

# Pharma & Healthcare Update

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## MASHELKAR COMMITTEE SUBMITS ITS REPORT ON PATENTABILITY OF NCE'S AND MICRO-ORGANISMS

The much awaited report of the Technical Expert Group on Patent Law Issues, which was constituted under the chairmanship of Dr. R.A. Mashelkar (Committee) has been submitted on December 28, 2006.

Before the Patents Act, 1970 ("Act") was amended to introduce the product patent regime, various aspects of the proposed amendments were debated in Parliament and various other fora. The Committee was set up by the Ministry of Health and Family Welfare in April, 2005 to make recommendations on two highly debated issues:

- Whether restricting the grant of patents for pharmaceutical substances to a new chemical entity ("NCEs") or to new medical entity ("NMEs") involving one or more inventive steps would be TRIPS compatible;
- Whether excluding micro-organisms from patent protection would violate TRIPS.

The Committee submitted its report after taking into consideration inputs from stake holders such as industry associations, non-governmental organizations and intellectual property attorneys and relevant legal positions in China, U.S., Brazil, Europe, Japan, Australia and United Kingdom. In making the recommendations, the Committee was guided by the need for access of affordable medicines to the people of India, encouraging innovation by Indian industry, its current capabilities in R&D, and balancing of India's obligations under international agreements with wider public interest.

## RECOMMENDATIONS

NCEs/NMEs: The committee concluded that:

- Restricting grant of patent only to NCEs or NMEs and thereby excluding other categories of pharmaceutical inventions would run contrary to Article 27 of TRIPs, which mandates patent protection to all inventions.
- The option of resorting to articles 7 and 8 of the TRIPs Agreement or the Doha declaration on TRIPs Agreement and public health to circumvent Article 27 was also excluded.

Referring to the Indian government's concern over the phenomenon of "ever-greening", the Committee distinguished between "ever-greening" and "incremental innovations" as follows: "Ever-greening" refers to an extension of a patent monopoly, achieved by executing trivial and insignificant changes to an already existing patented product while "incremental innovations" is defined to mean sequential developments that build on the original patented product.

The Committee opined that incremental inventions ought to be encouraged by the Indian Patent regime as they may be of tremendous value to a country like India, while every effort should be made to prevent grant of frivolous patents and "ever-greening".

Section 3(d) of the Act prohibits grant of patent to inventions relating to (i) new property of use of a known substance; and (ii) new form of a known substance which does not result in the enhancement of the known efficacy of that substance. Thus, it already restricts "ever-greening". The "incremental innovations" will be granted patents only if it does not fall within the prohibition of Section 3(d).

## MICRO-ORGANISMS

Under the present Act micro-organisms are patentable subject to satisfaction of the other provisions of the Act. Upon review of Article 27.3 of TRIPs and considering the need to give boost to the Indian bio-tech industry, the Committee concluded that excluding micro-organisms per se from patent protection would violate TRIPs. At the same time, the Committee recommended formulation of strict guidelines to ensure that only micro-organisms modified by substantial human intervention are patented thereby eliminating the possibility of granting frivolous patents. To some extent Sections 3(c) of the Act would prevent grant of patent in relation to micro-organisms that occur in nature. The draft Manual of Patent Practice and Procedure as framed by the Patent Office, India also lays down as follows:

- The living entities of natural origin such as animals, plants, in whole or any parts thereof, plant varieties, seeds, species, genes and micro-organism are not patentable.
- The living entity of artificial origin such as micro-organism, vaccines are considered patentable.
- The processes relating to micro-organisms or producing chemical substances using such micro-organisms are patentable.

The Act does not define "micro-organism", which is likely to lead to interpretational issues. The report has faced criticism from some quarters. Critics to this report say that these recommendations, if implemented, would be more beneficial to the MNCs rather than the domestic pharmaceutical industry.

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## THE WAY AHEAD

The recommendations as laid down by the Committee are, however, not legally binding on the government. The burden will be on the Patent Office to strengthen its guidelines to comply with the above recommendations, if the same were accepted and also on the patent examiners to appropriately interpret and apply the same so that the spirit of the Act is protected and enforced.

**- Khushboo Baxi & Gowree Gokhale**

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Source: [http://patentoffice.nic.in/ipr/patent/mashelkar\\_committee\\_report.doc](http://patentoffice.nic.in/ipr/patent/mashelkar_committee_report.doc)

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