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***Opinion***

# TRIPS, WTO and IPR - Debate on Evergreening of Patents and IPA 2005

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## What is Evergreening?

Evergreening refers to the strategy adopted by patentees who seek to extend their patent protection by applying for secondary patents on subject matter related to the original patent. They have been criticized since practice is considered a ploy to effectively extend patent protection beyond initial term even though improvements in the invention are marginal and trivial. The patentees who indulge in such an 'abuse of the system' argue that from their perspective, all attempts to extend patent life to maximize returns on investment is a legitimate activity. Increasing credible patent life cycle of successful products is part of managements' patent strategies. The strategies adopted include obtaining broadest possible coverage for protection, developing patent clusters, thickets and minefields around original patents, filing secondary and defensive patents, obtaining patent term extensions (wherever allowed) and regulatory data protection. While new cluster patents are generally weak patents, they nevertheless act as serious deterrents to generic producers. Thus cluster patents and secondary patents not only provide new and wider coverage, but also extend exclusivity period offered by the additional patents. For example, while original patent on Paroxetine of Glaxo Smith Kline expired in 1990s, secondary patents filed before the expiry of the first patent extend the validity, some of them even up to 2018. Defensive patents are those meant for blocking entry of competing products with no intention to exploit the patents for commercial purposes. While adopting one, more or all of these strategies may be considered legitimate and strictly lawful, it has to be realized that the patent system itself is not meant to be a monopolistic and anti-competitive instrument favouring only the inventor without paying heed to the public's interests. The latter is assured through the early introduction of generic drugs which will increase competition and make patented drugs more affordable. However, ensuring non-infringement of all concerned patents on a blockbuster drug with several patents (some as many as 30 to 40) can be a very onerous task for generic manufacturers. Litigations on infringements will give a reprieve of even 30 months to the patent holder and prevent introduction of the generic version for considerable periods. Attempts to balance interests of both the innovator and the generic manufacturer have been part and parcel of many legislations in many countries. In the US, the Hatch-Waxman Act, creation of the Orange Book listing of patented inventions, incentives for encouraging early introduction of generics etc are all part of such attempts.

## Indian Patents Act 2005 and Section 3(d)

One of the most controversial and much debated issues on the Indian Patents Act (IPA) 2005 has been with respect to Article 27 of the TRIPS Agreement on patentability of inventions and corresponding provisions–Section 3(d) under the IPA, 2005. Article 27 clearly mandates that 'patents shall be available for any inventions whether products or processes in all fields of technology provided they are new, involve an inventive step and are capable of industrial application – and shall be available and patent rights enjoyable without discrimination as to the place of invention, field of technology and whether products are imported or locally produced.' According to this clause any new invention which satisfies the basic requirements of novelty, inventiveness and industrial application would qualify for patent grant and in that context Section 3(d) would appear to be violative of this provision since it dictates a discriminatory provision that 'mere discovery of a new form of a known substance which does not result in enhancement of the known efficacy (safety is not mentioned) of that substance — reactant.' However explanation which follows stipulates that derivatives

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of the known substance are not patentable unless 'they differ significantly in properties with regard to efficacy.' Once again safety and economic considerations have been left out. Assuming that there is agreement on the interpretation of the term 'significantly', thereby eliminating possible subjective interpretations, this section does not preclude grant of patents even for products derived from a known substance. Thus IPA 2005 does not violate spirit of the TRIPS Agreement since the IPA provides for protection of all inventions including derivatives of known substances as long as they satisfy the pre-requisites spelt out in the TRIPS Agreement. The only question is with regard to the inventive merits of the invention dealing with new derivatives of existing molecules. The incrementality or triviality (whether it differs significantly in properties with regard to efficacy) of the new invention dealing with derivatives mentioned in the explanation note under Section 3(d) would be decided by the patent office during prosecution phase. Decisions on several applications involving derivatives of known substances (patented or non-patented) are pending with the Indian Patent Office and some decisions have been made. While some patents have been granted, others have been rejected. Expectedly, these actions of the patent office have already led to litigations. It is therefore clear that the charge of evergreening is not valid as far as the provisions of IPA 2005 are concerned since inventive merits are the seminal yardsticks for grant of patents regardless of the nature and subject matter of the invention.