

The Patents (Amendment) Bill, 2005

The Patents (Amendment) Bill, 2005 has been passed by the Indian Parliament so as to be able to fulfill its obligations under the TRIPS Agreement and to achieve its goal of greater harmonization of patent laws across the globe. The Bill is the third amendment to the Patent Act, 1970 and primarily seeks to introduce product patents for food products, drugs and chemicals, to remove the transitional provision of exclusive marketing rights and rationalize and reduce the timeline for processing patent applications.

The Bill replaces the Patents (Amendment) Ordinance, 2004, which was issued by the Government of India in December 2004 to fulfill India's commitments in accordance with the TRIPS Agreement.

The chief highlights of the Patents (Amendment) Bill, 2005 may be enumerated as follows:

- **Extension of product patent protection to all fields of technology:** 'Product Patents' can now be issued in respect of food products, drugs and chemicals. A product patent prevents others from manufacturing, selling, distributing or importing the patented product-even the versions through different processes- without authorization.
- **Omission of Provisions pertaining to 'Exclusive Marketing Rights (EMRs)':** The Bill omits the provisions pertaining to EMRs since applications for product patents would become open to examination and grant with effect from 1 January 2005. Every pending application for grant of EMRs will be treated as a request for examination for grant of patent. Also, all granted EMRs shall continue to be effective till the grant/refusal of patent.
- **Patent rights in respect of "mailbox" applications:** The rights of "mailbox" applications have been rendered prospectively operational; that is, only from the date of grant of the patent and not retrospectively from the date of application. Also, the Bill has a provision whereby enterprises that have already made substantial investment and have been manufacturing products in respect of "mailbox" applications can

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continue to manufacture products after a patent is granted for a corresponding “mailbox” application on payment of reasonable royalty to the patentee.

- **Re-definition of “inventive step”:** A definition of the “inventive step” to mean “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” substitutes the definition of the “inventive step” as “a feature that makes the invention not obvious to a person skilled in the art”.
- **Definition of “new invention”:** A definition of “new invention” has been added to mean “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.
- **Definition of “pharmaceutical substances”:** A definition of “pharmaceutical substances” has been added to mean “any new entity involving one or more inventive steps”.
- **Re-definition of “new use”:** A definition of “new use” in the context of what is not considered to be an invention is “ 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”. Further, the Bill provides an explanation that 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.
- **Omission of the software-hardware combination provision:** The Bill has dropped the provision

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introduced by the Patents (Amendment) Ordinance 2004 whereby technical application of software to industry or software in combination with hardware was patentable.

- **Provisions for both pre-grant and post-grant opposition:** The Bill provides for both pre-grant opposition (where the application has been published but a patent has not been granted) and post-grant opposition (any time after the grant of patent but before the expiry of a period of one year from the date of publication of grant of patent). The pre-grant opposition includes all the eleven grounds available for post-grant opposition. Also, a provision for hearing at the pre-grant opposition stage has been made.
- **Provisions for compulsory licence for export of patented pharmaceutical products:** The Bill has introduced a provision for the issuance of compulsory licence for manufacture and export of patented pharmaceutical products to countries, which have insufficient, or no manufacturing capacity in the pharmaceutical sector to address public health situations, in accordance with the Doha Declaration.
- **Quantification of “reasonable period” with regard to compulsory licence:** The “reasonable period” for negotiations between the patentee and the applicants seeking compulsory licence has been made six months.
- **Foreign filing permission for Indian residents:** The Bill has introduced a provision whereby any person resident in India would have to obtain written permission from the Indian Patent Office for making a patent application for an invention outside India, unless a patent application for the same invention has been made in India, not less than six weeks before the patent application is made outside India.
- **Provisions for simplifying procedure and reducing the processing time for patent applications:** The provisions pertaining to procedure and timelines have been rationalized with a view to introducing flexibility, simplifying procedure and reducing the

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processing time for patent applications. Some important changes that have been brought about to expedite the processing of patent applications are as follows:

- Provision of the ‘acceptance of the specification’ and its ‘advertisement’ have been deleted and the Act now provides for the direct grant of a patent.
- Provision for the sealing of a patent has been deleted.
- Provision for a request for early publication
- Provision for an express request for examination
- The time for putting an application in order for grant is reduced from twelve months to six months from the date on which the first statement of objections has been issued to the applicant to comply with the requirements.

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