

## Pharma & Healthcare Update

January 18, 2007

### 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.

## Research Papers

### Structuring Platform Investments in India For Foreign Investors

March 31, 2025

### India's Oil & Gas Sector— at a Glance?

March 27, 2025

### Artificial Intelligence in Healthcare

March 27, 2025

## Research Articles

### 2025 Watchlist: Life Sciences Sector India

April 04, 2025

### Re-Evaluating Press Note 3 Of 2020: Should India's Land Borders Still Define Foreign Investment Boundaries?

February 04, 2025

### INDIA 2025: The Emerging Powerhouse for Private Equity and M&A Deals

January 15, 2025

## Audio

### CCI's Deal Value Test

February 22, 2025

### Securities Market Regulator's Continued Quest Against "Unfiltered" Financial Advice

December 18, 2024

### Digital Lending - Part 1 - What's New with NBFC P2Ps

November 19, 2024

## NDA Connect

Connect with us at events, conferences and seminars.

## NDA Hotline

Click here to view Hotline archives.

## Video

Vyapak Desai speaking on the danger of deepfakes | Legally Speaking with Tarun Nangia | NewsX

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

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

DISCLAIMER

The contents of this hotline should not be construed as legal opinion. View detailed disclaimer.

This Hotline provides general information existing at the time of preparation. The Hotline is intended as a news update and Nishith Desai Associates neither assumes nor accepts any responsibility for any loss arising to any person acting or refraining from acting as a result of any material contained in this Hotline. It is recommended that professional advice be taken based on the specific facts and circumstances. This Hotline does not substitute the need to refer to the original pronouncements.

This is not a Spam mail. You have received this mail because you have either requested for it or someone must have suggested your name. Since India has no anti-spamming law, we refer to the US directive, which states that a mail cannot be considered Spam if it contains the sender's contact information, which this mail does. In case this mail doesn't concern you, please unsubscribe from mailing list.

Vaibhav Parikh, Partner, Nishith Desai Associate on Tech, M&A, and Ease of Doing Business

March 19, 2025

SIAC 2025 Rules: Key changes & Implications

February 18, 2025