IP Hotline

May 26, 2003

PATENTS AMENDMENT ACT, 2002 AND PATENTS RULES, 2003 COME INTO FORCE

The Patents Act, 1970 , of India, has been amended with effect from May 20,2003 vide the Patents (Amendment) Act, 2002 .The new Patents Rules, 2003 have replaced the Patents Rules, 1972. The amendment has been introduced to meet India's obligations under TRIPS. The new Rules aim at procedural simplification and speeding up of the patent delivery mechanism.

Some of the important amendments are :

- The term of a patent has been extended to 20 years in respect of all inventions.
- The following have been added to the list of innovations which are not inventions within the meaning of the Act and in respect of which no patent can be granted: plants and animals (other than micro-organisms) including seeds, varieties and species and biological processes for production or propagation of plants and animals; a mathematical or business method or a computer program per se or algorithms; a literary, dramatic, musical or artistic work or any other aesthetic creation including cinematographic works and television productions; a mere scheme or rule or method of performing mental act or method of playing game; a presentation of information; topography of integrated; an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components. *TRIPS permits member states from excluding certain innnovations from patentability.*
- In process patent infringement suits, the defendant may be directed to prove that the process used by him to obtain a particular product, which is identical to the product of the patented process, is different from the patented process. The concept of reversal of burden of proof has thus been introduced. *A Plaintiff in a process patent infringement suit , may , at the discretion of the court, not have to bear the burden of proving that the process used by the Defendant is identical to the patented process. This provision apart from being in compliance with TRIPS, is also similar to a provision in the existing law on evidence in India , which states that when a fact is especially within the knowledge of someone the burden of proof should fall on that person.This would make it easier for patentees to prosecute process patent infringement suits.*
- The following acts do not constitute infringement:
  - making, constructing, using or selling a patented invention solely for uses reasonably related to the development and submission of information required under any Indian law or in a foreign law, that regulates the manufacture, construction, use or sale of any product;
  - importation of patented products by any person from a person who is duly authorised by the patentee to sell or distribute the product. *In the absence of this provision all imports of patented products by third parties, without the patentees consent was an infringement. The implication of this provision is that import of the patented product from a person who is duly authorised by the patentee to sell or distribute the product will not consitute an infringement of the rights of the patentee.*
- In infringement suits, the Court can now order seizure, forfeiture or destruction of infringing goods and also materials and implements, used for creation of infringing goods.
- An additional ground for the grant of a Compulsory License has been inserted, viz. "the patented invention is not worked in the territory of India". An implication of this provision could be that the mere import of the patented product by the patentee in India may not be viewed as "working in the territory of India".
  The following grounds are also to be taken into account for grant of compulsory license: a circumstance of national emergency; or a circumstance of extreme urgency; or a case of public non-commercial use, which may arise or is required, as the case may be, including public health crises, relating to Acquired Immuno Deficiency Syndrome, Human immunodeficiency Virus, tuberculosis, malaria or other epidemics. Some Pharma Multinational Companies (MNC) bodies like Organisation of Pharmaceutical Producers of India (OPPI) had mooted introduction of a parameter for determination of the "reasonable price" qua compulsory licenses, (*'patented invention not available to the public at a reasonably affordable price' - is one of the grounds for the grant of compulsory licenses*). However, the Patent Rules, 2003 have not introduced any such parameters. In any event, the Rules cannot override or restrict the meaning of or operation of the main legislation.

The Government of India has also rejected a pharma MNC's proposition that the 'TRIPS agreement prohibits use of data filed in the course of obtaining regulatory clearance for commercial research' and has not included 'data exclusivity' in the Amendment Act, 2002. *"Data exclusivity" is jargon for mandatory non-reliance on originator's data (mainly of drugs and agro chemicals), published to meet regulatory obligations , for unfair commercial use during a fixed period of time. In other words, the data filed by a company on the results of clinical trials and side effects should not be used by other companies for their commercial purposes.*

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