷ്ട്രം ഉള്ളിട്ടേഷ്ട്രാസ്സ്സൂളിക്കുന്നുള്ള പ്രാപ്രാധ</mark>്യ will take care of all deficiencies in the Patents' Law i.e., the Patents' Act 1970 as well as the type and the type and the contents produced it is possible for the content of the beentaliefexceptionave ibaenstructed in a half hearted manner. It is necessary to highlight these points, so that when the Patents The Amerian en Bitscorres Lip Certand the hear liament during the Budget session, these deficiencies can be corrected. It may nextended the company of the content of the property of the government such as a three-month period for an appealable pre-grant

president, Indian Drug Manufacturers'

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