Pharma & Healthcare Update

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REVISED MASHELKAR COMMITTEE REPORT ON PATENT LAW ISSUES ACCEPTED BY THE GOVERNMENT

The Government of India has reportedly accepted[1] the recommendations of the Mashelkar Committee Report that was recently re-presented to it in relation to patents for pharmaceutical substances and micro-organisms.

BACKGROUND

Introduction of the product patent regime in India in early 2005 was preceded by many rounds of discussion and debate, not only among stakeholders, but also among members of the Parliament. Two of the chief bones of contention were whether micro-organisms deserve a patent and whether the product patent for pharmaceutical substances should be limited to only "a new chemical entity" ("**NCE**") or "new medical entity" ("**NME**"). The erstwhile Minister of Commerce and Industry had then assured the Parliament that these issues would be referred to an "expert committee" for detailed examination. Accordingly, a Technical Expert Group ("**TEG**") on Patent Law Issues was set up by the Government of India, Ministry of Commerce & Industry[2] in April 2005.

The TEG was constituted under the chairmanship of Dr. R.A. Mashelkar, which on December 29, 2006, submitted the Report of the Technical Expert Group on Patent Law Issues ("Mashelkar Committee Report" or "Report") to the Government. Following its release, there were allegations of certain portions of the report being plagiarised from another source, subsequent to which the report was withdrawn on the grounds of 'technical inaccuracies'. Post its withdrawal, the TEG re-examined the report and resubmitted the Mashelkar Committee Report ("**Revised Report**") to the Government in March 2009.

This time around, the Report has been reportedly accepted by the Government[1].

The debate that necessitated the setting up of the Mashelkar Committee itself, however, refuses to die out. While one of the two debated issues has now become settled law, the other issue still has stakeholders disagreeing.

WHAT THE MASHELKAR COMMITTEE REPORT DEALS WITH

In line with the issues debated in the Parliament before the enactment of Patents (Amendment) Act, 2005, the TEG in its Report analyses the following two issues in light of provisions of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), India being a signatory to it:

1. Whether excluding micro-organisms from patent protection would violate TRIPS; *and*

2. Whether restricting the grant of product patents for pharmaceutical substances to new chemical entities ("NCEs") or new medical entities ("NMEs") involving one or more inventive steps would be TRIPS[3] compatible.

ON THE ISSUE OF PATENTABILITY OF MICRO-ORGANISMS

In its 2006 Report, the TEG had concluded that excluding micro-organisms, *per se,* from patent protection would be in violation of the TRIPS Agreement in light of Article 27.3[4] of TRIPS. This was incorporated in Section 3(j)[5] of the Patents Act, 1970 in its 2002 amendment.

The Report cites and draws support from the first decision in India of the High Court of Calcutta,*Dimminaco AG vs. Controller of Patents*, which in 2002 had held that a patent on a micro-organism is valid.

In its revised form too, the Mashelkar Committee Report maintains its stand that while naturally occurring micro-organisms do not qualify for receiving a patent, "*micro-organisms involving human intervention and utility are patentable subject matter under the TRIPS Agreement, provided they meet the prescribed patentability criteria*."

ON THE ISSUE OF GRANT OF PATENTS FOR PHARMACEUTICAL SUBSTANCES

The 2006 Report had 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 Agreement, which mandates patent protection to all inventions.

The conclusions in the Revised Report are essentially on similar lines as those contained in its 2006 version.

The Revised Report once again refers to Article 27.1 of TRIPS that states "…*patents shall be available for any inventions, whether products or processes, in all fields of technology*…", in light of which, linking the grant of patents for pharmaceutical substances merely to a NCE or NME is found to *prima facie* amount to 'excluding a field of technology' inspite of satisfying the basic requirements of patentability. It thus concludes that it would be possible to hold such limitation as being not TRIPS compatible.

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The 2006 Report had concluded that Articles 7 and 8 of the TRIPS Agreement or the Doha Declaration on TRIPS Agreement and Public Health ought not to be resorted to in order to circumvent Article 27.

The Revised Report re-examines the flexibilities allowed under the Articles 7 & 8 of the TRIPS Agreement and the Doha Declaration and concludes that it is debatable whether national interest and such flexibilities can be a valid excuse for statutory exclusion of an entire class of inventions.

In addition, the Revised Report recommends that "*every effort must be made to prevent the practiceof 'ever greening'…….by making claims based sometimes on 'trivial' changes to the original patented product*". In its opinion, the Indian Patent Office has the full authority under law and practice to determine what is patentable. Further, such authority should decide what would constitute only a trivial change with no significant additional improvements or inventive steps involving benefits in order to prevent 'ever-greening', rather than introduce a 'statutory exclusion' of incremental innovations from the scope of patentability**.**

A curious deletion in the Revised Report is that of the definition of ever-greening and incremental innovation. The 2006 Report contained the following explanation for these terms, which, inspite of their frequent usage, have no statutory definition in India:

"*It is important to distinguish 'ever-greening' from what is commonly referred to as 'incremental innovation'. While 'ever-greening' refers to an extension of a patent monopoly, achieved by executing trivial and insignificant changes to an already existing patented product, 'incremental innovations' are sequential developments that build on the original patented product and may be of tremendous value in a country like India. Therefore, such incremental developments ought to be encouraged by the Indian patent regime.*"

NO COMMENTS ON EXISTING PATENTS ACT

The TEG does not comment on the controversial Section 3(d)[6] which is the statutory provision relating to patentability of pharmaceutical substances. The Revised Report contains a disclaimer in paragraph 4.5 as follows:

"*The TEG was not mandated to examine the TRIPS compatibility of Section 3(d) of the Indian Patents Act or any other existing provision in the same Act. Therefore, the committee has not engaged itself with these issues.*"

IMPLICATIONS OF THE REVISED REPORT

The conclusions drawn by the TEG's Revised Report are fairly unchanged in comparison with the 2006 Report. In view thereof, there does not seem to be any incumbent amendment to the present Patents Act.

The immediate issue that needs to be addressed by the Patent Office and the judiciary is the appropriate interpretation of Section 3(d) and the applicability of the test of inventiveness in relation to pharmaceutical product patents.

As suggested in the Revised Report, in addition to formulating guidelines for examination of patent applications involving micro-organisms, and avoiding ever-greening of patents, the Patent Office can also play a vital role in setting out parameters for measuring 'enhanced efficacy' as is required by Section 3(d), and providing guidance on how to apply the test of inventiveness in relation to pharmaceutical product patents, thus balancing national interest with India's international obligations.

- Aditi Nadkarni & Gowree Gokhale

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1 http://www.business-standard.com/india/news/govt-accepts-panel-report-against-narrowingindian-patent-law/00/26/367342/

2 *vide* O. M. No. 12/14/2005-IPR-III dated April 5, 2005

3 The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) administered by the World Trade Organization (WTO) sets down minimum standards for certain forms of intellectual property laws for member nations, including for patent law.

4 Article 27.3 of the TRIPS Agreement states that Members may also exclude from patentability:
"(a) diagnostic, therapeutic and surgical method for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes."

5 Section 3(j) of the Patents Act, 1970 on what are not inventions: "plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals."

6 Section 3(d) of the Patents Act, 1970 prevents the following from being granted patent: "*the mere discovery of new form of 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.*

Explanation: For the purpose of this clause, 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."

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