India’s Tryst with TRIPS Continues!

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This short note discusses the politics of TRIPS compliance and legal intricacies involved in India’s attempt to read further limitations into TRIPS. It further explains how hard the Committee (entrusted with the task of reading further limitations into TRIPS) will find its tight rope walk. Will the Committee’s Report open the pandora’s box yet again? – the box this time contains all sorts of controversies on pharmaceutical patents!

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It was indeed a hard task for the Indian Commerce Minister to push through the latest amendments to the Patents Act in the Indian Parliament in March 2005, which made the Indian Patents Act TRIPS compliant. The Minister had to make several compromises, which even lead to interfering with some of the time-tested fundamentals of patents law.

During the discussions on the amendments, it was also agreed upon to constitute an Expert Committee to review two contentious issues. These issues being:
(a) Whether it would violate the TRIPS Agreement if India excludes ‘non-NCE pharmaceutical product inventions’ from patentability; and
(b) Whether it would be TRIPS compatible to exclude microorganisms from patentable subject matter?

The recommendations of the Committee – answering either way the questions referred to it – will definitely lead to yet another heated public debate in India on the social and economic fall out of introducing product patents for food, drug and medicines. India’s tryst with the TRIPS Agreement will continue.

The Committee Enquiry: Issues Involved

Deeper questions emanate from the legal and technical intricacies surrounding the terms of reference to the Committee. Considering this, one may assume two approaches. One line of enquiry by the Committee could be premised on the overriding economic, public health and related social ramifications of India granting patents for ‘non-NCE pharmaceutical product inventions’ and ‘microorganisms’. The attempt to premise the enquiry on the wider economic, public health and related social context may make the Committee’s recommendations more controversial in India and less acceptable at WTO.

The other line of approach could be more legal, thus interpretational. Such an enquiry can traverse through the trajectory of an interpretational process finding room to read limitations in the relevant provisions of TRIPS Agreement with an objective to make TRIPS -‘TRIPS Minus’. This line of approach, if adopted with caution and care, may find a higher level of acceptability at WTO. However, technical intricacies of this approach may overshadow the efforts to highlight the public health perspectives.

Limiting Patentability to NCEs & NMEs

One of the issues before the Committee will be to see if patentability can be limited to new chemical entities (NCEs) having one or more therapeutic use (which the generic drug makers often call as ‘perennial patents’ leading to ‘evergreening’), without violating TRIPS. In other words, would India violate TRIPS if it excludes a variety of inventions around a NCE having one or more therapeutic applications?

The first step in answering this question is to look at what TRIPS originally mandates the WTO Member Countries to provide as against what the Indian patent law (as amended in 2005) provides. The second step in answering this question is to look at whether the Doha Declaration on TRIPS & Public Health, the research exception decision (Bolar) and other ‘TRIPS Minus’ developments post 1 January 1995, can be used by India as justification for excluding all ‘non-NCE pharmaceutical product inventions’ from patentability.
Article 27(1) of TRIPS provides that ‘patents shall be available for any invention, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application’.9

Article 27 of the TRIPS, therefore, does not allow member countries to discriminate patentable and non-patentable inventions on the basis of: (a) field of technology, (b) place of invention, and (c) domestic production as against importation.

Article 27 (2) of TRIPS enables member countries to exclude only those inventions, which are necessary to protect human, animal or plant health, from the purview of patentability.

The Indian Patents Act, 1970 (as amended) does not limit patentability of pharmaceutical inventions to NCEs or New Medical Entities (NMEs). An effort has been made by the drafters of the third amendment to increase the threshold of patentability by setting higher standards of ‘novelty’ and ‘inventive step’ and by excluding additional categories of subject matters from patentability. As for example, the new definition for ‘new invention’ [Section 2(1)(l)], the amended definition for ‘inventive step’ [Section 2(1)(ja)], the amended definition for ‘pharmaceutical substance’ [Section 2(1)(ta)], the addition of a new explanation to Section 3(d) and the expansion of Section 3(d) in general were all aimed at stepping up the threshold of patentability in general.

‘Invention’ is defined by the Act to include ‘any new and useful product or process involving an inventive step and capable of industrial application’. The new definition of ‘new invention’ makes the novelty requirement absolute. Novelty of an invention is destroyed if ‘it is anticipated by prior publication, prior public knowledge and/or prior public working anywhere in the world’.

The recent amendment also made certain changes to the definition of ‘inventive step’. The new definition reads as follows:

‘Inventive step’ means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art’.

By qualifying the classical definition of ‘inventive step’ as a feature of an invention that makes it non-obvious to a person of ordinary skill in the art has probably eroded the gravity of the age-old principle.

The amendment also redefined ‘pharmaceutical substance’ as any new entity involving one or more inventive steps. The amended provision did not attach a further limitation that ‘pharmaceutical substance’ must have at least one new therapeutic application. It is also worth noting that the amended ‘pharmaceutical substance’ does not find place anywhere else in the body of the Act.

The intention in carrying out these amendments, i.e., to step up the threshold of patentability, has just stopped short of limiting patentability to NCEs and NMEs. Section 3(d) of the Act contains the most important provision in this regard. The expanded ‘Explanation’ to 3(d) excludes a number of subject matters from patentability. However, the following subject matters continue to be patentable:

(a) A new form of a known substance with enhancement of the known efficacy of that substance;
(b) Salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance with significant difference in properties with regard to efficacy.

The Patents Act, 1970, as amended, therefore permits patentability of a number of pharmaceutical substances other than NCEs or NMEs.

It is therefore obvious from a combined reading of TRIPS provisions and the Indian Patents Act is that TRIPS Agreement will be violated if the Indian Patents law expressly excludes non-NCE pharmaceutical product inventions from patentability. This express violation of TRIPS Agreement is something that India should probably avoid, as it could lead to yet another embarrassment at WTO’s dispute settlement process.10

An alternative line of thinking is to ask the following question – Whether TRIPS Members are free to define the threshold of ‘novelty’ and ‘inventive step’ in such a manner to exclude almost everything other than NCEs from the scope of patentability. TRIPS does not mandate member countries to provide for a certain standard definition of ‘novelty’ or ‘inventive step’. Therefore, it could be a possibility to set a high degree of ‘non-obviousness’ requirement and connect this high threshold with Section 3(d) to justify the exclusion of non-NCE pharmaceutical inventions from patentability. For example, possibly, re-define 3(d) to exclude ‘any pharmaceutical
substance the discovery of which does not involve one or more inventive steps and having no new therapeutic application’.

**Exclusion of ‘Microorganisms’ from Patentability**

The question under consideration is - whether it would be TRIPS compatible to exclude microorganisms from patenting?

The relevant provisions of TRIPS and Indian Patent Act in reference to the issue concerned are as follows:

(a) Article 27(3)(b) of TRIPS mandates Members not to exclude ‘microorganisms’, ‘non-biological’ and ‘microbiological processes’ from the scope of patentability. Thus under Article 27(3)(b) of TRIPS, the Members are under obligation to provide patents for microorganisms.

In order to bring the Indian law in compliance with the aforesaid TRIPS provision, a new clause to Section 3 was added in the Indian Patents Act (by the Patents (Amendment) Act, 2002) which excluded from patentability, plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals. Thus TRIPS and the Indian law clearly provide that ‘microorganisms’ are patentable. As such, it will violate TRIPS if ‘microorganisms’ *per se* are excluded from the scope of patentability. The approach, therefore, has to be more ‘definitional’ and ‘interpretative’ than a blanket direct exclusion that attracts yet another dispute at WTO. The key question that follows is – whether it is possible for India to adopt a very narrow and limited definition of ‘microorganisms’ to exclude everything other than ‘microscopic organisms including only algae, bacteria, fungi, protozoa and viruses’. Alternatively, should there be an expansive definition of ‘microorganism’ to include within its scope all ‘biological materials’ containing genetic information and capable of reproducing itself or being reproduced in a biological system as in the European Patent Examination Guidelines?11

A pragmatic approach therefore, is to redefine the enquiry from – would it be TRIPS compatible to exclude ‘microorganisms’ from patentability? to - can paternity of ‘microorganisms’ be restricted to only algae, bacteria, fungi, protozoa and viruses or should it be extended to DNA fragments, genes, peptide and proteins as in the Chinese Patent Examination Guidelines.12

In this context, it must also be noted that there exists no explicit definition for ‘microorganism’. Neither the Indian Patent Act nor TRIPS Agreement define ‘microorganism’. Moreover, no single commonly accepted scientific definition exists. The classical scientific dictionaries define them differently with no consensus. Some definitions are as follows:

(a) a microscopic organism; those of medical interest include bacteria, rickettsia, viruses, fungi, and protozoa.13
(b) a microscopic plant and animal.14
(c) an organism which can only be seen with a microscope.15

In choosing one of the above-mentioned definitional approaches (one expansive and the other restrictive), one should keep in mind India’s intellectual property preparedness in the biotechnology and bio-pharmaceutical sector. Is Indian R&D globally competitive to make use of a patent system that provides for an expansive definition of ‘microorganisms’ that extends to ‘biological materials’?

It could be in India’s national interests to make ‘microorganisms’ patentable and also to provide an expanded definition of ‘microorganism’ so as to include in its scope ‘biological materials’ including DNA fragments, genes, peptides and proteins.

An alternative approach could be to adopt the European approach16 and provide for a further broader definition of ‘biological material’ to ‘any material containing genetic information and capable of reproducing itself or being reproduced in a biological system’ and bring that under the scope of patentable subject matter.

An explanation could be added to Section 3 (j) with a definition of microorganism (for purposes of determining patentability) as follows:

Explanation—For purposes of this clause, ‘microorganism’ means only microscopic organisms including algae, bacteria, fungi, protozoa, viruses, DNA fragments, genes, peptides and proteins.

**Conclusion**

The Committee’s deliberations may lead to the following:

(a) Exclusion of microorganisms and non-NCE pharmaceutical product inventions from patentability will violate TRIPS provisions. In this line of approach, the Committee shall have
the limited burden of explaining how a literal interpretation of TRIPS as against the Patents Act, 1970, does not permit India to exclude microorganisms or inventions other than NCEs from patentability.

(b) Exclusion of microorganisms and non-NCE pharmaceutical product inventions from patentability will not violate TRIPS provisions. Consequently the Patents Act can be further amended to incorporate the additional limitations. This line of approach will attach enormous burden on the Committee to show how this would not violate TRIPS provisions.

Many IPR stakeholders in India continue to deliberate on a variety of legal and technical issues connected with the Patents Amendment Act, 2005. Addressing most of these issues will require going back to the Parliament for yet another amendment in the law, which is unlikely to happen in the near future. Further the terms of reference of the Committee are clear and concise and that relates to the two questions referred to it. Addressing any additional issue connected with TRIPS compliance amendments to the Patents Act will go beyond the terms of reference of the Committee.

References

4. The Government of India has appointed an Expert Committee to address two key questions in relation to India’s obligations under the TRIPS Agreement. For the full text of the terms of reference of the Committee, www.nic.in/commerce.
8. Bolar exception refers to an exception from the general rules of infringement whereby a generic drug maker is permitted to use patented products, without authorization and prior to the expiry of the patent term, for the purposes of seeking regulatory approval from public health authorities for the marketing of their generic version as soon as the patent expires. WTO Panel decision in Canada — Patent Protection for Pharmaceutical Products, http://www.wto.org/english/tratop_e/trips_e/pharma_ato186_e.htm#exceptions.
10. India has a history of losing cases at the WTO Dispute Resolution process, table of disputes by member countries at http://www.wto.org/english/tratop_e/disp_e/disp_e_count ry_e.htm.