The Patents (Amendment) Act, 2005 and TRIPS Compliance–A Critique

Manoj Pillai†
LEX ORBIS Intellectual Property Practice, 709/710, Tolstoy House, 15-17, Tolstoy Marg, New Delhi110 001

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The main objective behind the introduction and passing of the Patents (Amendment) Bill, 2005 was to meet India’s deadline, 31 December 2004, to comply with the TRIPS Agreement. While the Ordinance attempted to make the Indian patents law TRIPS compliant rather literally, the Patents (Amendment) Act, 2005 (hereinafter ‘the Act’) deviated from the Ordinance in certain fundamental respects. This note analyses the difference in the ‘language of law’ between the Ordinance and ‘the Act’. An attempt has also been made to analyse the implications of the amendments proposed in the Act to ascertain if the Act makes the Indian patents law TRIPS compliant.

Keywords: TRIPS compliant, inventive step, new inventions, Swiss-type ‘new use’ claims, software patents

One of the major impediments in India’s way to TRIPS compliance was the controversial Section 5 of the Indian Patents Act that provided only limited term process patent protection for inventions relating to ‘food, drug, and medicines’. It is this provision that enabled the growth of a generic pharmaceutical industry in India, which helped in public’s access to cheaper generic drugs for several decades. Therefore, omission of Section 5 of the Patents Act, 1970, the Principal Act, was the most critical aspect of India’s TRIPS compliance. Thus, the Patent (Amendment) Act 2005 has omitted Section 5 of the Principal Act. However, to minimize the negative impact of this amendment, a number of safeguards have been brought into the law. While many of these measures do safeguard public interests, at least some of the amendments raise fundamental questions about their legal validity and appropriateness.

An attempt has been made to analyse the legalities of the amendments contained in the Patents (Amendment) Act, 2005 as against the Patents (Amendment) Ordinance, 2004 to find out if the amendment has made the Indian patents law TRIPS compliant.

With the omission of the controversial Section 5 from the Principal Act, patents shall now be available for inventions claiming pharmaceutical, food and agricultural chemical products for a term of 20 years.

The exceptions to this general norm on patentability are the subject matters specified in Section 3 of the Patents Act. Currently, a joint reading of Sections 2(1)(j), 2(1)(l) with Section 3 would determine the general ambit of patentability under the Indian law. The new definition of ‘new invention’ will have a bearing on the interpretation of ‘invention’ as occurring in Section 2(1)(j). The redefined expression ‘pharmaceutical substance’ in Section 2(1)(ia) will have an overall influence in determining what is patentable in the area of pharmaceutical arts.

Inventive Step Redefined

A new Section 2(1)(ja) substituted the existing definition of ‘inventive step’ to mean “a feature of an invention that involves technical advances as compared to the existing knowledge or having economic significance or both and makes the invention not obvious to a person skilled in the art”.

This amendment attempts to redefine a cardinal principle of patents law. The legislative intent behind this amendment is to make the threshold of inventive step required for an invention to be patentable higher than the existing standard. If so, for an invention to be patentable, it must involve an inventive step and this is a feature of the claimed invention that involves technical advances compared to the existing knowledge or having economic significance or both. Further, the new definition retains the original language of the law that inventive step is a feature of the invention that makes it not obvious to a person of ordinary skill in the relevant art. Does the new definition achieve or defeat the legislative intent?

‘Inventive step’ was originally defined in the Patents Act to mean ‘a feature that makes the invention not obvious to a person skilled in the art’. An explanatory note to Article 27 (1) of the TRIPS Agreement states that ‘inventive step’ is synonymous with ‘non-obviousness’. There exists a plethora of judicial pronouncements on what constitute ‘non-obviousness’ as a criterion of patentability. Further, many national patent offices have practice guidelines explaining the fundamental propositions concerning what is not obvious to a ‘person of ordinary skill’ in a given technological art – so as to make an invention patentable. The revised language of law does not reflect the distilled stock of knowledge on what constitutes ‘inventive step’. The wording ‘technical advances as compared to existing knowledge’ has the potential to dilute the very basis of obviousness/novelty requirements. If an invention is not adequately distinct

†Email: manoj@lexorbis.com
over the prior art – it is not patentable. As such, arguably, no additional safeguard is achieved by adding expressions that make the whole definition vague.

The second phrase is 'economic significance'. As per the new definition, an invention to be non-obvious must have ‘economic significance’ or ‘technical advances as compared to existing knowledge’ or both. The use of ‘or’ makes the presence of both the aspects– ‘economic significance’ or ‘technical advances as compared to existing knowledge’ non-mandatory, but desirable. ‘Technical advances as compared to existing knowledge’ is the quintessence of the jurisprudential tenet that ‘an invention to be patentable must be distinctive over the closest prior art’. It is this that makes an invention non-obvious to a person of skill in the relevant art. If so, the language used in the new definition leaves room for dilution of the condensed principles on ‘what constitutes inventive step’.

The other important expression occurring in the new Section 2(1)(ja) is ‘economic significance’. The aspect of economic significance is very well covered under another cardinal patentability requirement, namely, ‘usefulness’. If so, the inclusion of the expression ‘economic significance’ in the definition of ‘inventive step’ may further dilute this cardinal criterion of patentability. Arguably, this can make the legal position TRIPS non-compliant. However, a lot would depend upon the interpretation of the new definition by the patent office and thereafter by the judiciary.

A New Definition for ‘New Inventions’

The Act retains the old definition of ‘invention’ in Section 2(1)(j), but adds a definition on ‘new invention’. ‘New invention’ means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of a patent application with complete specification, i.e., the subject matter has not fallen in public domain or that it does not form part of the state of the art.

The key question in this context is whether the aforesaid definition of ‘new invention’ would act as a limitation on the definition of ‘invention’ under Section 2(1)(j). And if it is, does this amendment conform to Article 27 of the TRIPS Agreement. ‘Novelty’ of an invention is typically ascertained by testing if the invention has been anticipated by prior publication, or prior public working or prior public knowledge. There are ways to ascertain this as well – of course with some levels of inherent limitations in carrying out prior art searches. But, redefining the ‘novelty’ requirement in the manner provided in the Act purportedly makes it an absolute requirement. The absolute novelty requirement, as against relative novelty, thus applies to all the aforesaid aspects, i.e., prior publication, prior public knowledge and/or prior working.

The newly introduced definition of ‘new invention’ can be interpreted to act as a check on Section 25(d), (e) and Section 64(e) and (f) of the Patents Act, 1970 (as amended). These provisions deal with the use of anticipation by prior public knowledge or prior public use in India as grounds for opposing or revoking a patent application or patent as the case may be. While the novelty requirement as provided in Section 2(1)(j) conforms to Article 27 (1) of the TRIPS Agreement, the definition of new invention read with the definition of invention as above, has taken the legal provision away from TRIPS. The amendment, however, may avoid granting of frivolous patents for low-threshold inventions.

‘Patent’ Redefined

The definition of ‘patent’ has been amended. Originally ‘patent’ was defined to mean ‘a patent granted under the Act’, the amended definition of ‘patent’ means a patent for any invention granted under this Act. When attempting to understand the legislative intent behind this amendment, the first question that arises is–whether there can be a patent for anything other than an invention. The legislative intent seems to further qualify the definition to ensure that a patent can be granted only for an ‘invention’ as provided under the Act, meaning thereby that the combined reading of the provisions of the Patents Act, 1970 will have an overriding effect in ascertaining the validity of a patent even after its grant.

Swiss-Type ‘New Use’ Claims

The Ordinance amended Section 3(d) to ensure that what is not patentable is only mere new use. If a second medical indication or therapeutic use of a known drug molecule passes the test that it is not a mere new use – as per the Ordinance, it would have been patentable. The Patents Amendment Act, 2005, changed this position. Instead, it contains a rather too long explanation on the exemption to patentability under Section 3(d). According to this Section what is not patentable is:

(a) The mere discovery of a new form of a known substance which does not result in the
enhancement of the known efficacy of that substance;
(b) The mere discovery of any new property or new use for a known substance; and
(c) The mere use of a known process, machine or apparatus—unless such process results in a new product or employs at least one new reactant.

Consequently, if a discovery of a new form of a known drug molecule results in an enhancement of its known efficacy, it is patentable. Similarly, the mere discovery of a new use of a known substance is not patentable. The amended Section 3(d) when read in conjunction with Section 3(i) would ensure that all methods of use inventions are unpatentable. A joint reading of the amended Section 3(d) and Section 3(i) keeps a major portion of pharmaceutical R&D outside the scope of patents. On the other hand, the amendment will restrict patent holders from making undue commercial benefit by developing a portfolio of patents around drug molecules. Typically, innovators of drug molecules use patent prosecution strategies (including filing divisional applications, continuation applications and continuation-in-part applications) for patent term extension. The patent term extension strategies often stem from continued research and development on new use of the drug. If a drug that is originally therapeutically indicated in the treatment of disease condition ‘X’, if later on clinically proved to be useful for the treatment of disease condition ‘Y’, the new use claims coupled with methods of treatment claims will enable the innovator-patentee to keep all the competitors off from the market space. The amended Section 3(d) has taken this into consideration to the advantage of the generic pharmaceutical industry. However, what is kept off from the patentability is Swiss-type new use claims.

The Act further provides an explanation to Section 3(d) that 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. The phrase ‘differ significantly in properties with regard to efficacy’ is the final test of patentability as regards all inventions around a drug molecule. While the law would attach a higher level of obligation on the patent applicant to pass this test, a lot would depend upon the invention claimed and also the way in which the specification in general and the claims in particular are drafted.

Software Patents
The Act did not retain the amendments to Section 3(k) as contained in the Ordinance. The Ordinance had introduced a new Section 3(ka) to exclude ‘mathematical methods, business methods or algorithms’ from the scope of patentability. As per Section 3(k) (as contained in the Ordinance) a computer program’s technical application to industry or a computer program in combination with hardware was patentable. What was not patentable was only computer program per se.

The key expressions contained in the above amendment are ‘technical application to industry’ and ‘combination with hardware’. The legislative intent behind these words is clear. If an invention is directed at computer software having technical application to industry or coupled to hardware – then it is patentable. The phrase ‘technical application to industry’ was identical to the ‘technical effect’ test in the European patent parlance. As such, it was a progressive legal development. The latest amendment dropped it.

The law as it stands now reverts to the original position of excluding computer program per se from patentability. In the absence of an examination guideline explaining what is and/or is not software per se, stakeholders will have to depend upon how the patent examiners interpret the provision on a case-to-case basis.

Patents through the ‘Mail Box’
There has been a widespread concern that India is going to witness a flurry of litigations once pharmaceutical product patents come into force. The new proviso to Section 11 (A) brought in by the Amendment (which was not present in the Ordinance) ensures that a patent obtained through the ‘Mail Box’ route cannot be used to initiate infringement action against a generic manufacturer who has made significant investment for producing and marketing the patented product prior to 1 January 2005. Most Indian pharmaceutical companies had stopped their product development activities on molecules, which are either directly or indirectly covered by patent applications pending in the ‘Mail Box’.

On the other hand, a knowledge-based pharmaceutical company that spends substantial amount of time and money in developing a new molecule or an invention around a new molecule will
not be able to make commercial use of the invention in India. After routing an application for patent through the ‘Mail Box’ all that a patentee can ask for is ‘reasonable’ royalty from an Indian company who would continue to commercially exploit the claimed invention. As such, this provision has the potential of nullifying the very purpose of the transitional protection provided in the TRIPS Agreement.

Pre-Grant and Post-Grant Opposition

All grounds available for post-grant opposition have been made available to pre-grant opposition as well. The Act thus envisages two oppositions, first when the patent application is published, and second when a patent is granted. The post-grant opposition has to be initiated by an ‘interested person’. But any person can institute pre-grant opposition with the same ground as that of the post-grant opposition. The law allows a pre-grant opponent the right to be heard, whereas there is no provision in the Act enabling the Applicant to counter the pre-grant opposition.

It is pertinent to highlight that the Rules mandate that a pre-grant opponent has to file ‘a statement supported by evidence’. That makes the pre-grant opposition a legal proceeding involving a process of adducing evidence. In a proceeding when an opponent is allowed to adduce evidence against a patent applicant and if the patent applicant is given no chance to counter the evidence, it may not conform to the principles of administrative law and justice.

Compulsory Licence

The grounds to seek compulsory licences have been expanded. The newly inserted Section 92A(1) of the Act extended the scope of issuance of compulsory licenses for manufacture and export of patented pharmaceutical products to countries having insufficient manufacturing capacity in the pharmaceutical sector, if that country has by notification allowed such importation.

Conclusion

Patent as an institution of private property was by and large alien to India. The predominantly public funded research and development in the post independent India kept the patents law some where at the periphery of the economic system. Coupled to this was the exclusion of product patents for ‘food, drug, and medicines’ in the scheme of the patents law. This lead to a widespread misconception that product patent is not available in India in any field of technology. The national debate on TRIPS compliance, however, marked a new beginning for India’s thus far premature patent system. Thus, a positive outcome of the recent public debate on patents and TRIPS compliance is that it resulted in substantial increase in the public awareness on patents in the country.

The one question that needs to be revisited relates to the very purpose for which the patents law has been amended on multiple occasions – that is, TRIPS compliance. Is the Indian Patents Act, 1970 (as amended by the Patents (Amendment) Act, 2005) TRIPS compliant? While there cannot be a final answer to this until competent bodies address and decide on it, there are reasons to consider that the law as it stands now is not TRIPS compliant. It is time to wait and watch how the international community responds to India’s latest attempt on TRIPS compliance.

References

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5. Benmax v Austin Motor Co Ltd (70 RPC 284); Beecham Group Ltd’s Appln. (1980 RPC 261); Biswanath Prasad Radhey Shyam v Hindustan Metal Industries (1979) 2 SCC 511 at p 519; Martin & Biro Swan Ltd v Millwood Ltd 1956 RPC 125, p 139
7. Section 2(1)(l) of the Patents Act, 1970 (as amended)
8. Section 2(1)(m) of the Patents Act, 1970
9. New use claims are first granted by the Swiss Patent Office, hence are known as Swiss-type claims, http://www.mondaq.com/article.asp?article_id=30975&lk=1
10. For a general commentary on what is ‘Mail Box’ mechanism, see http://www.wto.org/english/tratop_e/trips_e/in- tel2c_e.htm#transitional
11. Section 2 (1)(t) of the Patents Act, 1970