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The patents amendment Act, 2005 and TRIPS Compliance: A critique

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Abstract
The Patents (Amendment) Act, 2005 introduces pharmaceutical product patents in India for the first time. This Act attempts to balance out competing interests of a variety of stakeholders, including domestic generic medicine producers, foreign multinational pharmaceutical companies and civil society groups concerned with medicines. December 2004 saw an unprecedented national debate on patents in India. Patents, as an institution of private property, were alien to most Indians. The national debate on compliance with the World Trade Organization (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPs) agreement thus marked a new beginning for India's premature patent system. One of the important positive outcomes of the recent public debate on patents and TRIPs compliance is the establishment of a national awareness of patents.
The main object behind the introduction and passing of the Patents (Amendment) Act 2005 was to meet India's deadline, 31 December 2004, to comply with the TRIPS Agreement. While highlighting the key of the 2005 amendments and the lack of clarity, this article analyse the implications of the amendments proposed in the act to ascertain if the Act makes the Indian patent law trips compliant.

Keywords: world trade organization, trade-related aspects of intellectual property rights, pharmaceutical product

1. Introduction
The Patent (Amendment) Act 2005 (hereinafter referred to as the 2005 Amendment) was passed by the Parliament in its budget session of 2005 with TRIPS compliant [1]. India is under the obligation of introducing patent protection in new technologies, chemicals and pharmaceuticals under the TRIPS agreement of the WTO with effect from 1.1.2005. The new Act introduced some important changes on the legal regime of patent protection so as to address patent issues in technology, chemicals and pharmaceuticals sectors.

Some Major Changes Introduced by the 2005 Amendment
This note highlights some of the main changes brought about by the 2005 Act and reflects on some of their broader implications. In particular, the note focuses on the introduction of product patents for pharmaceutical inventions and the changes in Patents Act.

1. Extension of product patent protection to all fields of technology
The most prominent and controversial change of the 2005 Amendment has been the deletion of section 5 of the Act, thereby paving the way for product patents in the area of pharmaceutical and other chemical inventions. Section 5 of the Act (as it stood after the 2002 amendments) had provided that, in the case of inventions being claimed relating to food, medicine, drugs or chemical substances, only patents relating to the methods or processes of manufacture of such substances could be obtained. Before this Amendment in the Act, Product Patent was not granted on the inventions related to drugs, foods and chemicals and only process patents were granted on these inventions. It means if a company invented a medicine to cure a disease using a certain process. That company can't claim a patent on that medicine while the company can claim a patent on the process which it has used to manufacture that medicine. In the other words that company can't stop other competitors from manufacturing the end product but can stop others from producing the end product using their patented process or method. This resulted in a situation in which reverse engineering mechanism was highly used to develop the same medicine and drugs with slightly or substantially different process [2].

2. Software Patentability
Section 3(k) of the Patents Act, 1970 excluded "a computer programme per se" from the scope of patentability. This exclusion met with conflicting interpretations at the patent office, with some examiners granting patents to software combined with hardware or software with a demonstrable technical application of some sort. The 2004 Ordinance therefore qualified this exclusion by stating that software with a "technical application" to industry or when "combined with hardware" would be patentable [3]. Owing to vigorous opposition from the free software movement, this provision was removed from the 2005 Act. The earlier position under the Patents Act, 1970 that a computer programme per se is not patentable now prevails.

3. Problematic Definitions
a. **New Invention redefined:** The act retains the original definition of 'invention' in Section 2(1) (j). However, it does add a definition of 'new invention' to mean any invention or technology that 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.

The novelty of an invention is typically ascertained by testing whether the invention has been anticipated by prior publication, prior public working or prior public knowledge. There exists much case law on this issue and there are ways to ascertain novelty, albeit with some limitation when carrying out prior art searches. However, redefining the novelty requirement in the manner provided in the act deviates from the norms set out in the novelty test (which in turn ascertains patentability). This is another amendment that deviates from the TRIPs agreement, putting an unreasonable burden on a patent applicant to substantiate the novelty and consequently the patentability of the claimed invention [4].

b. **Inventive Step redefined:** The 2005 Act makes a critical change to the earlier 'non-obviousness' or 'inventive step' test. The definition now reads: "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 the person skilled in the art" [5].

As can be seen from this definition, while the fundamental yardstick for measuring an 'inventive step' remains that which is "not obvious to a person skilled in the art", a requirement that the invention involve a 'technical advance' or have an 'economic significance' of some sort has been added. This change in the standard seems odd, given that the very purpose of the 'inventive step' criterion is to determine whether an invention sufficiently advances the technical arts so as to warrant an exclusive right. This is no doubt achieved in an optimal manner by the simple test of whether the invention, though novel, is non-obvious to a person skilled in the art. By itself, the non-obviousness test is a difficult one to apply - additional criteria such as 'technical advance' and 'economic significance' only further the complexity. Contrary to suggestions by some commentators, the addition of 'technical advance' or 'economic significance' to the 'non obviousness' test does not dilute the 'inventive step' requirement - on the contrary, it is susceptible to being interpreted in a manner that renders it more onerous to satisfy.

c. **Section 5 Removed:** The Patents (Amendment) Act 2005 deleted Section 5, which provided for only a limited-term process patent protection for inventions in relation to food, drugs and medicines. The amendment now provides for 20 years' protection for all categories of inventions except those excluded under Section 3 of the act [6].

d. **Patent redefined:** The definition of patent has been amended. Originally 'patent' was defined to mean 'a patent granted under the Act'[7], the amended definition of 'Patent' means a patent for an invention granted under this Act [8]. 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 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 [9].

4. Pre and Post-grant Opposition

All the grounds previously available for post-grant opposition of patents have now been made available to pre-grant opposition as well. The act thus envisages two oppositions - first when the application is published, and second when a patent is granted. The post-grant opposition must be initiated by an interested person, but any person can institute pre-grant opposition [10].

5. Compulsory License

Compulsory licenses are generally defined as "authorizations permitting a third party to make, use or sell a patented invention without the patent owner's consent [11]. Compulsory license are licenses that are granted by a government to an individual or company seeking to use patents, copyrighted works or other types of Intellectual Property, to do so without seeking the owner's consent. The individual or company granted compulsory license have to pay the owner a set fee for the license. The objective of granting compulsory license is to prevent the abuse of monopoly granted [12].

The already elaborate compulsory licensing grounds have been given another boost. The newly inserted Section 92A(1) of the act expands the scope of issuance of compulsory licences for manufacture and export of patented pharmaceutical products to countries that have insufficient manufacturing capacity in the pharmaceutical sector, if that country has allowed such importation by notification.

6. Deletion of the provisions relating to Exclusive Marketing Rights (EMRs)

Section 21 of 2005 Amendment deleted the Chapter IVA of the Act. The 1999 Amendment inserted this chapter in the Act to provide that applications claiming pharmaceutical inventions would be accepted and put away in a mailbox, to be examined in 2005. These applications are commonly referred to as 'mailbox applications'. This amendment was in pursuance of a TRIPS obligation aimed at preserving the novelty of pharmaceutical inventions in those developing and least developed country (LDC) members that did not grant product patents for pharmaceutical inventions in 1995. By virtue of this 'mailbox facility', applications would be judged for 'novelty' on the basis of the filing date and not with reference to 2005, the year in which product patents were first incorporated into the patent regime [13].

Provisions relating to Exclusive Marketing Rights (EMR) have been removed. EMR provision was introduced in India in the year 1999 in compliance with TRIPS as product patent for drug and medicine was not available in the Indian Act. As product patents can now be granted for Drugs, medicines, food, and chemical processes the EMR provision has become redundant and has been repealed [14].

7. No Swiss Claims and Expansion of Exclusion under Section 3(d)

A 'Swiss Claim' is a claim for patent wherein the use of a substance or composition that has already been used for a

medical purpose is intended or specified to be used for a new medical purpose. Section 3(d) as amended by the 2005 Amendment clarifies that mere discovery of a new form of a known substance, which does not result in the enhancement of the known efficacy of that substance is not an invention and therefore not patentable [15]. For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substances are to be considered to be the same substances, unless they differ significantly in properties with regard to efficacy.

In order to fully understand the amended Section 3(d), one need to first address the issue of what exactly the term "efficacy" means. The term has not been defined in the Act, but in Novartis AG v. Union of India [16], the High Court of Madras, while answering the question, whether section 3(d), as amended by the Third Amendment, is violative of the fundamental rights guaranteed under Article 14 of the Indian Constitution, interpreted the phrase "efficacy" as „the ability of a drug to produce the desired therapeutic effect i.e. how effective the new discovery made would be in healing a disease/having a good effect on the body, for which an applicant in order to pass the test of "efficacy" needs to show that the discovery of a new form of a known substance has resulted in the enhancement of the known efficacy of that substance and if the discovery is nothing other than the derivative of a known substance, then, it must be shown that the properties in the derivatives differ significantly with regard to efficacy.

In this case a Swiss drug company Novartis had challenged Section 3(d) of the Indian Patents Act claiming immunity for their drug Gleevec, a major drug for leukemia on the pleas that the new Gleevec was a major improvement over a older version whose patent was over. This was disputed by Indian companies such as Natco Pharmaceuticals. The plea of Novartis was rejected consequently enabling manufacture by Indian generic companies. Cost estimates of the new generic drug place it at one tenth the price of Gleevec.

The Hon'ble High Court also noted that though section 3(d) is not only limited to drugs and pharmacological substances, it is clear that certain portions of the section and the attached explanation is only referable to pharmacological substances [17].

There are many changes brought by the 2005 Amendment in the provisions of the Act, that can be summarized as follows -

a. The 2005 Amendment amend the definition of "New Invention", "Inventive Step" and insert a new entry of "Pharmaceutical Substances" in the definition clause.
b. Provision of 'acceptance of specification' and its advertisement have been deleted.
c. Modification in the provisions relating to opposition procedures with a view to streamlining the system by having both Pre-grant and Post-grant opposition in the Patent Office.
d. Application for patent will be published in Official Journal. At that time opposition can be made on limited grounds but hearing is not mandatory.
e. After grant of patent, opposition can be made within 12 months.
f. Suit for infringement of patent cannot commence before date of publication of publication of the application.
g. Penalties enhanced substantially.
h. Strengthening the provisions relating to national security to guard against patenting abroad of dual use technologies.
i. Rationalisation of provisions relating to time-lines with a view to introducing flexibility and reducing the processing time for patent applications, and simplifying and rationalising procedures [18].

8. Conclusion

In all possibility, it can be said that Indian Pharma Industry will not end up where it started in pre 1970 era but it is safe to assume that Indian drug companies might become dependent on MNCs for technology to produce new drugs. It is likely that the existing drugs say about 10 per cent of the marketed drugs are likely to become expensive due to amendments made in new Patents Act. It must be noted that the remaining 90 percent of drugs will be unaffected by this amendment.

The safeguards provided under the Act and other laws, if implemented in a manner conducive to Indian consumers can prove a boon for them. The Indian consumers in that case can enjoy the benefits of both innovative as well as affordable drugs. To conclude it can be clearly said that, this amendment will definitely have a varied implication on Indian economy. On one side it may compromise with the interest of certain Indian companies and consumers but on the other side it will act as decisive step in internationalization of Indian Patent System and cultivating an innovation culture in Indian Pharmaceutical Industry.

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