



Country: INDIA

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Further Reporting

(1) The Patents (Amendment) Ordinance, 2004 amended Section 3 (d) and substituted the words 'new use' with the words '*mere new use*' of the known substance. The Patents (Amendment) Act, 2005 reverted to 'new use' from '*mere new use*' of the known substance. Section 3(d) provides for that mere discovery of a new form of a known substance which does not result in the enhancement of known efficacy of that substance will not be termed as 'invention'.

(2) An explanation added 3(d) that mere combinations and derivatives on known substance shall be considered as same substance, unless they differ significantly in properties with regard to efficacy. Any improvement made to the known substance shall not merit protection. Ever greening of the pharmaceutical products results where the incrementally modified (IMDs) are accepted for patent protection. IMDs could be new formulations, new combinations of active ingredients or new salts or esters of approved compound. Thus it would be difficult to get extensions of existing patents by simply claiming new form of old drugs or other substance.

Further the process for the medicinal, surgical, curative, prophylactic or other treatment of the human beings was also kept outside the purview of the term 'invention'.

(3) Patentability of software in India prior to the 2002 amendment was solely governed by the defining clause of the invention. The definition permitted for apparatus claims, however, for a method or process, should have resulted in the manufacture of a tangible and vendible article or substance. This precluded any claims to algorithms or to a method of performing a task or function to achieve a certain end. Protection could be obtained for novel hardware with aspects of software integrated with it. The amendment of 2002

expanded the definition of invention in line with the principles laid out in TRIPs and at the same time excluded matter covering mathematical or business methods or computer programs *per se* or algorithms. Patent Ordinance of 2005 explained that technical application to industry of mathematical or business methods or computer programs would be patentable. It was also clarified that a combination of software with hardware is allowable. Unfortunately such amendments were removed in the 2005 Amendment.

(4) According to Section 39 of Patent Amendment Act 2005, Resident in India cannot apply abroad for any patent without written permit from Controller. But if an application for patent for the same patent has been made in India not less than six weeks before the application outside India and when no secrecy directions has been given to inventions relating to defence purposes in relation to the application in India or all such directions have been revoked.

(5) Information regarding appointment of Dr.R.A Mashelkar as head of Technical Expert Group :

KAMAL NATH CONSTITUTES TECHNICAL EXPERT GROUP ON PATENT LAW ISSUES

New Delhi: April 06, 2005

Shri Kamal Nath, Union Minister for Commerce & Industry, has constituted a Technical Expert Group to study certain patent law issues.

The five-member committee headed by Dr. R.A. Mashelkar, Director General, Council of Scientific and Industrial Research (CSIR), New Delhi (Chairman), will comprise the following as members: Prof. Goverdhan Mehta, Director Indian Institute of Science, Bangalore; Prof. Asis Datta, Director, National Centre for Plant Genome Research, New Delhi; Prof. Madhav Menon, National Judicial Academy, Bhopal; and Prof. Moolchand Sharma, Director, National Law Institute University, Bhopal.

The Expert Group will have the following terms of reference:

(a) whether it would be TRIPs (Trade-Related Intellectual Property Rights) compatible to limit the grant of patents for pharmaceutical substance to new chemical entity or to new medical entity involving one or more inventive steps; and

(b) whether it would be TRIPs compatible to exclude micro-organisms from patenting.

The setting up of the Committee is a direct follow-up of the assurance given by Shri Kamal Nath while moving the official amendments to the Patents (Amendment) Bill 2005 in the Lok Sabha on March 22 that the issue of patent availability of new chemical entities and micro-organisms would be referred to an Expert Committee and if as a result any amendments were suggested to safeguard the interests of these products, they would be incorporated in the new legislation later.

According to the Order dated 5th April, 2005 constituting the Technical Expert Group issued by the Department of Industrial Policy & Promotion (DIPP), Ministry of Commerce & Industry, the Group will submit its report to the DIPP and would be serviced by the Department of Industrial Policy & Promotion.

It is also reported that the Committee headed by Dr R A Mashelkar **RECOMMENDED** that only '*new chemical entity/ new medical entity*' should be given patented protection. Formulations – combinations of drugs, changes in dosage, new use, etc. should not be patentable as there is no inventive step involved.