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Indian Parliament has passed the Patents (Amendment) Bill 2005 that would replace the Patents (Amendment) Ordinance 2004 earlier issued by Government of India in December 2004. The Patents (Amendment) Bill 2005 introduces product patent regime for food, chemicals and pharmaceuticals. India was required to introduce product patent protection in these sectors from 1.1.2005 in accordance with the obligation under the TRIPS Agreement of the WTO. To fulfill this requirement, Government of India had issued an Ordinance in 2004. The Ordinance was to be approved by the Parliament. While introducing the Patents (Amendment) Bill 2005 in the Parliament, Government introduced certain changes from the provisions in the Ordinance.

Salient features of the Patents (Amendment) Bill 2005

Features in the Patents (Amendment) Bill, 2005 that are same as the provisions in the Patents (Amendment) Ordinance, 2004

a) Extension of product patent protection to all fields of technology (i.e., drugs, foods and chemicals);
b) 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;
c) Introduction of a provision for enabling grant of compulsory license 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);
d) 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;
e) Addition of a new proviso 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.
f) Strengthening the provisions relating to national security to guard against patenting abroad of dual use technologies;
g) 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.

Important changes incorporated in the Patents (Amendment) Bill, 2005 as compared to the Patents (Amendment) Ordinance 2004

(The Bill was moved by Shri Kamal Nath, Minister of Commerce & Industry, in the Lok Sabha

on 22/3/05 and in Rajya Sabha (Upper House) on 23/3/05)

1. The 2nd amendment in the Patents Act had made a provision under Section 107A (b) providing for 'parallel import'. However, this required that the foreign exporter was duly authorized by the patentee to sell and distribute the product.

In the Bill this has been amended to say that the foreign exporter need only be 'duly authorized under the law'.

Scope of patentability:

2. Modification in Section 2 – Definitions as follows:

· Section 2 (ja) "Inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art;

· New definition "New invention" means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e., the subject matter has not fallen in public domain or that it does not form part of the state of the art.

· New definition "Pharmaceutical Substances" means any new entity involving one or more inventive steps.

3. Changes in Section 3:
(Section 3 lists out the exceptions to patentability, i.e., what are not considered to be inventions)

Section 3 (d): the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation to Section 3 (d): "Salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

4. The word "mere" introduced by the Ordinance before the words "new use" in Section 3 (d) is now deleted.

5. The clarification relating to patenting of software related inventions introduced by the Ordinance as Section 3(k) and 3 (ka) is omitted.

Strengthening of Pre-grant Opposition:

6. Opposition to grant of patent: The new Chapter heading concerning opposition, namely,

"Representation and Opposition Proceedings" is substituted with the heading, namely, "Opposition Proceedings to Grant of Patent".

7. Hearing at pre-grant opposition stage: A provision for hearing at pre-grant opposition stage has been made in the Rules. This is now introduced upfront in the law itself, as follows:

"25 (1) Where an application for a patent has been published but a patent has not been granted, any person may, in writing, represent by way of opposition to the Controller against the grant of patent within the prescribed period on the grounds of

(a) .. ……..

(b) .. ……..

and the Controller shall if requested by such person for being heard, hear him and dispose of the representation in such manner and within such period as may be prescribed.

8. Extension of time for filing pre-grant opposition: A minimum period of 6 months, from the date of publication is provided for making representation as against the present period of 3 months.

(Since all time-lines have been provided in the subordinate legislation, this will also be done in the Rules).

9. Expanding the grounds for pre-grant opposition: The grounds of pre-grant opposition in the Ordinance were novelty, inventive step and industrial applicability, non-disclosure or wrongful mentioning of source and geographical origin of biological material and anticipation of invention by knowledge, oral or otherwise, available in public domain. These are substantive grounds of opposition. Now the grounds are listed in the same way as in the Act before the Ordinance. Accordingly, in the pre-grant opposition also all the eleven grounds (formal as well as technical) are being specifically mentioned.

10. Deletion of Section 25(2): Section 25 (2) introduced by the Ordinance denies the person making an opposition representation the right of becoming a party to any proceedings under the Act. Sub-section 2 of Section 25 is deleted.

11. Facilitation of pharmaceutical exports to LDCs:

The new provision (Section 92A) relates to compulsory license for export of patented pharmaceutical products (provided for in Para 6 of Doha Declaration), to such countries, as have inadequate production capacities.

Here the condition of obtaining compulsory license is expanded, (in case of LDCs having no Patent Law or provision for compulsory license) to include an 'authorization' or notification from such a country. This is done by modifying sub-section (1) of section 92A as follows:

Adding the following words after the words "provided compulsory license has been granted by such country":

"or such country has by notification or otherwise allowed importation of the patented pharmaceutical products from India."

12. Transitional arrangement applications:

A 3rd new proviso is added under Section 11 A (7) as follows:

"Provided also that after a patent is granted in respect of applications made under sub-section (2) of section 5, the patent holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product prior to 1.1.2005 and which continue to manufacture the product covered by the patent on the date of grant of the patent, and no infringement proceedings shall be instituted against such enterprises."

13. Quantifying 'reasonable period' in relation to compulsory licensing:

The present Act already contains provisions under Section 84 (7) (a) (iv) whereby a compulsory license could be requested on the ground that "the establishment or development of commercial activities in India is prejudiced".

Similarly, Section 84 (6) (iv) provides that in considering an application for compulsory license the Controller of Patents is required to take into account "as to whether the applicant has made efforts to obtain a license from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period as the Controller may deem fit. An explanation is now incorporated to the existing Section 84 (6) (iv) for quantifying the 'reasonable period' referred to above, as under:

"Explanation: - The reasonable time period under this clause shall not ordinarily exceed six months".

14. Amendment to Section 90 relating to compulsory license:

Section 90 (1) (vii) and (viii) has been redrafted in the Ordinance. A further modification is now made to clarify that even when compulsory license is granted for pre-dominant purpose of supply in Indian market, the licensee may export the patented product, if need be; Similar facility of export is also permitted when license is granted to remedy a practice determined after judicial or administrative process to be anti-competitive.

Sub-Section (vii) and (viii) of Section 90 (1) is modified, and a new sub-section (ix) is introduced, which is as follows:

(vii) that the license is granted with a predominant purpose of supply in the Indian market and that the licensee may also export the patented product, if need be in accordance with Section 84 (7) (a) (iii); (viii) that in the case of semi-conductor technology, the license granted is to work the invention for public non-commercial use;

(ix) that in case the license is granted to remedy a practice determined after judicial or administrative process to be anti-competitive, the licensee shall be permitted to export the patented product, if need be.