Public Health concerns addressed in Indian Patent Amd Act 2005, while being TRIPS Compliant

In fulfillment of its WTO commitments, India replaced the Patent Act 1970 (eif 1972) with the Indian Patent (Amd) Act in 2005. The 1970 Act– served us well as a industrial policy instrument to encourage industrialization and promote self reliance. It is also credited with addressing public health concerns and growth of a strong generics industry.

Public health concerns in a country of over a billion people with 600 million living under $ 2 a day needs no elaboration. The 2005 Patent Law effectively balances and calibrates Intellectual Property Protection with public health, national security and public interest concerns. It contains several public health safeguards, which I will list:

o Availability of products at reasonable price is ensured through the provision of compulsory licence (Section 84).

o Compulsory licence can be issued to deal with circumstances of national emergency, extreme urgency or public non-commercial use (Section 92).

o Parallel import can be allowed to ensure availability of patented drugs at reasonable prices through parallel imports (Section 107 A). Parallel import need not be only from a person authorised by the patentee.

o With a view to make available patented drugs through Government dispensaries, hospitals, etc. the Government can import patented drugs without the consent of the patent holder (Section 47).

o For public purpose the Government can compulsorily acquire patent rights. Compensation may be determined by mutual agreement between the Government and patent holder and failing which by High Court (Section 102).

o Patent can be revoked on the ground of non-working or the patented invention not being available to the public at reasonably affordable price (Section 85).

o Patent can be revoked by the Government in public interest if it is prejudicial to the public or exercised in mischievous manner (Section 66).

o No rights accrue to a patent holder for mailbox applications for the period prior to the date of grant of patent (Section 11 A).

o Manufacturing of products by enterprises having made substantial investment to continue on payment of reasonable royalty, even if patent is granted on a mailbox application (Section 11 A).

o Bolar Provision: Those interested in manufacturing generic version of patented product on expiry of the patent can make necessary preparations for production even during the validity of the patent (Section 107). This provision facilitates availability of generic version of the patented product at competitive prices immediately on expiry of the patent.

o No Ever-greening: No patent is allowed for a new use of a known drug or substance **(Section 3[d]):** This provision is unique to Indian law and one of the most important safeguards included to protect public health. It is a bonafide provision to combat the problem of ever greening. (Ever greening is a technique companies use to stagger patent applications so as to extend market monopoly and prevent entry of generic drugs.

o Mere discovery of a new form/ use/ property/ process etc. of a known substance which does not result in enhanced efficacy is not patentable.

o Salts, esters, ethers, polymorphs, etc. of known substance are to be considered to be the same substance until these differ significantly in properties with regard to efficacy.

o Export of medicines to other countries

To use the Para 6 system, India has already adopted the implementing legislation. For export of medicines to countries w/o adequate production facilities, Section 92A has been introduced in the law for obtaining CL for manufacturing and exporting the pharmaceutical products

from India, in accordance with the August 2003 Decision.

o Production and export of medicines for treatment of AIDS

The 12 main ARVs (Anti-Retro Viral Drugs) for treatment of Aids (namely, Zidovudine, Lamivudine, Stavudine, Nevirapine, Nelfinavir, Abacavir, Efavirenz, Didanosine, Saquinavir, Lopinavir, Ritonavir, Indinavir) are all pre-1995 molecules, and these will always be off-patent in India, and so it would be possible for Indian companies to keep manufacturing and exporting these medicines to those countries which require such drugs.